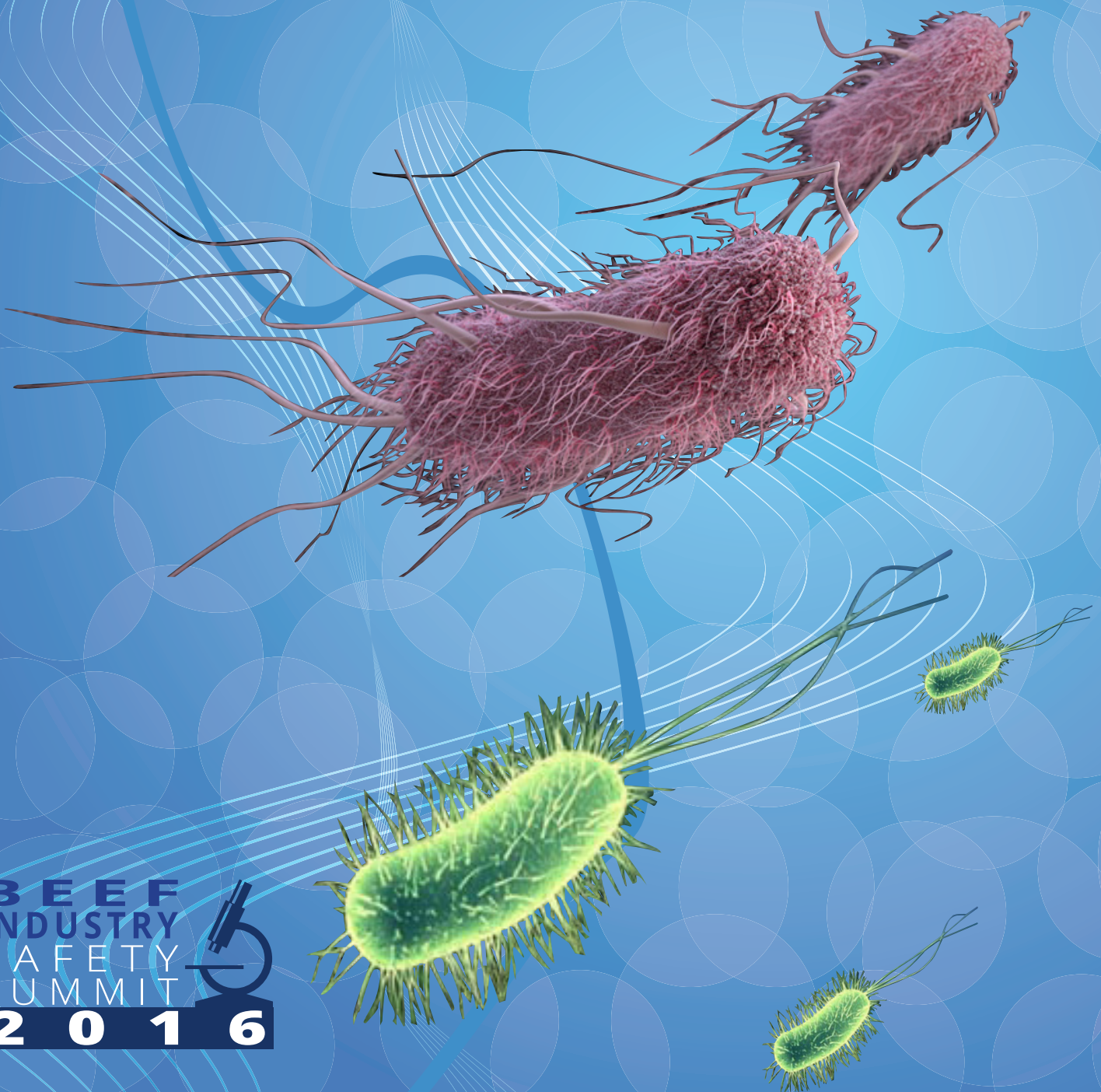


BEEF INDUSTRY SAFETY SUMMIT SUMMARY

Austin, Texas • March 1-3, 2016



BEEF
INDUSTRY
SAFETY
SUMMIT
2016

General Session I: Water, Food Safety, and Sustainability Crossroads

Moderator: Chad Martin, Tyson, Beef Industry Food Safety Council Chair

Chad Martin moderated the Opening General Session of this year’s Safety Summit with a panel of experts to discuss the balance between beef safety, water use and sustainability. What solutions and challenges have beef and other animal proteins explored to meet customer demands without jeopardizing food safety?

Marty Matlock is executive director of the University of Arkansas Office for Sustainability and professor of ecological engineering.

Though some may see agriculture as slow to change, it actually is continuously changing, but changes happen with a purpose. Water poses a unique challenge as it is a critical resource for all industry, but water is not evenly distributed around the world. A scarcity of water is emerging globally and regional scarcity currently exists.

Sustainability is an area where continuous improvement is necessary. For instance, limited land area makes expanding agricultural production into the future a difficult challenge, so agriculture must

increase yields with current resources. Additionally, water will be scarce until sea water can be made fresh using fusion reactors.

Not all water is created equal. Rainwater is considered green water (GW). Blue water (BW) is sourced from surface or groundwater resources, and grey water is the fresh water needed to sufficiently dilute the pollutants resulting from producing a product. Beef production primarily uses green water (**Figure 1**). The agricultural industry needs to continually improve in the area of water usage to increase global food security and decrease the impact of agriculture on the environment.

Agricultural Sustainability Challenges

1. In order to meet projected demands for food, feed, fiber and fuel from the land, global agriculture must increase production (output per year) by 50 to 100 percent in the next four decades.
2. To preserve biodiversity and other land-based ecosystem services, global food production must freeze the footprint of agriculture.
3. Yield (output per area) must more than double in the next 40 years in the United States and Europe.
4. Energy scarcity will drive innovation while limiting expansion of productivity.
5. Water scarcity will limit productivity globally.

Wayne Morgan is a corporate vice president and the president of Protein Products for Golden State Foods, which supplies many restaurant chains with food products and services.

For customers of the beef industry, sustainability is important, but their perception may vary from the reality. Beef production requires water use to meet safety goals, e.g. refrigeration and cooling, cleaning and sanitation, and interventions. Water conservation is an area where all segments of the industry can affect improvements. As with safety, all participants in the beef industry are connected and everyone must be responsible. It makes good business sense for all industry members to make good decisions today that enhance opportunities for long-term success.

Mike Gangel is president of Chad Equipment, a division of Birkco Corporation, the leading designer and manufacturer of automated washing and pasteurizing equipment for the meat industry.

Gangel explained the evolution of water usage in packing plants. Water conservation has always been a priority of the industry but little technology has been available to support this initiative. Decreasing water consumption requires a strong commitment from top management,

Relative blue/green water use.
Global material averages, Mars fraction usage

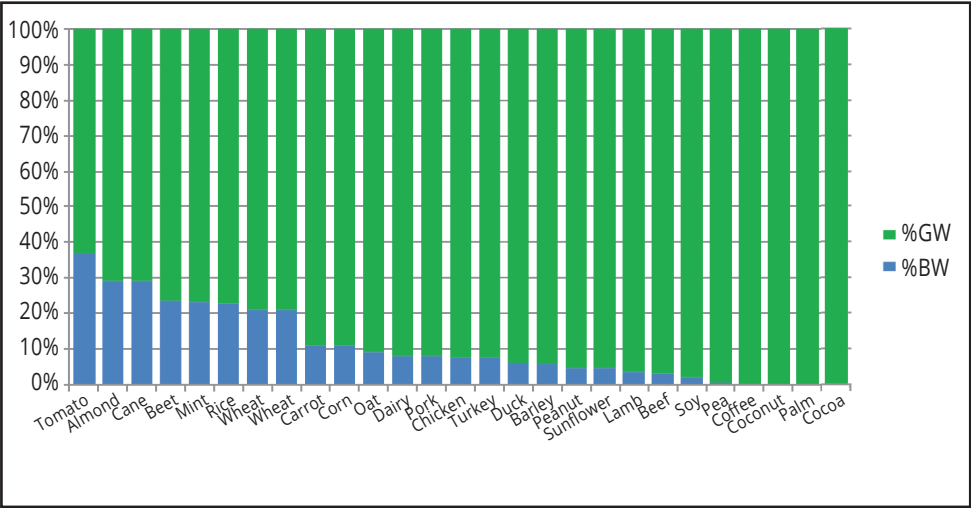


Figure 1.

