

THE RENDERING INDUSTRY'S BIOSECURITY CONTRIBUTION TO PUBLIC AND ANIMAL HEALTH

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Summary

Animal proteins are a valuable class of ingredients for animal nutritionists to use in feed formulas. The U.S. rendering industry manufactures products that are highly digestible, do not contain antigrowth factors, and are safe to use in livestock, poultry, pet, and aquaculture feeds. Conserved nutrients within rendered products help sustain animal agriculture and protect marginal lands from misuse. The primary outlet that gives economic value to these products is as ingredients in animal feeds. Restricting feed use of rendered products may inadvertently result in severe economic and environmental problems, spread of disease to humans and animals, and a loss of valuable nutrients with consequential health risks for animals, especially young animals and those in intensive production (FAO, 2002).

Rendering is society's best available control technology for addressing the disposal of animal by-products and mortalities. An examination of traits, such as process controls, infrastructure, volume reduction, and timely processing, inherent to the industry, plus regulatory requirements, such as traceability and environmental regulations, validate this statement and make rendering the preferred method for the collection, transportation, and processing of animal by-products and mortalities. The rendering industry is uniquely structured to provide the critical components necessary to handle all raw animal materials safely and responsibly, including those that are considered, by science or perception, to be unsuitable to use in animal feeds. To accomplish this, it may be necessary for the rendering industry to develop a two tier system consisting of dedicated facilities. Feed-grade facilities can process materials for use in animal feed. Disposal facilities can destroy unsuitable raw animal materials after first removing all or a portion of the unrestricted components in order to reduce their total volume.

The U.S. rendering industry, through the National Renderers Association (NRA) has encouraged the Food and Drug Administration (FDA) and Animal and Plant Health Inspection Service (APHIS) to carefully consider the impact new regulations will have upon the viability and survivability of independent renderers that serve a vital role in monitoring, controlling, and eradicating animal diseases in the United States. Agencies must seriously consider creating policy and regulations that will ensure that these perishable animal by-products are disposed of properly. Some level of funding may be required to provide the incentive necessary to maintain a viable infrastructure. Without attention to their disposition, further regulation of specific finished rendered products will exacerbate the improper and illegal disposal of animal by-products and mortalities. In effect, efforts to prevent the spread of bovine spongiform encephalopathy (BSE) in the United States will

inadvertently weaken the rendering industry and pathogenic agents that have been controlled by rendering in the past will become an increasing threat to both animal and human health.

The Rendering Industry

On a global scale, modern efficient rendering facilities are concentrated in countries and regions possessing strong and well-established animal production industries. This is especially true in the United States where the rendering industry is closely integrated with animal and meat production (Figure 1). These industries generate approximately 54 billion pounds per year of animal by-products and on-farm mortalities that are subsequently collected and processed by the rendering industry.

Figure 1. Interrelationships of Rendering with Animal Agriculture.

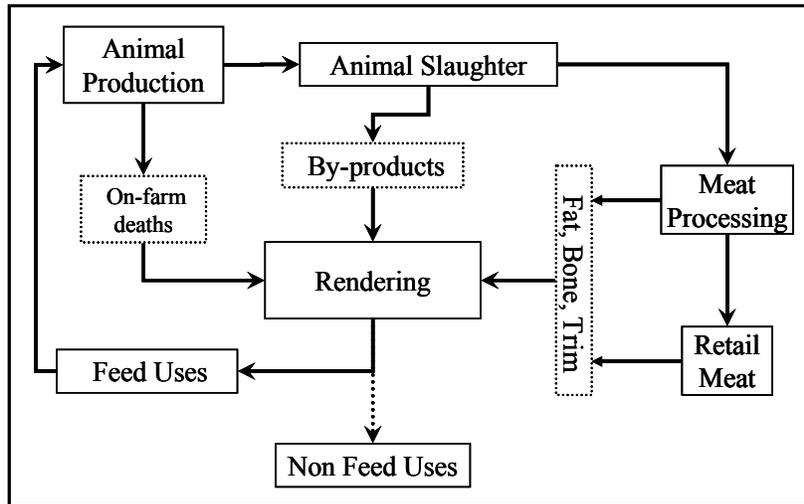


Table 1. Edible and Inedible Portions of Animals, Percent of Live Weight.

	Edible	Inedible
Cattle	51	49
Swine	56	44
Poultry	63	37

Animal by-products are derived directly from the meat processing industry. Between 37 and 49 percent (Table 1), of the live animal weight is removed during slaughter and when the meat is further processed (the inedible portion is even higher for fish). These animal by-products, which include fat trim, meat, viscera, bone, blood, and feathers are also collected and processed by the rendering industry. On-

farm mortalities are an unfortunate fact associated with animal production. Each year, more than 4 million cattle and calves, 7 million pigs, and 100 million chickens and turkeys die and must be disposed of (ERS, 2001; NASS, 2001). The U.S. rendering industry has a long history of efficiently handling, processing, and disposing of animal mortalities, used cooking oils, and by-products from the meat packing and meat processing industries. Historically, these materials have been used to produce high quality fats and proteins for use by the animal feed and oleochemical industries around the world.

Feeding is the Primary Use for Rendered Proteins

Rendering adds nearly \$1 billion in value to the U.S. livestock production sector in the form of proteinaceous feed ingredients alone. This value approaches \$2 billion when contributions from rendered fats and greases are also considered. In addition, rendering removes the need to dispose of by-products in landfills or by other methods that might pose potential environmental risks, health risks, or strain existing space (Sparks, 2001) and/or facilities. The economic value of this service is certainly high, but difficult to measure.

