AAAP Symposium 2005

Microbiological Safety

of

Ready to Cook and Ready to Eat Poultry Products

July 17, 2005

Food safety has always been important, but is now even more critical as the poultry industry produces the value added/further processed food items demanded by today's busy consumer. The presentations in this symposium represent a variety of perspectives ranging literally from "the farm to the fork" which are important to fully understand the complexity of the subject.

AAAP has long been a leader in classical poultry disease research. As such, the organization is ideally positioned to study food safety issues and attempt to develop solutions. The Food Safety Committee appreciates the timely direction and support from AAAP to allow this symposium to happen.

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SYMPOSIUM PROGRAM
July 17, 2005

Session I. The Different Perspectives on Food Safety
Moderator: Dr. Birch McMurray

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8:35 – 8:50	Mr. Bob Thrash	Independent Auditor's Perspective on the Domestic Market	11
8:50 – 9:05	Dr. Mark Lobstein	International Situation and its Ramifications	15
9:05 – 9:35	Dr. Elizabeth Krushinskie	Overview of Raw and Cooked Foods of Poultry Origin	16
9:35 – 9:45	Questions to Speaker Panel		

9:45 – 10:15 BREAK

Session II. Interaction of Live Production and Food Borne Pathogens
Moderator: Dr. Dave Hermes

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10:15 – 10:30	Dr. Greg Rosales	Reduction of Risk in the Primary Breeder Production System	19
10:30 – 10:45	Dr. Marshall Putnam	Reduction of Risk in the Integrated Broiler Production System	28
10:45 – 11:00	Dr. Eric Gonder	Reduction of Risk in the Turkey Production System including Breeder and Hatchery Operations	30
11:00 – 11:20	Dr. Eric Gingerich	Reduction of Risk in the Commercial Layer Production System including Breeder/Hatchery and Egg Processing Operations	34
11:20 – 11:30	Questions to Speaker Panel		

11:30 – 1:00 LUNCH

SYMPOSIUM PROGRAM
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Session III. Role of Processing in Control of Food Borne Pathogens Including Research Initiatives
Moderator: Dr. Marty Ewing

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1:45 – 2:00	Dr. Bruce Stewart-Brown	Industry Perspective in Broilers and Turkeys	40
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2:25 – 2:45 BREAK

Session IV. Role of Further Processing in Control of Food Borne Pathogens
Moderator: Dr. Bruce Charlton

2:45 – 3:00	Dr. Alice Johnson	Overview and Impact of FSIS Rule on Listeria	46
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3:15 – 3:30	Mr. Ken Rutledge	Role of Facility Design in Microbial Process Control	54
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Session V. Programs and Issues
Moderator: Dr. Barry Kelly

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4:25 – 4:55	Dr. Jill Hollingsworth	Retail Perspective of the Domestic Market Relative to Food Safety	65
4:55 – 5:00	Dr. Spangler Klopp	Wrap Up of Symposium	

5:00 ADJOURN

Welcome to AAAP Food Safety Symposium

Spangler Klopp, DVM, Dpl ACPV

Townsends, Inc.

Georgetown, DE

The committee has worked for the past two years developing this program and defining speakers and has done a good job. AAAP has long been a leader in poultry disease research and the chart below shows the change in field related condemnations from 1965 through 2004.

Category	1965*	2004**
Leukosis	.51	.038
Septicemia/Toxemia	.56	.24
Airsacculitis	.92	.11
Inflammatory Process (IP)	.13	.11
Synovitis	.10	.003
TOTAL	2.22	.49

*** Dr. L. V. Sanders, USDA, National Meeting on Poultry Condemnations, Salisbury, MD, October 18-19, 1966**

**** USDA Slaughter Report**

The hope is that AAAP science can lead to similar results in the food safety arena as in today's world, healthy chickens are not enough.

FSIS OVERVIEW OF POULTRY INITIATIVES AND OPERATIONS

Dr. Barbara J. Masters

Food Safety and Inspection Service, United States Department of Agriculture, Washington, DC

FSIS: PRIORITIES FOR 2005

The Food Safety and Inspection Service (FSIS) is the public health regulatory agency, within the United States Department of Agriculture, responsible for ensuring that meat, poultry and egg products are safe, wholesome and accurately labeled. FSIS has been in existence for close to 100 years and has made many significant food safety and food security advancements in the last few years.

FSIS has a large workforce of approximately 10,000 employees, most of whom are stationed throughout the country and are present in plants everyday. Last year, over 7,500 inspection personnel stationed in about 6,300 federally inspected meat, poultry, and egg products plants verified that the processing of 43.6 billion pounds of red meat, 52.8 billion pounds of poultry, and approximately four billion pounds of liquid egg products complied with statutory requirements. Ensuring that these products are safe, secure, and wholesome is a serious responsibility.

Although regulation is an important component of the food safety system, it takes cooperation from government, producers, processors, educators and scientists, consumers and many others to protect public health most effectively. This cooperation is necessary when dealing with the complex issues of food safety. Individuals and organizations all have valuable input and a different way of looking at things. FSIS considers opportunities to address food safety together with its stakeholders, such as during the poultry medicine sessions at the AVMA and with the American Association of Avian Pathologists, pivotal for making further advancements.

FSIS PRIORITIES

FSIS is holding itself accountable for improving public health. Last year, FSIS outlined a series of priorities to better understand, predict, and prevent contamination of meat and poultry products to improve health outcomes for American families. FSIS is determined to build upon these priorities and continue to improve the Agency's infrastructure with greater attention to risk so that performance is further improved under the public health model. The six priorities, all equally important, will drive FSIS policies and actions.

THE FIRST PRIORITY IS TRAINING, EDUCATION AND OUTREACH

FSIS can only achieve its public health, food safety, and food security missions with adequate preparation of its workforce through scientific and technical training that reflects the Agency's risk-based approach to food safety and security. Results demonstrate that a highly trained workforce will lead to definitive advancements in public health.

In 2003, FSIS inaugurated Food Safety Regulatory Essentials (FSRE) training, which was designed to better equip inspection personnel in verifying an establishment's HACCP food safety system. All participants receive training in the fundamentals of inspection, covering HACCP, the Rules of Practice, Sanitation Performance Standards and Sanitation Standard Operating Procedures. This program also provides food safety training based on the types of products being produced at the establishments where inspectors are assigned. We expect to have this segment of our workforce fully trained by the end of the year.

Furthermore, FSIS has successfully launched training for newly hired Public Health Veterinarians (PHVs) and for newly hired food inspectors. We are also going back to ensure that any employees who did not initially receive this training are now fully equipped with the latest scientific knowledge. In addition, it is required that entering Consumer Safety Inspectors undergo and pass FSRE training. FSIS is in the process of implementing policies to require passage of mandatory training courses for entering Enforcement Investigations and Analysis Officers (EIAOs) and for PHVs.

We have also posted the training modules for the Food Inspector, PHV, and FSRE training on the FSIS Web site (www.fsis.usda.gov). This is significant because it makes the materials we are using to train our workforce more accessible to everyone, including our food safety partners and industry. When Agency policies change, these training materials, including the information posted on the Web site, are updated to reflect the latest scientific information.

OUR SECOND PRIORITY IS COMMUNICATIONS

FSIS is improving communications within the Agency and between the Agency and its stakeholders. An Internal Communications Board was established and is developing ways to enhance the flow of communication laterally and vertically within FSIS, as well as with the Agency's outside partners.

It is important to gather input from partners on communication issues. With FSIS' redesigned Web site, a tailored e-mail subscription service is available that notifies you when popular pages that you select are updated. In this current environment, we are all tasked with doing more and moving faster. It is critical that FSIS be able to effectively and efficiently communicate with partners. We are developing a virtual resource center that will provide broad access to food safety and security information as well as training.

OUR THIRD PRIORITY IS MANAGEMENT CONTROLS AND EFFICIENCY

FSIS is looking at ways to best achieve our operational goals and objectives to improve consistency and interdependence within and across program areas. In order to better focus its resources; FSIS is establishing a documented management control program. Management controls are operational checks and balances that safeguard policies, procedures and structures that ensure that tasks are carried out as planned, in the most efficient and effective manner.

OUR FOURTH PRIORITY IS RISK ANALYSIS, INCLUDING RISK ASSESSMENT, RISK MANAGEMENT AND RISK COMMUNICATION

Risk analysis is an extremely important process, one that provides regulatory agencies with a solid foundation for policy changes that can improve public health. FSIS is using science-based risk assessments to support new regulations aimed at ensuring that meat, poultry and egg products are safe, wholesome and properly labeled. Risk assessments allow us to focus resources on hazards that pose the greatest threat to public health. Risk assessments are an essential part of policy making, and for any economically significant regulation, FSIS is required by law to base rulemaking making on them.

In addition, FSIS is conducting baseline studies that will help determine the nationwide levels of various pathogenic microorganisms in raw meat and poultry. Baseline data provides better information for risk assessments, providing more representative data. They will also provide both benchmark information on the national trends and a tool to assess performance of initiatives designed to reduce the level and prevalence of pathogens. Together, risk assessments and baseline studies help us guide our policy making.

OUR FIFTH PRIORITY IS FOOD SECURITY

We will continue substantial efforts to improve food security measures. The Agency has accomplished much in the area of food security, making a strong system even stronger.

Recently, we issued and updated a series of directives to employees that outlined specific instructions on the procedures, monitoring, and sampling to be taken in the event the Department of Homeland Security (DHS) declares a Yellow, Orange, or Red Alert. We particularly wanted to ensure that all FSIS divisions had specific instructions in place so that the U.S. meat, poultry, and egg products supply could remain the safest in the world should a threat to the nation occur. In addition, we issued a directive, which defined what steps the Agency would take if an emergency incident occurs. These instructions specifically outline steps and procedures for FSIS personnel to take so that the agency's daily operations are not interrupted by an incident.

Also FSIS published an Industry Self-Assessment Checklist for Food Security to distribute to a variety of audiences. It is vital that all food slaughter and processing establishments, and all import, export, and ID Service establishments, take steps to ensure

the security of their operations. FSIS created this self-assessment instrument to provide a tool for establishments to assess the extent to which they have secured their operations. The final outcome of this self-assessment should provide establishments with a relative measure of overall security of their operations and guide them in the development and/or revision of their food security strategies. This checklist is one of several outreach efforts by FSIS to assist the industry to enhance the security of its regulated food products. The Checklist is available on the FSIS Web site.

Finally, FSIS has developed four new model food security plans. These model food security plans are designed to assist federal and state-inspected meat, poultry and egg products establishments, as well as import facilities, develop their own security measures to deter the threat of intentional contamination and similar attacks on the food supply. FSIS is conducting workshops around the country to assist small and very small processors in development of food security plans for their operations.

THE SIXTH PRIORITY IS EVOLVING INSPECTION AND ENFORCEMENT

Another Agency priority is to continue the evolution of inspection and enforcement. A risk-based approach, encompassing all we do and combined with the Agency's scientific commitment, will facilitate FSIS' ability to combat ever-changing threats to public health. Today, we have a much better reaction to the hazard landscape. Our ability to target resources for food safety and security verification systems has greatly improved. FSIS has refined its risk-based approach from a fairly static environment to one that is more fluid and can better react to food safety challenges that exist, and those that may arise, in order to further improve public health.

As we approach the completion of the first decade under HACCP, FSIS is determined to take a risk-based approach to food safety and security verification in order to realize the next dynamic in food safety. With recent developments in science and risk analysis, it is clear that there are enhancements that can be made to HACCP that offer a more complete approach to inspection and ensuring public health. This enhanced risk-based system builds on the strong foundation provided by the HACCP/Pathogen Reduction regulations and allows the FSIS workforce to more effectively utilize their expertise in assuring the safety and security of America's meat, poultry, and egg products.

SUMMARY

To meet it's goal of protecting public health, FSIS will continue to review policies and regulations and work with interested parties to modernize and further enhance its inspection and food safety and security verification efforts. It is clear that progress has been made, and FSIS is committed to continue making positive progress. The bottom line is that to continue being a successful public health regulatory agency, FSIS must ensure several things:

- Science-based policies are necessary
- Effective communication is critical
- Management controls must be in place for all parts of the Agency; ensuring efficient and effective program management
- Food security must remain a top priority – we must remain vigilant
- FSIS employees must be properly trained
- Inspection and enforcement must keep moving forward, both in the domestic and international arenas.

Protecting public health is neither accomplished through one lone action nor through just one organization. We are all in this together. We need to challenge ourselves, challenge each other, and above all hold ourselves accountable for improving food safety.

ROLE OF THE VETERINARIAN IN COMMUNICATION OF FOOD SAFETY ISSUES TO THE CONSUMER

Dr. Scott Gillingham

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INTRODUCTION

North Americans enjoy some of the safest food in the world with the consumer expecting an unlimited supply of appealing, convenient, and reasonably priced food. When properly handled and prepared, foods derived from animal products are generally safe and wholesome Even with this said, food-borne infections remain a major public health concern. In our society the consumer is not held responsible for eating spoiled meat, not cooking the food properly or handling it like it is a perishable product. To further the concern, sensationalized media reports and non-scientific accusations from some consumer activists have capitalized on the fears of a more health-conscious society. Changes in animal production systems, from small farm to large farms (intensified farming) have also impacted on the incidence of consumer fears.

An area of opportunity, the public health principle approach, can be used for addressing foodborne illness focused on the society. A society should identify and take preventive measures to reduce the risk of illness and focus its efforts on those hazards that present the greatest risk. (Miller et al. 1998). The idea of "Food Safety, it is up to You" came to fruition with the birth of "Fight Bac" as an educational tool. An area of education, the "Fight Bac" campaign focused on changing unsafe food handling behaviour by consumers in their homes with future implementation of education efforts targeted at health care workers, food service workers and veterinarians.

The link from the chicken barn to the processing plant is another area that needs to be further addressed as well. Therefore, food safety, at all levels, is a goal that all stakeholders want to achieve. A valuable resource for education, instruction and advice, the veterinarian has a great opportunity to be instrumental in the future of food safety policies.

TRUST AND OPPORTUNITY

One huge advantage for veterinarians that other organizations sometimes lack is credibility. According to the recent Gallup polls (www.gallup.com) "Nurses top Gallup's annual survey on the honesty and ethics of various professions, followed by other medical professionals like Doctors, Veterinarians and Dentists". Whenever the public health is concerned, veterinarians are trusted, as we are not aligned with the economic interests of any special group. Consumers are asking for production practices or food

products to be verified under good production practices standards. The issue of Trust is moving to "Trust with Verification". The public is asking for that a credible "third party" assure them that the production practices they see are implemented in the production chain for the food product. (Paybum 2002). Who is better qualified then the Veterinarian, a highly trusted member of society with the extensive knowledge of poultry production, husbandry and food safety? The veterinarian, having the highest qualifications, can add significant value to food animal products and consumer confidence and relationships.

