

## THE RENDERING INDUSTRY'S ROLE IN FEED AND FOOD SAFETY

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### Summary

The role of the rendering industry in feed and food involves the formulation and administration of progressive, forward-looking programs under the auspices of the Animal Protein Producers Industry (APPI), the biosecurity arm of the rendering industry. While end-product testing for *Salmonella* has played a historic role in the industry's endeavors to assure the safety of feed ingredients of animal origin, the industry recognizes that the current and future challenges of feed/food safety necessitate innovation and new modeling. The industry has approved a robust Code of Practice that mandates long-term commitment and accountability, while accepting that the success of such a program could only be realized through a comprehensive third-party certification audit. The production of safe feed ingredients for the manufacture of feed/food for livestock, poultry, aquaculture, and pets is the ultimate goal.

### Introduction

A little over two decades ago, the industrialized societies of the world recognized the urgent necessity to address the broad realm of issues linked to safe food production. In the United States, this was exemplified by two major conferences in 1984. At the National Conference for Food Protection held in Washington, D.C., sponsored by the Food and Drug Administration (FDA), the keynote speaker extolled the country's "plentiful, wholesome, nutritious, and safe food supply" (Knauer, 1984), recognizing that the benevolent food supply took hard work, imagination, and cooperation among the food producing industry, consumers, and government.

This initial conference was followed three months later by an international symposium on *Salmonella* held in New Orleans, Louisiana, where the keynote speaker highlighted the challenging dimensions of *Salmonella* control internationally that "confronts government, industry, and the scientific community as both a challenge and a reproach. It is a challenge because it taxes our ingenuity in dealing with its various dimensions. It is a reproach because it sometimes appears that with our science and technology we are better able to strive toward a certain well-defined objective, like the moon, than to overcome a chronic, food-poisoning hazard" (Houston, 1984). This symposium was one of the earliest proponents, using *Salmonella* as a prototype, to heighten the interrelationship of animal feed, food animal production, food processing, public health, and global trade.

These two conferences clearly had an impact on the policy-making directions that government agencies took during that period, including the

subsequent consideration of hazard analysis and critical control points (HACCP) as an interactive, scientifically based protocol that can be used to eliminate food safety hazards, or at least reduce them to acceptable levels. It is interesting to note, although not necessarily surprising, that HACCP was operational as a concept in the private sector (the Pillsbury Company) as early as 1973, and was later embraced by FDA as a regulatory mandate for canned acidified and low acid foods packed in hermetically sealed containers (Corlett, 1998).

These two early conferences had a definite impact on the United States' direction of food safety policy. Amplification followed in 1989 at an international symposium of the World Association of Veterinary Food Hygienists held in Stockholm, Sweden, and co-sponsored by the European Association for Animal Production, the International Union of Food Science and Technology, and the World Health Organization. The theme of the symposium was: Healthy Animals, Safe Food, Healthy Man. One of the keynote addresses reviewed the challenges of the coming decades and included the need to control latent infections in livestock and poultry, including those that are readily transmitted to humans (zoonoses) through monitoring programs. It was also stated that future initiatives should prioritize detection methods through monitoring the health status of farm animals through the process of slaughtering and processing, including the assessment of risk using the HACCP concept (Grossklaus, 1989).

While it is obvious that conferences/symposia were not the sole factors in molding the food safety agenda at the time, they played a significant role in bringing together in a transparent environment, a broad spectrum of academia, government, research, consumers, and the industry to examine the changing dimensions of feed/food safety and the establishment of priorities. It was recognized that the complexities of food production needed the elements of cooperation, collaboration, and communication to succeed and that no one group could do it alone. Since each segment of the food chain had distinct challenges, working together in unison was the most logical and progressive approach.

The purpose of this chapter is to review the rendering industry from a holistic perspective and profile the contributions the industry makes in supplying safe feed ingredients and sources of energy to enhance the health of livestock in producing safe food. Clearly inherent to safe food production is the acceptance and responsibility that feed ingredients meant for livestock, poultry, and aquaculture are part of the food chain. Manufacturers must conform to standards of sanitation and hygiene in production to preclude hazards that could impact the health of animals and humans, directly or indirectly.

### **Historical Background**

The historical record clearly demonstrates that feed and food safety policy progressed because of cumulative influencing factors to create change. While dramatic and distinct changes were clearly evident in the early 1980s, these developments were related to earlier events that brought new or changing dimensions to the broad realm of both policy and safety issues. In essence, no

single force has the capability to create a long-lasting momentum in complex industrialized societies such as the United States and Canada. However, a policy decision at the FDA in 1967 by then Commissioner Goddard served as a significant force for change. Goddard's policy expanded the meaning of adulteration that was hitherto limited to human food, to include food for animals. Therefore, ingredients used in food for animals are included within the definition of food in Section 201 (f) of the Federal Food, Drug and Cosmetic Act. Further, *Salmonella* contamination of such animal feeds having the potential to produce infection and disease in animals must be regarded as an adulterant within the meaning of the Act (Franco, 1999). This established the genesis of the regulatory implications associated with *Salmonella* microorganisms in animal feed.