Due to rapid population growth in the world and increased demand for animal products (such as meat, milk, eggs, etc.), the global requirement for vegetable as well as animal protein sources that can be used in animal feed is increasing (FAO, 2002). Animal proteins have traditionally been important sources of proteins and other nutrients for livestock and poultry in the United States and acceptance in Latin America and Asia grew substantially up until December, 2003 when BSE was first reported in the United States. Total domestic use of meat and bone meal (MBM) in animal feeds was approximately 5.7 billion pounds per year (Table 2) before the export markets for MBM closed in late 2003. Changes in domestic and export use of all animal proteins since the year 2000 are discussed in a subsequent chapter of this book.

Table 2. Domestic Use of Animal Proteins by Various Animal Species.^a

Species fed	Meat and Bone Meal		Blood Products	
	Million pounds	Percentage	Million pounds	Percentage
Ruminant animals ^b	567.4	10	158.55	70
Swine	737.6	13	45.3	20
Poultry	2439.6	43	22.65	10
Pet food	1304.9	23	-----	---
Other	624.1	11	-----	---
Total	5673.5	100	226.5	100

^a Sparks, 2001.

^b All meat and bone meal consumed by ruminant animals is from nonruminant origin.

The poultry industry uses the largest percentage of domestic MBM, followed by the pet food industry (Table 2). Significant amounts are used in swine

and ruminant feeds. While there are no restrictions on feeding MBM to poultry and swine, cattle and other ruminant animals are fed only MBM that is strictly of nonruminant origin. A serious disposal problem will result if animal proteins and animal fats are not used in feeds for pigs, poultry, pets, and/or aquaculture (FAO, 2002).

Usage patterns for blood products differ from MBM, as shown in Table 2. Ruminants, especially cattle, are fed most of the blood products, usually as blood meal, produced in the United States. Most usage in the swine industry is for spray-dried products such as plasma proteins.

Continued usage of animal proteins as feed ingredients is largely due to the rendering industry's on-going commitment to improve the nutritional value of these products. For example, new processes and processing technology, improved equipment, and greater understanding of the effects of time, temperature, and processing methods on amino acid availability have resulted in significant improvements in the digestibility of animal proteins. Data published since 1984 demonstrate that the digestibility of essential amino acids, especially lysine, threonine, tryptophan, and methionine, in MBM have improved (Table 3). Better understanding how best to use animal proteins in commercial formulas and improved formulation procedures have also improved nutritional value.

Table 3. Digestibility of Meat and Bone Meal Since 1984.

Amino Acid	1984 ^a	1989 ^b	1990 ^c	1992 ^d	1995 ^e	2001 ^f
Lysine, %	65	70	78	84	94	92
Threonine, %	62	64	72	83	92	89
Tryptophan, %	---	54	65	83	---	86
Methionine, %	82	---	86	85	96	92
Cystine, %	---	---	---	81	77	76

^a Jørgensen et al., 1984.

^c Batterham et al., 1990.

^e Parsons et al., 1997.

^b Knabe et al., 1989.

^d Firman, 1992.

^f Pearl, 2001.

The conservation of nutrients contained in animal by-products helps sustain animal agriculture in the United States by minimizing the need to farm marginal lands or environmentally sensitive areas, as well as by moderating the price of competing nutrient sources like corn and soybean meal.

MBM is an especially strategic feed ingredient since it contains economical sources of both protein and phosphorus. The incorporation of MBM into livestock and poultry diets spares the annual use of 2.6 billion pounds of mined and industrially manufactured feed grade phosphate compounds like dicalcium phosphate and deflourinated phosphate. Loss of animal based phosphorus sources would double the use of mined phosphorus for animal feed supplements. The annual protein contributed by MBM is equivalent to 12.2 billion pounds of 48 percent soybean meal. In 2002, this amount of MBM protein represented over 11 percent of the soy protein produced in the United States. In other words, another

8.4 million acres of soybeans would have been required to produce the same protein equivalent as MBM.

The amount of metabolizable energy contributed by animal fats and MBM is equivalent to more than 474,000 truckloads of corn each year. In 2002, it would have required nearly three million more acres of corn production. The combined number of acres of additional soybeans and corn needed to produce the protein and energy contributed by animal fats and MBM is equal to 33.6 percent of Iowa's farmable land, the leading state in the production of corn and soy in the United States.

Biosecurity

The U.S. rendering industry recognizes its role in ensuring food safety and in protecting human and animal health. The rendering process is an effective method for ensuring biosecurity because processing conditions assure the destruction of pathogenic viruses, bacteria, and other microorganisms. Rendering is the most logical method for collecting and processing animal by-products and mortalities because it has the infrastructure in place to safely and responsibly recycle or dispose of these products, allow traceability, and produce safe, biosecure finished products that comply with all federal and state regulations.

Processing

Unprocessed animal by-products and mortalities contain large numbers of microorganisms, including pathogenic bacteria and viruses. Unless properly processed in a timely manner, these unstable materials provide an excellent environment for disease causing organisms to grow and potentially threaten animal health, human health, and the environment. If allowed to accumulate and decompose without restraint, these tissues would become a substantial biohazard, promoting disease, attracting and harboring rodents, insects, scavengers, and other disease vectors, and attract predatory animals into densely populated areas.