ROLE OF THE VETERINARIAN

Recommendations from an AVMA workshop in 1992, on the safety of foods of animal origin, suggested that the veterinary profession must effectively communicate to people and public officials that veterinarians are concerned about the welfare of the people. With credibility, as a valuable resource, we have a wonderful opportunity to promote food safety to the consumer. Veterinary medicine is a unique and an important health profession, contributing to human health, welfare and wellbeing and quality of human life through enhancement of health, disease control, treatment and productivity of all kinds of vertebrate animals. As a profession, we can offer food safety leadership by providing a scientifically credible and socially responsible professional workforce. We can ensure the safety of foods of animal/poultry origin throughout all levels of the food chain with attention to production, processing, marketing, distribution and preparation of the final product (Heildelbaugh, 1992).

A point worth re-emphasizing, poultry health and food safety are inextricably linked. Full veterinary involvement and a strong State/Provincial Veterinary Service will be essential in ensuring that the necessary integration and the management decisions about on-farm food safety are actually achieved. Veterinarians in food animal practice are on the front lines of food safety, we must weigh the concern of animal health protection vs. public health protection. Above all we must be PROACTIVE.

PROACTIVE

As practitioners we are on the front lines of food safety, every day we must weigh the concern of animal health protection vs. public health protection (Strahm, 1992). All veterinarians (private, public, industrial) should be proactive in protecting the safety of the food supply. Our proactive responsibilities should include:

1) Proactive in the periodic review and revision of food safety regulations to ensure that our laws are consistent with public expectations. The regulations can be interpreted and enforced and not based on economics and other non-scientific factors.
2) Our knowledge must reinforce the realities of food safety issues.
3) We must help consumers separate fact from fiction and interpret the information they receive regarding food safety issues.
4) Assist official agencies to inform the public regarding the wholesome food supply. Be a part of "Food Safety Rapid Response Teams" (Cooperative

Extension Service in Maryland), which communicates information on food safety issues, defining newspaper articles or prime television shows that create alarm among consumers.

5) Furnish position papers and correspondence with the media concerning animal health, food safety and poultry welfare.
6) Serve and support, by positive example, the various commodities served by the veterinary profession. Be proud to exhibit and share the "Success Stories" in our operations at all levels of production.
7) Know the organisms linked to food safety security; differentiate among actual, perceived and nonexistent risks.
8) Help to assist official agencies to inform the public regarding the effectiveness of the nation in producing a safe, wholesome food supply.

INTENSIFY OUR EFFORTS

As a professional organization, more than ever, we must intensify our efforts to ensure and communicate the safety of foods of animal origin through the following suggested activities. (Acuff et al, 1991,Crawford, 1992)

1) Actively support, develop and participate in "Hazard Analysis and Critical Control Point" (HACCP) approaches to science-based food processing safety programs (Payburn, 2000)
   a. Contribute to the success of HACCP or similar programs by filling the role of producer on-farm educators and on-farm verifiers (Moore et al, 2000)
2) Document and communicate the contributions of veterinarians in food safety, poultry health and animal welfare.
3) Encourage our profession to communicate food safety issues to the public, coordinated with other groups having the same interests. Our message should be:
   a. The food supply is safe, of high quality with abundance and affordability. We are supplying a valuable source of protein.
      i. It must be stated that animal proteins, an important part of the human diet, provide the consumer with a highly nutritious component of their food at a low cost. In the American diet about 35% of the energy, 67% of the protein, 35% of the iron, 75% of the calcium and virtually all of the vitamin B 12 come from animals and animal products. (McCapes et al, 1991).
   b. Reality is, food is not expected to be "sterile". It is safe and nutritional
   c. We work as a team, providing a knowledge base to the safety of foods of animal origin.
   d. Food safety begins with a healthy live production system; and
   e. Consumers must be responsible for the storage and handling of foods after purchase.
4) As veterinarians we must educate consumers knowing very well that we are a trusted integral part of the food safety chain (www.Gallup.com). We are dealing with a very educated base of consumers who read, listen to and observe all as to what product they put on the table (Barr, 1992) We must intensify our efforts and get the message out there;
   a. Find out and ascertain the extent of knowledge the average food consumer

possesses concerning poultry production, processing and handling (Herrick, 1990). At the same time identify things within our business that we do to protect the food supply.

b. Coordinate and implement an industry wide program by disseminating accurate information on poultry production practices. Reach out to the media, consumer groups, schools (Teacher Research Guide), and local/regional health departments.

c. Be an active part of hotline sites linking research and science to the consumer (USDA Meat & Poultry Hotline). Actively contribute with the home economists, public health and community nutrition experts, and consumer advisor specialists. Actively pursue participation, be a part of the TEAM (Together Everyone Achieves More).

d. Consumers will have questions about related diseases, treatment applications (residues and resistance) and zoonosis that appear in the news Le. BSE, AI etc.

   i. Create or be a part of a company website to answer consumer questions.

e. Advocate that the chicken industry is committed to Environmental protection

   i. Companies in the USA have spent more than $300 million in the last ten years on wastewater treatment facilities

   ii. To ensure that litter is used in an environmental sensitive manner, the industry created a formal dialogue with EPA, USDA, NASDA and a host of others.

f. We must not only produce safe, clean quality poultry products but we support a "pride-in-product" that poultry producers believe in.

g. g. Timely involvement in education during seasonal festivities (Thanksgiving, Christmas, Easter)

5) Food safety starts at the farm, live production units. Create and supervise on-farm site tours. Actively lead school, church or community groups through the farm. An opportunity to separate fact from fiction that we are producing food not just chicken. This is our opportunity to reveal to the consumer the direct role the veterinarian plays in food safety at the production level. We are a valuable source of food safety information, not simply pet health.

CONCLUSION

Our profession needs a program to reinforce food safety from Farm to Fork revealing the positive approach to food safety at all levels. Installing confidence, quality and wholesomeness of poultry products to the consumer. We need a Slogan, to tell the consumer. Remember the slogans such as "Where's the Beef" "Just Do It", and the impact it had on the product. What should ours portray? **"The Power of Poultry"** New and serious challenges will face producers, processors and our marketing industries as we enter and promote our food to the consumer. These challenges are our opportunity as we actively provide solutions to foodborne zoonotic problems. Our goal must be to help the teachers, laboratory technicians, food managers and health workers from schools, government agencies, hospitals and other organizations improve their knowledge of food safety issues. A new era of animal disease control programs will emerge, the control of noneconomically disruptive zoonotic disease agents principally for public health rather

than animal health reasons McCapes et al, 1991). As leaders and as communicators, our changing role will focus on production efficiency towards those issues of public health importance. Our challenge is to actively pursue and actively participate in the promotion of food safety. As a good friend always says "Have Fun Get it Done".

Websites and Contacts

1) www.aeb.org
2) www.eatchicken.com
3) www.nationalchickencouncil.com
4) www.eatturkey.com
5) www.aamp.com
6) www.unitede~g.com "5-star" Food Safety Program
7) www.gallup.com
8) www.fightbac.org
9) www.agnr.umd.edu
10) www.hoptechno.com
11) www.dekalbfarmbureau.org
12) USDA Meat and Poultry hotline 1-800-535-4555
13) Email communication with Beth Glynn, public health educator, Tacoma-Pierce County Health Department

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INDEPENDENT AUDITOR'S PERSPECTIVE ON THE DOMESTIC MARKET

Mr. Bob Thrash

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HISTORICAL FOCUS ON BASICS

- Pest Control
- Sanitation
- Personal GMPs
  - 21 CFR, Part 110
- Buildings
- Equipment

US FEDERAL FOOD, DRUG AND COSMETIC ACT

Sec 402 A food shall be adulterated –

(a)(4) if it has been prepared, packed, or held under unsanitary conditions, whereby, it may have become contaminated with filth, or where it may have been rendered injurious to health…..

FOOD SAFETY AUDITS TODAY

In addition to Basics, most food safety audits today include:

- HACCP basics
  - 5 preliminary steps
  - 7 principles
- Recall and traceability
- Allergens
- Food Security (Focus on Access and Exclusion)

HACCP AUDITS

- Typically included in food safety audit at surface level
- Based on either
  - HACCP as defined by NACMCF / Codex
  - Regulatory
- Typically not performed by Certified HACCP Auditor (ASQ-CHA)
-

KEY TOPICS ON THE FOOD SAFETY AUDITING HORIZON

- Allergens – requirements expanding
- Irradiation
- Sustainable Agricultural Practices
- Organics
- Genetically Modified Foods
- Bio Security (Focus on organism threats)

FOOD SECURITY AUDITS

- May be part of food safety audit
- Guidelines published by FDA and USDA
- Initiated in response to 9/11 and current events.

CHANGE IN AUDITOR APPROACHES

- Previously inspection driven
  - Visual inspection of facility, equipment, people, and processes
- Auditors – old model
  - Boot strap training
  - Retired professors
  - Retired managers

CURRENT AUDIT APPROACH

- Review of procedures
- Review of records
- 30-50% of audit based on facility inspection
  - 1% to 3% devoted to associate interviews

CURRENT AUDIT APPROACH

- Most rely on QA Managers to handle
- Management of many facilities appear to only want a score – not interested in improvement aspects of audit

FUTURE APPROACH

- Minor changes in current investigation approach
  - Observe tasks in progress (e.g., sanitation and pre-op processes)
  - Meet with entire facility food safety team to get a sense of their priorities
- Participation by all responsible parties
- Findings derived by root cause versus symptoms

CURRENT FOOD SAFETY AUDITORS

- Practical Experience: 3 to 10 years
- Education: Technical degree
- Training: unstructured auditor training
  - Auditor principles and process
  - Basic HACCP training
  - Specific audit criteria calibration
  - Some annual or ongoing training

FUTURE FOOD SAFETY AUDITORS

- Competency-based Food Safety Auditor Certification (referencing ISO/IEC 17024:2003)
  - Audit knowledge and skills based on ISO 19011:2002, Guidelines for quality and/or environmental management systems auditing

COMPETENCY-BASED FOOD SAFETY AUDITORS:

- Qualifications: Education & Experience
- Personal Attributes: PAAS Master® Exam
- Key competencies: demonstrated though the successful completion of an exam by a Certified Trainer
- Skill competencies: demonstrated though successful performance of a skill examination by a RABQSA Approved Examiner

COMPETENCY-BASED FOOD SAFETY AUDITORS PERSONAL ATTRIBUTES INCLUDE:

- Ethical
- Proactive and organized
- Systematic
- Decisive
- Observant
- Diplomatic
- Flexible
- Process focused
- People sensitive

- Adaptable and resourceful
- Confident

NEW FOOD SAFETY STANDARD

- ISO 22000 (Draft), Food safety management systems – Requirements for organizations throughout the food chain
  - Interactive communication
  - System management
  - Process control
  - HACCP (Codex) principles
  - Prerequisite programs
- Draft may be purchased at www.iso.ch/iso/en/ISOOnline.frontpage

APPROVED AUDIT PROVIDER LISTS

- Each purchaser creates their own approved audit provider list
- No universal criteria for approval
  - bigger is better mindset
- Some program performance:
  - typically dollar and report submission timeliness
- Some programs are audit provider and auditor specific

FUTURE APPROVED AUDIT PROVIDER LISTS

- No immediate change in process for attaining recognition
- Long term: expect all auditors to be certified

CONCLUSIONS

- New standards will significantly change the way food safety audits are executed over the next 5 years
- Increased variation in audit outputs during transition period
- New standards will require strategic approach to food safety

INTERNATIONAL SITUATION AND ITS RAMIFICATIONS

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No text submitted

OVERVIEW OF RAW AND COOKED FOODS OF POULTRY ORIGIN

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Processed poultry products come in a wide variety of forms and constitute a major component of the typical American diet with consumers eating poultry products of various kinds multiple times a week. Because of this, the microbiological safety of these products is of the utmost importance to the industry as well as the consuming public. Several bacterial pathogens have been associated with poultry products, both in the raw ready-to-cook (RTC) form and the ready-to-eat (RTE) categories and foodborne illnesses are considered to be a substantial health burden in the United States. Fortunately, the incidence rates of human illness caused by many of the pathogens associated with poultry products has declined substantially in recent years. This presentation is intended to provide a general overview of the pathogens of importance as they relate to raw and cooked products of poultry origin.

RAW POULTRY PRODUCTS

Raw poultry products, or RTC products, consist of those products that are minimally processed and require cooking to an internal temperature of 160 ^{o} F prior to eating. These include products that are intact, such as whole birds or cut-up pieces, and those that are ground. This category also includes products that are tenderized, marinated, and cured. Breaded and parfried products are often heat treated but not fully cooked. Commonly produced product categories include traypack, foodservice cut-up, deboned, ground chicken and turkey, and battered, breaded and parfried breast fillets, tenders, and nuggets.

The pathogens most commonly associated with raw products are S*almonella sp.* and C*ampylobacter sp.* Generic *E. coli* are identified as indicator organisms for evaluating fecal contamination and process control, but the types found in poultry are not known to be pathogenic for humans.

Salmonella enteritica are a ubiquitous group of enteric bacteria that consist of a wide variety of serological types identified. There are over 2400 recognized serotypes. They are generally considered to be commensal organisms in poultry, causing little to no disease, which makes eliminating their presence difficult. Salmonellosis is defined as illness in humans caused by S*almonella* infection. Salmonellosis from food poisoning occurs 8 hours to 3 days after consumption of contaminated product and lasts 4 to 7 days. The disease is characterized by severe nausea, vomiting, diarrhea and fever along with abdominal pain, headaches, and chills. Severe cases can result in hospitalization and death, especially in immunocompromised individuals. Salmonellosis is a notifiable

disease, physicians and laboratories are required to report identified infections to their local health departments.

Campylobacter are also ubiquitous enteric bacteria that do not cause disease in birds. Two species of *Campylobacter* are of interest in poultry, *C. coli* and *C. jejuni*. Human campylobacteriosis is most frequently caused by *C. jejuni*. Clinical symptoms of diarrhea, abdominal pain, cramping, and bloody stools occur within 1 – 7 days after infection. While seldom fatal, campylobacteriosis has been associated with a rare neurological disorder known as Guillane-Barre syndrome.

COOKED PRODUCTS

Fully cooked, or RTE, products are those food items that have been sufficiently cooked so that they are safe to eat as they are with no further preparation required by the consumer. Many of these products (such as hot dogs), however, are customarily eaten hot and cooking instructions may be included on the label. The vegetative forms of pathogenic bacteria are inactivated during the cooking process, but two types of bacterial contamination can still be an issue.

Spore-forming bacteria such as *Clostridium perfringens* and *Clostridium botulinum* can survive cooking when in the heat-resistant spore form. Thermal processing (canning) at a minimum retort temperature of greater than 240°F for a specific amount of time is necessary to destroy most spores and toxins. Sporulation and outgrowth of these bacteria is, therefore, of greatest concern and is prevented by cooling product from the peak cooking temperature to the storage temperature (below 40° F) very rapidly. This prevents product from being in the optimal range for bacterial growth long enough for sporulation into the vegetative state or the production of bacterial toxins to occur.

