2010 Beef Industry Safety Summit

Pre-Harvest Symposium Executive Summary

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Introduction

Beef producers, through the Beef Checkoff, have devoted millions of dollars to beef safety research, intervention development and outreach. In fact, since 1993, the beef industry has spent about $28 million. Combined with private industry efforts, collectively, the industry spends more than $350 million annually on improving beef safety.

The majority of these efforts have focused on the harvest and processing sector as it was the stage in production where the most impact could be made on improving beef safety. However, ten years ago, the industry began to more aggressively research food safety interventions at the pre-harvest level. The goal was to build upon the success that had been achieved using in-plant safety interventions and apply the same concept further back in the production chain to create another layer of safety in beef production. At the 2010 Beef Industry Safety Summit, a special Pre-Harvest Symposium was conducted to take the discussion to the next level and guide future research efforts.

2010 marked the largest attendance ever at the annual Beef Industry Safety Summit, which was first held in 2003. The Beef Industry Safety Summit is coordinated by the National Cattlemen's Beef Association (NCBA) on behalf of the Beef Industry Food Safety Council (BIFSCo) and is partially funded by The Beef Checkoff.

Product Development and Regulatory Aspects

Kent D. McClure, D.V.M., J.D. – Animal Health Institute

One of the obstacles often cited to effective implementation of pre-harvest beef safety interventions is the challenges in getting products approved for commercial use.

Kent McClure, general counsel for the Animal Health Institute (AHI), discussed this challenge with symposium attendees. "For a conventional animal health product, i.e. one that is developed to address an illness within livestock, it can take a pharmaceutical company six to eight years to bring the product to the marketplace," said McClure. "It takes a $40 to $100 million investment and typically another six to eight years to recoup the investment."

Products developed for *livestock* to prevent illness in *humans* are in a product category that McClure says is new to the regulatory agencies. As such, the approval process is not as clearly defined. "When industry and researchers are evaluating the efficacy of pre-harvest food safety interventions in livestock, our goal is not necessarily 100 percent; that's not realistic," said McClure. "Rather, the goal is to reduce pathogen loads on live animals, so when they are presented for harvest, they don't overwhelm the in-plant safety interventions. That's a difficult concept for regulatory staff to incorporate into the existing approval process."

As a result, AHI and other organizations, including NCBA and the American Meat Institute (AMI) have been working with various government agencies, including the Center for Veterinary Medicine (CVM), a branch of the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) Center for Veterinary Biologics (CVB), to define the appropriate regulatory process for the approval of current pre-harvest safety interventions. Once finalized, this process could serve as a template for future technologies as they are developed.

Until that time, conditional licensure provides a mechanism for developing a product that is targeting an unmet need, such as has occurred with the introduction of *E. coli* vaccines. "The sponsor must show purity, safety, a reasonable expectation of efficacy and a plan to complete efficacy work," said McClure. "This system allows a product to be marketed while final data is generated."

Food Safety and Best Management Practices Working Together to Make a Difference

John Butler, C.E.O. – Beef Marketing Group and James Marsden, Ph.D. – Kansas State University

Butler manages a beef feedlot cooperative, established in 1987, with a mission to provide a consistent supply of beef that meets certain end-user specifications. The cooperative has attempted through various initiatives to provide more information about its products to customers and uses third-party verification systems to authenticate that information.

In what he described as a "work in progress," Butler said Beef Marketing Group has implemented a trademarked system into its member feedyards called Progressive Beef™. "This is not a silver bullet, but our goal was to identify vectors of contamination that might occur at the feedlot level and apply a systems approach to prevent safety hazards at the production level." To accomplish this, Beef Marketing Group implemented a Pre-harvest Hazard Analysis Critical Control Point (HACCP) Plan in 1999. The group is currently working with Kansas State University researchers to validate improvements to food safety that have occurred through the application of its Progressive Beef™program.

Progressive Beef ™ encompasses the daily activities of feedlot production focusing on three areas: 1) food safety, 2) animal care, and 3) sustainability.

The standard components include:

- Administration of conditionally licensed *E. coli* vaccine for cattle
- HACCP program requirements for all member feedlot feed mills
- Animal welfare and handling program
- Beef Quality Assurance (BQA) certification for all member feedlots
- Sustainability requirements that include meeting or exceeding all federal and state environmental regulations, and sourcing cattle and commodities locally
- Monitoring requirements and third-party evaluations
- Incorporation of a bacteriophage wash prior to harvest

While Butler says that clearly defined premiums have not necessarily been paid, the Progressive Beef™ system has allowed Beef Marketing Group to deliver products to the specification of certain companies or target markets, such as McDonalds, Japan and the European Union.