Temperatures of between 240° and 295°F (115° to 146°C) are used in the rendering process, which are more than sufficient to kill bacteria, viruses and many other microorganisms, to produce an aseptic protein product that is free of potential biohazards and environmental threats. Trout et al. (2001) sampled unprocessed animal by-products at 17 different rendering facilities in each of two seasons.

Clostridium perfringens, *Listeria* species, and *Salmonella* species were found in more than 70 percent of the samples taken before processing (Table 4). All samples taken after heat processing were negative for these and other pathogens. These data suggest that rendering is an effective tool for use in controlling pathogenic bacteria.

Table 4. Efficacy of the U.S. Rendering System in the Destruction of Pathogenic Bacteria.^a

Pathogen	Raw Tissue^b	Post Process^b
<i>Clostridium perfringens</i>	71.4 %	0 %
<i>Listeria</i> species	76.2 %	0 %
<i>L. monocytogenes</i>	8.3 %	0 %
<i>Campylobacter</i> species	29.8 %	0 %
<i>C. jejuni</i>	20.0 %	0 %
<i>Salmonella</i> species	84.5 %	0 %

^a Trout et al., 2001. Samples from 17 different facilities taken during the winter and summer.

^b Percent of positive samples found to be for pathogen out of the total samples collected.

The value of the rendering process as a mechanism to control risks from microbial pathogens as well as other hazards was validated in a United Kingdom Department of Health (2001) study (Table 5). Risks of human exposure to biological hazards were found to be negligible when animal mortalities and by-products were processed by rendering, incineration, or funeral pyre. However, incineration and pyres were reported to cause moderate to high exposure to chemical hazards associated with burning. Only materials that had been rendered yielded negligible exposure to both biological and chemical hazards. The agent causing BSE was the only exception and it was found to pose a negligible risk to humans when the solid products from rendering were subsequently incinerated.

Rendering is Regulated

The rendering industry is closely regulated by state and federal agencies, with each routinely inspecting rendering facilities for compliance to applicable regulations and finished product safety tolerances. Officers of the FDA inspect rendering facilities for compliance to BSE related regulations and chemical residue tolerances. APHIS issues export certificates and inspects rendering facilities for compliance to restrictions imposed by the importing country. State feed control officials inspect and test finished products as they enforce quality, adulteration, and feed safety policies. Other state agencies also regulate the rendering industry through the issuance of air and water quality permits and feed and rendering licenses. This inspection system also helps to assure that dead or diseased animals are not illegally diverted for use in human food.

Internal controls are used by the rendering industry to ensure that biosecurity is maintained and that the finished products are safe and in compliance with all state and federal regulations and tolerances. Two types of control procedures that are common among rendering companies are good manufacturing practices (GMPs) and HACCP-like process control (PC) programs.

GMPs are preventative practices that minimize product safety hazards by instituting basic controls or conditions favorable for producing a safe product. A “raw material GMP” would be one example and would provide validation that raw

materials were not exposed to toxic chemicals or metals prior to processing in a rendering facility. GMPs are necessary for development of a PC program.

Table 5. Summary of Potential Health Risks for Various Methods of Handling Animal By- Products. ^{ab}

Disease/Hazardous Agent	Exposure of Humans to Hazards from Each Option				
	Rendering	Incineration	Landfill	Pyre	Burial
<i>Campylobacter, E. Coli, Listeria, Salmonella, Bacillus anthracis, C. botulinum, Leptospira, Mycobacterium tuberculosis var bovis, Yersinia</i>	Very small	Very small	Moderate	Very small	High
<i>Cryptosporidium, Giardia</i>	Very small	Very small	Moderate	Very small	High
<i>Clostridium tetani</i>	Very small	Very small	Moderate	Very small	High
Prions for BSE, scrapie ^c	Moderate	Very small	Moderate	Moderate	High
Methane, CO ₂	Very small	Very small	Moderate	Very small	High
Fuel-specific chemicals, metal salts	Very small	Very small	Very small	High	Very small
Particulates, SO ₂ , NO ₂ , nitrous particles	Very small	Moderate	Very small	High	Very small
PAHs, dioxins	Very small	Moderate	Very small	High	Very small
Disinfectants, detergents	Very small	Very small	Moderate	Moderate	High
Hydrogen sulfide	Very small	Very small	Moderate	Very small	High
Radiation	Very small	Moderate	Very small	Moderate	Moderate

^a Adapted from the United Kingdom Department of Health (2001).

^b Legend: Very small—least exposure of humans to hazards.
 Moderate—intermediate exposure of humans to hazards.
 High—greatest exposure of humans to hazards.