Interestingly, prior to Goddard's *Salmonella* adulteration policy, the U.S. Department of Agriculture (USDA), Animal Health Division, had already started surveillance sampling of animal by-products and meals at varying periods from 1965-1970 for the incidence of *Salmonella* (Franco, 1999). This active surveillance program was done in collaboration with FDA, the agency with regulatory responsibility for feed safety. It is logical to assume that Goddard's decision in 1967 was based on some of the initial findings of the collaborative surveillance-testing program. Additionally, over a period of years starting in the late 1950s, there were several research publications that could have added impetus to Goddard's policy.

Research by Boyer and colleagues (1958) found that some serotypes identified in animals and man can be isolated from feed ingredients and animal feeds. In another study, Watkins et al. (1959) recovered 28 different serotypes from 37 (18.5 percent) of 200 samples of poultry and other animal by-products used in feeds. Pomeroy and colleagues (1961) reported on one comprehensive study in which 43 different serotypes of *Salmonella* were recovered from 175 (18 percent) of 980 samples of by-products of animal origin used in animal feeds from 22 states.

The National Academy of Sciences Committee on *Salmonella* of the National Research Council (NRC) published a scholarly text, "An Evaluation of the *Salmonella* Problem" (Anon., 1969) that examined the concerns of *Salmonella* in the United States with the intent of advising both the USDA and FDA on the aspects of the problem relating to both regulatory agencies' responsibilities in animal and human health. The study also made comprehensive assessments of feed ingredients from a risk perspective, indicating that prior to the report, it was generally accepted that animal feeds were of little importance of transmitting *Salmonella* to animals. This theory was promoted based on the observation that *S. Typhimurium*, the most common isolate of both animals and man, was infrequently isolated from feeds. Nonetheless, the report further implied that rendering plants could play a role in the transmission of *Salmonella* because of investigations that affirmed the presence of various serotypes in finished processed meals of animal origin. Similarly, *Salmonella* serotypes were also isolated from protein meals of vegetable origin used in animal feed rations.

Concurrent with the National Academy of Sciences *Salmonella* report in 1969, and the resulting heightened visibility of the subject, scientists of the Bacterial

Diseases Branch of the Center for Disease Control (now Centers for Disease Control and Prevention) in Atlanta, Georgia, reported on the epidemiology of an international outbreak of *Salmonella agona*. The authors cited *S. agona* as a public health problem in the United States, the United Kingdom, the Netherlands, and Israel during 1969 and 1970 (Clark et al., 1973). The investigators stressed that “in each country an initial isolation from Peruvian fish meal was followed by recovery of *S. agona* from domestic animals and subsequently from man. By 1972, *S. agona* was the 8<sup>th</sup> most commonly isolated serotype in the U.S.A.....and the second most common serotype in the U.K.” Investigation of a food borne disease outbreak in the United States associated with this serotype occurred in Paragould, Arkansas, that traced infections between March and May 1972, to 17 residents of a town of 10,500 people. The source of the outbreak was traced to a local restaurant, and then back to a Mississippi poultry farm that fed Peruvian fish meal. The epidemiological data indicated that Peruvian fish meal was the vehicle of introduction of *S. agona* into the United States. This was the first inference that implicated an animal by-product as a potential source of disease transmission to humans.

The outbreak also heightens the complexity involved in the transmission of human salmonellosis and illustrates problems inherent in making finite conclusions (Clark et al., 1973; Franco, 1999). Nonetheless, the Clark report has been used by regulatory authorities to authenticate concerns for the use of rendered animal proteins in feed rations as a potential for disease transmission in animals and man. Unfortunately, the evidence remains anecdotal and nothing more than a hypothesis, because even though the assumption implicated a possible common source, a link between Peruvian fish meal and the Mississippi poultry farm was not substantiated by the isolation of *S. agona* from the feed. The study of the outbreak provided an excellent and provocative discussion of *Salmonella* epidemiology but did not contribute to a conclusive determination of cause and effect.

In September 1990, the FDA Center for Veterinary Medicine (CVM) announced a goal of zero *Salmonella* contamination in animal feed ingredients and finished feed. While zero tolerance remains a contentious issue, the philosophy of a concerted program to limit contamination was a definite message from the CVM, and it was recommended that preventive controls could be realized by applying the principles of HACCP to the manufacturing process (Franco, 1999).

A publication by Crump et al. (2002) stated that contaminated animal feed results in infection or colonization of food animals and this could result in human illness. Unfortunately, the theme of the inferences highlighted the *Salmonella agona* report of Clark and colleagues inappropriately. The 1973 study contained interesting analogies, but lacked validity and affirmation necessary for a causal linkage. In reality, the work of Clark and colleagues was nothing more than a compelling hypothesis worthy of professional consideration.

