BEEF INDUSTRY SAFETY SUMMIT

Dallas, Texas • March 3-5, 2015

MEETING SUMMARY

BEEF INDUSTRY SAFETY SUMMIT

At a historically significant Summit in 2003, the beef industry affirmed its commitment to connect the safety links in the beef supply chain. Prior to that first meeting, individual industry segments had worked somewhat independently to address the safety issues relevant to their segment of the beef supply chain. At the 2003 Summit, the safety experts from all segments openly compared and shared research, best practices, mutual expectations, and perspectives on emerging safety concerns. By sharing production practices and technologies the beef industry as a whole pledged to ensure the safest possible domestic and global beef supply.

Since then, as the safety issues facing beef production have evolved, the industry has reinforced its promise to develop industry-wide, science-based strategies to solve the problems of foodborne pathogens in beef. Convened annually, the latest Beef Industry Safety Summit was held in Dallas on March 3 – 5, 2015. The Summit is funded in part by the Beef Checkoff, the Beef Industry Food Safety Council (BIFSCo), and beef-producing companies that believe the Summit plays a critical role in the continued improvement in beef safety.

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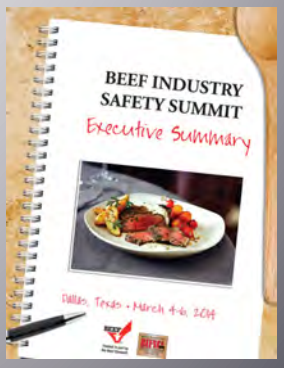


2014

General Session: Lessons Learned about *Salmonella* across Industries

The Beef Industry Safety Summit once again provided attendees the opportunity to learn from the experiences of a different food-producing industry that faced significant safety challenges. In 2014, Foster Farms was confronted with a *Salmonella* Heidelberg outbreak associated with poultry products that affected 634 persons in 29 states. In an effort to collaborate across animal proteins, experts involved in the outbreak shared their story and demonstrated how their learnings could help other industries improve their approach to food safety.

Moderator: Angie Siemens, Cargill, BIFSCo Chair

Laura Gieraltouski, Centers for Disease Control & Prevention (CDC)

Adriene Abbott, Foster Farms

Panel Response:

Scott Goltry, North American Meat Institute

John Ruby, JBS USA

Multi-state Outbreak of Multidrug-Resistant *Salmonella* Heidelberg Infections Linked to Foster Farms Brand Chicken – United States, 2013-2014

Laura Gieraltouski, Centers for Disease Control & Prevention (CDC)

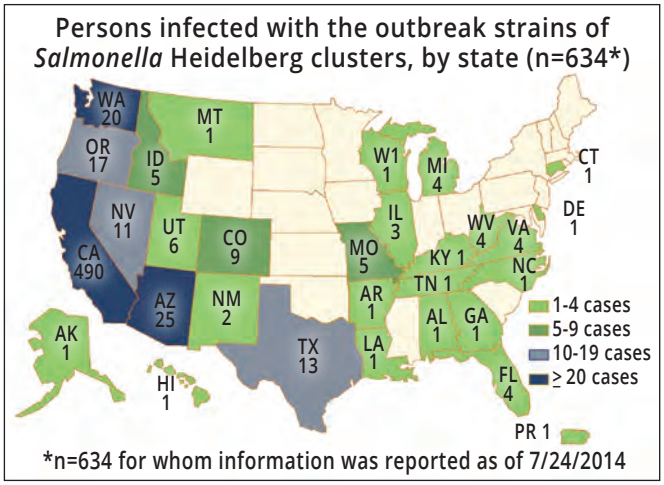


Figure 1.

Gieraltouski shared an overview of the foodborne illness investigation the CDC conducted related to the cluster of *Salmonella* Heidelberg illnesses (**Figure 1**) with a rare PFGE pattern. The investigative process lasted more than a year. In collaboration with other agencies including USDA-FSIS and the food company involved, the CDC identified key learnings for the future:

- reach out to industry for collaboration early in the investigation
- utilize experts in the field to help focus the investigation on suspect foods
- develop a working relationship with the company involved to accurately, but efficiently, work through the investigation

Reflections on the Foster Farms' Response

Adriene Abbott, Foster Farms

At the center of the investigation was Foster Farms, a family-owned and operated company for four generations. Since their founding in 1939, Foster Farms has been committed to providing consumers with the highest-quality, best-tasting poultry products available but, in 2013-2014, their product was involved in a multi-state illness investigation. Abbott shared the steps the company took throughout 2013 and 2014 to address the crisis and reinforce their ongoing commitment to improve the safety of their product. Along with forming a Food Safety Advisory Board comprising a variety of industry experts, a new philosophy of "Review, Commitment, Action, and Results" became the foundation for their safety program.

Panel Response

John Ruby, JBS-USA

In response, Ruby provided perspective on what participants at the Beef Industry Safety Summit could learn from the experiences of another animal protein. The beef industry has made great progress in addressing and mitigating *E. coli* O157:H7 with sanitary dressing procedures and multiple-hurdle intervention systems within the slaughter facility. However, *Salmonella* brings some new challenges. Though potential surface contamination can still be addressed with the same mitigation strategies used to reduce pathogenic *E. coli*, those alone will not address the internalization of *Salmonella* within the animal or carcass. The challenge for the industry is working together to identify strategies that mitigate *Salmonella* as successfully as the strategies that mitigate the seven regulated shiga toxin-producing *E. coli* (STEC).

Scott Goltry, North American Meat Institute

Goltry provided a comparison of the differing regulatory actions used today to mitigate safety threats posed by *Salmonella*, *Listeria monocytogenes* and *E. coli* O157:H7 in the beef processing system. Though

each pathogen is managed uniquely, the key to the industry's approach should continue to be a philosophy of non-competition in the safety arena. All industry players should unite to share experiences and data evaluation with the goal of improving public health.

General Session: Regulatory Update

Representatives from the key regulatory agencies shared the latest rules/notices and their potential implications for the beef industry. Topics included *Salmonella*, STEC, non-intact beef, testing updates, grinding logs, pre-harvest intervention update, baseline data reports, FMD and more.