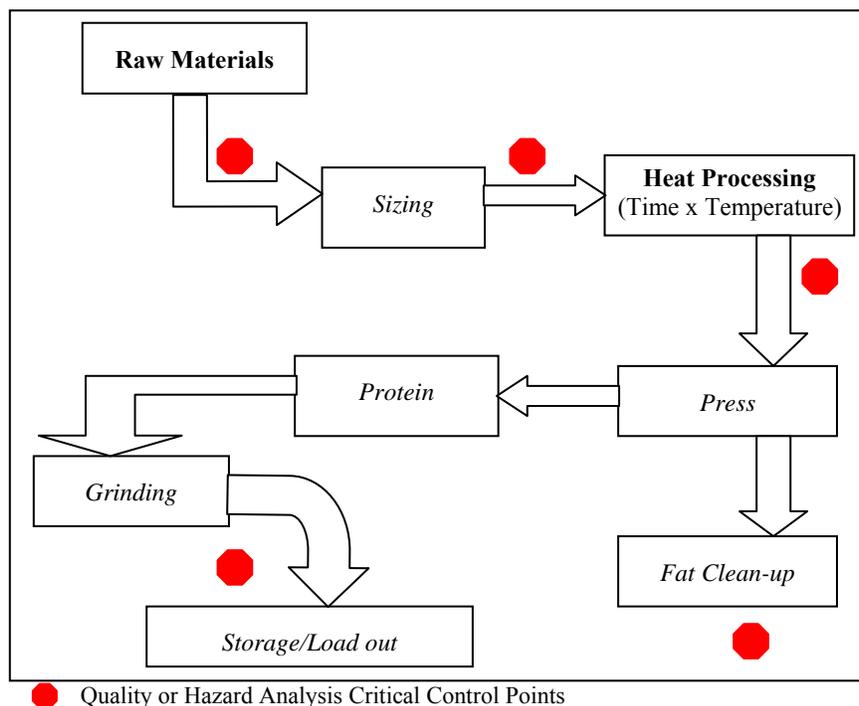
^c Risk of human exposure to TSEs was rated as very small when solid products of rendering were incinerated.

Rendering companies in the United States have adopted voluntary PC programs as an important component of their biosecurity and food safety programs. PC programs require (1) an evaluation of the entire rendering process; (2) identification of potential biological, physical, or chemical hazards; (3) identification of critical points in the process where the hazard(s) can be controlled; and (4) development of procedures to control these processes and ensure the hazard is eliminated or reduced to acceptable levels.

Processing temperature and particle size of the material are two examples of critical control points associated with the destruction of viral and bacterial pathogens present in unprocessed animal by-products and mortalities. These are critical control points because the transfer of heat through materials at temperatures sufficient to kill biological hazards within a given transit time is dependent on the interaction between processing temperature and particle size. Therefore, settings and condition of sizing equipment must be inspected and documented frequently. Process temperatures are also monitored and recorded. If either of these is out of tolerance, the material must be reprocessed with appropriate documentation.

Additional quality assurance (QA) controls may also be included at various points in the process to assure quality of the finished product(s). A generalized PC/QA program for a typical rendering facility is shown in Figure 2.

Figure 2. Production Flow Chart with Critical and Quality Control Points.



The FDA has announced its intention to implement an Animal Feed Safety System by 2007 that will incorporate a risk-based approach to identifying and developing limits for hazardous contaminants within feed, and establish process controls with regulatory oversight to ensure compliance (FDA, 2005). This is consistent with recommendations from the Food and Agriculture Organization (FAO), which called for full traceability and implementation of a code of practice for handling animal by-products and mortalities to ensure safety (FAO, 2002).

Although individual rendering companies have voluntarily implemented their own GMPs and PC programs for years, the industry adopted the APPI Code of Practice in 2004 that formally established minimum industry standards for product safety that include GMPs and PC programs. Participating facilities receive accreditation upon passing an audit conducted by the Facility Certification Institute, a third-party auditing firm.

Rendering Meets APHIS Objectives

The Veterinary Services division of APHIS developed their Strategic and Performance Plan for the 2003 – 2008 fiscal years. Three specific goals were developed. These are presented in Table 6 along with the current impact and benefits contributed by rendering. Processing animal by-products and mortalities through rendering is consistent with each of these goals.

The rendering process provides a means by which the disease cycle can be broken. For typical pathogens, this may be through the rapid destruction of the organism caused by processing at lethal temperatures. For other disease agents, such as the one responsible for causing BSE, the infected animal by-products may first be rendered to reduce infectivity, making the materials safer for handling and storage prior to their disposal. Cohen et al. (2001) reported that batch rendering systems achieved a 3.1 log reduction (1,000-fold) in BSE infectivity, while continuous systems with and without fat recycling reduced infectivity 2.0 log (100-fold) and 1.0 log (10-fold), respectively.

The U.S. government recognized the biosecurity benefits of rendering many years ago. As a result, rendering has been an important component of most animal disease eradication programs in this country. The voluntary pseudorabies virus (PRV) eradication program is the most recent example. PRV cannot survive the rigorous processing steps involved in rendering (Pirtle, 1997). Thus, the depopulation protocol required that euthanized pigs from PRV-infected herds be disposed of through rendering. This was a successful voluntary program, which led to eradication of the disease in the United States by the end of 2004.

Rendering has also become an important component of government surveillance for emerging animal diseases. Renderers provided APHIS nearly one-half of the samples collected during the heightened BSE surveillance initiative from 2004-2006. Recognizing renderers' unique capabilities for collecting farm mortalities and animal by-products, APHIS recently expanded its authority to collect blood and tissue samples at rendering facilities (*Federal Register*: 9 CFR Part 71) in order to enhance their surveillance capabilities.

Table 6. APHIS Goals for FY 2003 – 2008.

Goal	Objective	Rendering’s Role
1	Safeguard the health of animals, plants, and ecosystems in the U.S.	Rendering plays a preventative role by containing and killing disease-causing organisms before they can multiply and spread in the environment. Unprocessed animal by-products that are allowed to accumulate will pose a significant new or emerging threat.
2	Facilitate safe agricultural trade.	Marketability is associated with perceived safety. As animal disease spreads in a country, global markets will close, as the U.S. and Canada experienced after their discoveries of BSE. Renderers participate with APHIS in monitoring and eradicating animal disease in the U.S.
3	Ensure the effective and efficient management of programs to achieve APHIS’ mission.	Dead animals and other animal tissues are concentrated at rendering facilities, which facilitates access for sampling by government agencies.