### **The Rendering Industry’s Food Safety Programs: Responding to Change**

The subject of food safety in the 1980s took on a definite holistic approach, and different themes emerged in the discussions during that period. The emphasis started to examine safety assurances from the farm to the table, or farm to fork, with accompanying suggestions that the country needed new approaches to address the challenges. Consumers and consumer groups began to become more actively involved in the food safety movement as a result of what was perceived to be an increase in the incidence of food borne diseases. The rendering industry, cognizant of the changing dimensions of safety and the emerged new order, began to examine formal options to ensure the safety of the ingredients produced by the industry for farm animal nutrition.

With a goal to be futuristic and proactive, the industry founded APPI in 1984. APPI has become the arm of the industry responsible for the broad realm of biosecurity with specific and well-defined objectives: the administration of a *Salmonella* testing program; the coordination and provision of advice on chemical residues that could adulterate product and the needed testing methodologies; the development of guidelines to assure product integrity, such as HACCP; and the presentation of diversified continuing education programs for the membership.

Especially challenging, and a form of mockery to the industry’s resolve, shortly after APPI had started to function, bovine spongiform encephalopathy (BSE) was diagnosed in 1986 in the United Kingdom. The concurrent epidemiological hypothesis was that meat and bone meal (MBM) of ruminant origin fed to cattle was the likely cause. That theory of causation had gained wide acceptance as a logical assumption based on the investigative findings of government epidemiologists.

This incident still has an impact on the rendering industry to this day, characterized by regulatory changes and perceptions of risk. While the United States did not have any evidence of the disease based on extensive surveillance and risk assessments, the anxiety and concerns initially demonstrated by the U.K. government had direct and indirect inferences globally for all industrialized societies because of the likelihood that the newly defined cattle disease could have human health implications. This all transformed into reality when it was announced in the Spring of 1996, approximately a decade after the first diagnosis of BSE, that there was compelling evidence that the new disease had infected an identified “cluster” of 10 people linked to the consumption of beef products of affected cattle. This new development, with the supporting conviction of the scientific community that BSE could cause disease in humans, added unknown dimensions to the subject that would influence regulatory changes for future years, including those specific to the rendering industry.

During these frenetic times, the industry became hyper-conscious about every conceivable aspect of biosecurity. APPI decided to modify the organization’s by-laws in December 1994 to include safety aspects of animal fats and oils as an extension of the traditional surveillance responsibility. The rapidly changing circumstances of the industry forced APPI to establish a HACCP Council, a

Regulatory Affairs Committee, and a Forward Planning (21<sup>st</sup> Century) Committee to address the diverse issues of the future while introducing innovative measures to conform to the new challenges.

Dioxin remains a major concern in the food safety cycle because of its classification as a carcinogen. Dioxin's potential source as a contaminant was exemplified by a global food safety issue in the Spring-Summer of 1999 after the government of Belgium banned the slaughter of poultry and pork and placed about 1,000 farms that bought and fed dioxin-contaminated feed under quarantine. Preventive controls were examined because of the potential for inadvertent dioxin ingestion by animals. While dioxin contamination is rare, the rendering industry is conscious of its responsibility and has traditionally tested for pesticides (including a dioxin screen) using company laboratories or contract laboratories prior to shipment of fats to feed mills and pet food manufacturers. The industry is equally aware that dioxin is a natural by-product of combustion generated by the elements of life and living—motor vehicles, wood stoves, medical waste incinerators, garbage burning, and even cigarettes. The compound, therefore, is just another toxic component of natural origin that must be considered in context, while recognizing the serious implications for regulatory concerns and the importance of the potential effects to public health especially associated with accidental or malicious contamination.

APPI also established training initiatives during this period to familiarize the industry with the concepts and principles of HACCP in different regions of the country. This expanded the organization's educational efforts beyond the *Salmonella* testing, prevention, and control objectives of the time. APPI published basic HACCP guidelines in 1994 to assist companies considering the implementation of HACCP or HACCP-like programs prior to any formal government requirements. APPI considered an industry voluntary commitment to product safety a logical necessity, since government promoted the attributes of HACCP but did not establish a timeframe for whether HACCP would be the acceptable program for assuring product safety. As of this writing, FDA/CVM is still assessing options for a mandated Feed Safety System.

While these educational innovations were positive and gained much support and encouragement from the membership, APPI's leadership considered it a mandate to keep moving forward and formed an institute charged with the development and oversight of a training program in 1998. Founding the Institute for Continuing Education was to actively address the current challenges to the rendering industry associated with product safety and the prevention and control of hazards with a comprehensive program. A diversified faculty brought academic, industry, regulatory, and research experience to the presentations. The forum provides an interactive environment for participants and opportunities for discussion of the topics. This ambitious program set the stage for acquainting the rendering industry with the concepts of biosecurity to address the current and future needs of the industry. As a result of these introductory educational offerings, many member companies established HACCP or HACCP-like programs within their operations that would benefit them long into the future.