Several technologies have recently become available to conserve water including the following:

- Automated water control valves
- Automated personnel equipment washing
- Mechanical removal of visible contamination, brushes
- Use of recycled water
- Recirculated water — hot water pasteurization

has been shown to reduce water consumption by 35%. Additionally, more technologies are being developed and will become available in the near future.

Mark Ritsema oversees the environmental affairs and grease recovery operations at JBS USA, LLC for the fed-beef division.

Ritsema explained that those responsible for food safety in the plant need to continually innovate and create new safety interventions in sustainable ways. Ritsema described the amount of water that flows through a beef plant annually. He noted ten plants in the JBS system use 6 billion gallons of water and treat the same amount of water required for a city of more than 5 million people at a cost from \$5.08 to \$16.65 per 1000 gallons. Efforts to reuse a limited and costly resource are critical as the organization also balances an effective food safety program.

Regulatory Update

Moderator: Kristina Butts, NCBA Policy Division

Kristina Butts moderated this session in which representatives from USDA-FSIS shared the latest rules/notices and their potential implications for the beef industry. Topics included pathogen reduction performance, non-intact beef, baseline data reports and more.

One of the hallmark sessions of the Summit is the regulatory update. In this year's session, regulatory officials reaffirmed with the audience the agency's focus on science-based information to reduce pathogens and improve beef safety. USDA continues working against its [strategic plan](#)* and the strategic themes outlined including the prevention of foodborne illness. *Salmonella* continues to be a top priority for the agency as it is the organism most associated with

and water conservation decisions must be balanced with food safety.

Whole-plant, large-scale water reuse is a new technology that is currently available, but it's very expensive. Gangel shared information about new technology for washing the carcass, head and offal which

products FSIS regulates (**Figure 2**). Regulatory sampling results and trends were also provided for shiga toxin-producing *E. coli* (STEC) in both beef and veal as well as for the National Antimicrobial Resistance Monitoring System (NARMS). A summary of the last 20 years of NARMS is due to publish later this summer. As modernization of food safety continues to be discussed within the agencies, the industry is challenged to review their own processes and determine if changes should be made to continually improve beef's safety.

Food Safety and Inspection Service FSIS Related Outbreak Trends: FY 2007-2015

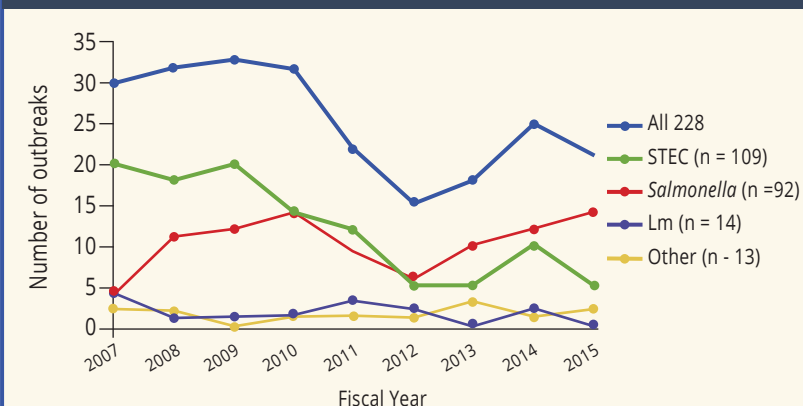
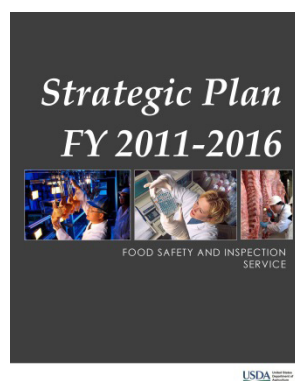


Figure 2. Since 2012, *Salmonella*-related illness clusters have comprised the largest proportion of outbreaks involving FSIS-regulated commodities.

Strategic Theme: Prevent Foodborne Illness



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.

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

General Session II: Whole Genome Sequencing

Moderator: Elaine Scallan, University of Colorado

Whole Genome Sequencing can be a powerful tool in the beef industry. Elaine Scallan moderated this general session providing information on how it is being used throughout

the industry, and specifically, its use for surveillance of foodborne illnesses across the United States.

Barb Masters is a senior policy advisor at Olsson, Frank, Weeda, Terman, and Matz (OFW). She works with the meat and poultry industry to ensure regulatory compliance.

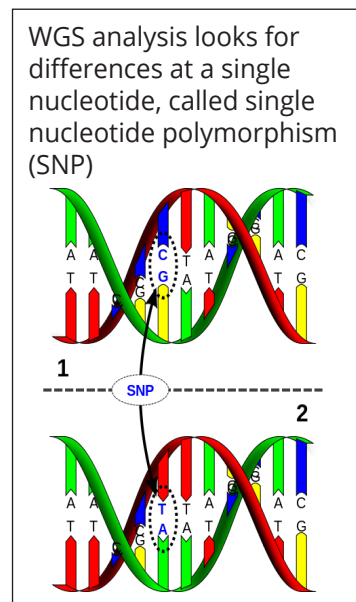


Figure 3. SWGS analysis illustration

To ground the audience, Masters gave an overview of Whole Genome Sequencing (WGS). The word “genome” means the genetic material of the organism, and the word comes from combining the two words “gene” and “chromosome.” Through WGS analysis, it is possible to plot out the entire DNA sequence of an organism, and with this data, it is now possible to find differences in genetic makeup of organisms at the nucleotide level (Figure 3). Whole Genome Sequencing is utilized

to look for relationships between genetic samples. All results gained from WGS are then entered into a publicly available database. The database is called GenomeTrakr and can be accessed by researchers, public health officials and the industry for real time comparison and analysis of samples.

A survey of the beef industry showed the participants would first and foremost like to know how USDA-FSIS and other public health agencies are using, and will continue to use, WGS from a regulatory perspective. Questions from the industry included the following:

- If FSIS can compare WGS results to previous regulatory results to determine the persistence of specific pathogens in the environment, what would FSIS expect an establishment to do to mitigate the bacterial persistence in a plant?
- How will regulatory and public health agencies use WGS to identify the source of foodborne outbreaks? How will these agencies determine from genetics whether samples from ill consumers and a food product are closely related?
- How will WGS be used moving forward to identify emerging pathogens and antimicrobial-resistance genes?

The regulatory implications of WGS technology were not the industry's only concerns when surveyed. Another question posed by the industry is how establishments can use WGS

for in-plant samples to increase their food safety program. Whole genome sequencing allows a company to identify and minimize/eliminate potential problems before they are uncovered by FSIS. Whole genome sequencing can track and survey pathogens within an establishment that could provide useful information addressing high event periods, add useful information to the establishment's food safety dataset (including sanitation efficacy and perhaps information linking a common supplier to positive samples) and allow for identification of antimicrobial-resistance genes within a facility. Whole genome sequencing also can track pathogens through an establishment and provide pathogen strain information to identify the source of contamination. Collection of WGS data will allow companies to compare sequence data to information publicly available on GenomeTrakr. Masters suggested that since this data is publicly available, a company surveilling WGS data should compare their results to this database.