Beef Marketing Group has an advisory panel of nationally recognized industry experts in animal handling, food safety and animal wellbeing. Member feedlots are required to take part in training sessions that feature the advisory board members and focus on key standard operating procedures (SOPs).

Jim Marsden, Ph.D. and regents distinguished professor of animal sciences at Kansas State University described how Beef Marketing Group developed HACCP plans for member feedlots "to systematically identify sources of biological,

chemical and physical hazards and implement systems to prevent vectors of contamination." According to Marsden, some of the identified opportunities for food safety improvements included water troughs, and other sources of environmental contamination, such as "hospital" pens, veterinary procedures and transport trucks. While control points were identified, the nature of the feedlot system dictates few opportunities to implement technologies that meet the definition of a "critical control point." Marsden is currently developing a system to quantify the food safety benefits of the Progressive Beef™ system.

"Pre-harvest food safety is an important component of an integrated food safety system for controlling *E. coli* O157:H7, *Salmonella* and other food safety hazards in beef," said Marsden. "An effective pre-harvest system in combination with systematic slaughter and post-slaughter interventions provides the best possible assurance that beef products will be safe for consumers."

Discovery to Policy: The Role of Research in Developing Evidence-based Pre-Harvest Policy

David Smith, D.V.M., Ph.D. – University of Nebraska, Lincoln

Smith, who is an extension veterinarian, said pre-harvest food safety is really nothing new when you look at historical examples such as bovine tuberculosis (TB). "Similar to some of the experiences that occurred at the turn of the twentieth century when TB was 'public enemy number one,' we have to realize that if we are going to work with *E. coli* O157:H7 at the pre-harvest level, we have to be comfortable with our ability to create a systems-wide approach to controlling food safety pathogens even though our knowledge isn't perfect."

Scientific discovery of the cause of tuberculosis eventually led to a national policy for bovine TB control. The bovine TB national eradication program has been controversial since its inception in 1917. However, it has been successful; the disease prevalence rate in cattle herds has dropped from 5 percent to less than 0.001 percent and public health benefitted greatly. In summarizing this example's relationship with current food safety issues, Smith discussed how foodborne illness impacts people individually, but when evaluating control methods, benefit versus cost on a large scale must be balanced.

"Health statistics are always personal for the individual who was impacted," said Smith. "Successful intervention programs require two things: 1) effective methods for control; that's science and 2) buy-in by the majority of participants; that's politics," he added. "Buy-in requires that participants recognize a favorable benefit-to-cost ratio and a program with well defined, logical methods and rules. Even successful programs cost something and, while there may always be a possibility for improvement, marginal gains must be evaluated against marginal costs." It is important to consider costs and benefits to the public, the beef industry, and the individual livestock producer who is often asked to shoulder much of the responsibility for implementation.

"You have to understand causal relationships to devise effective disease-control methods," said Smith. But the policy-making process includes deciding whether or not a causal relationship deserves action. "Evidence of a causal relationship is not always sufficient to suggest action should be taken, while uncertainty about a causal relationship may not be sufficient reason to *not* take action."

Smith asked the audience: "How do you know if a drug or a vaccine works, or if a management practice causes an animal-health or performance effect, and then how do you decide to act on that information?" Science can help with causal questions, but deciding whether to use the drug or vaccine requires an evaluation of costs and benefits.

"We know much more about how to study food safety pathogens and test pre-harvest interventions in cattle populations than we did ten years ago," said Smith. In laying a roadmap for future pre-harvest research, Smith suggested the following steps:

- Discuss intervention efficacies reported in published studies
- Address what is known and what we still need to know regarding the relationship between pre-harvest research needs and an envisioned pre-harvest policy
- Suggest pre-harvest needs

"We should be discussing if we have enough science to create policy, or if we need to investigate further," said Smith. "Can our plants and processing facilities tell us what it will take at the pre-harvest level for their food safety systems to be more effective, and what value that has? Does a pre-harvest intervention provide enough value to post-harvest sectors of the beef industry or to public health to pay for the cost of implementing it? Any of these questions that we can't currently answer point to future research needs. At the same time that we are addressing these questions for *E. coli* O157:H7, we also need to be determining if we should be studying other organisms."

Answering questions about the relationship between carcass contamination and pre-harvest carriage of *E. coli* O157:H7 by cattle versus the relationship between human illness and pre-harvest carriage of *E. coli* O157:H7 may help researchers arrive at the best methods to control this food safety pathogen.

In conclusion, Smith asked the audience, "What needs to be discovered on a system-wide basis before action is taken with a pre-harvest intervention?." He added, "We have to determine if an intervention has a biological effect; if so, is the effect useful to food safety? The answer to the second question will vary depending on what levels of efficacy are worthwhile and to whom. Finally, application in commercial environments has to be considered."