## Research Assessments of the Safety of Animal Protein Ingredients

### *Salmonella*

There has been a substantial amount of data indicating rendered protein meals are free from *Salmonella*, other genera of bacteria, molds, and viruses coming out of the cooker. This can be maintained if the product can be handled to prevent recontamination and the potential for microbial growth after processing. The most pertinent aspect of recontamination is the control of moisture. Ideally, meals contain moisture levels of four to seven percent, so the water activity of protein meal would be too low to support microbial growth. For organisms like *Salmonella* and other pathogens to grow, moisture content of meal must be around 40 percent. Thus, even if contaminated material (*Salmonella*) is accidentally introduced into the cooked product, proliferation will not take place unless the meal is moist (Meat Research Corporation, 1997).

During the period between 1978 and 1989, researchers at the University of Minnesota reported findings of the ten most frequently isolated *Salmonella* in MBM: *S. montevideo*, *S. cerro*, *S. senftenberg*, *S. johannesburg*, *S. arkansas*, *S. infantis*, *S. anatum*, *S. ohio*, *S. oranienburg*, and *S. livingstone* (Franco, 1999). These were compared with the four major serotypes isolated from cattle, representing 64.3 percent of total isolates during July 1992 and June 1993, and none were compatible. A similar comparison of the MBM isolates were made to the four major serotypes of swine during the same period, representing 82.9 percent of the total clinical swine isolates, and there was similarly no compatibility with the MBM isolations. The same was done with clinical isolates of chickens for the same period (July 1992-June 1993), representing 54.9 percent of total isolates, and there was also no compatibility to Minnesota's MBM isolates (Franco, 1999).

An assessment of the isolates found during the 11 year research initiative in Minnesota were compared to findings in Japan and the United Kingdom during the same approximate timeframe, and the only two serotypes isolated from MBM in all three countries were *S. livingstone* and *S. senftenberg*. This becomes an important consideration in the ongoing debate on serotype comparisons. The question is this: Does MBM in feed rations, at inclusion rates varying from three percent to five percent contribute to clinical salmonellosis in livestock and poultry? Existing data do not support the extrapolation that *Salmonella* in MBM is the cause of salmonellosis in food animals. In reality, the major serotypes isolated from MBM throughout the world appear to be relatively innocuous, and do not contribute to clinical salmonellosis in animals, nor are they significant in human food borne illnesses.

Comprehensive research work by Davies and Funk (1999) on *Salmonella* epidemiology and control indicates that while feeds of animal origin tend to receive the most intense scrutiny, often overlooked is the extent to which vegetable protein feed ingredients are contaminated. While the identified *Salmonella* serotypes exceed 2,300, only a few have been linked to clinical manifestations in animals and man, in spite of the acceptance that all feed ingredients may be contaminated with *Salmonella*. Additionally, *Salmonella* organisms are not highly resistant to either

physical or chemical agents, being killed at 55°C in one hour or at 60°C in 15 to 20 minutes (Franco, 1999).

In field trial studies, Troutt and colleagues (2001) demonstrated that samples of raw materials going into the rendering stream from 17 rendering plants in seven mid-western states were highly contaminated with *Salmonella* species, *Listeria monocytogenes*, *Campylobacter jejuni*, and *Clostridium perfringens*, all index-potential food borne pathogens. In another trial, processed protein materials from the expeller were sampled at nine rendering facilities in six mid-western states during winter and summer months. The researchers were unable to isolate any of the same group of index pathogens that were source contaminants in the raw material—showing that the time-temperature rendering process readily inactivated this broad range of potential food borne pathogens of public health relevance.

In an evaluation of the role of contaminated feed in *Salmonella* transmission in swine, Davies (2004) posited that “feed is only one of many potential sources of *Salmonella* introduction to farms, and risk of infection from non-feed sources appears to greatly exceed the risk presented by contaminated feed on modern U.S. swine farms.” These findings have been substantiated by other research workers, both domestically and globally. In extensive longitudinal studies using two modern multiple site production systems, Harris and colleagues (1997) demonstrated an insignificant role of feed in transmitting *Salmonella* to swine. According to work done by Cooke (2002) and Lo Fong Wong (2001), testing of commercial animal feeds in several European countries generally indicates a low level of *Salmonella* contamination (less than one percent), and serovars of greatest concern to transmitting human disease (*S. typhimurium* and *S. enteritidis*) are very rare in feed isolates.

A publication (Franco, 2005a) described a research survey by APPI to determine the pertinence of *Salmonella* population numbers and serovar identity in 197 animal protein meal samples that tested positive over a 12-month period. The *Salmonella* most probable numbers/gram (MPN/g) values ranged from less than 0.03 to 1,100, with a mean MPN/g value of 16.3 and a median MPN/g value of 0.09. The 10 most common serovar isolates in order of occurrence were: *S. senftenberg*, *S. livingstone*, *S. mbandaka*, *C2 Group Salmonella*, *S. havana*, *S. lexington*, *S. agona*, *S. arkansas*, *S. infantis*, and *S. johannesburg*. These top 10 serovars accounted for 48 percent of the serovars isolated. Four serovars associated with food borne illness—*S. typhimurium*, *S. enteritidis*, *S. infantis*, and *S. agona*—accounted for only 7.5 percent of the *Salmonella* isolated.

