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A PROCESSOR'S VIEW OF FOOD SAFETY

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Abstract

A global commodity handler and processor, Cargill has numerous connections to the meat and poultry industry, including animal production and processing, and animal feed production. Cargill is a global leader in food safety and production systems and is actively involved in all of the issues important to animal health and food safety. The issues to be covered in this address include the spread of foodborne human pathogens, the effectiveness of pathogen reduction regulations, the proposed broader application of HACCP, procedures to restrict the spread of antibiotic-resistant pathogens, mad cow disease, and food security.

Introduction to Cargill

From its beginnings in 1865, Cargill has grown into an international marketer, processor and distributor of agricultural, food, financial and industrial products and services with 90,000 employees in 57 countries. The company provides distinctive customer solutions in supply chain management, food applications and health and nutrition. The processing of grains such as wheat, barley, and corn; soybeans and other oilseeds; citrus crops; and beef, pork, and poultry animals; produces large streams of co-products that are the vital fuel of the animal feed industry. Additionally, Cargill slaughters animals and processes meat and poultry products at about 50 plants worldwide.

The Innovation Center of the Cargill Animal Nutrition platform provides facilities in Elk River, MN, for the production and research on animals and forage crops. The research areas on ruminants include investigations on lactation, nutrition, heifer grow-out, and forage and grain preservation. Additionally, an experimental feed pilot plant produces several thousand tons of experimental feeds per year. Commercially, Cargill Dairy Focus Consultants work directly with producers to develop customized production management and nutrition solutions for each operation.

Foodborne Human Pathogens.

The study of foodborne pathogens was a small and slowly-developing discipline in the first half of the twentieth century. By about 1960 four principal foodborne pathogens were recognized: *Salmonella* spp, *Staphylococcus aureus, Clostridium botulinum, and C. perfringens.* That situation has changed drastically. There are now about twenty principal foodborne pathogens and about another twenty minor pathogens. Some of the newly-emerged pathogens have always existed, but have only recently been found to be capable of causing foodborne illness. Others are truly new pathogens in that they have resulted from the evolution or recombination between different genera of bacteria.

There are three main sources of emerging human pathogens—the microflora of animals, the microflora of children in the developing world, and the opportunistic infections of immunocompromised individuals. In the early twentieth century, the major cause of human illness was the contamination of food and water by human sewage. In the late twentieth century, the major cause of human illness is the contamination of food and water by animal feces. Current concerns about environmental contamination by animal manure are heightened by the visible concentration of animals in large dairy and swine operations or cattle feedlots.

The Centers for Disease Control and Prevention (CDC) in 1996 began a Foodborne Diseases Active Surveillance Network (FoodNet) in which the pathogens involved in nine foodborne diseases (*Campylobacter, Cryptosporidium, Cyclospora, E. coli* O157:H7, *Listeria, Salmonella, Shigella, Vibrio,* and *Yersinia)* are tracked in eight sentinel sites (Minnesota, Oregon, California, Connecticut, Georgia, Maryland, New York, and Tennessee) representing just over ten percent of the U.S. population. In descending order, the pathogens responsible for the most illnesses are *Campylobacter, Salmonella, Shigella*, and *E. coli* O157:H7.

Extrapolating from the hard FoodNet data and other epidemiological considerations, CDC estimates that there are 76 million cases of foodborne illness each year in the U.S., resulting in 325,000 hospitalizations and 5,000 deaths. The cost of foodborne illness attributed to medical costs and lost productivity are estimated to be about $6 billion/year.