Moderator: Kristina Butts, NCBA Policy Division
Jack Shere, USDA-APHIS
Bill Flynn, FDA
David Goldman, USDA-FSIS
Al Almanza, USDA

One of the hallmark sessions of the Summit is the regulatory update. Jack Shere shared the beef industry's progress in Foot and Mouth Disease (FMD) preparedness. The United States has not seen a case of FMD since 1929, but with the global nature of today's beef market, it is critical for the industry to be prepared for a U.S. case to be identified. Many other protein groups have completed FMD preparedness plans which can provide insights for the beef industry's program. Through the Secure Beef Supply Plan Working Group, USDA-APHIS recently facilitated a discussion with representatives across the beef supply chain to identify next steps and working groups for biosecurity, surveillance, data management, communication, managed movement and continuity of business. The working groups will be developing key deliverables throughout the coming year. For more information on FMD, see *http://www.fmdinfo.org/*

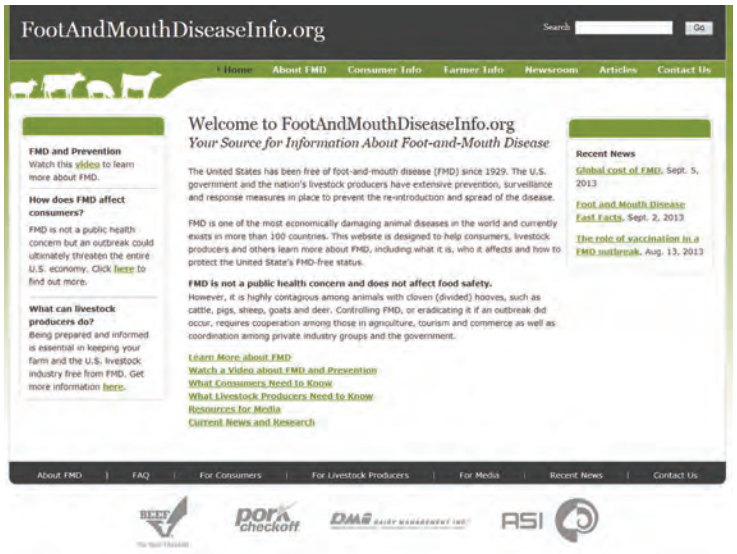
Bill Flynn updated attendees on the status of industry adoption of two guidance documents and other FDA initiatives. Flynn reported the intent of *Guidance 209** is to streamline the veterinary feed directive process to facilitate a transition to increased veterinary oversight of medicated feeds. *Guidance 213** is focused on medically important, feed/water uses of 7 classes of antimicrobials. The implementation of the guidance documents will eliminate growth-promotion uses of medically important antibiotics in feed and water and extend veterinary oversight.

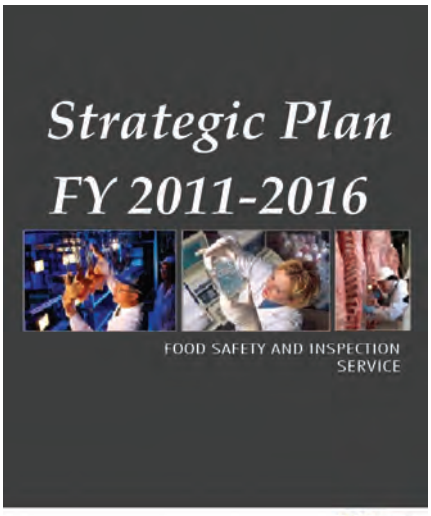
FOCUS OF GUIDANCE 213

7 Classes of Feed/Water Antimicrobials

- **Aminioglycosides**
- **Lincosamides**
- **Macrolides**
- **Penicillins**
- **Streptogramins**
- **Sulfonamides**
- **Tetracyclines**

By the end of 2016, the use of medically important antibiotics for livestock supplied in feed and water will be limited to treatment, prevention and control purposes under the supervision of a veterinarian. The agency will offer training and outreach for veterinarians, producers, feed distributors, and agency compliance officers on both the state and national levels to support the implementation of the guidance. Additionally, Flynn noted the release of the *Draft Guidance for Industry #229** which provides recommendations on study design and criteria for manufacturers to use when evaluating the effectiveness of animal drugs intended to reduce STEC. Lastly, FDA will be engaged in the White House's National Strategy for Combating Antibiotic-Resistant Bacteria through objectives 1.2, 1.3 and 2.4.





* See page 14 for links.

NATIONAL STRATEGY FOR COMBATING ANTIBIOTIC-RESISTANT BACTERIA

Objective 1.2 – eliminate the use of medically important antibiotics for growth promotion in animals and bring other in-feed uses of antibiotics, for treatment and disease control and prevention of disease, under veterinary oversight

Objective 1.3 – identify and implement measures to foster stewardship of antibiotics in animals

Objective 2.4 – enhance monitoring of antibiotic-resistance patterns, as well as antibiotic sales, usage, and management practices, at multiple points in the production chain from food animals on farm, through processing, and retail meat

Al Almanza and David Goldman shared key updates from USDA-FSIS related to the agency's *Strategic Plan.** In an effort to decrease the illnesses attributable to FSIS-regulated products and to drive against the Healthy People 2020 goals, key initiatives were outlined. The FSIS All-Illness Measure estimates the total number of foodborne illnesses from *Salmonella, Listeria monocytogenes* and *E. coli* O157:H7 from FSIS-regulated products. From 2011 through 2014, the number of illnesses attributed to *Salmonella* and *Listeria monocytogenes* from beef has steadily declined. The number of illnesses attributed to *E. coli* O157:H7, however, has not made as steady a decrease, but improvement was seen from 2013 to 2014.

> Preventing *foodborne illness* and *protecting public health* is the primary purpose of FSIS. FSIS will continually strive to become *more adaptable* to changing food safety risks, will *educate consumers* on food handling best practices, and work *closely with other organizations* to present a comprehensive approach to preventing illness.
>
> *FSIS Strategic Plan, 2011-2016*

In July 2014, FSIS moved from set-based *Salmonella* HACCP verification to routine sampling to allow FSIS to estimate an annual prevalence on an on-going basis. A "moving window" approach will allow for a 52-week view of samples and, along with routine sampling, would allow FSIS to better assess an establishment's process control. This is not specific to beef as it is proped for other FSIS-regulated products as well.* Additionally, the agency continues to assess the impact of lymphatic tissues as a source of *Salmonella* in ground beef and is considering draft, beef-slaughter guidance materials reflective of their assessment.

The agency also provided progress updates on the FSIS NARMS Cecal Sampling project, STEC results, the Beef/Veal Carcass Baseline Survey, the ARS Analysis for FSIS STEC Enrichments, National Residue Program, and Whole Genome Sequencing of FSIS Isolates.