The isolates of rendered animal protein meals, in general, have historically not been linked to the customary cause of clinical syndromes in animals and man. An evaluation of the 10 most frequently isolated serovars in this study affirms this inference. In both animals and man, three clinically significant isolates serotyped were: *S. enteritidis* (0.5 percent), *S. typhimurium* (0.5 percent), and *S. infantis* (1.0 percent) of the total samples serotyped (Franco, 2005a).

### *Viruses*

Viruses are submicroscopic infectious organisms that are incapable of independent existence but can grow and reproduce when they enter the cell of a host (plant or animal) causing altered metabolism or cell death as they multiply. Since viruses are important transmitters of disease, it was prudent for the rendering industry to assess viral inactivation, even though the logical assumption was that the time and temperature of the rendering process would inactivate all viruses that are normally associated with diseases in domestic animals.

Since the United States slaughters approximately 100 million pigs annually, the Fats and Proteins Research Foundation (FPRF) thought that determinants of the stability of an important viral disease of pigs, pseudorabies virus (PRV), could be used as an ideal prototype and be evaluated for the likely presence in intermediate rendering products and the finished product in the manufacture of MBM.

The research was completed in a series of six experiments at Iowa State University to determine whether PRV could survive the rigorous processing steps of rendering. The experiments varied from a worst-case scenario of swine heavily infected with PRV being rendered, to an end phase of finished product surveillance of MBM for the presence of PRV. The findings showed there was little or no possibility that PRV survived the rigorous processing steps in the production of MBM (Pirtle, 1999).

Using PRV as a disease model for other potential viral pathogens of interest to animal agriculture and the rendering process, the research findings substantiated what has commonly been assumed but never researched—that the time and temperature of the rendering process inactivates viruses readily, and a viral load is unlikely to exist in rendered protein meals to transmit disease to livestock or poultry.

### *Prions*

The diagnosis of BSE was confirmed in the United Kingdom in 1986. It was suggested that MBM produced from sheep infected with scrapie was the source of origin of the newly described disease. Since sheep are known reservoirs of the infectious agent, the prion, it seemed reasonable to assume that BSE was caused by scrapie infection of cattle via contaminated feed (Kimberlin, 1990).

Research by scientists at the USDA Agricultural Research Service in Ames, Iowa, was undertaken to test the hypothesis that scrapie infectivity does not survive the rendering process and is not transmitted orally to cattle through the use of MBM and tallow as feed ingredients. Neonatal calves were fed raw brain or rendered MBM and tallow from sheep infected with scrapie and subsequently observed for a varying period from one to eight years for signs, lesions, or prion protein deposits resembling either scrapie or BSE (Cutlip et al., 2001).

Twenty-four experimental calves were fed MBM at six percent of the ration for 12 months starting at three months of age and tallow at three percent of the ration for 20 months, starting at four months of age. Twelve calves were euthanized one year after the start of the trial, five were euthanized because of leg

and digestive problems five to seven years in the trial, and the other seven were euthanized at the end of eight years. During the feeding regimen, cattle were checked for clinical signs of disease twice daily. Necropsy of all calves were performed by collecting brain and spinal cord samples and fixed in a 10 percent formaldehyde solution for at least three weeks prior to staining and detection of prions using the immunohistochemistry method (Cutlip et al., 1994, Miller et al., 1993).

Experimental calves fed at the maximum amount of MBM and tallow that would normally be consumed by calves at that age did not exhibit any clinical signs during the trial period, nor were lesions present that were compatible with a transmissible spongiform encephalopathy (TSE). Additionally, sections of the spinal cord and brain that were examined did not reveal the presence of prion protein (Cutlip et al., 2001).

It should also be of general interest to all concerned with TSE research that representatives (Pearl of FPRF and Franco of NRA/APPI) of the North American rendering industry visited with government officials in the United Kingdom intent on obtaining BSE infected tissue, even by purchase, and bring those tissues back to the United States for trials that could have provided answers to some of the complex issues linked to BSE. As industry representatives, we felt too dependent on external research findings and wanted to have some research done in North America, especially on inactivation of the prion and transmission studies. This objective was never realized because the U.S. government was in the “abundance of caution” mindset, even though all the tissues would have been turned over to them and subject to whatever controls they deemed necessary.

It is unfortunate that government officials seem to be reluctant to have industry professionals involved in an activity that makes them uncomfortable, in spite of the continuing rhetoric how much we need each other, and that we should collaborate and cooperate with mutual concern for the protection of animal and human health. It is time that this barrier is examined with the hope of establishing a system where the industry, government, consumers, and other interested sectors could truly work together in unison, devoid of old prejudices. The complexity of the prion diseases would provide an opportunity accomplishment together. If this turf guarding continues, we will all lose because disease control, food safety, and public health are everybody’s business.