Preformed toxins are produced during the growth phase of some bacteria, such as *C. botulinum*, and when they are ingested, cause headaches, disorientation, neurological damage, paralysis, and possibly death. Other toxins are formed when the vegetative cell produces a spore. Some spore-forming bacteria, such as *C. perfringens,* form spores in the human digestive tract because the digestive juices are too harsh for the vegetative cell and the self-preservation mechanism (spore formation) is turned on. The common form of perfringens poisoning is characterized by intense abdominal cramps and diarrhea which begin 8-22 hours after consumption of foods containing large numbers of those *C. perfringens* bacteria capable of producing the food poisoning toxin.

Recontamination with bacteria must also be considered as cooked products are exposed to the environment, food contact surfaces, or cross-contamination with raw product prior to final packaging. Proper chilling and cold storage temperatures are also an essential component to limiting the growth of these bacteria.

Listeria spp. can be found in the processing environment. Although most forms of *Listeria* are not pathogenic, *Listeria monocytogenes* is. Listeriosis is characterized by meningitis, in adults, with flu-like symptoms, neck stiffness, severe headache, nausea and

high fever. It is highly fatal for the immunocompromised and fetuses *in utero* resulting in miscarriages and stillborn infants. The frequency of listeriosis cases is very low in the United States, but the case fatality rate can be quite high making this disease one of significant public health importance.

Recontamination of cooked products with bacteria such as *Salmonella* from raw product source materials is also of concern. In addition, post-cooking handling of product by employees (i.e. employee hygiene) is important in controlling contamination with *Staphylococcus aureus* which produces toxins capable of causing nausea, vomiting, abdominal cramps and diarrhea from 30 minutes to 6 hours post-consumption.

Many HACCP-based processes and procedures are already in place in poultry processing establishments to control or eliminate these potential pathogens and the resulting rate of foodborne illness associated with these products, such as campylobacteriosis and listeriosis, have declined to levels approaching, or even exceeding, those stated as goals in the US Department of Health and Human Services' Healthy People 2010 document. The poultry industry continually strives to reduce pathogen levels even further as the scientific understanding of how these organisms enter the production system and control and intervention technologies continue to improve.

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REDUCTION OF RISK IN THE PRIMARY BREEDER PRODUCTION SYSTEM

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INTRODUCTION

There have been many significant advances within all sectors of the broiler and allied industries to reduce the risk of pathogens associated with human food-borne illness. The poultry industry is under increasing consumer and regulatory pressure to guarantee food safety and meet export requirements. Public health agencies and producers of poultry meat continue to develop standards and control strategies aimed at eliminating or reducing enteric pathogens in the food chain. In this context, significant effort has and continues to be made to control the risk posed by *Salmonella* species at all levels of the broiler and broiler meat processing industries. This paper will review the practices used at a primary breeding company to completely control and eliminate Salmonellae from the breeding program.

Initially *Salmonella* control meant preventing infections caused by avian host specific species *S. pullorum and S. gallinarum* (SP and SG). Subsequently this task was expanded to include the control of species that were recognized by their zoonotic disease potential *(S. enteritidis* and *S. typhimurium*). Today, our goal is to control and eliminate all *Salmonella* species from the breeding program. The ability of the primary breeder to supply *Salmonella* free parent stock to the broiler industry is a key component of this industry's attempts to eliminate *Salmonella* from the finished product.

The major emphasis for preventing *Salmonella* infections is to avoid the introduction of these microorganisms into the farms, hatcheries and feed mills through a robust and effective biosecurity program. This requires the establishment of barriers and the implementation of practices aimed at suppressing the most common sources of infection. A comprehensive-integrated biosecurity program must be established as the first and most important line of defense and encourage participation. To be effective, every employee and grower must know that it is part of their job to prevent exposure to salmonellas, and the vertical and horizontal transmission following an infection.

An integrated-comprehensive biosecurity approach requires a strong commitment and has a significant cost. This cost should be considered an insurance policy. This approach requires routine evaluation, constant and gradual improvement, and, periodic training of employees and contract growers. Ultimately, the costs associated with these

tasks will be offset by the benefit of meeting the expectations of broiler meat producers.

In our experience, the development of an effective and comprehensive biosecurity program must include a series of practices designed to reduce the risk of infection. Some of the most relevant are listed below:

- Requirements for the location and layout of a farm (isolated, all in all out, single age, etc.)
- Requirements for house construction (ease of C&D, limited access of people, pests, wild animals, etc.)
- No contact or proximity to other poultry or back yard flocks
- Requirements for employment and contracts
- Restrictions and/or regulations for farm and hatchery visitation (limited visits, shower in and out, change of clothing, hand and boot sanitation, etc.)
- Restrictions to avoid contact with other avian or animal species
- Requirements for the movement of personnel and equipment
- Restrictions for visitors and outside service personnel (quarantines after visiting other poultry operations)
- Requirements for the disposal of dead birds
- Requirements for litter management and disposal
- Requirements for bedding quality and monitoring procedures
- Requirements for the cleaning, disinfection and monitoring of company vehicles
- Requirements for house cleanout, disinfection and monitoring procedures
- Requirements for water management, sanitation and monitoring procedures
- Restrictions for the movement of flocks and spent fowl
- Requirements for integrated pest control management
- Requirements for feed hygiene, transport and delivery

A comprehensive biosecurity program requires the identification of the most likely sources of salmonellas, and the establishment of practices designed to suppress the introduction and spread of these pathogens into the breeding populations. The most relevant areas of our program are described as follows.

DAY-OLD PLACEMENT OF BREEDING STOCK

A critical component of any enteric pathogen control program is the placement of breeding stock free of *Salmonella*. The control strategies, monitoring programs and laboratory methods used at the primary breeding level follow the provisions of the USDA's National Poultry Improvement Program (NPIP). These ensure that flocks and their progeny are Pullorum-Typhoid Clean, S. Enteritidis Clean and Salmonella Monitored. For the primary breeder, compliance with the NPIP's provisions and all classifications for meat type birds is mandatory for all flocks and hatcheries. Therefore, depopulation of any flock failing to meet these standards ensures the achievement of these goals. Provisions include specific testing protocols and schedules used to monitor the salmonella status of the flocks, their growing environment and their progeny at the

hatcheries. Producers in the USA and around the world recognize the value of obtaining day-old breeding stock from primary breeders with comprehensive biosecurity programs and that are in compliance with NPIP's health standards. Furthermore, monitoring of parent stock chicks, meconium and or chick box liner paper at delivery has become one of the most common critical control point (CCP) procedures.

POULTRY FEED

In a primary breeding operation with strict biosecurity practices feed could be the most common sources of salmonellas. Many species found during routine monitoring of the feed mill environment and feed ingredients can be found later in the environment of breeder flocks and in their offspring. In fact, breeder flocks act as biological filters and amplifiers of salmonellas that adapt well to their intestine and internal temperature. Some species commonly found in the feed mill environment can be extremely infectious to newly hatched chicks. It has been shown that one organism of *S. montevideo* per gram of feed can infect a day-old chick. Thus, an effective control program begins with the selection and routine microbiological screening of feed ingredients and the manufacturing environment. These screening procedures are useful CCPs.

Ideally, animal protein and fat sources should be avoided in the manufacture of breeder feeds. The design of the feed mill must prevent the introduction of rodents, wild birds and insects that might contaminate ingredients or finished product. The feed mill must have completely separate areas for ingredient reception and storage, grinding and mixing, decontamination by thermal treatment in pre-pelleting feed conditioners (82 to 85°C), pelleting, cooling, and the storage of the finished product. The goal is to achieve effective partitioning of clean and dirty areas. This is achieved by physical separation and aided by air filtration systems that prevent recontamination. Stringent rules for personnel/visitor traffic are also critical to avoid cross contamination. Routine monitoring procedures have shown that footwear and clothing are effective carriers of dust and are potential sources of contamination.

Hazard analysis of critical control points (HACCP) has been introduced in feed mills to reduce the risk of contamination with salmonellas. The major CCPs include monitoring of the thermal treatment process (time, temperature, etc), and routine microbiological monitoring through environmental sampling to evaluate levels of contamination through the different areas of the mill. In addition, samples of finished feed are periodically screened for total viable cell counts (TVCs), coliform bacteria, and salmonella. The goal is to produce feed free of coliform bacteria and *Salmonella*.

From an enclosed storage and loading area, finished feed must be delivered to the farm by dedicated transport vehicles. Feed transport vehicles should be thoroughly decontaminated on a periodic basis and monitored routinely for *Salmonella* contamination.

In addition to a robust feed manufacturing and heat treatment process, feed additives such as organic acids or other antibacterial products in raw ingredients or finished feed have been effective in reducing total counts of enteric bacteria and the risk of re-contamination. These antibacterial and/or feed acidifiers can, when properly applied, prevent the growth and proliferation of enteric pathogens and mold. These products have also been recommended to maintain clean silos, feed milling equipment, feed delivery vehicles and feed distribution equipment at the farm.

RODENT AND PEST CONTROL

Rodents are major vectors and reservoirs of *S. typhimurium*, *S. enteritidis,* and many other *Salmonella* species for poultry populations. Mice naturally infected with *S. enteritidis* can excrete at least 200,000 organisms per pellet. Besides their role in increasing the levels of contamination in the environment, rodents can effectively transmit the infection to other houses and farms. Therefore, it is critical to prevent rodent access to feed, water and shelter by:

1. Building rodent-proof poultry houses (metal doors and concrete floors)
2. Eliminating potential harborage areas inside and outside the poultry houses
3. Disposing of dead birds and unused or spilled feed promptly and securely.
4. Appropriate house management and sanitation
5. Regular inspections and monitoring of rodent activity
6. Rodent baiting and trapping

The control of insect vectors (particularly flies and beetles) through good management practices, and careful selection and use of pesticides is essential. Darkling beetles (*Alphitobious diaperinus*) have been found to carry over five different serotypes of *Salmonella* and shed *S. typhimurium* in their droppings for up to 28 days. Darkling beetles are one of the main vectors in the reintroduction of salmonellas to the chicken house after it has been cleaned and disinfected. In fact, it is known that beetles and flies can fly more than a mile, introducing salmonellas into other farms in their path.

OTHER FARM, DOMESTICATED OR WILD ANIMALS

All warm and cold-blooded animal species are potential carriers of *Salmonella*. For this reason, poultry houses should be constructed to exclude the entrance of wild animals and perching of birds inside and outside (roof, eaves). Feed spills should be cleaned up immediately to avoid attracting wild life. Monitoring procedures have shown the presence of *Salmonella* in the droppings of rats, mice, raccoons, skunks, opossums and reptiles. Any other kind of farm animals and pets (dogs, cats, etc.) should be banned from the poultry farm. Experiences with salmonellas and *Campylobacter jejuni* (another human enteric pathogen getting increasing attention) have demonstrated the high risk of allowing cattle to graze in close proximity to the poultry farm and/or in-between chicken houses.

WATER SANITATION AND MANAGEMENT

Drinking water can be another source of *Salmonella* and enteropathogenic *E. coli*. Studies of effluent from sewage treatment plants and the monitoring of individual wells and municipal water sources have shown the presence of *Salmonella spp.* Chlorination (3-5 ppm) and other methods of water sanitation are gaining popularity in the broiler industry as effective means of reducing exposure to pathogens and boosting flock performance. Water pH (< 6.5) can enhance the effectiveness of chlorine and other water sanitizing agents. Water acidification is showing encouraging results as a method of promoting healthy intestinal flora and suppressing the colonization by pathogenic organisms.

Water activity in the litter has a direct effect on the level of *Salmonella* in it. Increased moisture levels promote the survival and transmission of salmonellas. Water restriction programs and the use of closed drinking systems, along with proper ventilation, have resulted in reductions of moisture and levels of *Salmonella* in the poultry house environment.

REVIEW AND UPDATES

For all the above reasons, an effective biosecurity program should be set and practiced as a multidisciplinary team effort. It is imperative to understand that, while the enforcement of a biosecurity program should be rigid, the program itself should never be "set in stone". Constant review and updating are necessary for its success. Individuals should be encouraged to ask questions and offer suggestions for continuous improvement of the program. Furthermore, employee and grower participation must be recognized and be part of the periodic performance evaluations.

HOUSE CLEANOUT AND DISINFECTION

House cleanout and disinfection procedures are an integral part of the biosecurity program. These procedures are required between growing cycles to eliminate or reduce the concentration of salmonellas and other pathogens that may infect subsequent flocks. Chicks are extremely susceptible to salmonella infections after hatch and during the first days of life. Likewise, pullet flocks transferred from growing to laying facilities are highly susceptible to salmonella infections. This is due to stress and changes in their normal gastrointestinal flora. As new flocks arrive at farms, it is important that their environment be as clean as possible. Bacteriological monitoring of new litter material has proven to be valuable in avoiding the introduction of Salmonellas and mold. Primary breeders prefer litter material that has been heat-treated and transported in clean and disinfected vehicles.

The first step is to plan a flock placement schedule that allows sufficient down time for all houses to be cleaned. A minimum period of 4 weeks for pullet houses and 6 weeks for laying houses is needed to do repairs and maintenance followed by thorough cleaning and disinfection. A complete house cleanout and disinfection schedule usually includes the following procedures:

- Insect and rodent control
- Litter removal and disposal
- Washing with a high pressure washer, hot water, and detergent (ceiling, walls, curtains, feeders, drinkers, other equipment, and concrete floor from back to front)
- Water system cleaning and sanitation
- Cleaning of external areas
- Repairs and maintenance
- Inspection and securing of the farm
- Disinfection (inside and outside)
- Fumigation
- Bacteriological monitoring (*Salmonella* and total bacterial counts)
- Laboratory approval ("passing" status before re-stocking)
- Placement of new bedding material
- Litter treatment
- Application of a disinfectant to the outside perimeter

Education and training of specialized crews are needed to develop a philosophy of "cleaning and disinfection of a food producing facility" instead of "a chicken house". Attention to detail must be emphasized in order avoid failures or having to repeat steps. The effectiveness of these procedures must be monitored routinely by testing schemes and the evaluation of CCPs.

HATCHERY

Chicks may be exposed to salmonella in the hatchery, either by exposure to infected hatch-mates or from environmental contamination. Essential components of a Salmonella control program in the hatchery are robust biosecurity and hygiene programs. A routine environmental monitoring program should be implemented to evaluate their effectiveness. Interventions like fumigation of the hatchers during hatch may limit cross-exposure. Single stage incubation provides a higher degree of biosecurity as it allows the segregation of hatching eggs and chicks sourced from flocks if these are found *Salmonella* positive during routine monitoring procedures. Therefore, stringent biosecurity along with an effective traceability system greatly reduces the risk of lateral transmission during the hatching and chick servicing processes.