From Masters presentation, it became clear that with WGS, timing is everything. The use of WGS in the beef industry is not a question of if, it is a question of when, how and for what purposes it will be used. As with any new technology, a knowledge curve exists, and the need to understand the technology prior to implementing it is critical.

Anna Carlson is Nebraska's foodborne disease epidemiologist at Nebraska Public Health Department and coordinates the Enteric Disease Surveillance Program.

In order to understand how public health departments and agencies are beginning to use WGS, Carlson began with a background of surveillance and subtyping for listeriosis. She shared that *Listeria monocytogenes* (LM) is very WGS-centric, as it was chosen as the first pathogen for the CDC's WGS pilot project with the goal of sequencing all LM isolates in the United States. *Listeria monocytogenes* was chosen as it is rare, but serious if associated with an outbreak. It is also relatively hard to assess through Pulse Field Gel Electrophoresis (PFGE) as it has low population diversity and a relatively small genome that is easy to sequence and analyze. Furthermore, a great collection of epidemiologic data is available since the *Listeria* initiative was adopted in 2004.

Figure 4 demonstrates that each time another level of surveillance for LM was added, an increase in the number of LM outbreaks was seen; however, a decrease in median cases per outbreak was noted. The reasons for the decline were twofold: 1. outbreaks were detected faster with each level of surveillance, and 2. smaller outbreaks were now more easily detectable. Outbreak detection for *Salmonella* and *E. coli* are very different than for LM, and are still mostly PFGE-centered. Epidemiologic data collection for these pathogens is not as strong as it is for LM, and currently, states

maintain their own interview data in the case of an outbreak. The data are not nationally available.

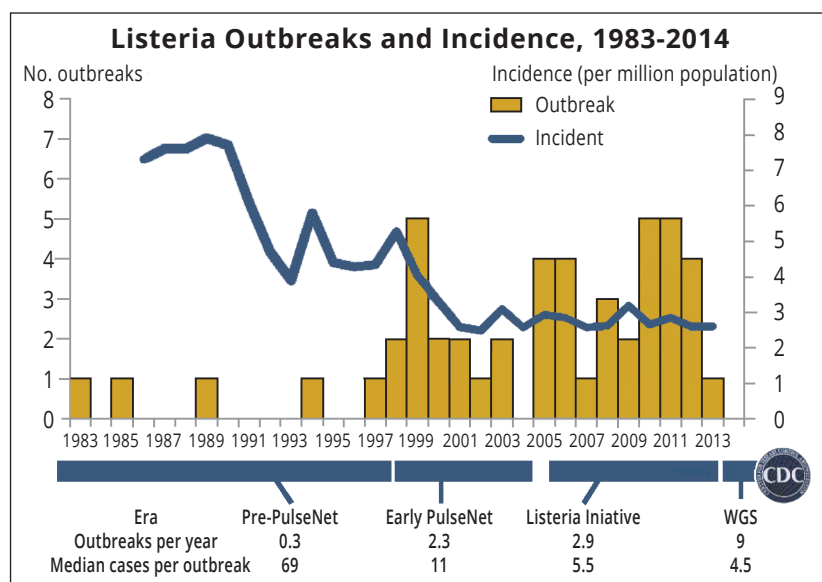


Figure 4.

Given these current uses and limitations for WGS, Carlson outlined why a drive to switch to WGS in public health departments is occurring, and why PFGE is now considered inferior. The use of PFGE in a foodborne illness case would require anywhere from seven to nine PFGE tests to fully characterize an enteric pathogen, and the process of classifying the pathogen can take one to two weeks. Whole genome sequencing however, is a single test that gives all the information that the seven to nine PFGE tests can give in about a one-week time frame. Furthermore, using PFGE does not ensure 100 percent accuracy when typing bacterial genomes. In Figure 5, organisms A and B are different as displayed by the red and green sections of the genome. They, however,

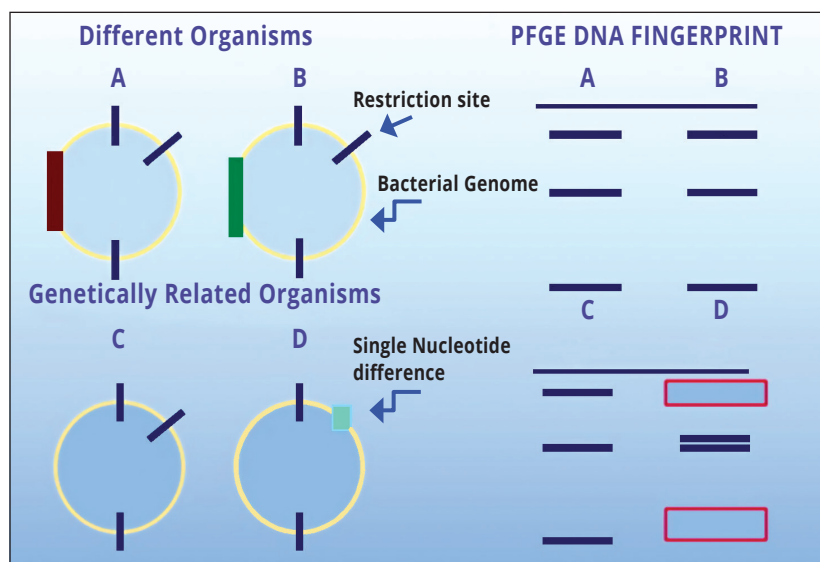


Figure 5. Illustration of PFGE and WGS results.

produce the same PFGE patterns. Organisms C and D are genetically related; however, a small, single nucleotide change occurred (as seen by the small aqua section) and one of the enzymes can no longer cut that sequence. They now have different PFGE patterns by two bands and look unrelated. Whole genome sequencing provides every letter of a pathogen's genome, and at a very high resolution. This technology is also "future proof," meaning that researchers cannot get a better understanding of a pathogen than knowing the entire genetic makeup of that organism.

Whole genome sequencing helps the public health industry break up PFGE clusters. For instance, more than 85 percent of *Salmonella enteritidis* (SE) isolates can be classified into 5 PFGE types. Therefore, by gaining more information about differences in genetic profile of SE, the public health departments can further separate the isolates to group cases that have a related outbreak origin. Whole genome sequencing also provides the opportunity for public health officials to tie PFGE patterns together, and link between human and product isolates to better

identify the source of infection.

This technology does not come without challenges. A need still exists to harmonize methods, provide data storage and develop a common method of analyzing results to understand what can be considered a match and how to interpret these matches. Collaboration between epidemiologic data and lab data is essential.

Uday Dessai serves as the senior public health advisor at FSIS-USDA, in the Office of Public Health Science. In this position, Dr. Dessai leads major interagency programs - FSIS NARMS, FSIS whole genome sequencing, role of science in policy development and scientific innovation in the agency's strategic planning.

Giving the regulatory response to industry questions posed by Masters, Dessai began by stating that WGS is a very powerful tool that promises a superior resolution of identifying and characterizing species and strains of bacteria. In the FSIS perspective, WGS technology and analytic tools are evolving rapidly, and WGS can help in the investigation of foodborne disease outbreaks by more definitively identifying the specific type and sub-type of bacteria involved in an outbreak and help reduce incidents of illness or death due to foodborne pathogens. However, it was stressed that WGS is only one piece of information in determining the source of the outbreak.