* *See page 14 for the link.*

Antibiotic Use and Resistance

Morgan Scott, Texas A&M University

Mike Apley, Kansas State University

Shawn Darcy, NCBA, a contractor to the Beef Checkoff

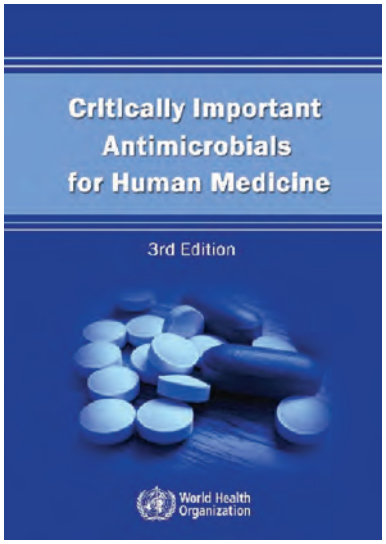
This session explored the real, and perceived, safety challenges facing animal agriculture when it comes to antibiotic use and the potential for resistance formation.

Antibiotic Use

Morgan Scott, Texas A&M University

In 2000, the World Health Organization strengthened its earlier recommendations to terminate the use of antimicrobial growth promoters pending comprehensive human health safety evaluations and to provide surveillance systems on antimicrobial consumption.

The United States has banned animal use for certain antibiotics because they are needed for specific human uses. In the late 1990s, fluoroquinolones and glycopeptides were banned for extra-label use by the FDA. In 2012, cephalosporins were limited to the same use. The WHO published a third revision of their list of critically important, highly important, important and unclassified antimicrobials for human medicine in 2011. Four antibiotics important for



animal agriculture are on the WHO's critical list: fluoroquinolones, 3rd and 4th generation cephalosporins, macrolides and glycopeptides. In 2013, the Centers for Disease Control and Prevention prioritized bacteria into three levels of resistance threat: urgent, serious, and concerning.

Differing perspectives exist as to the use of antibiotics for animals but most can agree that antibiotics enhance the health and well-being of humans and animals alike, and overuse/misuse can occur in both settings. The conflicts revolve around both the therapeutic and subtherapeutic use of antibiotics critically important to human medicine in animal medicine. Some promote eliminating all critically important human drugs for use in animals, while others claim antibiotics help improve food security in a world with growing food needs and help control disease in food animals which improves both animal and human health.

Antibiotic Resistance

Mike Apley, Kansas State University

The first antimicrobial was developed more than 100 years ago. The last new group of antimicrobials was developed in 1978 and, since then, only modifications have been made within the group (**Figure 2**). The first penicillin emerged in 1942 and, regarding the development of resistance, Alexander Fleming wrote in 1945, "There may be a danger, though, in underdosage. It is not difficult to make microbes resistant to penicillin in the laboratory by exposing them to concentrations not sufficient to kill them, and the same thing has occasionally happened in the body." Since this first mention, the scientific community has learned that antibiotic resistance is a complex issue and more data is needed before it will be understood.

According to the Infectious Disease Society of America, "antimicrobial stewardship refers to coordinated interventions designed to improve and measure the appropriate use of antimicrobials by promoting the selection of the optimal antimicrobial drug regimen, dose, duration of therapy, and route of administration. Antimicrobial stewards seek to achieve optimal clinical outcomes related to antimicrobial use, minimize toxicity and other adverse events, reduce the costs of health care for infections, and limit the selection for antimicrobial resistant strains."