EDUCATION, TRAINING AND CONTRACT GROWING REQUIREMENTS

Understanding and following the company's biosecurity practices must be part of everybody's job. The first step in achieving this goal is the establishment of a detailed program in writing. This program should be easy to understand and practical. Induction, training and review sessions with all participants must be conducted periodically. Likewise, the management team must take responsibility for the implementation and enforcement of participation in the biosecurity program. Mandatory participation in all

aspects of the biosecurity program is a condition for hiring personnel and establishing growing contracts. This must be enforced by written policies establishing consequences for failures or breeches in the execution of the biosecurity program. Consequences include termination of employment or contract growing agreements.

AIDS TO COMPLEMENT THE PROGRAM

The implementation of an effective integrated-biosecurity program that prevents the introduction and infections caused by enteric pathogens is the main tool to protect valuable breeding stock, contribute to customer satisfaction, and ensure the profitability of the primary breeder operations. The effectiveness of this program is monitored routinely by testing schemes and the evaluation of CCPs. The combination of biosecurity practices and evaluation procedures are the main focus of our program.

Healthy intestinal flora has shown to protect chickens against colonization by salmonellas and other pathogenic bacteria of the intestinal tract. Unfortunately, the normal acquisition of flora is complicated by the fact that chicks are hatched and placed in clean environments. Consequently chicks are not exposed to healthy intestinal flora that in nature would come mostly from their parents. The use of defined and non-defined avian gut flora (competitive exclusion) has been shown to aid chicks to establish a normal flora that protects them against *Salmonella* infections. Other bacteria such as *Lactobacillus* (probiotics) have been used to maintain a healthy intestinal flora and help flocks during periods of stress or after antibiotic treatments.

Evolving methods and products used to manipulate intestinal microflora are becoming increasingly important since growing public pressure against the use of antibiotics in food animals, and the ban of many of them have become a reality in many countries around the world. The uses of essential oils, carbohydrates, herbs, or spices (prebiotics, natural substances or nutraceuticals, etc.) are being considered as potential alternatives to prevent colonization by enteric pathogens.

Immunization has been used strategically to protect at-risk flocks and prevent vertical transmission. This method is not used to control host specific avian salmonellas. Inactivated salmonella vaccines formulated against specific serotypes (autogenous products) have shown benefits for breeders and their offspring. The induction of immunity in the hens against specific salmonella serotypes prior to the onset of egg production helps to reduce of the risk of vertical transmission. Also, field experiences suggest that maternal antibody can protect chicks against early exposure. A few live salmonella vaccines (deletion mutants) have become commercially available to protect against specific *Salmonella* species by reducing the risk of colonization, persistence, and spread of pathogenic-field strains. The use of any immunization method by a primary breeder company requires careful selection and planning to avoid interfering with routine microbiological and serological monitoring procedures.

INTERVENTIONS

A high degree of success has been achieved at reducing environmental shedding and egg transmission of salmonella using antimicrobial treatment. The effectiveness is dependent on two factors; selection of the most appropriate antimicrobial, dosage and length of treatment, and moving the treated flock to a clean house so that the flock is not re-exposed to environmental contamination. As the breeding program progresses to a nearly or completely salmonella-free status, the use of interventions becomes infrequent and the strategy may be revised to incorporate depopulation of all *Salmonella* positive flocks.

Aids or interventions provide additional protection but they are not a "quick fix". They cannot substitute for an effective integrated-biosecurity program. The success and value of these complements depend largely on the biosecurity program's ability to limit exposure.

MONITORING

As mentioned before, a comprehensive monitoring system for *Salmonella* is essential to determine the effectiveness of routine biosecurity and hygiene practices at many different points of the production system, to evaluate progress, and to define the status of flocks and their progeny. Today, serology, cultures, and PCR assays are part of the Hazard Analysis of Critical Control Points (HACCP) approach used increasingly by the primary breeders and producers of poultry meat products. Samples for monitoring procedures must be routinely collected from the birds and their housing environments during the rearing and production phases, their progeny and hatchery environment, egg storage facilities, equipment and transport vehicles, feed and feed manufacturing environment, designated clean and dirty areas, facilities after cleaning and disinfection procedures, and all other potential inputs. Laboratory results then are circulated to appropriate managers in order to verify freedom from infection or take corrective actions as needed.

Robust laboratory procedures and good information management systems are needed to guarantee that accurate data are generated and distributed promptly. Overall, it is imperative to have the ability to trace back any positive results to individual flocks, locations and/or the specific source of contamination. In most instances, this task requires additional and more detailed testing. A good reflection of the employees' and growers' commitment to a *Salmonella* free program, and their understanding of the value of monitoring is when they acknowledge that "they are as good as the last test".

As it was mentioned earlier, the NPIP and its provisions are a great service to the primary breeders and the industry as they include monitoring protocols that have been shown to be optimal for the detection of *Salmonella* in breeding populations. Furthermore, the NPIP periodically and extensively reviews these protocols with the input of regulatory agencies, academia and the industry in order to incorporate improvements or technologies that will enhance their effectiveness and maintain them

scientifically sound. In addition, the NPIP provides a mechanism for laboratory certification and workshops to increase the proficiency of personnel from authorized laboratories to isolate and identify *Salmonella* from a variety of specimens.

In closing, it is hoped that further developments aimed at increasing the effectiveness of current biosecurity and monitoring procedures, along with the evolution and/or discovery of novel-suitable intervention strategies will result in further advances in the health status of breeding and broiler flocks leading to increased safety of broiler meat products. We consider food safety a top priority and broiler primary breeders will continue to support the industry's efforts by using the best methods available to ensure the production and delivery of healthy-safe breeding stock. Also, this commitment includes the willingness to share and transfer knowledge and experiences that could benefit the industry as a whole.

REDUCTION OF RISK IN THE INTEGRATED BROILER PRODUCTION SYSTEM

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When I asked for feedback on the actions companies had taken to reduce the risk of Salmonella in their operations, the silence was deafening. As I talked with the companies there were several reasons for the deafening silence. First most companies are not having any problem controlling Salmonella at the plant level and see no reason to spend significant monies to reduce the risk at this time. Second, for the complexes having to intervene to meet the requirements, some are reporting success while others applying the same practices are not seeing any benefit. Last, customers while eagerly asking for salmonella free product, they know practically it is not achievable right now and are not willing to pay any extra to have it.

At present the industry attacks the risk factors long the integrated continuum at the multiplier pullet/ breeder operation, feedmill, hatchery, and broiler growout.

In the integrated broiler production system reduction of risks at the multiplier pullet breeders level have focused on trying to keep the pullets clean and maintain clean birds through lay. The effort has met with mixed success. Parent stock is cleaner than it has ever been and plant Salmonella levels seem unaffected. Live vaccines with autogenous killed vaccines targeted at the serotypes found in the plant plus house C and D with rodent control have apparently been successful at some complexes and not at others. We currently have two complexes on this program and positive results have been hard to find to date. Vaccination, C and D and rodent control for the million-bird 5 pound complex would cost approximately 150,000 dollars per year.

At the feedmill, products are available that have label claims for reducing or eliminating salmonella in ingredients for a short period of time. The effectiveness of these products in final feed is influenced by the other raw ingredients used for the final feed. The additives are very expensive and rarely used on the broiler side of the business. For a million-bird complex raising a 5 pound bird, just this additive alone would add 1.3 million dollars to feed cost without returning any value to the sale of the product.

In the hatchery several interventions are practiced. Not reusing chick box paper and washing chick boxes each day instead of weekly are done at times. Application of a germicidal product in the hatching cabinet is also a common practice. All of these have logical academic results but mixed practical results as measured by Salmonella levels in the plant. The cost for these interventions on a million-bird complex in the hatchery is roughly 96,000 annually.

Broiler growout provides the most challenges to risk reduction due to the size of the operation and the fact that the growers are independent contractors. The effort to reduce the risk here has focused on early vaccination, competitive exclusion products and feed withdrawal practices. Early vaccination with live vaccines has some application but due to the expense and limited results is rarely used except in desperate times. The competitive exclusion product is still classified as a drug and not approved yet. A product with no label claim for Salmonella is now back on the market but results are limited. The efforts around feed withdrawal focus on accuracy of feed withdrawal and water acidification of the crop during the first 10 days in the house and last three days prior to processing. While a good practice, it is hard to see where the acidification has a noticeable effect in the plant. If this was done annually on all broilers processed at a million bird complex is 75,000 dollars annually.

As companies have studied what influences the level of Salmonella in a complex, they have learned more about what is and is not associated with higher Salmonella risks.

Surprisingly, Salmonella levels are not influenced by good versus poor managed farms and rodent control on those farms. Feed and water space differences do not affect Salmonella risk. Distances from roads and traffic patterns have no affect. Some farms are always positive and some are always negative. They don't seem to change regardless of circumstances

Salmonella risk are consistently influenced by litter moisture and ventilation methods that drive litter moisture. Higher moisture and caked litter does increase risk. Subsurface soil moisture increases the risk. Reduced intestinal health does increase the risk. Decreased use of feed additives antibiotics to prevent disease does lead to increased Salmonella. Coccidiosis breaks increase the risk. The withdrawal of 3 nitro increase the risk.

Even with all the interventions, Salmonella levels at many complexes fluctuate independent of the interventions. The question remains why. While there are over 2100 serotypes of Salmonella, only a few are significant food borne pathogens. All 2100 plus serotypes are classified the same when it comes to meeting the USDA requirements. Reducing the risk factors for *Salmonella* load in the integrated broiler production system requires that you know where all the risks are. The fact that Salmonella levels fluctuate independent of interventions tells us that there are still significant risk factors we have not identified that are influencing Salmonella load.

Historically, this industry is very good at taking something that works and applying it across the industry with consistent results and continuous improvement. All of us are food consumers. We work constantly in the environment that produces the birds. We have a real interest in any health risk that exists. If the industry were allowed to focus on the Salmonella's that are a health risk instead of all Salmonella the results would be much different in a short time.

REDUCTION OF RISK IN THE TURKEY PRODUCTION SYSTEM INCLUDING BREEDER AND HATCHERY OPERATIONS

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When we began our salmonella reduction program in 1999, the goal was to reduce/eliminate clinical salmonellosis in our turkey poults due to *Salmonella arizona*, originating from in-house, company-owned breeders. The program involved intensive farm cleaning and sanitation prior to flock placement in any house, discontinuing range breeder farms, expanding the existing egg quality control program to include financial incentives for removing dirty eggs, use of autogenous arizona bacterins, and a very dedicated effort by the company-owned breeder division. 2000, 2001, and 2002 were years of implementation, fine-tuning, and waiting to see what happened, since turkey breeders' entire lives can span up to two years if recycled, and the primary interventions were early in the birds' lives. After a 4-year effort, by 2003, *S. arizona* had virtually disappeared from the system.

After achieving that goal, the new goal became reduction/elimination of significant human pathogens in our turkey breeders and meat birds, in the absence of any clinical signs in those birds. Our goal has not been to eliminate all salmonella. I (Gonder) do not believe in chasing ghosts, and see little utility in eliminating serotypes that cause significant clinical disease in neither turkeys nor humans. I am trying to advance human and animal health rather than influence total bacterial loads at the processing plant by eliminating bacteria on the farm. I believe appropriate processing controls and cooking/food-handling practices are much more effective than trying to develop a national certified sterile raw meat program. The certified raw milk program hasn't worked that well, and meat is more complex. Consequently, we retained the autogenous arizona vaccination, but added *S. typhimurium* since this is the principal serotype in most nearby swine units, and *S. heidelberg* since it occurred occasionally in the turkeys, and because these two strains occur with some frequency in humans. We did not add *S. enteritidis* since it has not been found in our system. *S. typhimurium* has not appeared in our turkeys system in several years, and *S. heidelberg* appeared once in early 2004. We will concentrate on *S. hadar* next.

We continue to use salmonella-positive feed ingredients, but extensive feed ingredient testing and isolate serotyping showed serotypes in feed ingredients were not those appearing in the turkeys, and extensive finished feed testing showed no incidence of salmonella in finished feeds during this period. Our mills use high-temperature conditioning and pelleting, with a modern dust collection system feeding back into the mash conditioning system. After over a decade of testing, we have discontinued extensive

feed testing for salmonella as unproductive in our milling system, and are concentrating on other areas (temperature and conditioning control).

Despite the unexpected success of the salmonella control program in the breeders, salmonella incidence at the processing plant by the USDA testing regimen remained virtually unchanged until adequate measures were taken to effectively control chiller pH, dwell time, chlorination levels and product flow into the grinders. However, salmonella serotypes from cloacal swabs at processing during an extensive survey during the summer of 2004 showed less than 5% to be one of the top 20 serotypes accounting for the majority of human salmonellosis in 2002. Interestingly, turkey from another company on a much less rigorous program had virtually the same incidence of cloacal swab salmonella-positive flocks.

This 5-year episode begs the following questions:

1. We successfully reduced *S. arizona* in a large turkey operation, but it took 4 years to do it. However, human arizoonosis continues to be associated primarily with reptile/amphibian contact, not turkey. What does this mean? If arizona was that hot, why no human association with turkey?

2. Our efforts at the farm to date have had no apparent effect on turkeys delivered to the processing plant compared to turkeys not subject to our control program, nor on salmonella incidence within the plant, which has been reduced by other methods. However, serotypes recovered at the plant do not appear to be those associated with human disease. What have we achieved public health-wise by beating ourselves up over non-pathogenic serotypes at either the farm or the plant? How is public health being served by the current salmonella standards at processing?

Obstacles to further progress:

1. Current salmonella standard. How can a successful farm-based program influence the level of salmonella as detected by a series of 25 gram ground turkey samples collected at one per shift over a 50-odd day period? From our data, it can't. Internal plant controls are much more effective. From a public-health standpoint, if we aren't finding serotypes that occur frequently in humans, what are we accomplishing by potentially "failing" a test based on a 25 g sample of the plant's daily throughput? In our case, that sample represents 0.0000054% of the day's liveweight throughput. Consequently, I'm much more interested in the serotypes related to human disease than incidence based on such a minute sample, especially if that tiny sample represents a "failure" based on isolation of an insignificant serotype. I fail to see how such a "failure" represents a risk to human health.

   However, actions taken to reduce the incidence of human-important serotypes must recognize the time-frames involved in pushing salmonella control programs through from the field. It takes years to make an effective program work (this is old news to the primary breeders), and in some management structures it may be impossible.

Personally, I favor an approach that would recognize the occurrence of important human salmonellae – say, the top 4 serotypes, and a long-term plan to reduce their incidence in the field. However, any regulatory body contemplating action under this scenario must recognize that current technology requires years to address a breeder-related problem, and years should be allowed, given that processing controls appear to be much more effective, at least in our system. Farm-to-fork is a long-term approach, and must be regulated in that manner. Running into the field with one's hair on fire in pursuit of "adulterants" that are, basically, normal gut contents would seem an extreme approach. Cooking meat is much more effective. That said, we will pursue our in-house long-term plan.