The USDA-FSIS continues to build WGS capacity and is expected to be fully functional with six

sequencers in operation by 2017, which will allow sequencing of at least 5,000 isolates per year. In collaboration with the Centers for Disease Control and Prevention (CDC), FSIS uses the WGS information in addition to PFGE and epidemiological information to further understand the suspect pathogen and source products. At the moment, with limited capacity for WGS, the agency is currently placing the focus on samples for the National Antimicrobial Resistance Monitoring System (NARMS). When WGS is at full capacity for the FSIS, the agency intends to share WGS information, in addition to the serotype, PFGE, and antimicrobial susceptibility results, with the establishments in which it was collected for further considerations and actions.

In addition to reporting results to establishments in which samples were collected, WGS metadata will also be shared with the National Center for Biotechnology Information (NCBI), a national resource for molecular biology information. This information includes the product/source type, year the sample was collected, state where the sample was collected, and subtyping information (when available).

The FSIS also has goals to implement WGS into investigations of all foodborne illness outbreaks. Presented as a case study in 2015 as part of NARMS retail testing, the Food and Drug Administration (FDA) isolated *Salmonella* with extended spectrum beta-lactamase (ESBL) resistance from a retail poultry product purchased in December, 2014. After the detection of this gene, the isolates were investigated for their sources/origin and their possible connections to human cases. Even though no human illness from FSIS-regulated products was found, the FSIS promptly notified all corporations with ESBL-resistance gene matches of the possible food safety implications of this serotype, mitigating further possibility of a foodborne illness outbreak due to this strain of *Salmonella* showing antimicrobial resistance. This case demonstrates the ability to proactively reach out to the industry to warn establishments of a possible contaminating pathogen before an outbreak occurs.

The next step in WGS utilization by the FSIS is the use of an interagency working group called Gen-FS. Agencies involved include CDC, FDA, NCBI/ National Institutes of Health, and FSIS, which are all agencies with mostly a public health and regulatory focus. Gen-FS provides the participating agencies with a governance structure for collaborative decision making. It will focus on the development and implementation of WGS tools and data analysis pipelines for the in-depth analysis of pathogens from food, feed and environmental, clinical and animal sources. The goal of

Gen-FS is to harmonize the planning and implementation of WGS activities, including surveillance, detection, investigation and research activities, as well as further strengthen outbreak cluster detection and response and the detection and transmission of antimicrobial resistance.

Breakout Session I

Using Data to Assess Your Food Safety Program

Moderator: Chad Martin, Tyson

Chad Martin moderated this breakout session designed to show how a plant's food safety data and microbial results can be used to help improve safety systems.

Art Rogers currently serves as the technical services director for food safety and regulatory affairs for JBS USA Food Company Fed Beef Division.

Rogers alerted attendees to the importance of always knowing the following before collecting and analyzing samples:

- What is the lot size the sample represents?
- Do you have all the product in the lot controlled?
- What are the potential ramifications of an undesirable result?
- Is everyone in the supply chain aware the samples are being collected?

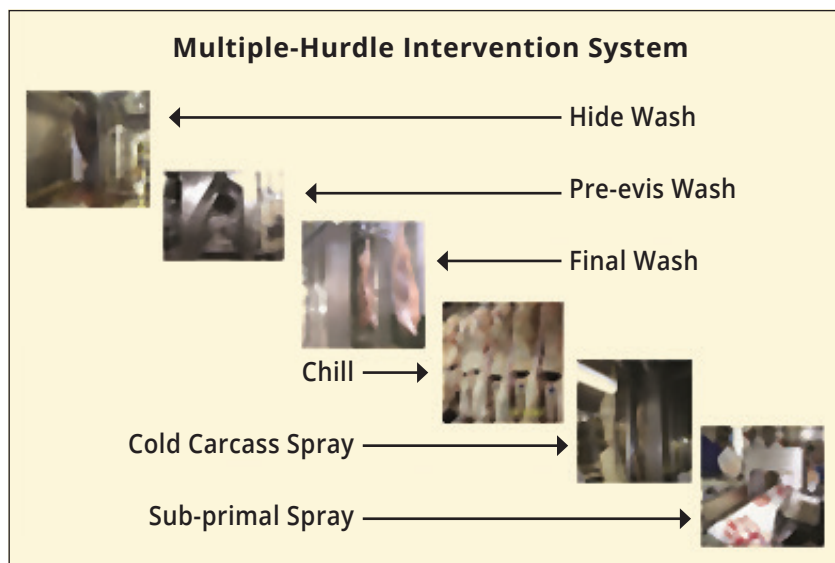


Figure 6.

Intervention validation is a critical part of a food safety system. Rogers shared an example of validating a hot water re-circulating pasteurization system. In a multiple-hurdle approach to pathogen reduction (**Figure 6**), seven different phases of the process are monitored: 1) hide-on, 2) hide-off pre-intervention, 3) post-PECs/pre-evisceration, 4) pre-

pasteurization/lactic acid spray, 5) post-pasteurization/lactic acid spray, 6) pre-hot box chilling process, PAA and 7) post-chilled. Monitoring the effectiveness of each hurdle in the process indicates if the plant is meeting its performance objectives. Rogers suggested focusing on achieving bacterial levels at specific locations, not log reductions.

A program to measure bacterial load that can be used to evaluate process effectiveness can provide critical information. One example is the breakdown of the carcass into individual areas to evaluate dressing defects immediately after hide removal and before trimming or interventions are applied. Each area of the carcass can have an individual limit established and all areas of the carcass can add to the cumulative limit for the audit. Audit failures require immediate evaluation of the harvest process and re-audits. An advantage of such a program is real-time feedback on process control and employee training needs on certain operational procedures.

Additionally, Rogers shared that a robust sampling method for *E. coli* O157:H7 trim testing is the real measure of whether or not systems are working. The data generated helps predict emerging trends and investigate occurrences of trim positives. When trim results vary, an investigation into the latest physical and performance changes in the harvest process can identify anomalies in the slaughter process that could have contributed to the spike in trim results. Adjustments can then be made to prevent recurrence.

Adam Marconi is responsible for corporate account management in Ecolab's Food & Beverage division.

Beef production faces numerous challenges including USDA compliance, product quality, production efficiency, operational costs, labor issues, globalization/standardization, employee safety and consumer perceptions. In the average food and beverage plant, more than 5,000 data points are monitored hourly with 70 – 280 diagnostic food safety tests run weekly (**Figure 7**).

The challenge for a manager is to use the data to better understand operational risks, see how operational choices affect one another, optimize plant processes and drive improved outcomes.

With the explosion in the amount of data available, it's important to understand what is relevant. Marconi shared Ecolab's robust systems for collecting data and the challenge of understanding and using the data. Algorithms that joined data allowed for monitoring trends over time to identify both patterns and exceptions. This resulted in corrective action when necessary and a strategic approach to risk mitigation, product quality and cost control. Evolving technology allows for faster data collection followed by appropriate responses.