Source: USDA, 2003.

Timely processing, processing temperatures, and the concentration of animal mortalities and other animal tissues at a finite number of locations provides APHIS with many of the necessary tools needed to prevent disease outbreaks, eradicate diseases, and monitor the health status of animal herds and flocks in the United States. It will be difficult for APHIS to realize their goals if the rendering industry is not utilized to its fullest potential.

Traceability

Except for incineration, which is cost prohibitive and environmentally unsuitable, the alternatives to rendering for the disposal of animal by-products and mortalities do not provide adequate biosecurity. The origin and ultimate disposition of these materials are not traceable when methods other than rendering are used. This is problematic when attempting to prevent, control, or eradicate disease. Only rendering companies are held accountable and required to document and maintain written records suitable for governmental agencies to trace animal by-products back to their source and the finished products forward to their disposal or use. Once the USDA National Animal Identification System is fully functional, renderers’ capabilities will be even more efficient and precise.

Animal by-product traceability was provided for when the FDA implemented the ban on feeding proteins derived from ruminant animals back to cattle and other ruminants (*Federal Register*: 21 CFR § 589.2000; the so called

“FDA feed rule”). This rule required that renderers manufacturing products that contain or may contain protein derived from mammalian tissues intended for use in animal feed take measures to ensure that prohibited materials are not used in feed for ruminants. One of these provisions is to “maintain records sufficient to track the materials throughout their receipt, processing, and distribution and make the copies available for inspection and copying by the FDA.” Compliance to this requirement is verified by periodic inspections by FDA compliance officers or state officials under contract to the FDA. Similarly, the Bioterrorism Act of 2002 contains a “records retention” section (Title III, Part 306) that expands those requirements to include all materials received and shipped by renderers. The requirement is for each step in the production chain to keep track of where materials came from and where they were delivered—“one step forward and one step back.”

Even firms processing materials that are exempt from the 1997 FDA feed rule, such as those derived exclusively from nonruminant animals, must maintain records sufficient to allow traceability. These firms are also subject to inspection by FDA officers and must be able to demonstrate that their products do not contain materials derived from ruminant animals.

Infrastructure

Full-service rendering companies are capable of efficiently transporting and processing large volumes (one million or more pounds per day) of raw animal by-products and mortalities. Rendering, as we know it, was established in the United States more than 100 years ago. Since then, it has developed as a service orientated industry that continually embraces new technology, science, and sound business decisions to improve process efficiency, product safety, finished product quality, and the environment. Even though the rendering industry has undergone significant consolidation during the past 30 years, most areas of the United States continue to be serviced by one or more renderers.

The equipment used by the rendering industry is specialized and not commonly found in other segments of the agricultural industry. In order to safeguard the food supply and prevent the spread of disease and damage to the environment, many states regulate the collection and transportation of unprocessed animal by-products and mortalities and require that only vehicles equipped with leak-proof vessels be used to transport these materials. This is industry-specific equipment and not commonly found on vehicles used by common carriers or on farm equipment. Renderers must also install air scrubbers, thermal-oxidizers, wastewater treatment facilities, and other equipment necessary to meet state air emissions, odor, and water discharge permits for their facilities. Tens of millions of dollars in equipment, monitoring instrumentation, and analytical testing are invested at rendering facilities in order to meet state and federal standards.

Because the rendering industry is committed to the continual improvement in the safety of its products, it has formed organizations to provide technical support and education in quality assurance and feed safety. The Animal Protein Producers Industry (APPI) administers industry-wide programs for biosecurity, PC training, *Salmonella* reduction, continuing education and third-party certification for

compliance to BSE related regulations and APPI Code of Practice accreditation. The Fats and Proteins Research Foundation (FPRF) solicits and funds industry and university research to address pertinent biosecurity and nutrient value issues as well as search for new uses. To focus research on biosecurity issues and develop new uses for rendered products, FPRF entered into an agreement with Clemson University to establish the Animal Co-Products Research and Education Center (ACREC). More about the development and purpose of ACREC is explained in a subsequent chapter of this book.

Volume Reduction

Unprocessed animal by-products contain large amounts of water (Table 7). Heat is used to process these raw materials primarily to remove the moisture and to facilitate fat separation. Removing most of the moisture reduces total volume by more than 60 percent, from 54 billion pounds of raw material to about 11.2 billion pounds of animal proteins and 10.9 billion pounds of rendered fats. Stored properly, these finished products are stable for long periods of time. Dry protein meals provide an unfavorable environment for pathogens to grow because the water activity is below the threshold needed for microbial proliferation.

Table 7. Water, Protein, and Fat Composition of Animal By-Products.

	Protein	Fat	Water
Blood	10	0	90
Fat Trim	5	55	40
Bones	35	10	55
Offal	15	15	70

Timely Processing

Because of the equipment and processing conditions used in modern rendering facilities, bacteria and viruses are rapidly destroyed and not allowed to reproduce and spread. This is critical in order to contain, prevent, or eradicate disease. Alternative methods of disposal do not consistently eliminate pathogens. Incineration does provide for quick pathogen destruction. However, other methods such as burial or composting are based on tissue decomposition, take months to complete the process, and are less effective than rendering.