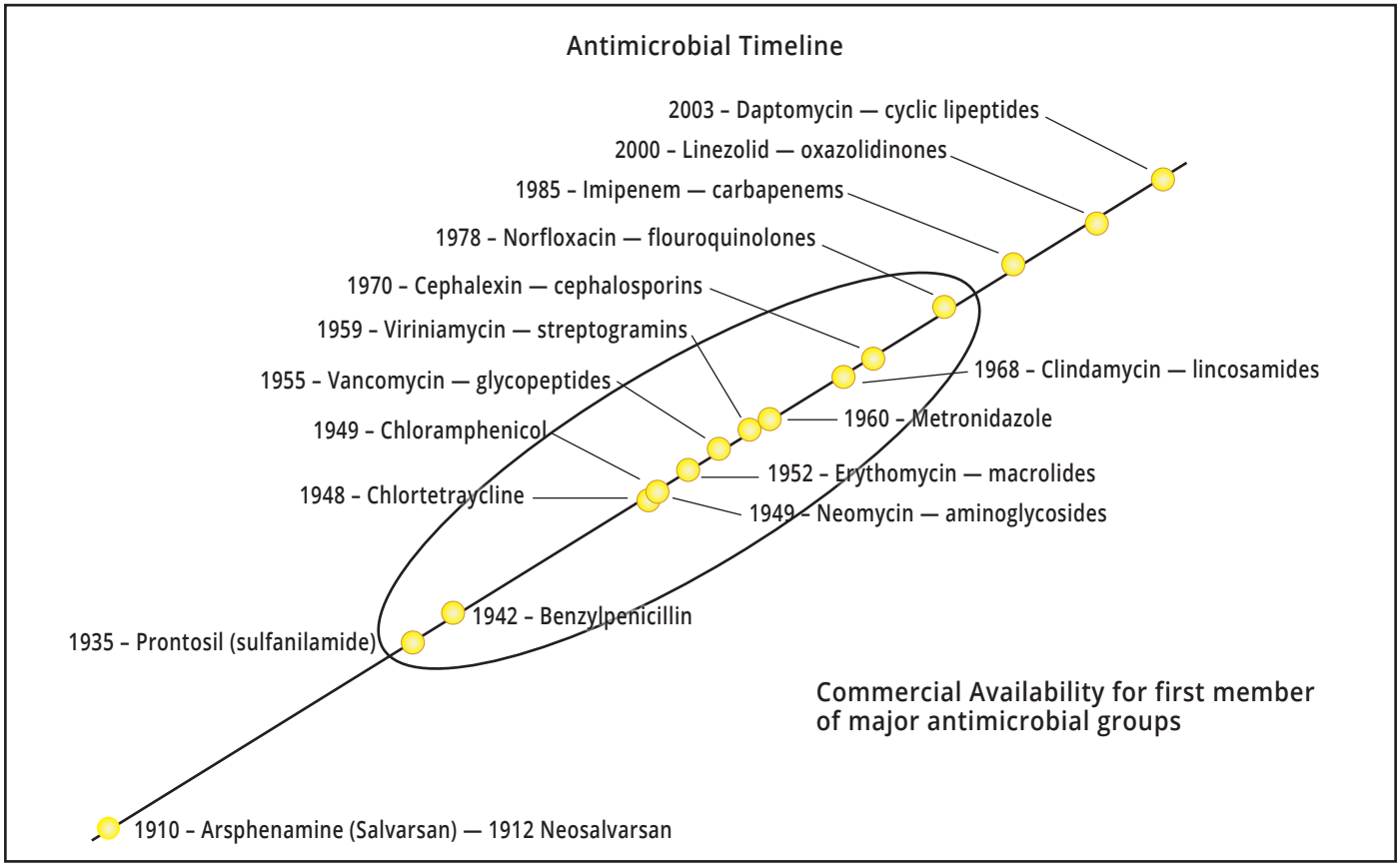


Figure 2

Antibiotic Resistance: Consumer Market Research

Shawn Darcy, National Cattlemen's Beef Association, a contractor to the Beef Checkoff

Darcy presented the most recent research regarding consumer perceptions of antibiotic use in the beef industry. Generally, consumers are positive about the industry though they rank certain production areas to be important concerns, including food safety, treatment of animals, transparency of the industry and specific practices such as hormones/antibiotics.

While many believe attention to antibiotic issues is a growing trend, the percentage of the public attentive to the use of antibiotics in beef has held steady at 25 percent since 2007. Furthermore, when deciding to eat a meal at home, consumers take into account many factors such as taste, nutrition and price before considering 'animals raised without antibiotics.' Generally, consumers approve the use of antibiotics when an animal is sick, though 24 percent believe it is never appropriate to give antibiotics to animals raised for food.

After exploratory messaging research with millennials in October 2014, four basic insights emerged:

- Keep it simple - complex terms may be seen as attempts to overwhelm, impress or mislead
- Collaboration – group-oriented approach taken by a major industry is preferred
- About now – it's not just about plans
- Do not dismiss – lack of explanation may be seen as dismissing the issue

Between November 2014 and January 2015, a checkoff study evaluated antibiotic-resistance perceptions and messaging with 300 millennials aged 20-34 and 302 adults aged 35-plus. Only 28 percent of the total population (31 percent of millennials) are familiar with the use of antibiotics in food production.

Thirty-seven percent either strongly or somewhat oppose the use of antibiotics in food animals, 32 percent either strongly or somewhat support, and 31 percent are unsure (**Figure 3**). Most consumers who support or oppose the use of antibiotics have mild feelings behind the argument (somewhat oppose/support = 50 percent of consumers) leaving room to shift in either direction. While familiarity with antibiotic resistance is low, when specifically asked, 53 percent of consumers say they are concerned with antibiotic

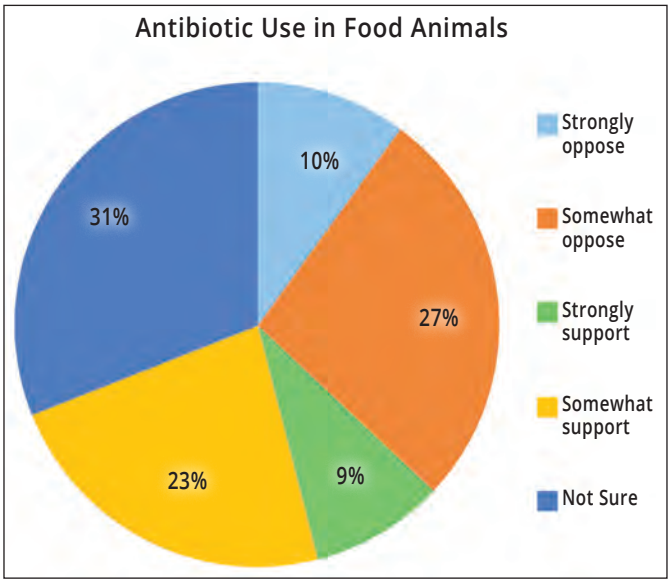


Figure 3

resistance in food production showing the most concern with the eventual "impact on human health."

Consumers responded most postiviely to holistic, high-level messages centered around using antibiotics responsibly, building safeguards, pinpointing the right treatment for the illness, and conducting the right research. This research resulted in a distinct pathway to consider when developing a communication approach/plan/messages on the topic of antibiotic use in food animals. It's important to start with why antibiotics are used and the benefits to humans, then statements should include how they are used, the robust research available, the collaborative industry approach, and lastly, present consumers with additional information to show how these efforts lead to a safe food supply.

Economics of Beef

Randy Blach, CattleFax

Travis Arp, U.S. Meat Export Federation (USMEF)

This session provided attendees an opportunity to learn about the impact future U.S. and international markets and supply could have on the domestic industry.

U.S. Cattle and Beef Situation

Randy Blach, CattleFax

Blach described the beef industry's current economic situation as the "perfect storm" for high cattle and beef prices. The beef industry has seen one of the biggest drops in numbers of cattle harvested in the history of the business, a drop of nearly 2.5 million head. This drop in beef supply is coupled with low-protein

supplies across all species, resulting in no substitute for high-priced beef. Supply of protein is changing in the near future however, as the smallest supplies for pork and poultry are behind the industry, and the smallest supplies of beef will likely be seen in Quarter 1 of 2015.

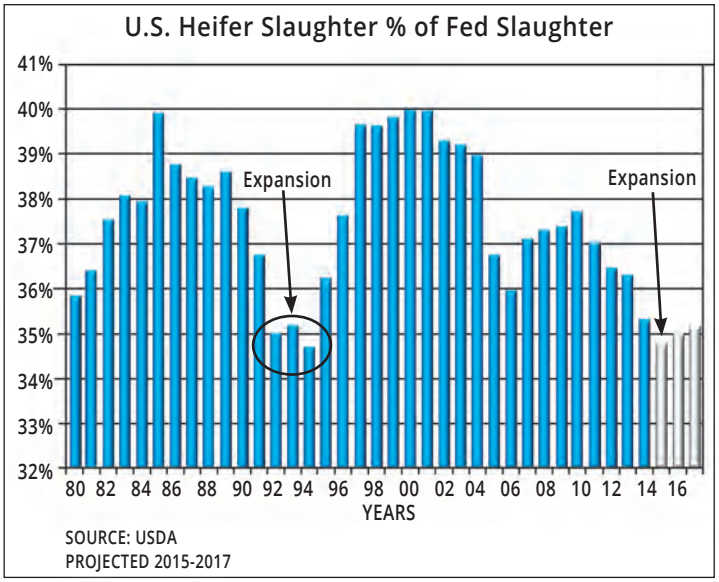


Figure 4

Lean beef supplies will remain tight as cattle ranchers begin to rebuild herds (**Figure 4**). Green grass and profitability were cited as the two factors that influence rancher's decisions to grow cattle herds. The drought conditions are nearly over and the affected areas will see continual improvement in the next 18 months. Corn prices are down from the all-time highs seen in 2012. Thanks to lower prices for inputs, and strong domestic and export demand, profit has increased for cattle producers.