In a plant, converting data into information and then action safeguards quality, increases output and reduces downtime and effluence. For corporate, this process enhances brand protection, gives system-wide visibility, reduces organizational

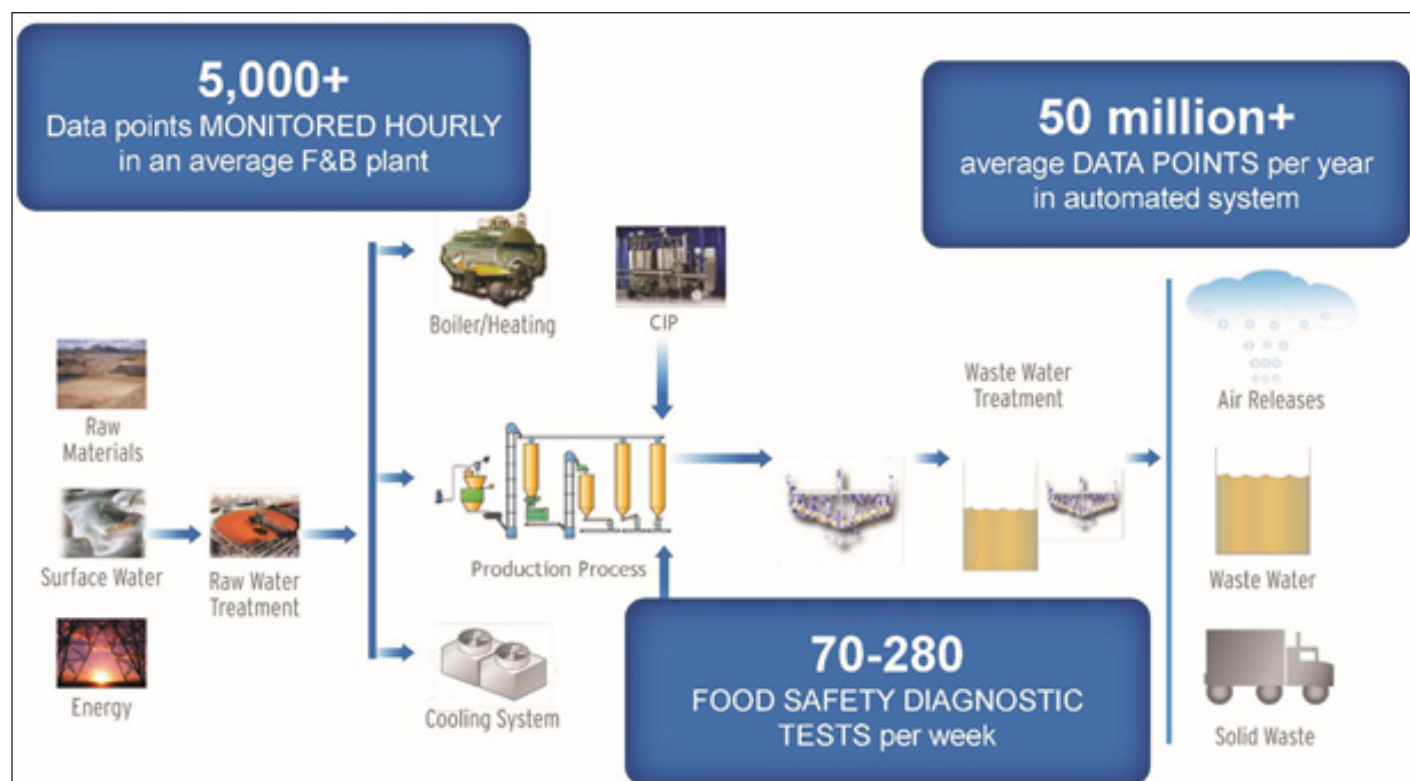


Figure 7. Data in a plant

risk and provides an opportunity for standardization. By linking challenges, technology and action (**Figure 8**), an organization can protect its brand, mitigate food safety risks, improve asset utilization, achieve sustainability goals and drive consistency.

Angie Siemens is the vice president of food safety, quality & regulatory for Cargill.



Figure 8.

Siemens provided perspective on turning data into information. First, it's necessary to assess what and why something is being measured, whether or not the data is trustworthy, and what it's being used for. Every plant should make use of some kind of rationalization process because testing is expensive, labor-intensive and not efficient if the data cannot provide meaningful information.

Siemens discussed the limitations of using data averages to support decisions such as performance over a period of time. Weekly averages at an intervention location have been used to assess overall trends and to review supplier performance. Averaging, however, does not account for the natural variation in the processes and cannot evaluate process improvements.

The identification of outliers, those points that fall outside the expected range, makes data actionable because it shows a variation in the process, a possible pattern to the outliers, and process capability limits.

Jennifer Williams is currently the senior director, beef food safety and quality assurance for Tyson Fresh Meats.

Data is required to objectively measure, but food safety experts know the processes in their plants and their experiences and intuition also provide input into decisions. Pathogen data is often used to determine acceptability of

an individual lot or product as well as products in aggregate (event days). Pathogen data should be used to determine the following:

- Priority issues within the food safety system
- Solutions used to prevent/minimize future pathogen findings
- Acceptability of program effectiveness

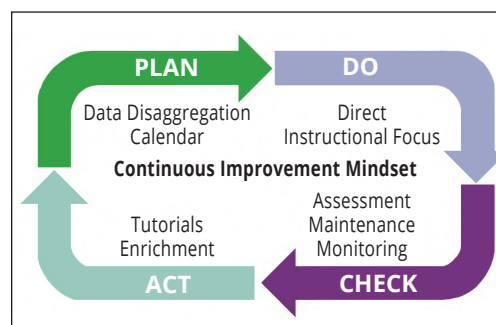


Figure 9.

The mindset of the food safety expert must be one of continuous improvement (**Figure 9**) and willingness to compare

your plant systems with other plant systems (harvest versus further processing versus grind), the regulatory baseline and industry data.

Pathogen data tracking is moving from Excel spreadsheets to scorecards. It's essential to choose the right tools to share your plant's safety information. Trend data shows if an investigation is necessary. Charts, graphs and pictures are more easily deciphered compared to data rows and columns.

Food safety research (microbiology, statistics, epidemiology and applied sciences) leads to changes in processes, intervention strategies and expectations at all stages of beef production. Use research to establish your plan. After planning, do direct product disposition using specific detailed data selection based upon the pertinent investigational questions. Assess long-term and short-term trends to determine continuous improvement or emerging concerns.

To deal with negative trends, begin again with the planning process and make new decisions to act.

Jack McReynolds is a partner in Passport Food Safety Solutions which provides an innovative “systems” approach to help meat packers and processors develop practical solutions that consistently meet stringent food safety standards.

Without data, you're just another person with an opinion.

W. Edwards Deming
Data Scientist

McReynolds explained how data is changing how vendors and customers relate to each other. Data improves operational efficiencies and mobile

data leads to new business processes. As the amount of data increases and becomes more complex, the value of data increases. McReynolds shared how data is moving beyond providing business intelligence, and now has the ability to be prescriptive.

McReynolds provided examples of how other industries have benefited by taking data to the next level. The Walmart.com search engine includes semantic data relying on text analysis, machine learning and even synonym mining to produce relevant search results, which has improved the number of shoppers completing a purchase by 10 – 15% and revenue by billions of dollars.

By increasing data knowledge, the beef industry can move from descriptive analytics of what happened, through why, and what will happen, to prescriptive analytics or how do we make it happen.

So, You Think You are Ready for a Recall?

Moderator: Tammi Frederick, H-E-B

Tammi Frederick moderated this session designed to test attendees' preparedness for a recall, which is, and will remain, a challenge for the beef industry and others. Recalls are not decreasing in number, but rather increasing with better detection technology and an increased focus placed on pathogens and allergens by regulatory industries.

Gale Prince of SAGE Food Safety Consultants, has been referred to as the “Dean of Product Recalls,” with 48 years of experience in managing product recalls including not only food but also consumer products, from some of the largest recalls to the smallest.

“Those who do not learn from history are doomed to repeat it,” said by Winston Churchill, remains true today, and is especially

true when learning from recalls. Recalls are not going away; however, they are becoming more complex. Companies within the beef industry can learn not only from recalls that they have had themselves, but also from recalls of other products and other companies. On average, retailers are faced with seven recalls per day, and product recalls are costly, estimated to cost upwards of 50 million dollars, and in some instances the price tag of a recall has surpassed 200 million dollars, not including reduced sales and shelf space loss.