Building a Common Framework for Intervention Studies

Guy H. Loneragan, B.V.Sc., D.V.M. – West Texas A&M University

Loneragan, who is an epidemiologist, began his presentation by asking if it is possible to effectively compare different studies conducted in pre-harvest beef safety. "Using *E. coli* O157:H7 as an example, we have to recognize that different methods are being used in research, such as different enrichment broths for bacterial isolation or different methods for bacterial quantification," he said. "Those differences beg the question of whether we can effectively compare studies."

Loneragan provided several examples of how different research methods, while all valid, can impact the results of studies. As part of his presentation, Loneragan suggested that the research community could develop standardized procedures through a consensus effort to recommend the investigative methods that should be used in future studies. In order to gain compliance, he suggested funding entities might consider funding future projects based on use of the standardized methodology.

"Standardization of research methods would be of most value in prevalence studies or when we are interested in comparing the burden of shedding across more than one study," said Loneragan. "Standardization within studies is critical when we have projects that are conducted over multiple sites or over a course of time."

But in intervention studies, Loneragan said standardization of bacterial detection methods may not be as critical. "If an appropriate design and method is used to evaluate a safety intervention, should we really expect efficacy to vary if other methods are used? Additionally, limiting researchers to certain methods may restrict opportunities to use improved or more cost-effective detection methods."

In conclusion, Loneragan said that the most productive effort may be to focus energy on standardizing research project design based on the

ecological aspects of the pathogen under investigation. A standardized reporting framework will allow other researchers to reproduce studies. "Doing this would be analogous to the development of the 'CONSORT Statement (Consolidated Standards of Reporting Trials)' in human medicine," said Loneragan.

The CONSORT Statement was developed through a collaborative effort and is intended to improve the reporting of a randomized controlled trial (RCT), enabling readers to understand a trial's design, conduct analysis and interpretation, and to assess the validity of its results, according to the CONSORT Group (www.consort-statement.org). Loneragan added evidence exists that this approach has improved the quality of reporting in human clinical trial results and has improved the quality of the science supporting the various conclusions. The CONSORT Statement has been adapted to animal-based clinical trials through the REFLECT Statement.

In approaching future pre-harvest research, Loneragan also emphasized the importance of working from a systems point of view. "We often take a very compartmental approach to evaluating an intervention," he said. "For example, what is the level of contamination present on a carcass before and immediately after a lactic acid wash? Instead, we should begin to ask ourselves to what extent does a system output change in response to modification of a system input."

Determining Pre-Harvest Food Safety Education Needs of Feedlot Managers

Todd Brashears, Ed.D. – Texas Tech University

In the fall of 2006, researchers from Texas Tech University and West Texas A&M University submitted a grant application to USDA Cooperative State Research, Education, and Extension Service (CSREES) for the development and implementation of a multi-day training workshop for pre-harvest food safety at the feedyard production level.

The goals of the field-based trainings were:

- Educate feedlot managers and industry professionals about their role in pre-harvest food safety
- Provide hands-on field experiences to reinforce comprehension and retention
- Evaluate the immediate effects of the training sessions, knowledge acquisition, behavioral change and impact at the feedlot

To develop the training programs, the researchers surveyed a panel of industry and academic experts and determined the top ten content areas from which they developed eight workshop presentations. Initially, the researchers determined the entry-level knowledge of the workshop participants through a pre-test. By cross-referencing the information collected from the expert panel (importance) and the participants (knowledge), the group was able to identify critical needs for education.

The workshop was held over the course of two days and focused on the following topics:

- Overview of food safety
- Distiller's grains and *E. coli* shedding
- Transportation and lairage and its impact on food safety
- Link between pre-harvest and post-harvest safety
- Vaccines as interventions
- Direct-fed microbials as interventions
- Dust control as an intervention
- Other interventions and emerging issues in pre-harvest food safety

At the end of each day, participants took part in focus groups with the goal of determining common themes.

A total of 32 participants, who are all employed in the cattle feeding industry from the United States, Mexico and Canada, took part in the educational workshops. Participants scored 49.8 percent on the pre-tests and 74.8 percent on the post-tests, which equated to a 25 percent increase in content knowledge. Post-post-tests are currently being conducted to determine knowledge retention and behavioral change.

Prior to the training workshops, researchers established baseline pathogen levels at several of the participating feedlot locations. The researchers will now begin validation research to determine if behavioral changes have made any impact on pathogen shedding and subsequent product safety.

Closing Remarks

Ross Wilson – Texas Cattle Feeders Association

Wilson, who serves as president and chief executive officer for the Texas Cattle Feeders Association (TCFA), offered closing remarks at the pre-harvest symposium.