The U.S. Rendering Industry and BSE

The rendering industry has been actively involved in programs to prevent the spread of BSE in the United States since before 1995, when renderers voluntarily stopped rendering sheep material. This was done to prevent any scrapie-infected material from entering the food chain, especially via feed for ruminant animals.

When the FDA first considered preventative measures in 1996, renderers and cattle producers voluntarily stopped using MBM derived from ruminant animals

in cattle feed. This later became official when the FDA published the feed rule (*Federal Register*: 21 CFR § 589.2000), which prohibited the use of these materials in feeds intended for cattle and other ruminant animals. The rendering industry was actively involved in preparing this rule and fully supported it from its introduction in 1997.

The only MBM permitted for use in ruminant animal feed in the United States is material that comes from plants that slaughter or process only non-ruminant materials. If the raw material cannot be verified to be 100 percent nonruminant origin, then the resulting finished material is prohibited from use in feeds for cattle and other ruminant animals. While PC programs target known hazards that can be eliminated or controlled through the rendering process, they also include in-plant enforcement of policies that apply to the acceptance or rejection of raw material. This provides further assurance that material from suspect cattle (such as those being tested for BSE through the APHIS surveillance program), sheep, and goats are not received and processed for feed.

The FDA feed rule includes requirements that finished products are clearly labeled and records of raw material receipts and finished product sales be kept and made available for inspection by the FDA. This allows the FDA to verify the source of raw materials and verify compliance to the feed rule among feed manufacturers, dealers, distributors, and end users. For renderers who process proteins exempt under the feed rule, safeguards to prevent cross-contamination must be demonstrated in practice and in writing.

The APPI Code of Practice for rendering companies introduced in 2004 includes the requirement that facilities be in compliance with the FDA feed rule. An earlier third-party audit (2001) of the industry for compliance to the FDA feed rule showed 100 percent compliance among participating rendering companies which accounted for nearly all of the industry capacity.

Although two cases of indigenous BSE have been identified in the United States as of this writing, it is extremely unlikely to become established because measures taken by agencies of the U.S. government were and continue to be effective at reducing the spread of BSE (Cohen et al., 2001). As a result, the United States is highly resistant to any amplification of BSE or similar disease. Cohen et al. (2001) considered the FDA feed rule to be one of the most important safeguards because it will prevent amplification of the disease. Hueston (2005) concurred that although small doses of contaminated feed are sufficient for BSE transmission, amplification requires significant recycling within the cattle population. The FAO (2002) reflected agreement with these assessments by recommending that the feeding of ruminant MBM to ruminant animals be prohibited worldwide as an additional safeguard against the further spread of BSE.

The U.S. rendering industry fully supports science-based BSE prevention programs and efforts developed by the FDA, APHIS, and other federal and state governmental agencies. The rendering industry is committed to achieving 100 percent compliance to the FDA feed rule as a keystone for its success.

Challenges

Concern about BSE has been the most serious issue affecting the use of rendered products in the past 10 years. Since the FDA promulgated the feed rule, the value of restricted use (prohibited as feed for ruminant animals) MBM has been discounted an average of \$18.13 per ton, compared to exempt MBM derived only from nonruminant animals (Sparks, 2001).

Table 8. Annual Production of Animal By-Products (Sparks, 2001).

Protein Meal	Million Pounds/Year
Meat and bone meal (MBM)	
Restricted use (banned in feeds for ruminants)	
Pure ruminant origin	2,734.1
Mixed containing ruminant origin material	2,263.1
Total restricted use MBM	4,997.1
Exempt (available for use in ruminant feeds)	
Exempt (pure porcine origin)	1,640.5
Mixed containing only exempt material	14.6
Total exempt MBM	1,655.1
Blood products (all exempt from feed rule)	
Ruminant origin	121.9
Porcine origin	54.8
Mixed	49.8
Total blood products	226.5
Poultry meals (exempt from feed rule)	
Poultry by-product meal (pure)	3,073.5
Feather meal	1,200.0
Total poultry meals	4,273.5

The effects of price discounting and lost markets because of real or perceived consumer concerns have severely impacted the rendering industry. The reason for this impact is best understood by considering the amount of product affected by this regulation (Table 8). Approximately 75 percent (2.5 million tons) of the MBM produced in the United States is totally or partially derived from ruminant animals and cannot be used in feed for cattle or other ruminant animals. Directly, this has had little impact on the rendering industry. Indirectly, compliance issues for feed manufacturers who make both ruminant and nonruminant feeds in the same facility, food safety concerns, media coverage, and marketing campaigns advertising meat from animals fed “animal by-product free” diets have severely impacted the rendering industry. As a result, it has been necessary to pass a portion of the costs associated with rendering on to the generators of animal by-products and mortalities. This has stimulated interest in alternative methods for the disposal of these materials, some of which are legal and some not.

Recent events in North America and proposed rulemaking published by federal agencies within the past two years suggest that additional restrictions on the

type and/or specie of raw animal by-products that can be rendered to produce materials for animal feed are likely. Canada and the United States each confirmed their first cases of BSE in 2003. Soon after each confirmation, each country banned specified risk material (SRM) from human food and cosmetics. Canada and the United States identified similar tissues to be SRM, including the skull, brain, trigeminal ganglia, eyes, spinal cord, and dorsal root ganglia from cattle over 30 months of age, and the distal ileum and tonsils from cattle of all ages.