The number of recalls has increased in all of the three recall categories:

- Class 1 - involves a health hazard situation in which there is a reasonable probability that eating the food will cause health problems or death
- Class 2 - a potential health hazard situation in which there is a remote probability of adverse health consequences from eating the food
- Class 3 - a situation in which eating the food will not cause adverse health consequences

Allergen recalls have risen by 200% since 2010 and have dominated the recall landscape, causing the greatest number of recalls in the meat industry (**Figure 10**). Undeclared soy has been the leader in allergen recalls in the last three years, with milk and wheat also contributing. Microbiological recalls have declined steadily since 2010, a good indication that the meat industry's recent emphasis on pathogen control and testing is helping to produce a safer product.

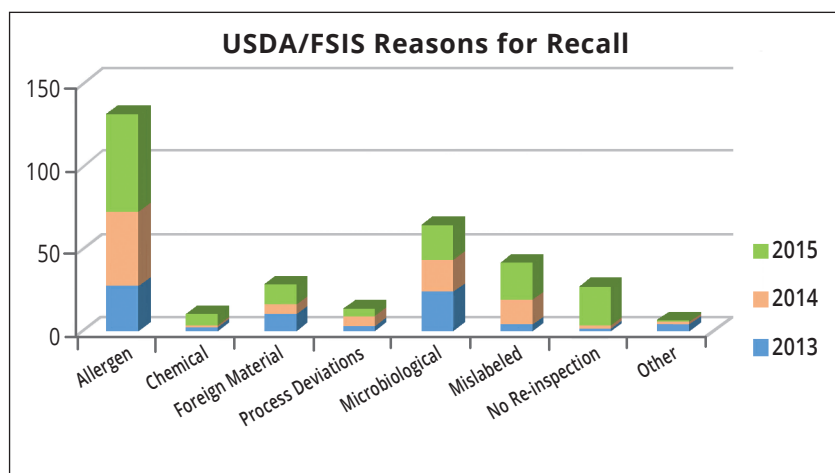


Figure 10.

To prevent recalls, the three “C’s” of food safety culture should be implemented in all companies. These three C’s are Compassion, Commitment and Communication, and should translate from the top down and have an effect on the company’s culture, supplier relationships, facility, process controls and all employees. Furthermore, a robust recall plan

should always be in place within a company. This plan should be executed in a mock scenario to increase awareness and give all members of the recall team practice so they are better able to handle a recall situation. Prince presented his five steps to a recall plan: 1. Incident Investigation, 2. Prepare Recall Information, 3. Recall Announcement, 4. Effectiveness Checks and 5. Close Out.

Other steps are required to create a robust crisis management plan, including having a criminal protection program and other insurance considerations. With recalls translating to criminal investigations more and more in today's recall landscape, these considerations become increasingly important.

Finally, it is the responsibility of every person and corporation in the meat industry to do what is right for the customers and to meet all regulatory requirements. Commitment and dedication to these ethics are essential in achieving safe food.

Breakout Session II

Non-Intact Products

Moderator: Angie Siemens, Cargill

Angie Siemens moderated this session exploring supplier and sampling requirements, current guidance documents, and cooking validation for non-intact products.

Norlyn Tipton is currently quality assurance department manager, specialty meat & seafood companies for Sysco Corporation.

Tipton shared key information on the development of regulations beginning with the Federal Register notice published October 7th, 2002, Docket No. 00-022N "*E. coli* O157:H7 Contamination of Beef Products." Suppliers could submit annual letters of guarantee stating their critical control points were validated to eliminate or to reduce *E. coli* O157:H7 below detectable levels. For further processors, these letters were used as common justification for why *E. coli* O157:H7 was not reasonably likely to occur in non-intact beef.

Unfortunately, many establishments only obtained letters one time which may not have been sufficient to arrive at these conclusions.

An increase in the number of beef-related O157:H7 outbreaks occurred in 2007 and 2008. FSIS began to question the frequency of verification in plants which led to [FSIS directive 10010.1 rev.3*](#) chapter 6, Measures to Address *E. coli* O157:H7, which states "there is no one, absolute way in which an establishment is to control or prevent *E. coli* O157:H7." Further processing establishments may use a prerequisite program to prevent *E. coli* O157:H7 but the directive is clear that purchase specifications as part of a prerequisite program without verification by the receiving establishment are not adequate. Section II.E describes FSIS's requirements of an establishment that uses purchase specifications in a prerequisite program. Chapter 5 explains verification activities for establishments processing mechanically tenderized product.

On August 20, 2015, [FSIS Directive 10010.2**](#), Verification Activities for Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef Products, was published. Tipton explained that Step 5 in Chapter II, IPP HACCP Verification Activities, provides the controlling rule on raw intact and non-intact beef products for the processor. In essence, annual audits and purchase specifications are not sufficient; antimicrobial

intervention preventive measures are necessary. FSIS contends, however, that "To the best of our knowledge, there are no known interventions that can be applied at the point of receiving chilled product that have been proven to achieve an undetectable level of *E. coli* O157:H7/STEC. Therefore, our contention is the most viable option is to rely on verification of interventions at supplier slaughter operations."

With a Robust Supplier Approval Program (Whole Muscle Non-Intact Raw Beef and Raw Ground Beef) and Validated Interventions for Raw Whole Muscle Non-Intact Beef, a further processor should not need to test subprimal beef for STEC or *E. coli* O157:H7* to justify a

FR Docket No. 00-022N "*E. coli* O157:H7 Contamination of Beef Products" October 7th, 2002

FSIS believes that the availability of certain scientific data on *E. coli* O157:H7 constitutes a change that could affect an establishment's hazard analysis or alter its HACCP plans for raw beef products. Therefore, under the HACCP regulations, if establishments have not already reassessed their HACCP plans for raw beef products in light of this data, they must do so now.

All establishments producing raw beef products are required to reassess their HACCP plans. **However, establishments receiving product for grinding may have purchase specifications requiring all their suppliers to have one or more critical control points (CCPs) validated to eliminate or to reduce *E. coli* O157:H7 below detectable levels.** Such establishments may determine that no additional steps to address this pathogen are necessary in their production process. **Establishments adopting this approach should incorporate these purchase specifications and their means of ensuring that their specifications are met in their HACCP plans, in their Sanitation SOPs, which FSIS has recognized as prerequisites for HACCP, or in other prerequisite programs.**

decision that *E. coli* O157:H7 is not reasonably likely to occur in further processed, raw, whole-muscle non-intact beef.

* <http://www.fsis.usda.gov/wps/wcm/connect/ae5e81d0c636-4de1-93f3-7a30d142ae69/10010.3.pdf?MOD=AJPERES>

** <http://www.fsis.usda.gov/wps/wcm/connect/0135652506b7-4f20-af3a-037bf24dc16e/10010.2.pdf?MOD=AJPERES>

Joseph J. (Joe) Harris is president/CEO of the Southwest Meat Association, which represents meat and poultry processors from across the United States.

The final rule for mechanically tenderized beef was published on May 18, 2015 and will be effective on May 17, 2016. The rule requires listing the applicable descriptive designation of “mechanically tenderized,” “blade tenderized” or “needle tenderized” on the label of a raw or partially cooked product subjected to one of these technologies. The label must include cooking instructions and whether or not the product was injected with marinade or solution.

FSIS issued [compliance guidelines](#)* to explain the label content required to validate cooking instructions: cooking method, a minimum internal temperature that will destroy pathogens throughout the product, dwell time and the instruction to measure the temperature with a thermometer. The label instructions must help the consumer easily understand how to reach a safe temperature throughout the product.

