Introduction

While practices and trends can affect human diets, much of the global population consumes meat. A meat diet generates quite a bit of material considered inedible and unusable. But by creating usable products from what the public might consider “waste”, the rendering industry protects the planet from diseases and health risks by providing sustainable solutions for these organic materials. Following all state, local and federal regulations and operating within a rigorous, industry-directed infrastructure, renderers prevent the spread of pathogens that take residence in improperly handled organic material. This Greenpaper will examine the rendering industry’s biosecurity measures and industry standards that ensure the safety of their facilities and products and help sustain and improve planet, people and animal health.
As the world’s population continues to grow, the demand for meat proteins in diets also continues to rise. This presents challenges that are unique to growing cattle, pigs and poultry for human consumption. Fortunately, the rendering industry meets these challenges with effective and efficient solutions and plays a major role in safeguarding our food supply.

When left alone to decompose naturally, unprocessed meat by-products and animal mortalities present a critical threat to human, animal and planet health. These decomposing materials serve as the perfect breeding ground for pathogenic bacteria and viruses, such as Salmonella and E. coli, that could result in human and animal illness.

The rendering process assures the destruction of pathogenic micro-organisms, preventing their spread. Rendering has proven to be the most efficient and effective way to handle animal by-products and mortalities, while also providing full traceability and producing safe, bio-secure ingredients that comply with all federal and state regulations.

Biosecure Systems in the Food Chain

A complete biosecurity program is critical to maintaining a safe and secure food chain.

**Biosecurity involves any management practice or systematic application that prevents the transmission of pathogens from one living organism to another.**

In food chains, microbial forms of organic life, such as bacteria, viruses, parasites and protozoa, are the primary causes of disease in humans, animals and plants.

As foodborne pathogens receive more public attention, the interest in biosecure operations has surged for all industries. Though specific industries have different needs and practices, the principles and practices that address biosecurity are similarly structured. All identify the various risks and address them to minimize or help prevent biosecurity threats to human and animal health and welfare.
Investing in Modern Facilities and Equipment

Over the last century, the rendering industry has evolved from simple cookers and boilers into a sophisticated logistical operation with multiple layers of controls that ensure not only the safety of the products produced, but also of the raw material supply chain. While the steps of the rendering process have stayed largely the same over the years (cook the material, kill the pathogens, extract the water, and separate the fats from proteins), the rendering process has evolved in sophistication to help prevent the spread of disease and avoid damage to the environment.

Renderers like Darling Ingredients invest time, talent and money to develop new, efficient equipment that will:

- Reduce the risk of personal injury or environmental harm
- Avoid contamination of product and protect the supply chain
- Build in safeguards and control points throughout the operational process
- Reduce the resources needed for operations with modern, automated logistics
- Monitor and prevent the release of odors or harmful emissions

From the transport of the animal by-products to the processing of fats and proteins, renderers use a variety of specialized equipment that can only be found within their industry. For example, the rendering industry is one of the few industries required by state and local agencies to equip transportation vehicles with leak-proof vessels. This precaution is to maintain biosecurity and prevent infectious disease and environmental damage during the transporting of unprocessed animal by-product from:

- Supermarkets
- Meat processors
- Agricultural operations
- Foodservice businesses

Rendering companies spend millions of dollars on equipment, analytical labs and monitoring instrumentation in order to meet federal, state and local standards and obtain operating permits for each rendering facility.
Biosecurity Elements in the Rendering Process

Processing animal by-products requires temperatures hot enough to lethally impact specific micro-organisms. In practice, this results in the instantaneous kill of pathogens, which are destroyed at lower temperatures than rendering’s normal operating temperatures that are used to separate fats from the solids.

Though the temperature treatment of rendering is a key asset to its overall biosecure operation, it only provides the framework for a complete and structured program. All biosecurity programs must be well documented, implemented and validated for compliance. A comprehensive, written plan of control must exist from the time raw materials are acquired and transported to the rendering facility until the finished ingredients are delivered to food, feed, pharma or fuel manufacturers.

As an industry, renderers are committed to adhering to these basic requirements. Principles similar to Hazard Analysis Critical Control Point (HACCP) plans were voluntarily adopted by the industry in the late 1990’s to ensure that consumers receive safe products and that safety controls are used industry-wide. Since then, renderers follow stringent regulations set by various industry associations or government organizations.

• In 2004, the industry developed their own Rendering Code of Practice (COP) program under the Animal Protein

Producers Industry (APPI), which evaluates and recommends feed safety practices for rendering facilities⁴.