As of this writing, Canada has confirmed eight cases of BSE and the United States three, two in native born cattle and one (the first case) in a cow imported into the State of Washington from Canada. All of the U.S. cases were born before 1997 when the FDA feed rule went into effect. Four of the Canadian cases, however, were born after 1997 when the Canadian government instituted feed restrictions that were similar to the FDA feed rule. As a result, the Canadian Food Inspection Agency announced regulations banning all SRM (skull, brain, trigeminal ganglia, eyes, tonsils, spinal cord, and dorsal rot ganglia of cattle aged 30 months or older and the distal ileum of cattle of all ages) from all animal feed and for use in fertilizers effective July 12, 2007 (CFIA, 2006).

On October 6, 2005, the FDA proposed to amend the FDA feed rule and prohibit certain cattle origin materials in the food or feed of all animals (proposed rule; *Federal Register*, Vol. 70, No. 193, pp58570-58601). Materials proposed to be banned include (1) the brain and spinal cord from cattle 30 months and older that are inspected and passed for human consumption, (2) the brain and spinal cord from cattle of any age not inspected and passed for human consumption (“dead and downer cattle”), and (3) the entire carcass of dead and downer cattle if the brain and spinal cord have not been removed. In addition, the proposed rule provides that tallow containing more than 0.15 percent insoluble impurities also be banned from all animal food and feed if such tallow is derived from the proposed prohibited materials. As of this writing, the FDA was reviewing comments submitted to the proposed rule and had not taken any further action.

The rendering industry estimated that brain and spinal cord can be successfully removed from only about 54 percent of dead and downer cattle, on average (Informa Economics, 2005). Removal of soft tissues such as these is negatively affected by the rate of carcass decomposition, which accelerates with rising ambient temperature. In areas where daytime temperatures exceed 80°F (27°C) much of the year, such as in the southern and western areas of the United States, the brain and spinal cord may only be successfully removed 10 percent of the time. Under the proposed rule, failure to remove the brain and spinal cord from dead and downer cattle will prevent their use in feed for any animal and create a significant disposal issue. Other potential unintended consequences of the proposed rule include disruptions in the collection of nonruminant mortalities, compliance issues associated with accepting by-products from non-federally inspected facilities that slaughter cattle over 30 months of age, and a reduction of rendering services in some areas of the country. In the proposed rule, the criteria that the FDA will use to determine compliance for the rendering industry were not clearly stated. As a result, renderers may stop processing prohibited materials rather than risk agency

action for non-compliance which would increase the amount of material that must be disposed of by other means.

The United States does not uniformly regulate the disposal of animal by-products and mortalities. Because these materials will have little to no value either in a raw or processed state if they are banned from animal feed, it is unlikely that renderers will be able to collect and process them. As a result, government agencies will lose control over the collection and disposal of SRM as well as any commingled materials. Such a loss of control is in conflict with the intent of BSE safeguards and could contribute to the spread of conventional diseases. While animal fats can be used for fuel or in some industrial applications, animal proteins are currently used almost exclusively as feed ingredients except for a small amount used for fertilizer. Unless large-volume non-feed uses for animal proteins are developed, materials prohibited from animal feed will have no economic value and rendering companies will be unable to collect, transport, process, and dispose of such materials unless their costs can be recovered from the by-product generators.

Figure 3. Improper Dumping of Butchered Deer Remains in a Cornfield.



Rendering is the Optimal Disposal Method

Failure to use the rendering industry for the disposal of animal by-products and mortalities will erode the infrastructure developed to safely handle these materials, resulting in sanitation and environmental challenges in the future (FAO, 2002). These issues may become insurmountable during widespread emergency situations, such as foreign animal disease outbreaks, extended periods of excessive heat, floods, etc. Sparks (2001) estimated that prohibitions against the use of all

animal proteins in animal feeds would reduce the market price paid for cattle (\$15.49/head), pigs (\$3.22/head), broiler chickens (\$0.07/bird), and turkeys (\$0.33/bird). These costs are based on the complete loss of economic value for animal proteins (not animal fats) and assume that rendering services will continue to be available and utilized. They do not address the potential costs associated with either a major reduction or complete loss of rendering services to the livestock, poultry, and meat industries.

Figure 4. Improper Dumping of Trash Bags Filled with Animal Remains.



Without the rendering industry, it would be necessary to discard or dispose of animal by-products and mortalities in community landfills, compost piles, burial sites, incinerators, or, worse, left in illegal dumping places causing a potential public health hazard. Each of these alternative methods has limitations with respect to animal by-product and mortality disposal, with limited space the most obvious.

When unprocessed animal by-products derived from ruminant animals are disposed of by methods other than rendering, their disposition is not regulated and the potential exists for cattle and other ruminant animals to be exposed to materials prohibited by the FDA feed rule. Domestic and wild ruminant animals may have direct exposure to unprocessed raw materials that have been improperly buried, composted, or placed in landfills. As a result, these non-rendering practices could contribute to the amplification of BSE in the United States. For example, spreading composted animal by-products of ruminant animal origin on land used for grazing and/or hay production is permitted under current regulations.

Figure 5. Improperly Managed Dead Calves.



Figure 6. Dead Animals Improperly Disposed of in Manure Pile.



Landfills

While rendering reduces volume, amendments (such as sawdust) must be added (one part amendment to three parts by-product) to compensate for the high moisture content of animal by-products and mortalities when disposing in a landfill. As a result, the total volume would be increased by approximately 25 percent. When properly prepared, the volume of animal by-products and mortalities generated in one year would take up approximately 25 percent of the landfill space in the United States at an estimated cost of \$105 per ton (Sparks, 2001).