In preparation for its Pathogen Reduction/HACCP rule of 1996, the Food Safety and Inspection Service of the U.S. Department of Agriculture (FSIS/USDA) conducted baseline surveys to estimate the incidence of foodborne pathogens in raw animal products. The results of these surveys are summarized here:

Incidence (%) of Foodborne Pathogens in Raw Animal Products[a]

Species	n	*Salmonella*	*Campylobacter jejuni/coli*	*E coli* O157:H7	*Listeria monocytogenes*	*Clostridium perfringens*	*Staphylococcus aureus*
Broilers	1297	20.0	88.2	0	15.0	42.9	64.0
Young turkeys	1221	18.6	90.3	0	5.9	29.2	66.7
Cows & bulls	2112	2.7	1.1	0	11.3	8.3	8.4
Steers & heifers	2085	1.0	4.0	0.2	4.1	2.6	4.2
Market hogs	2112	8.7	31.5	0	7.4	10.4	16.0
Ground beef	563	7.5	0.2	0	11.7	53.3	30.0
Ground chicken	285	44.6	59.8	0	41.1	50.6	90.0
Ground turkey	296	49.9	25.4	0	30.5	28.1	57.3

[a]from USDA Baseline Surveys, 1993-1995

Several recently-emerged foodborne pathogens originated from animal sources—*Listeria monocytogenes* and *E. coli* O157:H7. Additional human pathogens that may emerge from animal sources are *Mycobacterium* spp and *Helicobacter pylori.*

While *L. monocytogenes* was identified as the cause of listeriosis in 1926, it was not suspected as a foodborne pathogen until the first documented foodborne outbreak of listeriosis in 1981. Until that time, human listeriosis had been an illness usually associated with the wives of farmers and veterinarians.

L. monocytogenes is unique among foodborne pathogens because it is psychrophilic, capable of growth at temperatures as low as 32°F, and it is widespread in soil, vegetation and animals. Despite its frequent occurrence, listeriosis is an infrequent illness, owing to the very high infectious dose of *L. monocytogenes*. However, this illness gets a lot of attention because of its high mortality rate, about 20%. There are about 2,500 cases of listeriosis each year in the U.S., resulting in about 500 deaths.

While common in processed foods, listeriosis can be caused only by foods that are refrigerated, ready-to-eat (RTE), with a shelf-life greater that ten days, and capable of supporting the growth of *L. monocytogenes* to very high levels—foods such as soft and fresh cheeses, and some cooked meat, poultry and seafood, and smoked fish.

In the past several years, the U.S. has experienced two outbreaks of meatborne listeriosis involving 130 illnesses, 19 deaths, and 10 stillbirths. The direct costs of these two outbreaks is somewhat greater than $150 million. Beyond the costs of catastrophic illness outbreaks, the RTE meat and poultry industry spends many $millions each year in *Listeria* control programs.

Pathogen Reduction Regulations.

Since 1994 the FSIS has passed a number of regulations affecting control programs for pathogens in meat and poultry products. The watershed event that stimulated this burst of regulatory activity was a major outbreak of *E.coli* O157:H7 infections caused by undercooked hamburgers at a restaurant chain in the Pacific NorthWest. Peaking during the week of Jan. 12, 1993, this outbreak involved 602 documented illnesses, 144 hospitalizations, 45 cases of hemolytic uremic syndrome (HUS), and 4 deaths; and led to litigation estimated at a cost of about $400 million. Yet, these staggering statistics did not make this outbreak a watershed event. Rather, what happened the following week did.

The Clinton administration took office during the following week. Having campaigned in 1992 on a platform that included more attention to food safety matters, the administration was immediately embroiled (as the hamburgers had not been) in a swirl of political, activist and regulatory recriminations. The administration over-reacted for more than eight years. Even though the outbreak hamburgers had been grossly (and illegally) undercooked, in 1994 a rule declaring *E. coli* O157:H7 to be an adulterant in raw ground beef was passed. This was the first step in a series of attempts to regulate pathogens out of raw meat and poultry products. In 1996, *Salmonella* performance standards were included in the major Pathogen Reduction/HACCP rule. In 1998 the administration began efforts to initiate a *Campylobacter* performance standard; and announced intentions to have a performance standard for every pathogen. The listeriosis outbreaks in 1999/2000 fueled demands for *L. monocytogenes* standards in RTE meat and poultry products.

The pathogen performance standards have proven to be cumbersome to administer, expensive to monitor, and counterproductive in terms of protecting the public health. Before 1994 the beef industry was working very hard to implement process interventions to reduce or eliminate *E. coli* O157:H7 in ground beef. The 1994 rule declaring this pathogen to be an adulterant essentially forced beef companies to stop their testing programs, because any positive result would have required FSIS notification and a product recall.