The rendering industry was especially interactive in the process of collection and submission and the handling of samples from predominantly high-risk animals (including “downers” and animals dead on farms) to assist the government’s BSE surveillance and testing program. This form of response was responsible for the Animal and Plant Health Inspection Service (APHIS) meeting the objectives of testing the high-risk cohorts and provides a perfect example for the need to communicate and collaborate in disease control initiatives. In some sectors of the country, the program would not have accomplished its objectives without the rendering industry’s support.

### Current and Future Industry Initiatives

While the core of APPI's current program remains *Salmonella* testing, biosecurity issues, and training, the organization was convinced that to stay ahead of the entire feed and food safety paradigm, it had to be innovative and forward-looking. The programs were in need of a new vision to conform to the discussions throughout industrialized societies about food product safety. In 2000, this prompted APPI to explore the feasibility of a Code of Practice for the North American rendering industry "to promote the safety of animal proteins and rendered fats for feed use through the establishment of recommended industry programs and an accreditation process." This proposal was carefully studied by a dedicated group who worked diligently over the years considering the options, modifying the "Code" and consulting with diverse sources with an interest in the subject. The initiative was formally approved by the organization's board of directors in October 2004 (APPI, 2004).

The heart of the Code of Practice was to institute a system of process controls to preclude hazards, conceptually similar to HACCP principle, and it would be linked to requirements for accreditation with the following objectives:

- Promote the safety of rendered products.
- Legitimize the Code of Practice.
- Provide credibility to the industries.
- Promote consistency and conformity with accepted industry practices.
- Preserve existing markets and facilitate development of new markets.
- Provide assurance to regulatory agencies.

This is a dedicated commitment by the rendering industry to meet established standards of good manufacturing practices and to assure product safety through a third-party certification process. This sends a clear message that the rendering industry continues to be an active leader in the holistic approach to food safety.

The audit and certification process for the Code of Practice is administered by a third party, the Facility Certification Institute (FCI) of Arlington, Virginia, and is a comprehensive system of inspection requirements conducted by professionals with expertise and knowledge in the field of inspection auditing. The system uses a detailed matrix of operational procedures to be assessed on-site and covers all the salient features expected of a rigorous audit to assure that feed safety guidelines are followed, and the end products manufactured are safe and free of hazards that could likely impact animal or human health.

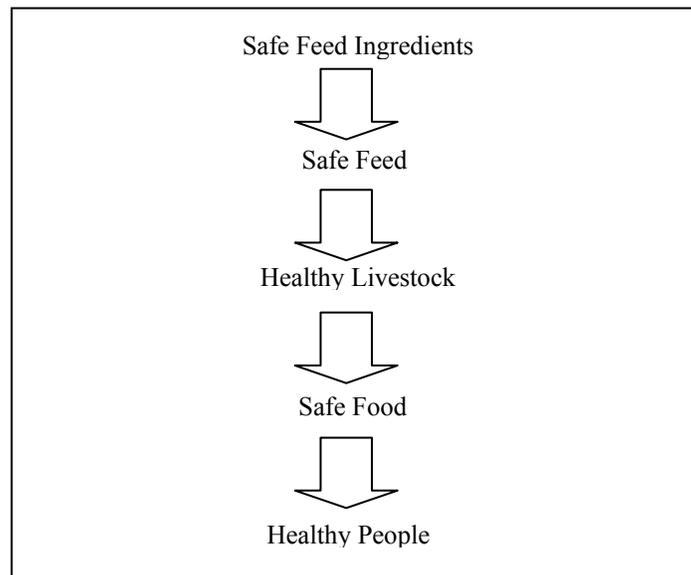
It should be of interest to note that this rendering industry/FCI relationship is expensive and exemplifies the commitment of the industry to the feed/food safety initiatives. This is especially so for multi-plant facilities and large companies. But, the industry has used independent third-party auditors before—to assess compliance with the FDA's BSE feed rule, in spite of the associated cost. The plants were found predominantly in compliance with the rule in the audit program as well as by inspections by FDA and state inspectors.

## Discussion

Rendered animal proteins and fats are an important component of feed rations and are an integral part of the feed manufacturing chain, playing an important and significant role in the entire feed/food production cycle. Animal proteins serve as concentrated sources of protein and amino acids and have been a standard in feed rations for over 100 years in agriculturally advanced societies of the world. Fats and oils have been historically potent feed energy sources and have also been used for years to increase the caloric density of rations. These products have been subjected to safety assessments and evaluations for decades, including regulatory scrutiny through inspection audits, but it remains imperative for the industry to continue to be proactive and transparent in responding to the current challenges to the use of its products. The higher public profile of the rendering industry in this new era of food safety is timely, providing assurances of product safety while addressing the prevailing misconceptions about the industry.