Decomposition proceeds slowly and at relatively low temperatures (130° to 150°F) in landfills, which limits pathogen destruction. Landfilling animal by-products contributes to methane gas production and odors, attracts vectors (such as rats, pets, and flies), and creates contact and/or inhalation exposures to humans.

Studies presented in Table 5 indicate that other options are superior to landfills in reducing the risk of exposing humans to potential biological and chemical hazards, including BSE. Further, the potential for increased disease among landfill workers and the transfer of pathogens to off-site locations may be increased when landfills are used for large animal disposal (Gerba, 2002). For these reasons, disposing of cattle carcasses in landfills is prohibited in California and possibly other states.

Composting

Composting is dependent on controlled microbial fermentation to decompose animal by-products and mortalities. Moreover, composting has limited large scale application because large amounts of carbonaceous materials are needed in order to balance the high nitrogen and moisture content in animal by-products and mortalities. Using pork industry guidelines for composting (Glanville, 2001), which consider blending and pile separation issues, approximately one trillion cubic feet of space (800 billion bushels) would be needed to compost the 54 billion pounds of animal by-products that are rendered each year. This is equivalent to the space needed to store all of the corn produced in the United States for the past 100 years. In addition, the spreading of composted animal by-products and mortalities of bovine origin on land used for grazing or feed production is inconsistent with the intent of the FDA feed rule and other federal programs to prevent the spread of BSE in the United States. Widespread composting would dilute the integrity of the FDA feed rule and make all existing risk assessment models (Cohen et al., 2001) invalid. Some states recognize the potential for environmental contamination when cattle carcasses and tissues are composted and prohibit such practices under state statute. California is one such state.

Effective composting is difficult to manage and, depending on the system used, could result in odors and failure to kill pathogens (Franco, 2002). The heat produced during composting (120° to 158°F) will kill most eggs of parasites and vegetative bacteria within four to eight inches of the surface, but are not sufficient to eliminate heat-resistant and spore-forming bacteria such as *Clostridium perfringens*. However, if compost piles are not properly turned, pathogen destruction cannot be assured. Independent renderers are in a unique position to

monitor the emergence and operation of alternative disposal methods because of their proximity to areas where livestock are produced. The rendering industry has observed and clearly documented failed and inadequate attempts at composting.

Burial

Burial is not a viable option in many states because of population density and/or the potential for ground and surface water contamination. If not done properly, burial can also create some of the same potential risks from pathogens that landfilling and composting do. Shown in Table 5, human exposure to all biological and some chemical (such as hydrogen sulfide) hazards is high when animal by-products and mortalities are buried (U.K. Department of Health, 2001). Space is also a major limiting factor for the disposal of large quantities of animal by-products and mortalities.

Incineration

Incineration can be cost prohibitive because of the fossil fuel needed to destroy animal by-products and mortalities. Significant amounts of ash residue are left after these materials are incinerated, causing a disposal issue. Incineration is an efficacious means of minimizing human exposure to pathogenic microorganisms. However, incinerators generate potentially hazardous chemicals, such as dioxins and particulates (Table 5). Further, as in the European Union, incineration capacity in the United States is inadequate to dispose of all of the animal by-products and mortalities produced annually (Goldstein and Madtes, 2001). There are also many regulatory challenges to permitting new incinerators.

Abandoned—Dumped

Due to its low cost and low risk of prosecution, the abandonment of animal carcasses or illegal dumping of infectious waste animal tissues is a tempting alternative disposal option (Figures 3-9). The potential to attract scavengers, contaminate ground and surface water supplies, and spread potential animal and human pathogens makes this a particularly harmful practice. Independent renderers are in a unique position to observe and document this growing trend. Employees traveling their daily collection routes observe these materials abandoned in fields or dumped in ravines or waterways. State solid waste regulatory agencies simply do not have the resources to monitor and enforce prohibitions against such activities and admit their awareness is limited to when they receive complaints.

Future Role of Rendering

Further increases in the volume of animal by-products that cannot be used in animal feed because of government regulations or consumer pressures will increase the likelihood of problems due to poor sanitation, spread of disease, and/or damage to the environment. Therefore, a need for a two-tier rendering system is emerging to address these issues and concerns. Under such a system, the risk associated with raw animal by-products and mortalities could be assessed and the

materials directed to facilities dedicated to either manufacture products that can be used in feed or products for non-feed applications. Absent any viable non-feed uses, materials that can not be used in feed would be prepared for disposal.

In order for a disposal segment of the industry to evolve, disposal rendering must be sustainable. The lack of regulations requiring all options used to collect, process, and dispose of animal by-products and mortalities to meet uniform standards for biosecurity, traceability, and environmental protection is the only reason that disposal rendering has not already developed as a viable mechanism for handling these materials. Without such standards, the United States will not have the infrastructure to handle a ban on the use of SRM in feed, even if only a portion of SRM is banned as the FDA proposed. Disposal problems that threaten animal health, human health, and the environment will continue to increase as the volumes of raw animal by-products and mortalities that cannot be used in feed increase.

Figure 7. Illegal Dumping Pollutes Water.



Figure 8. Illegal Dumping of Dead Animals in Waterway.



Figure 9. Rotting Swine Carcasses, Improperly Disposed.



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