2. Biologic product regulation. Current autogenous vaccine regulation require frequent resubmission of new isolates, viz., if your vaccine is effective, and you can no longer isolate the organism, you are doomed to eventual loss of the product, and reintroduction of the organism. You may also have the misfortune to isolate and submit an isolate that is not antigenic. This situation cost us something over 8 months progress in our arizona reduction program. There is no science behind this arcane requirement, and truthfully, changing the resubmission time requirement from 12 to 24 months for a breeder-based vaccine is an insignificant improvement. I am faced with this requirement for *S. heidelberg*, *S. hadar*, and *S. typhimurium* as well as *S. arizona*. If my autogenous vaccine program works – my birds are eventually left unprotected. How does this serve public health? NTF, AAAP, AVTP and others have protested this situation since at least 2002 with no effective response from USDA. How does this serve public health? Wouldn't the attending board-certified, graduate school-trained, USDA-accredited, state-licensed veterinarian with experience in both biologics and production (as most of us are) be the best authority to determine isolate utility?

   Competitive exclusion product regulation. While our European colleagues seem to have several different approaches available, the US biologics regulatory establishment appears to be in complete disarray in this area. Over the last 10 years, a somewhat promising product was forced off the market, a less promising product was approved, but subsequently failed in the field and has apparently disappeared, and mucosal competitive exclusion with undefined cultures does not appear to be catching on. FDA and USDA continue to spar over who has control over products labeled to reduce food safety hazards in food animals and what licensing criteria are required with no apparently clear focus on why progress should occur in some timely manner. Over a decade is not timely – the situation borders on the farcical. In-house production of undefined products may be the most appropriate approach from a clinical standpoint. I'm not fond of that approach, but 10 years of dithering seems to be sending a clear signal that our current regulatory structure is not motivated to move forward.

   I have not addressed listeria since an initial survey did not demonstrate its presence in live birds – I wanted to keep the processing plant firmly focused on listeria control at the processing level. I haven't addressed campylobacter since I'm not familiar with

any effective control measures in the field. Cooking and appropriate food handling seem the best approaches. We hope to pursue microenvironment management as described by Mallinson in the hope that it may influence campylobacteriasis, but that, likewise, will be a long-term effort.

At the end of the day, as public health professionals we should take what long-term measures can be taken within our purview to control food-borne pathogens, but an appropriate risk assessment will help direct resources most effectively for the long haul. From a long-term perspective, the federal regulatory establishment appears to be poorly equipped to pursue a program targeted to particular public health pathogens if the current reliance on generic testing for salmonella and the obstructive practices involving veterinary biologics continue. And help on serotyping would be nice. With over 2000 species of salmonella, handling them all generically as equal hazards in the face of the available human serotype data seems to contradict the first two letters in HACCP – "Hazard Analysis" - and those are the two that are supposed to be performed first……"

REDUCTION OF RISK IN THE COMMERCIAL LAYER PRODUCTION SYSTEM INCLUDING BREEDER/HATCHERY AND EGG PROCESSING OPERATIONS

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Prior to 1988, food safety issues associated with eggs were nearly non-existent. In fact, at the 1984 International Symposium on Salmonella in New Orleans, only one article concerning egg associated Salmonellosis was presented. Since the 1988 report by St. Louis et. al[1] associating Grade A shell eggs with *Salmonella enteritidis* (SE) infection in humans, the egg industry has had to adjust to life with SE. The response by the egg industry since this finding will be detailed in this presentation.

As SE transmission was determined to be vertical from parent to offspring or from hen to egg, breeder flocks were the first source of SE that needed to be investigated. Through sampling of manure swabs, dead-in-shell embryos, and chick box papers, several breeder flocks were found to be shedding the bacteria into the chicks and were likely responsible for seeding many commercial pullet and layer farms with SE through these contaminated chicks. The National Poultry Improvement Plan (NPIP) established a plan to provide SE negative chicks, the U.S. Salmonella Enteritidis Clean Program (U.S. SE Clean), in 1989[2] This program involved various means and intervals of testing breeders or their progeny to determine a flock's SE status. Today, the program relies on testing of manure from breeder flocks using the drag-swab method beginning the first month of life and continually testing every month thereafter throughout the breeder's life. In addition, 300 blood or serum tests are conducted on each flock just prior to the onset of lay using the group D Salmonella test for pullorum-typhoid. Since 1989 when records were started to be kept, 59 breeder flocks have been tested positive for SE[3] No positive flocks have been found since calendar year 2002.

Breeder companies practice very high levels of biosecurity to assure that SE does not contaminate a breeder flock. Rodent control, traffic control, sanitation of bird movement vehicles and equipment, providing workers and visitors with protective clothing, footwear, and hand sanitation are all key components of the program. Vaccination for SE is seldom used if at all. If meat byproduct is used as a feed ingredient, it must be from a source using practices according to the Animal Protein Products Industry's (APPI) Salmonella Education/Reduction Program. Feed containing animal protein products can either be pelleted, the protein product pelleted and added to mash feed, or have mash feed chemically treated with an FDA approved Salmonella control product. Some hatching egg producers apply disinfectant to hatch eggs by spray in an effort to reduce the total bacteria and Salmonella load of eggs going into the hatchery.

Hatcheries hatch chicks only from NPIP SE Clean flocks and use standard methods for hatchery sanitation.

At the commercial level, various programs to reduce SE are used depending on the history of the region or of a company. The Northeast U.S. egg industry was the first to be recognized as the source of egg-associated SE for Northeast consumers. In 1992, the U.S. Secretary of Agriculture declared SE an emergency. The United States Department of Agriculture (USDA), the Pennsylvania Department of Agriculture, and the egg industry embarked on a study, named the SE Pilot Project, of SE and its epizootiology in egg layers. The findings of the SE Pilot Project led to the formation of the first Egg Quality Assurance Program (EQAP), the Pennsylvania Egg Quality Assurance Program (PEQAP) in 1994. PEQAP incorporated the best management practices of SE negative chicks (chicks from NPIP SE Clean parent flocks and chick box papers tested), SE negative pullets (pullet manure sampled at 10 to 12 weeks of age), rodent control, cleaning and disinfection (C&D) of contaminated houses, vaccination (recommended option for contaminated facilities), egg refrigeration, egg processing, and record keeping into the program. In addition, verification of success is based on monitoring manure from layers during lay and after molt. Diversion of eggs to pasteurization is also part of the program should eggs from a manure positive flock test positive for SE.

Training of all participants in EQAPs is an essential component of these programs. Training in regard to rodent control, C&D of houses, biosecurity, egg processing, and sampling methods are all incorporated into EQAPs. Recertification on a regular basis for existing participants as well as certification for new participants is an ongoing process.

PEQAP has led to a great reduction in SE found not only in the percent of manure samples positive (23% in 1992 vs. 1.5% in 2003) but also in the percent of positive flocks detected (38% in 1992 vs. 4.4% in 2003). Approximately 90% of Pennsylvania flocks (300+) are participating in PEQAP. Knowledge of which houses are positive, C&D between flocks in positive houses, continual emphasis on rodent control, and the use of vaccination are felt to be the reasons for the success of this program.

Various other EQAPs have been adopted by other states and contain the basic premises of the SE Pilot Project and PEQAP. The monitoring programs vary the most depending on the availability of a nearby egg testing laboratory and the feasibility of diversion of eggs to pasteurization.

EQAPs have reportedly been successful in reducing the incidence of SE cases. One study showed that for each 1% increase in eggs produced under an EQAP, a 0.14% decrease in SE incidence was found[4]. The number of SE egg-associated outbreaks declined significantly during the 1990s, but has apparently stabilized since then. The SE isolation rate per 100,000 people in the U.S. peaked at 4.0 in 1995 and had declined to 2.0 by 2001[5]. According to the 2003 Center for Disease Control (CDC) Foodnet data, the rate of SE incidence is down from 2002 (1.82 per 100,000 vs. 2.32) and is below the 5 year mean of 2.00 per 100,000 population[6].

Much progress has been made by the egg industry in reducing the human risk of SE infection since it was first discovered as a problem in the late 1980s. U.S. government agencies (CDC, FDA and USDA) and state departments of agriculture have aided this effort greatly by supporting research, organizing EQAPs, and providing statistical services. Further reductions in human egg-associated SE will come from continued emphasis on farm-based risk reduction programs with microbiological based verification. The proposed federally mandated regulation "Prevention of *Salmonella* Enteritidis in Shell Eggs During Production" is expected to be implemented in 2007 with the goal of reducing the estimated incidence of egg-associated SE illness of 118,000 cases in 2001 by 50% by the year 2010. This program will broaden the impact of using a Hazard Analysis Critical Control Point (HACCP) based program used presently by state EQAPs.

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FSIS PERSPECTIVE ON HACCP AND CURRENT STATUS OF FOOD SAFETY

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The Food Safety and Inspection Service (FSIS) is the Department of Agriculture's (USDA) public health regulatory agency responsible for ensuring that meat, poultry, and processed egg products are safe, wholesome, and accurately labeled. FSIS enforces the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, which require Federal inspection and regulation of meat, poultry, and processed egg products prepared for distribution in commerce for use as human food.

The Hazard Analysis and Critical Control Point (HACCP) rule established Salmonella performance standards for seven categories of meat and poultry products. The poultry performance standards apply to broilers, ground chicken, and ground turkey. While the regulatory prevalence of Salmonella across all seven product categories shows a combined decrease from 1998 to 2003, the percentage of positive Salmonella tests increased in the three poultry categories.

Since 2001, FSIS has deployed a cadre of experts, Enforcement Investigations and Analysis Officers (EIAO), specifically trained in assessing the design of food safety systems. These EIAO's assess industry HACCP plans, Sanitation Standard Operating Procedures, and Sanitation Performance Standards and determine whether they are sufficiently designed, validated, and verified to produce safe food. Beginning in April 2005, FSIS assigned EIAO's in multiple districts to conduct food safety assessments in broiler slaughter operations that exhibited negative trends in Salmonella control. Preliminary findings from these assessments will be discussed.

INTERNATIONAL PERSPECTIVE ON BROILERS AND TURKEYS

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A UK PERSPECTIVE ON BROILERS

In 1987 in the UK, there was a sudden increase in the incidence of human food poisoning cases caused by *Salmonella enterica var enteritidis* pt. 4. The origin of this food borne pathogen was found to be poultry, and this marked the beginning of a series of new legislation that was introduced to combat salmonella in chickens. Initially the legislation targeted a reduction in the incidence of invasive salmonella (*S enterica var enteritidis* and *typhimurium*) particularly in breeding stock and high-risk protein raw materials for poultry feed.

This short history lesion gives an insight into the way that the UK, and subsequently the EU, addressed control of food borne pathogens in poultry. The focus of control started at the farm level and continues today with a new Zoonoses Directive and Regulation that were adopted by the EU in 2003. This legislation gives the power to address a variety of food borne pathogens in a range of species by setting maximum permitted levels. The focus is still primarily on salmonella in poultry with a desire to include Campylobacter controls at some time in the future. Control is not limited to farm and in addition to the Zoonoses Directive and Regulation a package of measures is encouraged with a strong emphasis on HACCP. Terms such as "farm to fork" or "plough to plate" are used to describe this all-inclusive approach.

In the UK, the drive to reduce the incidence of food borne pathogens in poultry also comes from a more powerful source: the market. Most of the poultry is sold by large supermarket chains as their own label product and these companies have an incentive to make sure their product is not found to carry high levels of Salmonella and Campylobacter.

The first objective is to deliver to the slaughter house stock that are either free of pathogens or contain a low level of contamination. This is being achieved with Salmonella but is not yet possible with Campylobacter. Almost all of the UK slaughterhouses have inline air chillers and sell their product as fresh rather than frozen. By keeping the carcasses separate, there is less chance of cross contamination with an inline air chiller than there might be with a contraflow spin chiller.

The measures that are adopted at processing are integrated into HACCP procedures to minimise cross contamination and reduce multiplication post processing. Emphasis is placed on

- where possible targeting positive salmonella flocks last in the day or prior to a break
- delivering clean birds with empty gastrointestinal tracts
- effective washing and disinfection of the modular live bird transport systems
- evisceration with minimal gut spill
- processing in a clean environment with the use of water sprays in key areas
- rapid chilling (to 4^0 C in 90 minutes) then maintaining this at all times post-processing e.g. when portioning.
- cleaning and disinfection procedures to prevent recycling of salmonella in key areas like the scald tanks and feather pluckers.

At this point in time, no substance other than potable water may be used to remove surface contamination. New draft regulations due to come into force on 1 January 2006 will permit the use of some approved substances but these must be used in accordance with strict guidelines and the product must be labelled as follows: "anti-microbial treatment for reducing contamination has been used".

Processing aids such as surface freezing employed in "Accelerated Inline Maturation" and steam disinfection are being used in trials, especially for Campylobacter control, but to date have not found universal acceptance.

The controls at all levels are only effective when they are supported up by a good monitoring program. This is a costly exercise but an essential element in understanding the epidemiology of salmonella in an integrated chicken business. Salmonella serotyping has proved to be an invaluable tool in this process. Unfortunately to date a typing system giving the same benefits has not been found for Campylobacter, although MLST typing is showing some promise.

Finally control of salmonella in breeding stock in the EU is being widened to include all salmonella of public health significance. The current definition of this is the top five serotypes found in humans. Today these are *Salmonella enterica var: enteritidis, typhimurium, hadar, virchow* and *infantis*.

INDUSTRY PERSPECTIVE ON BROILERS AND TURKEYS

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The processing plant, when designed properly and operated as designed, is a powerful reduction tool for food safety pathogens. The goal within the plant could be simplified into three simple steps: 1. provide as clean a bird as possible for evisceration and, 2. perform the evisceration step with as little contamination as possible, and 3. clean the bird – inside and out – as thoroughly as possible.

Reduction within the processing plant can be achieved using at least 3 different methods: 1. dilution with water, 2. mechanical removal – generally with water under various pressures, and 3. prudent use of sanitizing chemicals. Most places in the plant all 3 of these are part of a single intervention – chlorinated water sprayed with force in a bird washer.

The industry continues to work on Good Manufacturing Practices (GMP's) for salmonella reduction. GMP's that have been studied to varying degrees include: 1.) scalder ph, 2.) scalder overflow, 3.) rehang table management, 4.) chlorine on New York dress cabinet, 5.) chlorine on evisceration equipment, 6.) effectiveness of continuous sanitation of evisceration equipment, 7.) effectiveness of crop removal, 8.) effectiveness of sanitation at vent machine, 9.) capture efficiency of the inside outside bird washer (IOBW), 10.) chiller chlorine level at overflow, 11.) chiller chlorine at startup, 12.) chiller pH, and 13.) chiller overflow.