The label will need to be customized across whole-muscle products because of the variations in product size, thickness, method of tenderizing, quality grade and type of cut, etc. The processor will also have to consider how to label a larger cut that will ultimately be sold to someone who is cooking and cutting the product for resale. The guidance document provides suggestions for language that might be appropriate for various situations.

Harris suggested that further processors submit labels to FSIS for approval before the rule becomes effective. Most labels can be generically approved.

If a further processor is selling to a restaurant, the processor will be held accountable by FSIS for the product labeling and application of cooking instructions. The restaurateur is held accountable to the applicable Food Code requirements.

* http://www.fsis.usda.gov/wps/wcm/connect/606919b65192-40bd-a32b-99a41c75eeb6/Comp_Guide_MTB.pdf?MOD=AJPERES

Next Generation Sanitation and Interventions

Moderator: Keith Belk, Colorado State University

Sanitation will continue to be an area for potential improvement in the beef industry. Keith Belk moderated this session which focused on an increased understanding of biofilm formation and resilience, as well as a recap of emerging technologies for plant sanitation and antimicrobial interventions.

Rong Wang joined the U.S Meat Animal Research Center (USMARC) at USDA in 2010 as a research microbiologist. He has investigated STEC/*Salmonella* biofilm formation, sanitizer effectiveness against foodborne pathogen biofilms, as well as molecular mechanisms responsible for strong biofilm formation and their sanitization tolerance.

Wang explained that biofilms are a serious food safety concern as foodborne pathogens may form biofilms on food contact surfaces, equipment or other areas in the food processing environment. Detachment of these biofilms may lead to cross-contamination, and perhaps more importantly, biofilm formation enhances bacterial resistance to sanitation.

In the traditional contamination model of transferring pathogens from hides to carcasses during processing, a high genetic diversity would be seen when comparing contaminant strains. However, a High Event Period (HEP) in a plant generally shows bacterial strains with low genetic diversity, debunking the original contamination model and suggesting another. HEPs can be defined as short time periods during which commercial plants experience a higher than usual rate of multiple positive test results of *E. coli* O157:H7 in trim samples. Generally, the precise cause or contamination source responsible for a HEP remains unknown, but biofilm growth on food contact surfaces

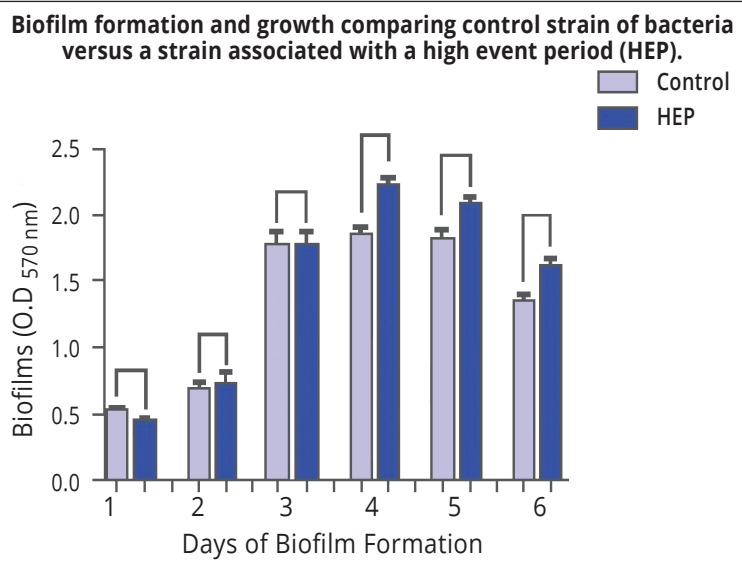


Figure 11.

and detachment could be one source of contamination. In recent research, *E. coli* 0157:H7 strains were isolated, allowed to form biofilms on contact surfaces and evaluated for biofilm cell survival and recovery growth after sanitation. Evaluating the growth patterns of these strains demonstrated that HEP strains had significantly higher potency of “mature” biofilm formation (**Figure 11**). Strains isolated from HEP also had stronger biofilm-forming ability on common contact surfaces like stainless steel and PVC. Even after sanitizer was applied, HEP strains demonstrated significantly higher survival rates and had a greater amount of recovery growth compared to the control strains.

In another research study focusing on *Salmonella* spp., a high percentage of *Salmonella* strains isolated from trim and post-intervention carcasses were found to be strong biofilm formers. These biofilm cells exhibited resistance to common sanitizers and strong recovery growth after sanitization. It was also demonstrated that *Salmonella* cells in biofilms could be easily and efficiently transferred to a meat surface multiple times via brief and direct contact.

Phil Stewart is a professor of chemical and biological engineering at the Center for Biofilm Engineering at Montana State University.

The first discussion point that Stewart brought to the audience’s attention is that biofilms are everywhere. They can be found in an alpine stream, in urinary catheters in the medical industry, and even on oilfield pipelines. To understand biofilm structure and growth, four different topics should be considered: diffusion, physiology, genetic basis and hydrodynamics.

Biofilms generally create a barrier to sanitizers by not allowing diffusion of the liquid into the heart of the biofilm.

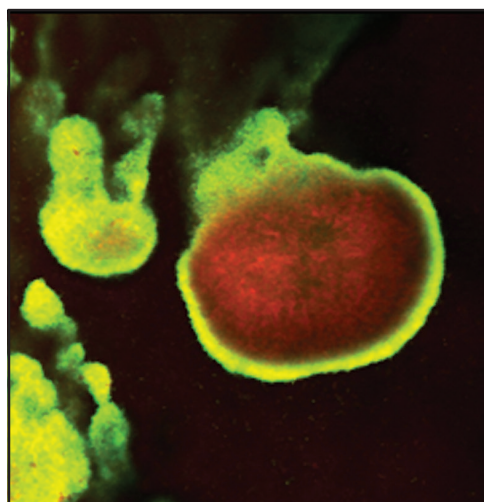


Figure 12. Protein synthesis occurs in outer layers of biofilms.

The sanitizer may work on the surface, but without diffusion of the sanitizer, the biofilm has the ability to persist and regrow. Biofilm removal is distinct from killing a biofilm. It is necessary to remove biofilms,

rather than just try to kill them with topical sanitizers. Stewart has demonstrated that peroxides are effective in removing biofilms through their foaming action.

With most biofilms, a physiological pattern in protein synthetic activity exists. In **Figure 12**, protein synthesis is illustrated in the bright yellow/green areas. It is apparent that the outer layers of the biofilm are responsible for growth and synthesis of proteins, while the inner layers lay somewhat dormant. These outer layers have also been shown to be the areas of highest glucose concentration. Finally, when addressing the genetic basis of biofilms, Stewart outlined the persister hypothesis. This hypothesis states that specific genes and gene products create “persister” bacteria within the biofilm. Many cells have the function to grow, build biofilm structure and reproduce within the biofilm, but a persister cell is a different type of cell found in biofilms. These cells are responsible for reseeding the community after a catastrophe. When a catastrophe strikes a biofilm, these persister cells have the opportunity to flip back in order to grow, build biofilm structure and reproduce in order to rebuild the biofilm.

Jeremy Adler is the director of technology and innovation at Birko where he oversees the development and commercialization of proprietary chemistries and their application systems designed to improve plant efficiencies and increase the microbiological quality of meat products and the production plant environment.

Adler’s message for attendees was that sanitizer should only be used as an establishment’s insurance policy; it should not be relied upon as an alternative to effective cleaning. Biofilms can be thought of as soils, and soils must be removed, not just inactivated with a sanitizer. Some of the most effective ways to remove biofilms is the use of scrubbing, foaming, high temperatures and chemical energy through the use of peroxides and pressure, although it should be noted that pressure could increase the distribution of the biofilm by blowing it onto nearby contact surfaces.