The beef industry is also seeing a regional shift in beef herd concentrations. With a lower harvesting capacity in the western plains of Texas, a shift toward more beef animals being fed and harvested in the Midwest (ex. Nebraska, Iowa and South Dakota) has occurred. Additionally, 20 percent of the cattle harvested in 2014 were dairy-influenced animals. The dairy industry is also seeing a shift in concentrations from the coasts of the country into the central plains (ex. Texas, Colorado, New Mexico and Idaho).

In the lean beef markets, the spread between differentiated and cash markets is extremely high. A spread of up to 2 dollars per pound is being seen when comparing premium to commodity grinds, and the United States had to increase imports of lean beef by 31 percent in 2014 to meet demand of the domestic markets. Consumers are still willing to buy premium beef products regardless of the price, and as prices soften, consumption is expected to increase.

Beef Industry Economics: Exports

Travis Arp – USMEF

U.S. beef exports had a record year in 2014 (**Figure 5**). The U.S. exported nearly 1.2 million metric tons of beef worldwide and set a value record of $7.135 billion, which added more than $300 per head slaughtered. The U.S. beef industry built upon the momentum of the 2013 export market, despite record-high beef prices and strong competition in the global marketplace.

Regardless, 2015 exports will face the challenges of limited market access in major export markets due to the lingering effects of BSE and various Sanitary and Phytosanitary Measures (SPS), a strong U.S. dollar, and high U.S. beef prices. While Japan and Mexico are two of the largest markets for U.S. beef, the China and Russia markets will play a key role moving forward and will be a major determinant for growing U.S. beef exports. Shrinking cattle supplies in competing markets will sustain high beef prices and provide an opportunity for the United States to expand market share in countries where U.S. beef already has a strong presence.

U.S. beef producers continue to benefit from the value of exports, as export value has supported

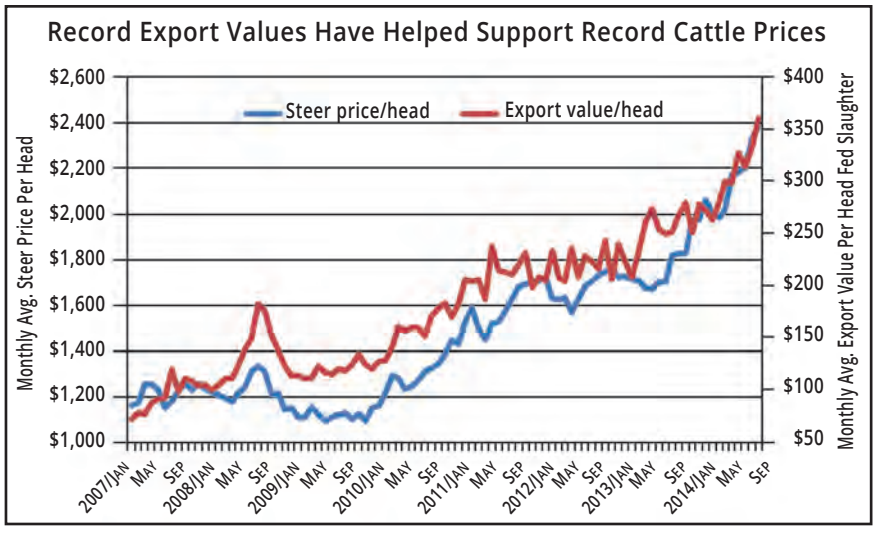


Figure 5

record beef prices over the last decade. 2015 is expected to be another banner year for U.S. beef exports, despite the challenges in the international marketplace, and sustained success in the export market will continue to provide benefits throughout the beef industry.

Molecular Approach to Microbial Ecology

Kendra Nightingale, Texas Tech University

Ken Jones, University of Colorado

Paul Morley, Colorado State University

The fast-growing area of metagenomics – or the study of genetic material recovered directly from environmental samples – is producing valuable data in volumes! This session provided a better understanding of bioinformatics and data management with updates in diagnostic methodology.

Molecular Subtyping of Foodborne Pathogens: From Fundamentals to Application

Kendra Nightingale, Texas Tech University

Nightingale provided Summit attendees with basic background information on molecular subtyping and its applications in identifying bacterial strains. The goal of bacterial subtyping through genome sequencing is to determine if isolates share a very recent common ancestor. Molecular subtyping can be a useful tool in outbreak investigations and identifying contamination patterns in food processing plants.

Sequencing of DNA molecules began in the late 1970s, first by degradation methods, followed by the Sanger method. The first bacterial genome sequence was completed in 1995 by shotgun sequencing, a method based on Sanger. The "next generation" sequencing (NGS) technologies exhibit vastly increased sequencing speeds with rapidly lowering costs (**Figure 6**).

In 2004, the National Institutes of Health (NIH) launched a $70 million program to support researchers working to sequence a complete mammal-sized genome initially for $100,000 and ultimately for $1,000.

Currently, several companies with varying equipment, speed and capacity are competing to be the first to offer the $1,000 genome. NGS applications include the identification of pathogens difficult to differentiate by PFGE, e.g. certain *Salmonella* serotypes and the taxonomy of *Listeria*.

The FDA is currently sequencing all DNA found after enrichment, which reduces the bias found in traditional detection. They are amassing data on all DNA found which will serve as a storehouse for "incriminating" data in the absence of public health hazards.

Deciphering and using the data collected through NGS sequencing is the current challenge. Bioinformatics pipelines are rapidly catching up with the hardware, thereby making application by public health labs feasible.