The “equation” that best addresses the safe food chain from the rendering industry’s perspective is safe feed ingredients – safe feed – healthy livestock – safe food – healthy people (Figure 1). This was the crux of the highlighted theme of the World Association of Veterinary Food Hygienists international symposium in 1989, and its applicability is still very germane and appropriate to the holistic food safety movement that has developed in the past two decades. It is fitting that it would be used to define the rendering industry’s role in producing safe feed ingredients leading to the ultimate objectives of safe food and healthy people.

**Figure 1. A Holistic Perspective.**



The presence of different *Salmonella* serovars in feed has been an ongoing element in the feed/food safety debate for decades. What does it mean, and what is the relevance to animal and human health? It is important because *Salmonella* has been used as the indicator organism for determining contamination or adulteration in feed or food by most industrialized societies intent on control. But, while isolates of *Salmonella* in feed ingredients and finished feed have been reported, the animal and human health impacts are only anecdotal inferences. APPI's *Salmonella* reduction program includes a very rigorous testing program for *Salmonella* in animal protein meals. This has been a continuous initiative for over 20 years, and demonstrates a progressive long-term program that used HACCP or similar concepts that enhance ingredient and feed safety. This is in recognition, however, that raw agricultural commodities are all potentially contaminated with microbes, including *Salmonella*, but processes like extrusion, pressure conditioning, high-temperature/short time treatment, and pelleting employed by feed manufacturers serve as additional controls to ensure feed safety (Sreenivas, 1998).

While conceding that *Salmonella* are a resourceful and defiant group of microorganisms capable of parasitizing a broad range of hosts, and that serovars possess distinctive host ranges, unique patterns of virulence, and geographic distribution patterns that complicate both the epidemiology and control, the historical record still supports the safety of feed ingredients and feed (Franco, 1999). The problems associated with asymptomatic carriage of the organism by livestock and poultry and linkages to farm environmental contamination by rodents and other vectors magnify the challenges of the entire *Salmonella* complex beyond the dimensions of feed. This serves as a reminder that while there is an excellent history of feed safety in North America, we must still combine our resources to pursue workable initiatives to counter the different avenues of contamination. End product testing by the rendering industry is simply an adjunct to the other controls recommended by APPI in the quest to assure ingredients of animal origin are safe and are not a hazard to animal or human health.

Research evidence shows that viruses normally linked to disease transmission in animals are readily inactivated by the time and temperature of the rendering process. Nonetheless, the rendering industry is challenged to operate in disease outbreaks caused by viruses normally associated with high mortalities and often reportable by law (e.g. high pathological avian influenza or foot and mouth disease). The ideal approach is for government agencies at the federal, state, or provincial levels to institute collaborative programs to assure that the industry can play a meaningful role to dispose of carcasses in compliance with government policies to assure safe disposal. The industry has played an exemplary role in the past, working with USDA disease control officials to assist the pseudorabies eradication program in swine. The joint effort was a success and could be applicable to other disease control programs if properly planned and coordinated. Since carcass disposal is an important regimen in disease control, government and the rendering industry should establish and maintain a working relationship to accomplish this objective.

From the onset, the rendering industry in North America was responsible and proactive as BSE presented risk implications for the United States and Canada. For example, a representative (Dr. Fred Bisplinghoff) from the rendering industry in 1989, in a joint meeting with government officials and invited members of the agricultural sector, made a public commitment to stop the rendering of all adult sheep material to remove it from the ruminant feed chain. Equally important, this became the industry's policy for years, albeit voluntary, long before any regulatory decision was made for that requirement. Of course, the rendering industry, totally conscious of the happenings, consequences, and uncertainty of what was taking place in the United Kingdom, and not knowing how reactive the U.S. government (and Canada) was going to be, wisely decided that commitment and cooperation in an environment with duress had distinct advantages. With utmost candor, and a source of interim comfort to the industry, was that the cessation of mature sheep rendering was a minimal economic factor overall. But, more than economics was involved; the rendering industry was genuinely concerned because of the uncertainty of the newly defined and complex disease. The industry honestly felt that overtures to assist were logical based on the existing theory that MBM of sheep origin could have caused BSE. [Given the effectiveness of the 1997 feed rule and that the sheep industry has implemented a scrapie eradication program, NRA discontinued the policy against rendering adult sheep material in 2004.]

The leadership of the rendering industry in North America was cognizant of what was taking place nationally and globally relative to the prevalence of BSE in the United Kingdom, and the subsequent spread of the disease to Europe and elsewhere via imported cattle or contaminated MBM from the United Kingdom. Modesty aside, many in the industry became well informed of the nature of the disease and were rightfully convinced that the evolving epidemiology, even though limited to hypotheses, was defined enough to elicit concern. The possibility of disease transmission was affirmed by a causal chain proposed by the World Organization of Animal Health (OIE): the consumption of MBM by cattle; the importation by countries of cattle and MBM that were infected or contaminated with the infectious agent of BSE, and animal feeding practices (Franco, 2005b). The industry readily recognized the disease was associated with an infectious process and unless the United States and Canada were subjected to the factors linked to exposure, the risk to generating the disease was minimal. This assumption was validated by numerous in-house risk assessments performed by APHIS staff epidemiologists and reported as early as 1993 in agency publications.