All of the prospective pathogen performance standards could have been replaced by the use of a single indicator test to validate and monitor process effectiveness. The total plate count (TPC) procedure, for example, would work much more quickly and inexpensively than specific pathogen detection procedures Meat and poultry processors bring live animals into one end of the plant, and ship raw products out of the other end. While it is Panglossian (Washingtonian?) to expect that all of the raw products will be pathogen-free; it should at least be expected that the processors will be able to reduce pathogen contamination. This reduction can be verified by the TPC test; specific pathogen tests are not necessary. For example, a process intervention that yielded a 3-log reduction in TPC would, *a priori*, yield about a 3-log reduction in each of the vegetative pathogens of concern. Among the many effective interventions that the industry was adopting—even before the first pathogen rule in 1994—are the use of hot water rinses, steam pasteurization, organic acid sprays, sanitizer dips and sprays, and improved evisceration and dehiding procedures.

In the past year the FSIS has tried to justify its Salmonella performance standard by promoting the results of a new *Salmonella* baseline survey that show a reduced incidence in raw animal products when compared to the 1993-1995 baseline surveys. FSIS credited these reductions to the *Salmonella* performance standard. Completely ignored were all suggestions that the same or greater reduction could have been accomplished much more expeditiously and economically by the use of a TPC guideline.

Incidence (%) of *Salmonella* in Raw Animal Products in USDA Baseline Surveys

Species	1993-1995	1999-2000
Broilers	20.0	9.9
Cows & bulls	2.7	1.6
Steers & heifers	1.0	0.2
Market hogs	8.7	7.7
Ground beef	7.5	5.0
Ground chicken	44.6	14.4
Ground turkey	49.9	30.0

FSIS has deflected most criticism of its new rules by claiming that they are "science-based." What has been passed off as science is usually a misguided application of statistics. One need do no more than consider the actual *Salmonella* performance standards to understand the regulators' confusion.

***Salmonella* Performance Standards**

Species	Performance Standard[a]	n[b]	c[c]
Broilers	20.0	51	12
Cows & bulls	2.7	58	2
Steers & heifers	1.0	82	1
Market hogs	8.7	55	6
Ground beef	7.5	53	5
Ground chicken	44.6	53	26
Ground turkey	49.9	53	29

[a]percent positive for *Salmonella*
[b]number of samples tested
[c]maximum acceptable number of positive samples

How can 29 *Salmonella* positives in 53 ground turkey samples be considered "safe," while 30 positives in the same 53 samples are considered to be "unsafe," or indicative of loss of HACCP control?

In 2001, a group of scientists, including some from FSIS who had been involved in developing the *Salmonella* performance standards, published an analysis which concluded that the *Salmonella* serotypes identified in human illnesses differ substantially from the serotypes detected in animals and animal products. The analysis is summarized here:

Serotypes of *Salmonella* Isolates Detected in Humans and Animals, 1990-1995

	% Isolates from:	
	Humans	Animals[b]
Serotype [a]	(N=25,842)	(N=951)
Typhimurium	29.0	12.4
Heidelberg	8.7	13.8
Newport	5.9	0.6
Hadar	4.6	11.7
Thompson	2.2	4.8
Kentucky	0.1	13.1
Derby	0.004	6.0
Others	49.5	36.7

[a]Enteritidis excluded (eggs only)
[b]chicken, beef & pork
(from *J. Infect. Dis.* (2001) 183: 1295-1299)

This analysis seriously undermines the frequent FSIS claim that the *Salmonella* performance standards have not only reduced the incidence of *Salmonella* in animal products, but have also reduced the incidence of human salmonellosis.