Identifying a GMP is sometimes the easy part. Determining how to control it adequately and measure that control effectively is a challenge. This has resulted in varying levels of agreement on the value or "real" reduction that can be realized from each GMP. It is clear that this challenge is being addressed throughout the industry. The answers will likely lead to automated controls, which will result in monitoring that provides accurate assessment of each intervention.

INDUSTRY PERSPECTIVE ON HACCP AND CURRENT STATUS OF FOOD SAFETY

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HACCP ORIGINS

The HACCP system was developed by the Pillsbury Company in 1959 in response to food safety requirements imposed by NASA for space foods. The HACCP concept was first presented to the public in 1971 at the National Conference for Food Protection. There were three principles in this original HACCP concept: identification and assessment of hazards, determination of critical control points, and establishment of systems to monitor critical control points. During the 1970s, FDA promulgated the low-acid and acidified canned food regulations based on HACCP concepts.

HACCP ACCEPTANCE

In 1985, the National Academy of Sciences issued a report strongly endorsing the use of HACCP as the most effective and efficient means of assuring the safety of the food supply. In 1989, the National Advisory Committee for Microbiological Control for Foods adopted a document titled "HACCP Principles for Food Production." In 1992, the NACMCF adopted a new document "Hazard Analysis and Critical Control Point System" which incorporated sections of the CODEX Food Hygiene HACCP Committee Working Group. These reports describe the seven principles of HACCP as we know them today. This report was updated again in 1997 to clarify definitions and reverse principles six and seven for record keeping and verification.

GOVERNMENT MANDATED HACCP

HACCP first became a mandated regulation in 1997 for seafood products as required by FDA. The initial 1985 NAS report recommended HACCP be a mandated requirement to assure widespread use of the concept. USDA published the "mega-reg" on July 25, 1996. These regulations required implementation of Sanitation Standard Operating Procedures (SSOP) by all meat and poultry companies in January 1997. HACCP was phased in over a three-year period dependent on plant size in January of 1998, 1999, and 2000. All meat and poultry companies now must have an SSOP and HACCP system written before start of operations and validated within 90 days of start up.

FDA has also mandated the use of HACCP for juice processors. HACCP is in the process of being phased in over a three-year period that began in January 2002, 2003, and 2004. HACCP is required by the FDA Food Code for establishments that vacuum package

products. Proposed rules are also pending for egg products, and fruits and vegetables. HACCP plans have been piloted at many dairy facilities.

HACCP NECESSITY AND RESPONSIBILITY

HACCP is necessary to reduce the number of foodborne illness related cases. It is estimated there are over 76 million cases of foodborne illness, 325,000 hospitalizations, and 5,000 deaths each year. HACCP is the primary tool to reduce these numbers. Data from the Centers for Disease Control demonstrate that these numbers are on a steady six-year decline as more companies and industries have implemented HACCP. In addition, the prevalence of pathogens on food products has decreased dramatically as the 20% baseline performance standard for salmonella in poultry products has been reduced to just over 10%.

In addition, HACCP has been widely encouraged by consumer groups. These groups routinely call for stronger enforcement actions following foodborne illness outbreaks. A benefit for regulatory agencies includes shifting responsibility from regulatory agencies to the processing companies where it belongs. Companies are responsible to produce safe food products and maintain records to prove their products are safe.

HACCP IMPLEMENTATION

Many people felt USDA would withdraw or significantly change the HACCP final rule prior to implementation. The agency remained committed to the HACCP concept and final rule. HACCP was implemented as required with great effort by many companies. Small processors did not have the time or resources to establish thorough HACCP systems. Local USDA inspectors basically accepted the company's HACCP plan if it met the fundamental regulatory requirements. This created a great deal of inconsistency in the way HACCP has been implemented. The final rule also established performance standards for *Salmonella*, generic *E. coli*, and *Listeria* for several categories of meat products.

REGULATORY HACCP

As time has progressed, USDA has raised expectations and standards for HACCP compliance. In addition, the gap between scientific HACCP and regulatory HACCP has widened as USDA attempts to structure HACCP systems. Critical control points have been dictated by agency positions on zero tolerance standards and the fact the agency now considers *E. coli* O157:H7 a hazard reasonably likely to occur in beef products. HACCP reassessments have been required for *E. coli* O157:H7 and *Listeria monocytogenes* following recent foodborne illness outbreaks and large recalls. USDA has taken the position that they are not aware of any processes that do not have a hazard that is reasonably likely to occur which in turn dictates every process must have at least one critical control point.

Regulations are being interpreted more strictly now. Following reviews by USDA Correlation Teams, many companies were required to remove the Receiving process step as a critical control point in their HACCP Plans. USDA took the position that this step could not meet the corrective action requirements of 417.3 and processors could not ship "adulterated" product back into commerce which meant even returning it to their suppliers. From a scientific viewpoint, this policy is invalid and receiving should be a CCP in many HACCP Plans.

A final rule published in June 2003, further involves FSIS in plant operations. This rule requires federal establishments producing certain ready-to-eat (RTE) meat and poultry products to take steps to further reduce the incidence of *Listeria monocytogenes*. The rule requires all establishments that produce RTE products that are exposed to the environment after cooking to develop written programs to control *Listeria monocytogenes* and to verify the effectiveness of those programs through testing. Establishments must share testing data and plant generated information relevant to their controls with FSIS. The rule also encourages (read requires) all establishments to employ additional and more effective *Listeria monocytogenes* control measures.

New regulatory requirements are coming routinely in the form of directives or final rules requiring further actions for ready to eat products. For instance, in March, 2005 the FSIS issued recommended changes to the Performance Standards for the Production of Ready to Eat Meat and Poultry Products that required a 6.5 $\log_{10}$ or a 7.0 $\log_{10}$ relative lethality for *Salmonella* (9CFR318.17) by providing new time/temperature tables for cooking chicken and turkey of different fat contents to achieve the 7.0 $\log_{10}$ reduction. These new guidelines (though not required as yet) basically are aiming at a zero tolerance for *Salmonella,* even though there is no evidence that the guidelines previously in effect were resulting in human foodborne disease. If an establishment is using the current required cooking times and a sample collected by FSIS for verification is positive for *Salmonella*, the establishment would be required to support its decision within its hazard analysis.

HACCP REVIEWS

In 2001, the Office of Inspector General issued an audit that was very critical of USDA and industry implementation of HACCP. It cited inconsistent implementation and regulatory enforcement as primary concerns. In response to this report, USDA launched an initiative of reviews by Correlation Teams, In Depth Verification Teams, and Consumer Safety Officers. The primary goals of these teams are to improve the consistency of HACCP implementation and assure that companies are meeting all regulatory requirements.

These reviews have created problems for the industry as it now adapts to the fact that was has been acceptable for the last two-three years with local inspection no longer meets the expectations of the new review teams. In addition, CSO's and IDV Teams carry enforcement authority to issue Notice of Intended Enforcement Actions (NOIE's). IDV Teams have been reserved for those companies failing salmonella performance standards and with repetitive pathogen/regulatory failures.

The Consumer Safety Officer position was created in 2002 to become the validators of HACCP systems for the agency. After training an initial class of 35 CSOs, USDA has continued to select and train CSOs so the current staff is reaching 150 with at least six CSOs assigned to each district. CSOs have been given the mandate to visit every company and review every HACCP Plan. Correlation Teams have been renamed Peer Review Teams and continue to visit districts on a rotating schedule.

During CSO reviews, written plans for SSOP and HACCP along with corresponding records and plant operations. Plans are strictly compared to regulatory requirements and operations for regulatory compliance. Companies often do not meet the regulatory requirements for corrective actions in 416.15(b) and 417. 3, HACCP systems in 417.2, the verification procedures required 417.4. In recent months, it is becoming far more common to be issued NOIEs rather than 30 day reassessment letters following a CSO review.

INTERNATIONAL HACCP

Other countries have not mandated HACCP systems similar to the United States. This seems to be a better approach as HACCP plans tend to be more comprehensive when written without the fear of regulatory review and oversight.

Canada has done an excellent job assisting food processing companies with HACCP. The Canadian Food Inspection Agency has issued standard model for prerequisite programs and HACCP systems that processors can customize for their operations and still meet regulatory expectations. HACCP has been successfully implemented on a voluntary basis in countries throughout the world, including Australia, South America, Europe, and Asia among others.

In the United States, the perspective seems to be the USDA expects you to implement HACCP with little guidance or models, then waits to tell you what you did wrong after a review.

HACCP FUTURE

Without a doubt, HACCP is here to stay. Regulatory agencies are committed to HACCP. The new leadership of USDA with Secretary Veneman, Undersecretary Murano, and Administrator Mckee are fully committed to continually improving HACCP with a science and public health perspective and aggressively promoting enforcement actions to improve compliance. USDA will continue to promulgate regulations based on science to further improve control of pathogens and products. With the mandatory E. coli reassessments complete, USDA will now focus on Listeria prevention in Ready To Eat products with implementation of the final rule. This rule will force more environmental testing and sharing of test results with USDA. It is anticipated that FSIS will be issuing new regulations that will further tighten lethality and stabilization requirements within the next few months. Beyond that, performance standards are likely to be addressed with tightening current standards and/or setting new standard for pathogens such as

Campylobacter. The ongoing review teams will continue to expand and have a tremendous impact on the industry to improve implementation of HACCP.

Companies accept the fact that they must meet regulatory requirements. Smart companies recognize that HACCP is the most effective method to assure the safety of their products. No executive or manager wants to have to sleep with the picture of a child in their mind that died as a result of mishandling at their company. Properly designed HACCP systems should assure food safety, meet regulatory requirements, and be manageable for the company rather than a burden to the operation.

HACCP is mandated by customer requirements as most large companies require third party audits that include HACCP components. HACCP has become a part of doing business in the food industry.

HACCP will continue to evolve and grow in other non-mandated sectors such as the foodservice and retail markets. Customized approaches that incorporate HACCP concepts are frequently being used to control processes and menu categories within these operations. Successful HACCP systems help a company reduce liabilities, minimize illness and recalls, and promote regulatory compliance.

OVERVIEW AND IMPACT OF FSIS RULE ON LISTERIA

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THE SURVEY

The survey was completed by the members of American Meat Institute (AMI), National Food Processors Association (NFPA), and the National Turkey Federation (NTF). Each association mailed the surveys to their members and asked that they be completed and returned to legal counsel for blinding. After data acquisition and entry into Microsoft Excel® for analysis, the original surveys were destroyed. No establishment identifiers were incorporated into the data file in order to protect confidentiality.

The survey was designed to evaluate industry *Listeria* control activities both before and after the issuance of the FSIS interim final rule on *Listeria* control in post-lethality exposed RTE meat and poultry products. The survey included sections on:

I. Sampling Program
II. Control Strategies

The Sampling Program section compared the pre-rule versus post-rule status of an establishment training programs, product contact and non product contact surface sampling programs, and actions taken when a positive result is found. The Control Strategies section was designed to estimate how many respondents have already or have plans to reclassify the Alternative categorization of their products. It was also intended to identify which incentives were most effective in encouraging changes to company programs.

SURVEY RESULTS

Of the surveys mailed, 62 were completed and returned. These responses represented a total to 87 meat and poultry establishments (Table 1).

Table 1. Establishments represented

Number of Establishments Represented by Each Survey Returned	***Responses***
1 to 3 establishments	83.9%
4 to 6 establishments	4.8%
More than 6 establishments	9.7%
No answer provided	1.6%

I. SAMPLING PROGRAM

Of the 62 responses, roughly 82% of the respondents conducted routine environmental testing of both product contact and non-product contact surfaces and 14.5% conducted only non-product contact surface testing prior to the issuance of the final rule. Implementation of the rule resulted in an 11 % increase in the number of respondents that conduct both product and non-product contact environmental testing (from 82.3% to 93.5% of respondents) (Table 2).

Table 2. Changes in product contact and non -product contact surface sampling program

Response	***Before Rule (%)***	***After Rule (%)***	***Difference (%)***
Product contact surfaces	1 (1.6)	4 (6.5)	3 (4.8)
Non-product contact surfaces	9 (14.5)	0 (0)	-9 (-14.5)
Both product contact and non-product contact surfaces	51 (82.3)	58 (93.5)	7 (11.3)
Not applicable	1 (1.6)	0 (0)	-1 (-1.6)

When asked about the frequency of product contact and non-contact surface testing for *Listeria* spp. or *Listeria monocytogenes (Lm),* 40% of the respondents indicated that the frequency of product contact surface testing has increased since the implementation of the rule, while 13% of the respondents indicated that the frequency of testing has decreased. Twenty-four percent (24%) of the respondents indicated that the frequency of non-product contact surface testing for *Listeria* spp. or Lm has increased, while 13% indicated that frequency of non-product contact surface testing has decreased.

Respondents were also asked about the frequency of finished product testing. Of the 62 responses, 19.4% indicate that finished product testing has increased while 64.5% suggest their finished product testing has remained the same.

Table 3. Frequency of product contact surface, non -product contact surface and finished product testing

Response	***Contact (%)***	***Non-contact (%)***	***Product (%)***
Increased	25 (40.3)	15 (24.2)	12 (19.4)
Decreased	8 (12.9)	8 (12.9)	5 (8.1)
Stayed the same	29 (46.8)	37 (59.7)	40 (64.5)
No testing	0 (0)	2 (3.2)	5 (8.1)

The survey also examined the availability of on-site establishment technical expertise to handle environmental testing and the source of additional training, if applicable. More than eighty-five percent (85.5%) of respondents indicated that prior to the June 6, 2003 publication of the final rule their establishment did have an individual or a team on-site that had received additional training in environmental testing or techniques to determine root causes of a positive finding.

Only 12.9% of respondents did not have on-site expertise. Approximately eighty-seven percent (87.1 %) of respondents indicated that after the rule was published their establishment did have an on-site individual or team, a 1.6% increase.

The respondents were questioned as to the source of additional training they may have received. Results can be seen in Table 4 below.

Table 4. Source of additional training

Source of Additional Training	***Responses****
AMI	31
External consultant	24
Formal education	14
All	2
Other	27
No answer provided	3

* Many respondents selected more than one source.

Corrective Actions for an Initial Listeria spp. *Positive*

Product Contact Surface Testing: Survey respondents were asked if they increased monitoring for *Listeria* spp. in subsequent production shifts if an initial positive is found on a product contact surface. Of the responses, 93.5% indicated that their corrective actions include increased monitoring when they obtain one positive result. Only 2 respondents suggest that they do not increase testing/monitoring when a positive result is obtained. Of those respondents that indicate that they increase monitoring, 55% of them continue increased monitoring for *Listeria* spp. until they obtain more than 2 consecutive negative test results from the product contact surface. While another 13% continue testing until they obtain exactly 2 consecutive negative results from the product contact surface and 27.4% continue increased testing of the product contact surface until they have 1 negative test result.

Non-Product Contact Surface Testing: When asked about increased testing on non-product contact surfaces, 84% of respondents indicated that when they receive a positive test result for *Listeria* spp. on a non-product contact surface, their corrective actions include increased monitoring. A little more than 53% of those respondents continue increased monitoring until they have 2 or more consecutive negative test results from the non-product contact surface. Over thirty percent (30.6%) continue increased testing/monitoring until only 1 negative test result is obtained.