"After listening to these presentations and the conversations that have taken place, it is my observation that we have a window of opportunity to do something for ourselves and our industry," said Wilson.

In summarizing the "action plan" that must take place based on the presentations, Wilson outlined the following:

- Develop and implement major commercial trials for the experimentally available pre-harvest technologies
- Understand price points for the various pre-harvest technologies and be able to communicate those to industry participants
- Conduct research using a systems approach and find ways for the packers and processors to cooperate in investigations

"It may turn out to be more effective and economical to apply certain interventions at the production level versus the packer level," said Wilson. "To determine the best way to move forward, we need a systems-approach evaluation, which might determine that an investment by packers and processors at the pre-harvest level provides more return on food safety investment than an additional post-harvest intervention process."

Conclusion

"The purpose of this symposium was to build upon the successes that have been achieved using post-harvest, in-plant interventions and apply these concepts to the pre-harvest production phase," said John Paterson. "Realistically, the goal of pre-harvest interventions should be to reduce pathogen loads on live animals so that when harvested, they do not overwhelm in-plant food safety interventions."

The outcomes of the Pre-Harvest Symposium conducted during the 2010 Beef Industry Safety Summit offer a roadmap for the next chapter in the industry's quest to improve beef safety. "The rate of human illness from *E. coli* O157:H7 significantly decreased in 2009, reaching the lowest level since 2004, according to a report released in April 2010 by the Centers for Disease Control (CDC)," said Michelle Rossman. "That kind of progress is only achievable through efforts like the Pre-Harvest Symposium that bring together some of the most progressive researchers in beef safety with the industry partners who will implement new innovations and technology to achieve the universal goal of providing the safest beef possible."

Pre-Harvest Timeline

Research in the area of pre-harvest is critical to improving beef safety and has been ongoing for almost a decade. Applying pre-harvest interventions at the production stage should improve the effectiveness of safety measures already being used at the harvest and processing level.

2001

Some of the initial pre-harvest research funded through the Beef Checkoff focused on feed additives, including chlorate and Tasco, as a means to reduce pathogen shedding rates. Feedlot sample shipping protocols were also evaluated.

2002

Researchers examined the effects of on-farm management practices on pathogen shedding.

2003

During the early part of the decade, research efforts focused on gaining an understanding of the dynamics of *E. coli* O157:H7 in feedlot settings. Projects evaluated management practices on pathogen shedding rates in cattle. Bacterial colonization and the effects of transportation stress on *E. coli* shedding were investigated. Developing effective *E. coli* O157:H7 vaccine technologies and gaining a better understanding of the recto-anal junction's (RAJ) role in pathogen colonization were also key focus areas.

2004

Research efforts expanded to examine the ability of sodium chlorate to reduce pathogen shedding in cattle, as well as its safe use as a pre-harvest intervention. Work to develop effective sampling methods for cattle continued. Additional work evaluating the effect of transportation on pathogen shedding rates in cattle expanded the industry's ability to address safety challenges.

2005

Continuing investigations identified the role of persistent shedders in transferring pathogens. Work also centered on the ability of *E. coli* O157:H7 to survive on cattle hides, nutritional strategies to influence pathogen shedding and the role of dust contamination on cattle hides. Validation of two different *E. coli* vaccines also continued. Another critical hurdle in the arena of pre-harvest interventions occurred when the U.S. Department of Agriculture (USDA) clarified policies regarding licensing of products for pre-harvest safety interventions.

2006

Work continued to evaluate the efficacy of *E. coli* vaccines. Bacteriophages and pond ash were identified and examined as novel methods to reduce pathogen contamination in feedyards. During this period, lairage was identified as a potentially important area for cross-contamination of cattle. The environmental effects of supplementing chlorate were also researched.

2007

Researchers conducted additional investigations involving the RAJ, as well as the role of feeding distiller's grains on pathogen shedding in feedlot cattle. More work investigated the role of dust during cattle load-out on pathogen contamination. Chlorate continued to emerge as an effective intervention. Researchers also investigated the effectiveness of a vaccine to prevent *Salmonella* shedding in beef cattle. While not supported by checkoff funds, another pivotal event included the formation of a working group comprised of USDA, FDA and industry representatives to discuss the regulatory framework for approving interventions to reduce or eliminate *E. coli* O157:H7 at the production level.

2008

Research continued to validate previously identified technologies.

2009

Years of research culminated in a conditional license for Epitopix *E. coli* vaccine. The industry continues to explore additional effective pre-harvest interventions.

2010

BIFSCo hosted a Pre-harvest Symposium during the Beef Industry Safety Summit.

For more information, visit

www.bifsco.org

www.beefresearch.org

or contact

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