Just as frustration ruled supreme in the meat and poultry industry at the end of 1999, the sun rose seemingly miraculously in the west Texas sky. FSIS took action to close Supreme Beef Processing because it had failed three consecutive rounds of testing for compliance with the *Salmonella* performance standard. Supreme Beef filed suit in federal district court to void the FSIS action. The court ruled in favor of Supreme Beef, claiming that FSIS had exceeded its authority in issuing the *Salmonella* performance standards. FSIS retaliations forced Supreme Beef into bankruptcy, but this case is still open. It may prove to be a watershed event that overturns pathogen performance standards. In the past two years, intense political efforts by Senate Democrats to outlaw the court decision have been defeated. Congress has requested that the issue of pathogen performance standards be reviewed by the National Academy of Sciences, and by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF).

E. coli O157:H7, one of the subjects of the pathogen rules, is also one of the emerging pathogens that was mentioned earlier. It is a particularly virulent pathogen with a low infectious dose. Illness complications can result in death. The major risk factors for this illness are exposure to farm animals and consumption of undercooked ground beef.

The first documented *E. coli* O157:H7 illnesses were attributed to undercooked hamburgers in 1982. The major 1993 outbreak described above led to the 1994 adulterant rule. Since that time FSIS has examined more than 47,000 samples of ground beef for *E. coli* O157:H7 and found 0.36% to be positive.

FSIS Survey of Ground Beef for *E. coli* O157:H7

Year	Number of Samples	Positive Samples Number	Positive Samples %
1994	891	0	0
1995	5407	3	0.06
1996	5703	4	0.07
1997[a]	6065	4	0.07
1998	8080	14	0.17
1999[b]	7786	32	0.41
2000	6374	55	0.86
2001	7020	59	0.84
	47326	**171**	**0.36**

[a]Oct 97...sample size increased from 25g to 325g
[b]Sept 99...more sensitive procedure (immunomagnetic capture)

While the incidence appears to have increased since 1994, the increases are overcompensated by a 13-fold increase in sample size and a four-fold increase in analytical sensitivity. Therefore, contrary to the initial impression of the raw incidence data, the true incidence has actually decreased since 1994, a tribute to the efforts of the beef industry.

In 2001 FSIS published a draft risk assessment on *E. coli* O157:H7 in ground beef. While the data cannot be presented in this outline, the risk assessment estimated that 19,000 people are infected in the U. S. each year by consuming ground beef. Among these, 380 are hospitalized, 83 contract HUS, and 11 die. The three ways we have to control these illnesses are, in decreasing order of effectiveness; adequate cooking, irradiation in consumer-packaged product, and the reduction of *E. coli* O157:H7 in animal husbandry and processing.

Hazard Analysis and Critical Control Points (HACCP) System of Food Safety

The HACCP system replaced the conventional system of quality control for the assurance of product quality and safety. Quality control, in widespread use into the 1970s, proved itself too costly and ineffective. HACCP is a system based on product design and process control. Unlike quality control, it is a preventive system based on the control of significant hazards at identified critical control points in the process. The current seven principles for the application of HACCP were jointly developed by the NACMCF and the WHO/FAO in 1992.

The application of HACCP in the food processing industry has been so successful that many now advocate the application of HACCP across the entire food spectrum from "Farm to Table." It is no accident that HACCP evolved in the middle of this spectrum, in consumer food processing plants. It is here that definitive food safety control measures can be applied, such as the pasteurization of dairy products, or the sterilization of canned foods. Such definitive control is not possible at the "Farm" end of the spectrum. Even at the "Table" end of the spectrum, interventions such as cooking are not always successful because many people will undercook food or make other foodhandling mistakes that result in illness.

While HACCP "doesn't work down on the farm" because of the lack of definitive control measures, food safety interventions are being developed that will eventually provide at least partial control at the "Farm." These include treatment of animal feedstuffs, drinking water, competitive exclusion by "good" microorganisms, and the use of vaccines.

Antibiotic-Resistant Pathogens

In the sixty years since their first use, antibiotics have become very widely used in the therapy of human and animal diseases and in the subtherapeutic promotion of animal growth. In the past two decades an intensifying public health debate has centered on the cause of the rise of antibiotic-resistant pathogens. Some claim the rise has been caused by the subtherapeutic use of antibiotics as animal growth promoters, thereby leading to more human illnesses. Others claim that the rise in resistant pathogens has resulted from the overprescription of antibiotics for human therapy, especially for viral illnesses, and by the incomplete use of individual prescriptions.