Root Cause Determination: Eighty-eight percent (88%) of respondents indicated that they are able to determine the root cause of multiple consecutive positives on product contact or non-product contact surfaces over 50% of the time. Twelve percent (12%) suggest they are only able to determine the root cause 50% or less of the time (Table 5).

Table 5. Root cause determination

Responses	*Results (%)*
≤ 50%	12 (19.4)
> 50 – 75%	16 (25.8)
> 75 – 95%	17 (27.4)
> 95 – 100%	13 (20.9)
No answer provided	2 (3.2)
Not applicable	2 (3.2)

II. CONTROL STRATEGIES

Since implementation of the *Listeria* interim final rule, post-process exposed RTE foods are classified as Alternative 1, 2, or 3 depending on product formulation and controls used during production. Survey respondents were asked if they have implemented additional control measures/formulation changes that allow reclassification of their products from Alternative 3 to Alternative 2 and from Alternative 2 to Alternative 1 (Table 6).

Table 6. Number of respondents reclassifying products from one Alternative to another

Response	*Reclassification from*	
	Alt 3 to Alt 2 (%)	*Alt 2 to Alt 1 (%)*
Yes	27 (43.5)	10 (16.1)
No	35 (56.5)	49 (79.0)
No answer	0	3 (4.8)

Over fifty-two percent (52.2%) of the 27 respondents that reclassified product from Alternative 3 to Alternative 2, have reclassified greater than 80% of their products. Forty percent (40%) of the 10 respondents that reclassified product from Alternative 2 to Alternative 1, reclassified more than 80% of their products. (Table7).

Table 7. Percent of products reclassified from one Alternative to another

Percent of products reclassified	*Alt 3 to Alt 2 (%)*	*Alt 2 to Alt 1 (%)*
0 – 20	3 (13.0)	2 (20)
21 – 40	3 (13.0)	2 (20)
41 – 60	3 (13.0)	1 (10)
61 – 80	2 (8.7)	1 (10)
81 – 100	12 (52.2)	4 (40)
No answer	4 (14.8)	0

Establishments reclassifying products from Alternative 3 to Alternative 2 were asked how many products were reformulated with antimicrobials. Seventeen (17) of those 27 respondents indicated that they have incorporated antimicrobials into their formulations.

Two of the 27 had not used antimicrobials and 8 respondents either did not provide an answer or their answers were unusable in the form submitted. Over thirty-six percent (36.6%) of those who indicated they had implemented additional control strategies have reformulated 20-100 of their products with antimicrobials.

Respondents were also asked how many products now receive a post-packaging lethality treatment. Of the 27 respondents who reclassified products from Alternative 3 to Alternative 2, 22.5% indicated they now apply a post-packaging lethality treatment to more than 10 of their products.

The 27 respondents that indicated they have moved product from Alternative 3 to Alternative 2 were asked, if prior to the final rule publication, how many products fit the Alternative 1 or Alternative 2 classification. Twelve of the respondents indicated they produce products that fit these classifications. Of these twelve respondents, 38% indicate that 10 or more of their products fit the Alternative 1 or Alternative 2 classification.

Of the ten respondents who reclassified products from Alternative 2 to Alternative 1, 66.6% moved the products to Alternative 1 after the final rule publication. 80% of those who have moved from Alternative 2 to Alternative 1 indicated that they have chosen to use thermal processing (i.e., Unitherm, Infrared) for post-packaging lethality.

Of those establishments who either have not moved product from Alternative 3 to Alternative 2 or from Alternative 2 to Alternative 1, 34.8% indicated that they have plans to move to reformulate products with antimicrobials within the next year. Another 34.8% of the respondents are not sure if they will be moving products within the next year. Of those who have not moved products from Alternative 2 to Alternative 1, 21.3% have intentions to incorporate a post-packaging lethality process to move product from Alternative 2 to Alternative 1 within the next year. Another 34.0% are unsure of future plans (Table 8).

Table 8. Future plans to reclassify product from one Alternative to another

Planning to move within	***Alt 3 to Alt 2 or Alt 2 to Alt 1 (%)***	***Alt 2 to Alt 1 (%)***
3 months?	3 (6.9)	1 (2.1)
6 months?	7 (16.3)	2 (4.2)
9 months?	1 (2.3)	2 (4.2)
Year?	4 (9.3)	5 (10.6)
Not sure	15 (34.8)	16 (34.0)
Not planning to move	13 (30.2)	21 (44.7)
No answer given	16	9
Answer not usable	2	0
Not applicable	1	6

The RTE final rule provided incentives for establishments to reclassify products from one alternative to another. The survey attempted to determine which incentives were more attractive to companies. Most respondents (62.5%) indicated that the reduced or eliminated environmental testing by FSIS and/or the reduced or greatly eliminated product testing by FSIS were the most lucrative incentives. The allowance of voluntary food safety labeling claims alone was not enough of a reason to prompt movement (Table 9).

Table 9. Incentives prompting movement from one alternative to another

	Reason	***Response (%)***
A	Reduced or eliminated environmental testing by FSIS	3 (5.3)
B	Reduced or greatly eliminated product testing by FSIS	10 (17.8)
C	Allowance of voluntary food safety labeling claims	0 (0)
A & B		22 (39.3)
B & C		1 (1.8)
A & C		5 (8.9)
A, B, & C		4 (7.1)
Other – Customer requirements, corporate requirements, produce safer products, already there – no need to change		11 (19.6)

The survey asked if respondents were concerned about the provision in the rule allowing voluntary food safety labeling claims and, if so, why they were concerned. Out of the 62 total respondents, 54 indicated that the voluntary labeling component was of some concern. 19% of respondents agreed with all of the following statements:

Voluntary food safety labeling claims:

a) may inhibit sharing of best practices for *Listeria* control
b) create a 'good food' vs. 'bad food' perception by consumers
c) mislead consumers into believing products with claims may be handled less safely
d) increase company liability.

14.5% agreed with statements b and c, while 16.1 % agreed with statements b, c and d. Others agreed with either one or many of the statements above.

Table 10. Reasons for concerns with the label claims provision of the RTE Rule

	Statement	***Response****
a.	Inhibit sharing of best practices for *Listeria* control?	23
b.	Create "good food" vs. "bad food" perceptions by consumers?	47
c.	Mislead consumers into believing products with claims may be handled less safely?	42
d.	Increase company liability?	30
e.	Don't Know	8

* Many respondents selected more than one statement.

For those respondents that circled more than one answer, they were asked to identify which issue was most problematic. Roughly 23% of those respondents who selected more than one answer believed that the creation of a 'good' vs. 'bad food' perception by consumers was the most troubling (Table 11).

Table 11. Prioritization of concerns

	Prioritize statements	***Response (%)***
Highest priority	"Inhibit sharing of best practices for *Listeria* control."	7 (18.4)
Highest priority	"Create a 'good food' vs. 'bad food' perception by consumers."	14 (36.8)
Highest priority	"Mislead consumers into believing products with claims may be handled less safely."	13 (34.2)
Highest priority	"Increase company liability."	4 (10.5)
	No answer	7
	Not applicable	17

ROLE OF THE FORMULATION OF POULTRY FOOD PRODUCTS

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No Text Submitted.

ROLE OF FACILITY DESIGN IN MICROBIAL PROCESS CONTROL

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No Text Submitted.

POST PACKAGING LETHALITY TREATMENTS IN POULTRY (BROILER, TURKEY, EGG)

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ABSTRACT

Many important food safety initiatives have resulted in significant improvements in the safety of our meat and egg products. A key component of these strategies have been the implementation of post packaging lethality treatments. By employing a lethality treatment after the consumer product is in the final package, risks associated with exposure to processing environments has bee greatly reduced. This talk will review a number of these strategies. Included will be a discussion of hot water pasteurization, a combination process of infrared and hot water, flash steam pasteurization, high hydrostatic pressure processing, irradiation, and egg pasteurization.

APPROACHES TO ANTIMICROBIAL RISK ANALYSIS IN FOOD SAFETY DECISION MAKING IN POULTRY MEDICINE

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ABSTRACT

Insufficient use of animal antibiotics may increase pathogen loads in retail meats, leading to increased human illnesses, increased need to treat human patients with antibiotics, and more rapid emergence of antibiotic resistance among humans. Quantitative risk models can be used to (a) quantify the potential human health risks from failure to use animal antibiotics to reduce microbial load; (b) compare them to potential human health risks from using animal antibiotics (due to increased selection pressures for resistant pathogens); and (c) identify risk management policies that best protect human health. Such models reveal that continued use of antibiotics such as fluoroquinolones, macrolides, and streptogramins in poultry may be highly effective in preventing or reducing human illnesses and in avoiding the need to treat human patients with antibiotics, thus slowing emergence of antibiotic resistance among human patients.

INTRODUCTION

Use of similar or identical antibiotics in both human and veterinary medicine has come under increasing scrutiny by regulators concerned that bacteria resistant to animal antibiotics will infect people, leading to treatment failures and excess illnesses and deaths. Scientists, regulators, and interest groups in the US and Europe have urged bans on non-therapeutic and some therapeutic uses of animal antibiotics, based on a belief that bans will help to preserve the efficacy of antibiotics in human medicine and thus promote human health. But empirical evidence for this judgment is not reassuring. This paper presents a quantitative assessment of the likely human health impacts of continuing *vs.* withdrawing use of fluoroquinolones and macrolides in production of broiler chickens in the US. Withdrawing animal antibiotics can potentially cause thousands of times more human illness-days than it would prevent, if it increases illnesses rates in animals, microbial loads in servings from the affected animals, and hence human health risks.

HEALTH RISK ASSESSMENT FRAMEWORK

To quantify the human health impacts – both positive and negative – of macrolide and fluoroquinolone antibiotic use in animals, we estimate and compare the following two quantities.

- Preventable RISK to human health from continued use of animal antibiotic = expected additional illness-days *caused* per year by increased antibiotic resistance in foodborne pathogens and *preventable* by ceasing use = (expected preventable resistant

cases caused per year) × (expected incremental health consequences per case caused) = $[p(1 - s)(P^-)MN] \times [f \times r \times (Q_r - Q_s)]$. (See Table 1 for notation.)

- BENEFIT (risk reduction) to human health from continued use = expected illness-days *prevented* per year by reduced animal bacterial diseases = (expected cases prevented per year) × (expected health consequences per case) = $[\Delta F(P^+ - P^-)] \times MN \times [Q_r - s'(Q_r - Q_s)]$ where $s' = [1 - (1 - p) \times (1 - s)]$ = post-ban susceptible fraction.

Table 1 summarizes the interpretations and estimated values of the model parameters in these formulas, and they are further discussed and explained below. An intervention such as withdrawing an animal antibiotic is expected to protect human health if and only if RISK > BENEFIT for continued use.

The RISK and BENEFIT formulas have the following interpretations for enrofloxacin, a fluoroquinolone currently used to treat fatal respiratory illness (airsacculitis, AS) in chicken flocks:

- (MN) = (average servings per capita) × (number of people in US) is the number of chicken servings ingested per year. $(P^-)MN$ is the expected number of resulting campylo-bacteriosis illness cases per year under the *status quo* (no ban).
- P^- denotes the current average risk of illness per serving, i.e., the expected number of illnesses caused per serving. It is estimated from the formula: P^- = (total illnesses per year × fraction caused by eating chicken servings)/(total number of servings).

Table 1: Parameters For Human Health Impact Model (Cox and Popken, 2005)

Variable	Meaning	Baseline Value/Source
ΔF	Fractional change in chicken servings from ill or high-risk flocks if current use ceases	0.5% = assumed baseline
P^-	Average probability of illness per serving from animals without disease. Includes indirect effects of cross-contamination.	1.3E-5 = (total *C. jejuni* illnesses per year) × (0.10 fraction caused by chicken)/(total chicken servings per year)
$P^+ - P^- = (1 + R)P^-$	Excess probability of illness per serving from ill flocks. (Includes cross-contamination)	1.2E-4 (for linear no-threshold dose-response model, microbial load ratio ≈ 10, from Russell, 2003)
M	Average number of servings of food commodity ingested per capita-year	38 FDA-CVM, 2001, Cox and Popken, 2002 for fresh chicken
N	Number of people in population	292E6 (U S Census)
$1 - s$	Fraction of the cases caused by bacteria in animal meat that are resistant to human antibiotic. (s = current *susceptible* fraction)	Erythromycin: 0.01 Ciprofloxacin: 0.064
p	Preventable resistance fraction = fraction of currently resistant illnesses	1 (upper bound) 0.3 may be more realistic for

	caused by eating the food commodity that a ban would remove (i.e., make susceptible)	enrofloxacin (Cox and Popken, 2005)
Q_s	Average human health harm (e.g., days of illness or QALYs lost) per susceptible case. Interpreted as "severity" of a case.	6 days (Marano *et al.*, 2000)
$Q_r - Q_s$	Average excess illness-days per resistant case failing to respond normally to antibiotic, for severely ill patients; or per untreated case for non-patients	2 days (Estimated upper bound for current clinical practice Ang and Nacham, 2003; Marano *et al.* 2000)
K	Q_r/Q_s = ratio of average clinical severities (e.g., illness-days) for resistant *vs.* susceptible campylobacteriosis cases	1.002 base case estimate; up to 2 in sensitivity analyses
f	Probability that resistant case fails to respond normally to prescribed antibiotic therapy, due to resistance	< 1 (Upper bound)
r	Probability that a resistant case is assigned resisted antibiotic	0.5

Each illness currently has probability (1 – s) of being resistant to the human antibiotic being considered (e.g., ciprofloxacin). If the current animal antibiotic use were to cease, a fraction p of these (1 – s)(P^-)MN currently resistant chicken-caused illnesses, called the *preventable resistance fraction*, would be eliminated – or, more accurately, would be replaced with susceptible rather than resistant pathogens. Thus, a ban would prevent a total of [p(1 – s)(P^-)MN] resistant illnesses per year. This gives the first part of the preventable RISK formula. For health consequences of a ban, suppose that a fraction f of resistant cases experience reduced treatment effectiveness due to resistance if treated with a resisted antibiotic. Let r denote the probability of being treated with a resisted antibiotic. Thus, r reflects screening and prescription practices, while f reflects the risk that resistance creates clinical harm. If the mean health impact is ($Q_r - Q_s$) additional illness-days (or quality-adjusted life-years (QALYs) lost, etc.) for each such case, then the average additional health harm per case is $f \times r \times (Q_r - Q_s)$. Multiplying this average consequence-per-case by the expected number of cases gives the complete formula for estimating the human health risk preventable by a ban on the current animal antibiotic use: RISK = $[p(1 - s)(P^-)MN] \times [f \times r \times (Q_r - Q_s)]$.