History of Next Generation Sequencing and its place in 21st century science

Ken Jones, University of Colorado

When first introduced, the capacity of Sanger Sequencing was 96 sequences per hour or 2,304 sequences per day which generated 0.13 human genomes per year. With NGS, the machines are capable of 3,000 times the annual output of Sanger in 4 days. Illumina generates 469 human genomes every 4 days with a very low error rate. Today, Illumina has X-Ten Sequencing or 10 machines in a tandem which can screen 18,000 human genomes per year.

NGS is producing data files with 10s of thousands to 100s of millions of sequences. Management, quality control and data assessment present the challenge of what do you do with NGS data.

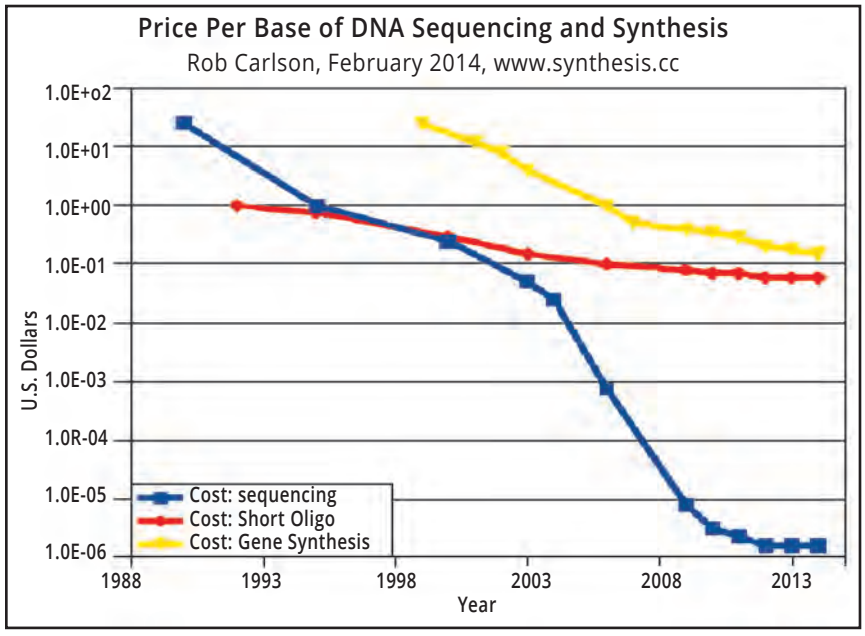


Figure 6

Jones listed three possibilities:

- Align the genome data to a known sequence (DNA, RNA, *Salmonella, E. coli*)
- Assemble the data like a jigsaw puzzle into a finished sequence
- Use the data as independent reads

BRIEF HISTORY OF SEQUENCING

- **1953: Watson and Crick elucidate the structure of DNA**
- **1973: First sequence of DNA published**
- **1977: Sanger methodology published**
- **1983: PCR conceptualized by Kerry Mullis**
  - **First published in 1985**
- **1985: Implementation of thermal-stable polymerase**
- **1987: Perkin-Elmer PCR-1000 Thermal Cycler**
- **1990s: Sequencing by synthesis conceptualized**
  - **~1997 by Nyren – leads to pyrosequencing**
    - **Based on release of pyrophosphate during nucleotide incorporation**
  - **~1997 by Balasubramanian and Klenerman – leads to Solexa**
    - **Based on reversible chain termination**
- **1990: $2.7 billion Human Genome Project – Sanger sequencing**
- **2003-2008: $138 million Genome-wide genotyping (GWAS)**
- **2003-2009: Bovine Genome Project**
- **2008 - 2012: Exome sequencing**
- **2012: Genome Sequencing**

Assembly is both time-consuming and costly. In assembly, sequencing can be optimized by knowing the small target needed from the genome.

Paradigm Shift: New Perspectives on Antimicrobial Resistance (AMR)

Paul Morley, Colorado State University

As background, Morley outlined the issues surrounding global food security in 2050. With an estimated 2 to 3 billion increase in the world population, food production will need to be doubled. As an additional challenge, the greatest production potential is not in the areas where greatest population growth will occur (**Figure 7**). Relative to meat production, North America needs to quadruple production amid increasing competition for limited natural resources.

AMR is one of the most important issues facing global societies. As a result, the use of antimicrobial drugs (AMD) in food animals is receiving increasing criticism. Since use of any antimicrobial in human or food animal production selects for resistance, it is important to determine what risks can be tolerated while considering the benefits.

Such a complicated topic needs to be centered with the best scientific data available. For example, in a study of conventional and natural feedlot cattle (Morley et al., 2011), the percent of AMR bacteria unresponsive to certain AMDs increased during the time the animals were on feed, with the greatest percentage of resistance in tetracycline, despite the animals' absence of tetracycline exposure. The natural cattle showed a slightly lower percentage of AMR bacteria but required an extra 50 days on feed to reach harvest weight.

Illumina X-Ten Sequencing

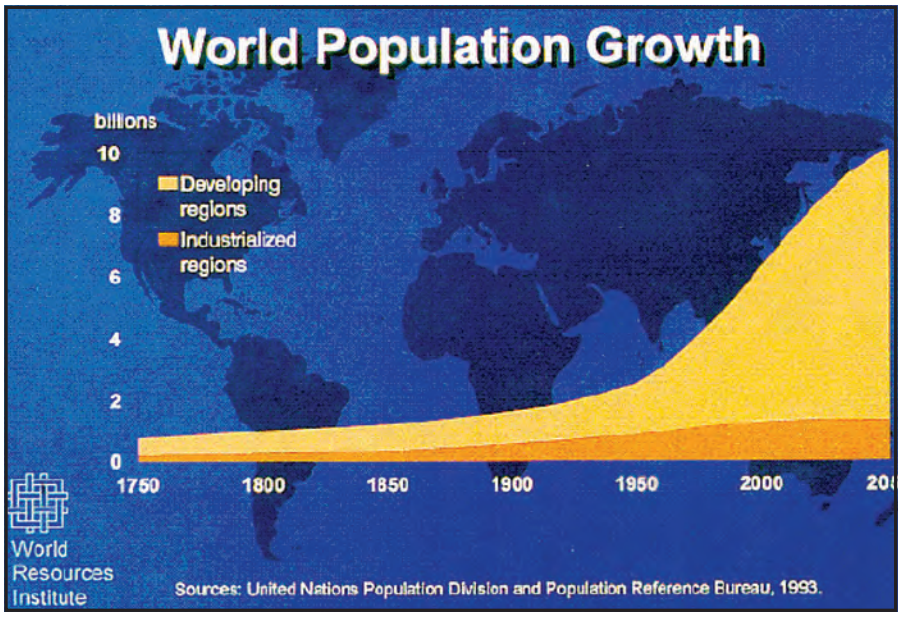


Figure 7

The use of metagenomics, the study of genetic material from communities of organisms, will provide a more holistic perspective to evaluate the complex interactions involved in AMR. The questions of the shifting microbiome (whole populations of microbes) and the resistome (all resistant genes) will be addressed with scientific evidence.