After the 1996 report of a "cluster" of unusual cases of a newly identified syndrome in humans linked to BSE in the United Kingdom, and defined as variant Creutzfeldt-Jakob disease (v-CJD), the disease dimensions changed rapidly. Additionally, the supporting epidemiology of the linkage influenced the U.K. government to institute change and new challenges emerged as a result. This advent had serious implications for the entire food safety network and heightened the hysteria-like reactions from some sectors of the media and government, and involved industries started to examine the immediate and long-term inferences.

The rendering industry, fully conscious that North America was a minimal risk region, nonetheless started to examine a series of logical options. There were meetings of agricultural coalitions, with all organizations intent on highlighting its biases in spite of the recognized acceptance that BSE risk, assessed from varying and diverse perspectives, was not a problem at this juncture. But, the concerns at the time were more intense than the evolving information, and included concerns about global trade and other political implications. In this changed environment, politics and the media frenzy also played an active role.

A detailing of the circumstances at the time would be impossible, but they took on frenetic dimensions and culminated in the FDA's feed rule of 1997. In the interim, nonetheless, the rendering industry assumed a pragmatic approach, collaborating with FDA, and engaging in joint ventures, including numerous public meetings to receive updates on the direction and interpretation of the rule, aspects of compliance, and training modules to ensure that the rule went through a smooth implementation. Not only did the rendering industry fully support the rule from its inception, but officially committed its full support to the measures during a joint FDA-industry meeting at the agency's headquarters in Rockville, MD.

The rendering industry, regardless of its conviction that BSE would not transmit and amplify in a manner that would impact animal or human health as it did in the United Kingdom, nonetheless, took the rule (21 CFR 589.2000) very seriously. As a result, the industry experienced a 99 percent compliance with the requirements during the agency's inspection audits. The industry, in a cautionary mode, introduced its own third party audit through an APPI contract with an auditing organization. Participation of U.S. rendering plants in the 2001 audit program in was 99.8 percent. The exemplary compliance with the feed rule found by the third-party audits in 2001 was very similar to FDA compliance findings.

Despite the existing minimal to non-existent risk of BSE in the country, FDA, because of the initial 2003 diagnosis of the disease in Washington State in an imported Canadian cow, and the subsequent case 18 months later in a Texas cow (although tested negative for the immunohistochemistry (IHC) test, the alleged "gold standard," this cow was subsequently considered positive after extensive deliberations), published a proposed rule to mitigate the perceived risk in the *Federal Register* on October 5, 2005, with solicitation of comments to the proposal by December 20, 2005. The comments by interested parties are presently being evaluated by the agency for likely consideration of formatting another final rule. As per custom, the rendering industry, through its organizational components, NRA, FPRF, and APPI, submitted well-studied recommendations for the agency's assessment, affirming the rendering industry's continuing efforts to be both responsible and accountable as efforts are sought to prevent any possible transmission and amplification of the infectious agent of BSE from infecting indigenous livestock, and, in the process, protecting human health.

## Conclusion

Prevention of health risks due to food intake is central in food safety policy and demands an integrated approach, defining the role of all stakeholders and their individual responsibilities. Cooperation, collaboration, and communication among the affected parties are prerequisites to success. Food safety must be based on sound and verified science, and continued progress is dependent on the commitment of every level of production to ensure the absence of hazards—from feed ingredient manufacturers that supply feed companies to processors responsible for the safe production of finished products for the table. This is a realization and acceptance of the farm-to-fork analogy promoted today by the industrialized countries of the world using a holistic concept to ensure a safe food supply.

The quality of feed ingredients produced by the rendering industry plays an important role in this complex system because the practices of the industry are a reflection of the food cycle of production. Raw materials processed by the rendering industry are the food residuals that did not enter human food channels, but are recycled through innovative processing technology to produce proteins and fats of animal origin for livestock, poultry, aquaculture, and pets. In reality, we are describing the alpha and omega of the food chain. As a result, the rendering industry is conscious of its responsibility in this program of progressive integration.

The industry concedes that feed ingredient safety is an important and attainable factor in total food safety objectives, thus, the rationale for proactive testing for pathogens and toxins that could influence product integrity. It is also the reason for educational offerings to train the workforce to achieve safety, including the applicability of HACCP, the internationally accepted concept for safety assurance, and the promotion of the APPI Code of Practice, carefully constructed, with an adjunct program of third party certification to demonstrate accountability, and the industry's significant role in sustainable food safety. This assures that safe feed will produce healthy livestock that contributes to safe food, and healthy people.

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