The formula for BENEFIT of continued use is interpreted as follows. Suppose that a ban would cause an increase ΔF in the fraction of chicken servings from ill (e.g., airsacculitis-positive, (AS^+)) flocks instead of healthy (e.g., airsacculitis-negative (AS^-)) flocks, and that each such serving has an incremental probability ($P^+ - P^-$) of causing illness. Then the expected change in number of illnesses per year is $[\Delta F(P^+ - P^-)]MN$. If a fraction s' = $[1 - (1 - p) \times (1 - s)]$ of these illnesses are susceptible after the ban has taken effect [reflecting a pre-ban resistant fraction (1 – s) that is reduced by the preventable fraction p when the effects of the ban are fully realized, leaving $(1 - p) \times (1 - s)$ as the new post-ban

resistant fraction and hence $s' = 1 - (1 - p) \times (1 - s)$ as the new susceptible fraction], then the new average health impact per illness will be $[s'Q_s + (1 - s')Q_r]$, which may be rearranged as $[Q_r - s'(Q_r - Q_s)]$. Thus, the expected human health impact caused by the fractional increase ΔF in animal illness prevalence if current animal antibiotic use were to cease is: $\text{BENEFIT} = [\Delta F(P^+ - P^-)]MN \times [Q_r - s'(Q_r - Q_s)]$ incremental illness-days per year. This is the human health benefit (= human health harm prevented) from continued use of the animal antibiotic (for which $\Delta F = 0$). Introducing the relative risk ratio $R = (P^+/P^-)$ for the ratio of probability of illness per serving from ill (AS^+) *vs.* healthy (AS^-) flocks, this formula can be written as:

$$\text{BENEFIT} = [\Delta F(R - 1)] \times [(P^-)MN)] \times [Q_r - s'(Q_r - Q_s)]$$

The ratio of additional illness-days (or other measures of adverse outcomes) per year that would be *caused* by banning a current animal antibiotic use to illness-days per year *prevented* by the ban is:

$$\text{BENEFIT/RISK} = [\Delta F(R - 1)] \times [(P^-)MN)] \times [Q_r - s'(Q_r - Q_s)]/[p(1 - s)(P^-)MNfr(Q_r - Q_s)]$$
$$= [\Delta F(R - 1)][Q_r - s'(Q_r - Q_s)]/[p(1 - s)fr(Q_r - Q_s)].$$

If a ban would be completely successful in preventing resistance in animals (i.e., the preventable resistance fraction is $p = 1$, which implies $s' = 1$), then this BENEFIT:RISK ratio for continued use simplifies to:

$$\text{BENEFIT/RISK} = [\Delta F(R - 1)]/[(1 - s)fr(K - 1)],$$

where $K = (Q_r/Q_s)$ is the ratio of average harm per resistant illness case to average harm per susceptible illness case. "Harm" may be measured in terms of QALYs lost, or the BENEFIT:RISK ratio can be calculated separately for each type of outcome, e.g., mild, moderate, severe, and fatal cases (Buzby *et al.*, 1996.) A ban is health-protective if and only if the BENEFIT:RISK ratio is less than 1.

Henceforth, we will conservatively assume that a ban on current animal antibiotic uses would eliminate *all* resistance in the corresponding food animal-borne resistant campylobacteriosis cases (i.e., $p = 1$ and $s' = 1$). Thus, we will focus on quantifying the parameters in the following formulas:

$$\text{BENEFIT} = [\Delta F \times (R - 1)] \times [(P^-) \times M \times N)] \times Q_s$$
$$\text{RISK} = (1 - s) \times [f \times r \times (K - 1)] \times [(P^-) \times M \times N] \times Q_s$$
$$\text{BENEFIT/RISK} = [\Delta F \times (R - 1)]/[(1 - s) \times f \times r \times (K - 1)]$$

DATA SOURCES AND PARAMETER VALUES

Recall that P^- denotes the average risk of a campylobacteriosis illness case per chicken serving from a healthy flock (including possible effects of cross-contamination to other foods in the kitchen). Since almost all chicken-borne *C. jejuni* cases currently come from

healthy (e.g., AS^-) flocks, P^- can be approximated by dividing the estimated total number of chicken-caused campylobacteriosis cases per year by the total estimated number of chicken servings ingested per year. The result is:

P^- = (total chicken-caused cases)/(total servings) = (total cases × fraction from chicken)/(MN) = (1.48E6 × 0.10 from chicken, from Cox and Popken, 2005)/(38 × 292000000) = **1.3E-5** average campylobacteriosis cases caused per chicken serving from a healthy flock.

The corresponding estimate of current cases per year, is: $(P^-)MN = (1.48E6 \times 0.10) =$ 1.48E5. These estimates are based on population averages, without accounting for interindividual variability in numbers of meals eaten, thoroughness of cooking, differences in immune status and vulnerability, etc. Thus, they should only be used to estimate population risks rather than risks to any specific individual.

If a linear no-threshold dose-response model is used (i.e., human campylobacteriosis risk is proportional to CFUs per processed carcass) and if the average risk of campylobacteriosis is about **R = 10** times greater for servings from AS^+ flocks compared to those from AS^- flocks (Russell, 2003), then $(P^+ - P^-) = (R - 1) \times P^- = 9 \times P^- =$ **1.2E-4** is the excess individual risk of campylobacteriosis per serving from an AS^+ bird. Fitting a log-exponential model instead, as suggested by FDA-CVM, 2001, yields an estimated $R \approx$ 140 instead of R = 10 (Cox and Popken, 2005. We use 10 as a conservative baseline estimate, i.e., to reduce the estimated human health benefits of continued animal drug use compared to the estimated benefits of a ban.

For airsacculitis (AS), historical treatment rates with enrofloxacin in the US have been between 0% and 2%. Table 1 assumes that if enrofloxacin and/or macrolides were withdrawn, then AS, NE (Brennan *et al.*, 2001), and perhaps other illnesses that lead to similarly increased microbial loads in processed carcasses (Dawe, 2004) would increase by half a percent, i.e., **ΔF = 0.005**. This is based on assuming that (a) No dramatic increase in flock illness rates (as occurred for NE in Norway) would happen in the United States; but (b) The historical need to treat at least 1% of flocks would continue; and (c) About half of these flocks would be treated successfully by alternatives to enrofloxacin, with the rest being ill at slaughter. (In reality, there may be no fully adequate substitute for enrofloxacin to treat airsacculitis, but perhaps other preventive and therapeutic measures might be developed.) Because this estimate of ΔF is uncertain, the resulting benefits estimated using Table 1 are benefits *per half-percent increase* in ill flocks following a ban.

Although the fractions of chicken-caused severe *C. jejuni* illnesses that are resistant to different antibiotics have not been well studied, about 1% of all *C. jejuni* illnesses were reported as being erythromycin-resistant in 2000, and this number has been relatively stable or declining for years (CDC, 2000). Thus, Table 1 assumes (1 – s) = 1% among *C. jejuni* for macrolides. The corresponding ciprofloxacin resistance fraction for domestically-acquired *C. jejuni* cases estimated from CDC FoodNet *Campylobacter* Case Control Study data is (1 – s) = 6.4%, (Cox, 2001, pp 110-111). This fraction also appears

to be fairly stable over time. A susceptible case of domestically-acquired chicken-borne campylobacteriosis is assumed to have an average adverse health impact of Q_s = 6 illness-days (Marano *et al.*, 2000). If resistant domestically-acquired chicken-borne campylobacteriosis cases have the same average clinical impacts as susceptible ones, then K = 1 and preventable RISK = 0. For purposes of analysis, the base case in Table 1 assumes that resistance leads to an average two-day delay in finding an effective therapy among those cases of campylobacteriosis that are severe enough to warrant antibiotic treatment – about 0.6% of all cases according to Buzby *et al.* (1996) – and that are initially prescribed the resisted antibiotic. Then $K = (Q_r/Q_s) = (0.006 \times 8 \text{ days} + 0.994 \times 6 \text{ days})/(6 \text{ days}) = 1.002$ in the base case (increased to 2 in some of the sensitivity analyses in Table 2), assuming that this delay is the only clinical adverse effect of resistance; that resistance does not otherwise impair recovery (Piddock, 1999); that *all* severe resistant cases are prescribed the resisted antibiotic, and that only those patients with exceptionally severe cases (for which antibiotic treatment might be indicated) are at risk of experiencing a delay in resolution of symptoms from time lost in finding an effective treatment due to resistance. Even for such patients, excess illness-days occur only of the resisted antibiotic is initially prescribed and then proves ineffective. ["Resistance" of *Campylobacter* to fluoroquinolones does not necessarily or usually imply clinical resistance (Piddock, 1999).] The probability of being prescribed the resisted antibiotic (e.g., ciprofloxacin for someone with fluoroquinolone-resistant campylobacteriosis, or a macrolide for someone with macrolide-resistant campylobacteriosis) is assumed to be at most r = 0.5 (FDA-CVM, 2001), especially if severe cases are screened for resistance (Ang and Nacham, 2003). The probability that prescription of a resisted antibiotic leads to compromised treatment or to a treatment failure, thus requiring a switch to a different antibiotic, is uncertain. [One study suggests 1/39 as a possible value (Piddock, 1999)]. It is estimated conservatively in Table 1 as f = 1.

RESULTS AND CONCLUSIONS

Table 2 calculates the human health RISK and BENEFIT from continued use of enrofloxacin and macrolides in chicken, expressed as expected illness-days per year caused and prevented, respectively, as well as their RATIO. In addition to the base case values (RATIO = 703 illness-days prevented per illness-day caused for enrofloxacin and 4500 for macrolides), RATIO is calculated for different combinations of input values, to illustrate the sensitivity of the BENEFIT:RISK ratio to changes in the parameter values.

Table 2: Human Health Impacts of Macrolides and Fluoroquinolones

Input and Meaning	**Base Case**	**Sensitivity Analysis Scenraio Inputs**				
	0	1	2	3	4	5
$[(P^-)MN)]^*Q_s$ = current illness-days per year from chicken	8.9E5 = 1.48E5 cases per yr. × 6 days/case					
ΔF = fractional increase in servings from ill flocks if ban	0.005				0.1	0.1
R = Ratio of risk-per-serving from ill *vs.* well flocks	10	2			139	139
(1 – s) = Resistant fraction if no ban	Macrolides: 0.01 Fluoroquinolones: 0.064					
f × r = Adverse clinical outcome probability for resistant cases	0.5 (= prob. given resisted antibiotic)				(0.5)× (1/39)	(0.5)× (1/39)
K = Consequence ratio of illness-days for resistant *vs.* susceptible cases	1.002		1.3	2	2	
Output		**Sensitivity Analysis Scenario Outputs**				
BENEFIT = Illness-days per year *prevented* by continued use = $[\Delta F(R - 1)] \times [(P^-)MN)]^*Q_s$	40050					
RISK = Illness-days per year *caused* by continued use = $(1 - s) \times [fr(K - 1)] \times [(P^-)MN] \times Q_s$	57 for enrofloxacin, 9 for macrolides					
RATIO for enrofloxacin = BENEFIT/RISK	**703 for enrofloxacin**	**78**	**4.7**	**1.4**	**1.7E4**	**8.4E6**
RATIO for macrolides	**4500 for macrolides**	**500**	**30**	**9**	**1.1E5**	**5.4E7**

The main conclusion from the baseline calculations is that *withdrawing either antibiotic from use in chickens in the US is estimated to cause significantly more illness-days (and more cases of each type of illness, both resistant and susceptible) than it would prevent.* The sensitivity analysis columns show how the results change as inputs are varied. (Each column for a sensitivity analysis shows the input values and resulting output values that deviate from the baseline values.) The health BENEFIT:RISK ratio is 703 for enrofloxacin and 4500 for macrolides in the base case, which made several conservative assumptions that tend to minimize it. But the ratio could exceed ten million under alternative assumptions (right-most column) in which a ban leads to a 10% increase in chicken flock illness rates; the effects on human illness rates are described by a log-exponential model instead of a linear no-threshold model; and resistance to the prescribed antibiotic has little impact on clinical outcomes (with only 1/39 of patients experiencing excess illness-days, Piddock, 1999.)

The possibility of such high BENEFIT:RISK ratios for continued use suggests a very high value of information (VoI) for studies directed at clarifying the magnitudes of ΔF and (R – 1) prior to any decision to ban these antibiotics from use in animals.

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RETAIL PERSPECTIVE OF THE DOMESTIC MARKET RELATIVE TO FOOD SAFETY

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Many factors can affect public policy and perception about food safety. Among these forces of change are consumers, government bodies, activist groups, the media and the food industry. The retail industry acts as the purchasing agent for consumers and they are the motivator for change. The retail industry reacts to consumer trends and preferences, and currently we see this in a number of areas. Food safety, natural and organic foods, diet and health, ethnic foods, animal welfare and environmental concerns are all factors influencing the domestic marketplace. According to the Food Marketing Institute's *U.S. Grocery Shopper Trends (2005)*, consumer confidence in the safety of food purchased at supermarkets is high. About 85 percent of shoppers say they are mostly or very confident that supermarket food is safe. But we are all aware of how a widely publicized food safety breach can quickly change food safety confidence.

When developing and implementing food safety programs at retail, supermarkets look at four different areas. First is the source of incoming food – their suppliers. Second is the actual in-store operations; third, food safety training for retail store employees. And lastly, consumer education. There are many retail programs within each of these four areas, but I am only going to highlight two of them.

Supplier certification: retailers are looking for suppliers who can provide assurance that they are operating under the best food safety practices and are able to demonstrate managerial controls throughout their processes. To achieve this goal, retailers are relying more and more on third-party audits and certification. FMI was tasked by its members to provide a reliable, credible and internationally accepted certification program — that program, Safe Quality Food (SQF), is now available.

Consumer education: the USDA-FDA risk assessment predicted that illness from listeria could be reduced by more than 90% if consumers maintained their refrigerators at 40°F or below. Project Chill is a campaign designed to educate consumers about home refrigerator temperatures and to make thermometers for this purpose readily available.

The retailers stay close to the needs and concerns of their customers, and these issues are passed up the food chain. Allergens, bioterrorism and nutrition are just a few. Working together, the food industry can respond and react; working together we can maintain consumer confidence and assure public protection.

Wrap Up of AAAP Food Safety Symposium

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Food Safety is a complex issue that demands scientific, educational and communication skills

Industry, government and advocacy groups should understand and utilize:

- Focused approach of egg industry vs. nonfocused approach of broiler/turkey industries
- The value of veterinary medicine
- The integrated poultry system
- The need for interventions and a regulatory process that works
- The evolution of poultry food products
- Fact that we are all consumers
- Collaboration and trust between government, industry and advocacy groups to formulate a sensible approach

Something is going right as there has been a 40% decrease in human listeriosis, 31% decline in campylobacteriosis and an 8% decrease in salmonellosis from the baseline years of 1996-1998. (CDC/FSN 4/15/05)

"But with the right direction, the future is even brighter"