Unlimited opportunities are available through high-throughput sequencing which provides an unprecedented view of microbial ecology. Further work is needed to understand gene functionality and expression and the interactions between the host, microbiome and the environment.

Regulatory Implications through Case Studies

Barb Masters, Olsson, Frank & Weeda

Kerri Gehring, Texas A&M University

This session provided attendees the opportunity to review case studies to better understand regulatory requirements and the resources available to make good safety decisions.

Validation for non-O157 STEC in ground beef components and ground beef

Barb Masters, Olsson, Frank & Weeda

Masters led a lively discussion presenting various opportunities to validate microbial intervention systems for non-O157 STEC for bench trim, other ground beef components and ground beef. FSIS learned many lessons when they began testing beef trimmings for non-O157, and the industry may be able to extrapolate this knowledge for use in bench trimming and ground beef processing if FSIS makes the decision to begin testing these products for non-O157 microbes. Sherri Jenkins, JBS-USA and Chad Martin, Tyson, presented the valuable lessons learned from each of their company's unique non-O157 validation process. Those lessons include the need to have a robust, sanitary dressing procedure, a strong, validated intervention system, and a properly implemented verification system. The discussion then turned to further processors and opportunities for testing for non-O157 in grinding systems, various lotting systems to protect the processor and the raw and finished products, how rework should be handled, and when validation and verification processes should be implemented into the production system.

Kerri Gehring, Texas A&M University

Gehring facilitated a discussion centered on high-event periods, or when establishments experience high numbers of positive results for non-O157 or other virulence markers. Many examples of how these days are handled within different processing plants were offered to the group. For instance, many processors are able to tie event days to contamination of just a portion of the carcass. This narrows down the investigation of the source of contamination, and provides less material loss. Other topics covered included the correlation of contamination in trim to the contamination in subprimals, and deciding what to do with product that was a part of a high-event period.

Breakout Session: Industry Sector Working Groups

BIFSCo Chair Angie Siemens challenged attendees to engage in industry sector breakout discussions based on 2014 regulatory actions, research results or industry changes. Each breakout group went through a HACCP/Sanitary Standard Operating Procedures reassessment, a research and education needs assessment and discussed best practice update needs. Members of BIFSCo will address best practice

WORKING GROUP SUMMARIES

HACCP/SSOP Reassessment Considerations – Equipment inspection and sanitation procedures, cold chain management evaluation, lymph node impact on hazard analysis

Best Practice Needs – hyperlinks to relevant FSIS/FDA guidance, evaluate for residues and allergen guidance, add supporting documents where applicable (data logs, supplier and consumer guidance program information)

Research Needs – approved pre-harvest interventions for STEC and *Salmonella*, understanding of intervention effectiveness across bacteria both pre- and post-harvest, understanding the potential beneficial use of surrogate strains for validation, understanding how a pathogen moves through processing equipment, understanding of packer-applied interventions benefit through transport/storage in retail/foodservice

Education Needs – outreach to small operators, better understanding of how cattle are raised and the Beef Quality Assurance program, validated cooking instructions for ground products (consumer and foodservice), consumer education on agriculture in general and how to properly handle food products

updates over the course of 2015 and provide updated versions at next year's Beef Industry Safety Summit. Research and education needs will be shared with other organizations that fund these activities for potential collaboration.

General Session: Residues & National Residue Program

Mike Apley, Kansas State University

Distinguishing the relationship between marketing claims and residue violations can be confusing. This session tackled this and other topics including regulatory requirements for new drug applications and the National Residue Program.

Understanding the science (and marketing) behind residues

Mike Apley, Kansas State University

Apley explained the scientific process behind setting residue tolerance and violative levels in animal products. A residue is a parent drug or metabolite which is detectible in edible tissue, where as a violative residue is a concentration of the residue which exceeds the U.S.-established tolerance or the internationally recognized Maximum Residue Level (MRL). By law, animal tissue cannot contain residues that exceed levels considered violative.

The veterinary antimicrobial approval process of the FDA targets an efficacy level that maximizes animal safety, environmental safety and food safety. To find violativity levels in animal products, toxicology studies first determine a no-observable effect limit (NOEL) based on a test species and its reaction to the compound. A safety factor is then applied to the NOEL in order to arrive at an acceptable daily intake (ADI), which is the safe concentration for drug residues that can be consumed by humans daily throughout a lifetime. Safe intake levels are calculated for each tissue that may be consumed, including liver, muscle, fat and milk or eggs if applicable.

The target residue tissue is determined to be the last organ that falls below the tolerance level and is used as the indicator of whether or not the carcass contains violative residues. A tolerance level is defined as the amount of a specific residue, which, when the total residue concentrations are near the safe concentration, will be a consistent percentage of total residues in that product.

TOP 10 RESIDUES IN CULL DAIRY COWS 2005-2010

- **Penicillin**
- **Flunixin (only elevaluated in cattle with initial KIS +)**
- **Sulfadimethoxine**
- **Gentamincin**
- **Ceftiofur**
- **Sulfamethazine**
- **Neomycin**
- **Tilmicosin**
- **Tetracycline**

FSIS is a participating member of the National Residue Program, a three-tier residue monitoring program: scheduled sampling in tier 1, targeted sampling of individuals in tier 2 and targeted sampling of herds in tier 3.

It has been found that in 70 percent of the cases where violative levels of residues were found, a veterinarian was not involved in the decision to use or administer the drug. It is always important to follow the label directions for milk and meat production

and the guidance of veterinarians when treating food animals with antimicrobials. Withdrawal times should be extended, never shortened, if using an antibiotic extra-label.

Best management practices to follow when using antimicrobials in food animal production include: follow the label, always observe withdrawal times, keep accurate records, have administration protocols in place, observe protocols, train employees and do not use an antimicrobial drug extra label without proper guidance from a veterinarian.

General Session: GFSI, Global Traceability & Food Defense

Moderator: Keith Belk, Colorado State University

Kristie Grzywinski, SQFI

Jerome Lawler, Silliker

As the food supply continues to navigate a global marketplace, programs related to food traceability and food defense have developed. This session focused on how standards are evolving, who is requiring them, their cost, requirements, and audits.