This debate is of utmost public health importance. Many pathogen isolates are resistant to more than one antibiotic. A few isolates of *Staphylococcus aureus* are resistant to all major antibiotics except vancomycin. Public health officials worry, for good reason, that if those isolates become vancomycin-resistant, we will be defenseless and millions of people could die from "ordinary staph infections." They worry because each year 2.5 million patients acquire infections in hospitals; 80,000 die from these infections, which are usually caused by *S. aureus, Enterococcus*, or *Pseudomonas*. Note that these are not pathogens derived from raw animal products. Reports of the National Antimicrobial Resistance Monitoring System (NARMS) are showing a decrease in the proportion of antibiotic-resistant human isolates of *E. coli* O157:H7, *Salmonella*, and *Campylobacter*.

Of the eighteen antibiotics used for animal growth promotion, 13 are used only in animals; the remaining five are also used for human therapy. Although thirteen major studies since 1960 have revealed no direct connection between the use of antibiotics for animal growth promotion and the high level of antibiotic-resistant pathogens in human illnesses, there is growing political pressure to reduce the use of antibiotics in animals.

After sixty years of squandering much of the advantage of antibiotics by permitting the rise of antibiotic-resistant pathogens, it is still important that national and international policy makers implement a strategy to curb or reduce the incidence of antibiotic-resistant pathogens. Potential actions that would contribute to an effective strategy include: better control of the use of human antibiotics, restricting some classes of antibiotics strictly to human use, and the expanded use of alternative practices to reduce the amount of antibiotics used in animal production. Note that this strategy does not ban the use of antibiotics in animal production.

Potential alternative practices to reduce antibiotic use in animal production include: competitive exclusion, enzymes, feed additives, clean water, cleaner environment, bacteriophage, and vaccination.

Mad Cow Disease

Since 1980 there has been a "convergence" of three transmissible spongiform encephalopathies (TSE). These are: scrapie in sheep, bovine spongiform encephalopathy (BSE) in cattle ("mad cow disease"), and variant-Creutzfeldt-Jakob Disease (vCJD) in humans. The TSEs are incurable and invariably fatal.

The BSE epidemic originated in England, eventually infecting over 180,000 cattle. Millions more were eradicated in attempts to control the disease. BSE is thought to have originated from scrapie prions that were able to survive altered rendering practices that were begun about 1980. The first BSE cases were detected in 1986, the first case of vCJD was detected in 1996. The agent for cattle infection was shown to be BSE-contaminated meat and bone meal (MBM). Even though this link was established by 1989, contaminated MBM continued to be exported from the UK for an additional ten years. Hence the BSE outbreak became an epidemic, spreading to all European countries except Sweden, and to Japan. More than 100 people have died of vCJD since 1996.

BSE has not been detected in North America. That situation is likely to remain unchanged if the three existing firewalls are maintained. These are: importation bans on live ruminants and ruminant products from BSE-infected geographies, in place since 1989; the USDA surveillance of brains from cattle with CNS symptoms, in place since 1990; and the FDA ruminant feeding regulation, in place since 1997. The political and activist pressure for additional firewalls is not justified.

Dairy farmers and veterinarians have a key role to help keep BSE out of North America. They can assure compliance with the FDA ruminant feeding regulation, and keep diseased animals out of the food chain.

Food Security

This topic has assumed vital importance to protect our food and agricultural systems from deliberate sabotage. The global areas that must be addressed are transportation, ports of entry, worker documentation, and facility security.

The single largest threat to agriculture is foot and mouth disease (FMD). Additional threats are crop pathogens and other animal pathogens.

=The immediate potential threats to dairy farms are FMD, bulk trucks with multiple pickups, feed security, and deliberate contamination with toxic chemicals such as dioxin or PCBs.

Conclusion

There are a great number of real and potential food safety, public health, regulatory, legal, and public relations issues associated with the production of all food products, but particularly of meat and poultry products. The list of issues will continually change, but probably will never shrink. We have got our work cut out to deal effectively with the relevant issues while maintaining commercially-viable enterprises. Enjoy the journey!