New cleaning and sanitation technologies have been discovered; however, it is important to remember that the industry will never see a “silver bullet” technology to end food safety challenges. The available products work, but they must be used correctly to have maximum impact. The cleaning and sanitation technologies being researched and developed are generally focused on operational efficiencies like decreasing water or chemical usage, increasing data gathering and analysis and increasing plant process customization, including automation technologies.

Regulation due to the FDA Food Safety Modernization Act (FSMA) will affect the way the beef industry transports

products. The FSMA was passed to prevent practices that create animal and human food safety risks, and this rule will affect shippers, receivers and carriers of food destined for consumption in the United States. The environmental monitoring program will divide products into zones for regulation. These zones affect the beef industry as swinging beef will be considered Zone 1, totes Zone 2 and boxed beef considered Zones 3 or 4. If an establishment is shipping product that falls into one of these zones, necessary steps may be needed to evaluate and enhance sanitation standard operating procedures and prerequisite programs.

General Session III: Antimicrobial Use and Risk Assessment

Moderator: Mandy Carr Johnson, NCBA, a contractor to the Beef Checkoff

Mandy Carr Johnson moderated this session which discussed how recent regulatory changes will impact antimicrobial use in the beef industry and recapped the progress towards a risk assessment for antimicrobial resistance.

Mike Apley from Kansas State University is a veterinarian with a PhD in physiology (pharmacology). He is a Diplomate of the American College of Veterinary Clinical Pharmacology.

Apley reminded the audience that the awareness of antibiotic use in livestock increased in 1969, when the Swann Report found the administration of antibiotics to animals raised for food was a hazard to human and animal health as it led to the development of antibiotic-resistant strains of bacteria. The U.S. Food and Drug Administration issued [Guidance for Industry #152](#)* in 2001 to “discuss a recommended approach for assessing the safety of antimicrobial new animal drugs with regard to their microbiological effects on bacteria of human health concern.” In 2012, [Guidance for Industry #209](#)* mandated veterinary oversight for the use of all antibiotics and the cessation of use of antibiotics important for humans in all livestock. This was again reiterated in 2013 with [Guidance for Industry #213](#).* In 2017, the use of medically important new antimicrobial drugs in food-producing animals must be prescribed by a veterinarian or under a Veterinary Feed Directive (VFD). The veterinarian is restricted to using the drug exactly as indicated on the label.

It is essential that both veterinarians and livestock

producers practice stewardship in their use of antimicrobials by using an antibiotic which has been demonstrated to be safe and effective for the specific purpose. Apley encouraged producers of livestock to audit and benchmark their current use of antimicrobials. Additionally, a veterinarian may seek non-antibiotic alternatives, when possible, that could prevent, control or treat the disease challenge.

Research is needed to help understand the relationship between the magnitude and duration of antibiotic exposure to both resistance development and to either success, failure or relapse rates.

* Guidance for Industry #152

<http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm052519.pdf>

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>

Francisco J. Zagmutt of EpiX Analytics is a consultant specializing in the application of quantitative risk analysis methods to risk management and strategic decision making.

Zagmutt explained the premise of the current Qualitative Risk Assessment research project is to answer these questions:

- Does tylosin and chlorotetracycline use in beef cattle affect antimicrobial resistance (AMR) in humans?
- If so, how much, and how does it compare with other sources?

To maintain the use of antibiotics:

- Veterinarians should have control of all uses of antimicrobials in animals.
- Veterinarians and producers must practice true stewardship.
- Duration of therapy research is an absolute requirement.
- The emphasis on prevention of infectious disease must continue.
- Enhanced protocols and record keeping are essential.

There are two approaches to qualitative risk assessment. In the bottom-up, farm-to-fork approach, every key step from production to consumption must be explicitly described and quantified. The same information must be then acquired for every key step from consumption to illness and AMR. The advantage of this approach is that the granular prediction of food risk changes with mitigations at individual steps in the farm-to-fork chain. The disadvantage is that it's data- and assumption-intensive.

The alternative approach is the top-down model, which follows the logic of the farm-to-fork continuum, but simplifies/eliminates some steps between production and consumption. The advantage to this approach is it requires less data and allows model calibration using national (foodborne) disease surveillance data. The disadvantage is it potentially results in a less granular prediction of intervention strategies.

Zagmutt provided examples of both approaches and gave an update on the status of the current project. The researchers have developed the models and collected the data on antibiotic use in humans and animals. They have also collected data on AMR in samples from human foodborne illnesses and determined per capita beef consumption. The research will identify key data gaps in the knowledge of the ecology of AMR and beef production and create a framework which would be potentially useful to evaluate other food safety AMR risks. This spring the researchers will highlight the current analysis limitations, data gaps, and future data collection efforts in a report of the pilot project.

The Evolution of Liability and Food Safety

Moderator: Michelle Rossman, NAMI, a contractor to the Beef Checkoff

The landscape of liability in regards to food safety has greatly changed with the advancement of technology and foodborne illness reporting. Michelle Rossman moderated this session which brought to life new and emerging regulatory and liability issues for the beef industry.

Mark Dopp is the general counsel and senior vice president of regulatory and scientific affairs for NAMI.

Dopp advised attendees that establishments must be aware of two fundamental regulations when it comes to liability and food safety, Statutory Authority and Adulteration Policy. Statutory Authority includes the Federal Meat Inspection Act, Poultry Product Inspection Act and the Egg Products Inspection Act. Adulteration Policy exists to reduce any poisonous or deleterious substance which may render a product injurious to health. The definitions within these acts and policies are important for an establishment to understand, as they are the first reference point to determine liability in the instance of pathogenic outbreak, or other food safety concern.

E. coli O157:H7 was labeled as an adulterant in 1994, and since then the industry has seen the “adulteration creep,” which has continued into Non-O157 STECS being labeled as adulterants in 2011 and some believe this creep will continue with the declaration of *Salmonella* as an adulterant in the

future. Two petitions have been presented, the second in 2014, seeking to declare antibiotic-resistant *Salmonella* in ground meat and ground poultry products an adulterant. If *Salmonella* is declared an adulterant, the resulting increase in performance standards related to *Salmonella*, as well as the increase in the number of recalls and public health alerts would cost the industry a great deal of time and money.

Shawn Stevens is a global food safety lawyer and founding member of Food Industry Counsel LLC, the only law firm in the world that represents the food industry exclusively.

In recent years, the food industry has witnessed an alarming increase in the numbers of foodborne illness outbreaks and food product recalls. Many of these were triggered by the presence of harmful pathogens in the food products or resulting outbreaks. In response to this increase in outbreaks, Congress ordered the FDA to overhaul the safety of the food supply when it passed the Food Safety Modernization Act (FSMA) in 2011.

To execute this mandate, the FDA is executing multiple policy changes including conducting microbiological profiling inside food processing facilities during routine inspection and testing vast amounts of food at retail. In addition, the FDA is initiating criminal investigations against food companies and executives who distribute food products that have the opportunity to cause human illness. FDA’s aggressive enforcement initiatives targeting harmful bacteria can be reasonably characterized as “the FDA’s War on Pathogens,” and these policies will continue to intensify.

Stevens asserted that the immediate challenge to the food industry is to find a more effective solution to identify and reduce pathogens like *Listeria monocytogenes* in the processing environment, while implementing written food safety protocols which provide additional protections against criminal sanctions. Unless companies act now to better quantify and control pathogens, they are exposing themselves to food safety risk, including brand damage and criminal sanctions. Companies should carefully consider the emerging risk facing them, and begin measures to decrease and eliminate their exposure.



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