SQF Program – An Overview

Kristie Grzywinski, SQFI

The Safe Quality Food (SQF) Program is owned by the Food Marketing Institute (FMI) and operated by the SQF Institute (SQFI), a division of FMI. The purpose of the program is to ensure the world's food supply is safe by setting global standards. SQF has set standards for 35 food sectors, including meat and poultry, and has certificates in more than 30 countries (**Figure 8**).

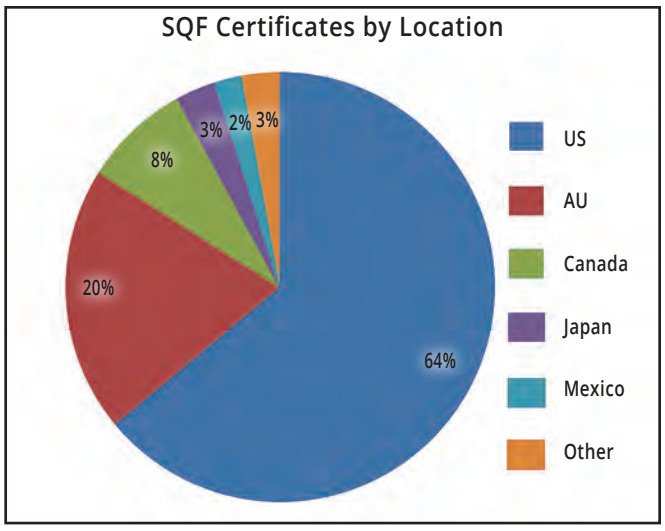


Figure 8

The Global Food Safety Initiative (GFSI) was launched in 2000 following a directive from food business CEOs and adopted the aim to "build confidence in third party certification and reduce inefficiency in the food system." Initially, GFSI planned to set up one audit to be globally recognized. Since this approach wasn't workable, GFSI at its inception approved four original benchmarking schemes which were determined to be equivalent to the GFSI Guidance Document requirements. The original schemes were BRC Global Standards, International Food Standards (IFS), Dutch HACCP and the Safe Quality Food Code (SQF). GFSI helps and encourages food safety stakeholders to share knowledge and strategy for food safety and to develop best food safety practices in a common global framework.

The SQF program operates through a third-party supplier audit program. Auditors, who have specific industry experience and understand critical control points in that sector/category, are credentialed to audit the food sector categories.

The SQF Institute was purchased by FMI to address retailers' concerns about the number of market withdrawals, most often caused by foreign material, labeling issues, allergen management or quality issues. GFSI investigates all recalls and holds all the data. In 2014, recalls in the United States totaled 2,155 with chemical hazards as the number one reason. Undeclared allergens represented 78.6 percent of the chemical hazard recalls (36.3 percent of total recalls). **Figure 9** illustrates the causes of the 2013 and 2014 recalls.

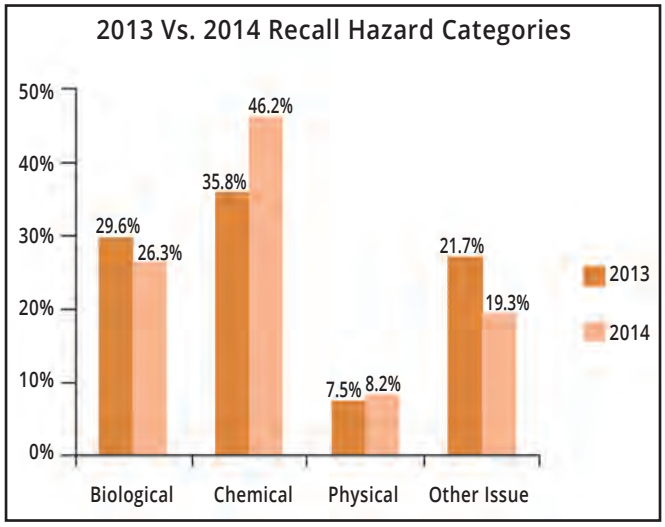


Figure 9

To ensure compliance, a supplier can:

- Conduct internal audits
- Conduct traceability exercises
- Implement effective training programs
- Maintain records
- Conduct validation activities
- Review facility condition

Traceability

Jerome Lawler, Silliker Inc.

Silliker auditors help food companies identify potential risks in food safety programs and meet the strictest industry and regulatory standards. Lawler explained key requirements for Silliker auditors:

- Be degreed in food-related or bioscience discipline
- Have work experience of a minimum 5 years
- Have audit log experience within each food category qualified to audit
- Complete HACCP 2-day course
- Complete training
  - Pass initial competency test
  - Pass food sector or category competency test
- Perform shadow audits
- Perform witness audits

Traceability involves connecting the dots between program areas to capture all inputs and outputs, including receiving, lot codes or product identification, stock rotation, operations or processing, and shipping. Lawler provided examples of potential obstacles to maintaining traceability throughout these processes.

GFSI STANDARDS

Requirements:

- **That the supplier develop and maintain appropriate procedures and systems to ensure identification of any out-sourced product, ingredient or service**
- **Complete reords of batches of in-process or final product and packaging throughout the production process**
- **Record of purchaser and delivery destination for all product suppliers**

For more information, go to *http://globalfoodsafetyresource.com/*

In terms of traceability, all GFSI-recognized schemes outline a minimal level of upstream and downstream traceability for food.

Conclusion

With more than 220 attendees, the 2015 Beef Industry Safety Summit was again the meeting place for safety experts in the beef industry to hear the latest science and regulatory information surrounding the current challenging safety issues facing the industry. As in the past, attendees took advantage of opportunities to exchange ideas and share individual experiences, thereby ensuring continued improvement in the beef industry through non-competitive collaboration.

SAVE THE DATE

2016
Beef Industry Safety Summit
March 1-3, 2016
Austin, TX

Links to documents noted on pages 4 and 5:

Guidance for Industry #209

http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf

Guidance for Industry #213

http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf

Draft Guidance for Industry #229

http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM435143.pdf

USDA-FSIS Strategic Plan

http://www.fsis.usda.gov/wps/wcm/connect/65602d92-d017-4edc-8536-5ed6aaa6b52a/Strategic_Plan_2011-2016.pdf?MOD=AJPERES








Beef Industry Safety Summit

Industry Safety Summit
2015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