• In 2011, the Food and Drug Administration passed the Food Safety Modernization Act (FSMA), moving the industry from HACCP-level precautions to the higher-standard Hazard Analysis and Risk-Based Preventive Controls (HARPC) principles⁵.

• Additionally, all of Darling’s facilities follow stringent standards of operation, such as APPI’s Safe Feed/Safe Food program and other third-party standards that certify the fundamental applications that demonstrate compliance with FSMA requirements⁶.

By the start of 2019, the rendering industry had certified 111 facilities in the U.S. ... 58 of them Darling plants, with 6 more due to be certified in 2019.

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FSMA controls are categorized into two major types: prerequisite programs or Current Good Manufacturing Practices (CGMPs) and Food Safety Plans, which may include Preventive Controls (PC).

CGMPs are preventative practices that use basic controls and conditions to produce safe products. For example, a “raw material CGMP” is a control that prevents raw materials from being exposed to or contaminated by outside sources prior to its entrance into a rendering facility.

CGMPs are the first necessary step in developing Food Safety Plans, which are programs that require:

- Continual evaluation of the rendering process
- Identification of potential chemical, physical or biological hazards
- Identification of critical points (such as temperature and particle size)
- Development of procedures to control processes and reduce potential threats

These controls align with the Food and Agriculture Organization’s call for full traceability and the implementation of a code of practice for the handling of animal by-product and mortality to ensure safety. The Food and Agriculture Organization (FAO) is an international group within the United Nations, dedicated to a safe food supply for our growing world population.
2. Biosecure Rendering Operations
Assure the Destruction of Pathogens

As the world’s population continues to grow, unprocessed animal by-products represent a growing threat to environmental, human and animal health. If allowed to decompose naturally, these materials can breed pathogens that can develop into disease or attract rodents, insects and scavengers. To avoid this, animal by-products must be collected and processed in a timely manner.

Disposal options may vary by animal species, but the most common methods of handling animal mortalities or meat by-products are:

- Landfills and Burial
- Incineration
- Anaerobic digestion
- Composting
- Rendering

While there is certainly a time and need for each of these methods, organic materials, such as animal by-products, require special attention that some disposal methods can’t always provide. In addition to being largely inefficient and unsustainable, these alternative methods lack the degree of regulatory controls placed on the rendering industry.

They also fail to put the material to its best use, i.e., repurposing it into usable products.

Inefficiency of Alternative Disposal Methods

The basic rendering process for animal by-products uses high temperatures (typically between 240-295°F or 115-146°C) that destroy harmful pathogens and microorganisms within the first 5 minutes of processing. This, along with other controls, results in aseptic proteins and fats free from disease that can be safely marketed.

Not all the alternative methods to rendering are capable of destroying pathogens, and in some cases encourage their proliferation. Other methods can kill off bacteria and viruses, but require more time and extended monitoring to ensure all pathogens are destroyed, placing it below rendering in terms of efficiency of process.

A brief comparison of these methods follow. Additional information on the disposal options for animal carcasses or meat by-products can be read in the other Greenpapers in our Gatekeeper series.

The North American Renderers Association promotes a “Best Use” approach in dealing with surplus food. Using the Food Recovery Hierarchy developed by the Environmental Protection Agency, the rendering industry identifies its place among the most efficient and preferred ways of handling food waste, asking “What is the material’s best use?”
A rendering plant captures & repurposes more carbon than it releases, compared to landfills with ZERO reuse, and composting where 96% of carbon is emitted as a GHG.

For example, anaerobic digestion and composting follow state and local air emissions, wastewater discharge, and solid waste regulations. However, their directives do not specifically address animal carcasses or by-products which threaten the spread of pathogens.

Industrial composting can reach temperatures capable of killing pathogens, but requires resources such as time and extended monitoring to ensure they are destroyed.

Composting and burial rely on natural decomposition to break down tissue over time, leaving a large window of opportunity for environmental, human and animal exposure to bacteria and disease. If not closely monitored and contained, the decomposition of these carbon-based materials can also emit harmful greenhouse gases, an environmental hazard that is avoided with rendering.

And while the temperatures used to incinerate by-products are high enough to decontaminate the material, the cost of running the incinerators greatly outweighs the benefit of the quick clean-up.

**Rendering is the Safest and Most Effective Option for the Destruction of Pathogens**

Pathogens are common in raw animal by-products. If not destroyed, they pose a threat to environmental health and the safety of animals and humans.

<table>
<thead>
<tr>
<th>Biological Hazards: Bacterial Pathogens</th>
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<tbody>
<tr>
<td><strong>Name</strong></td>
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<tr>
<td>---------------------------------------</td>
</tr>
<tr>
<td>Clostridium perfringens</td>
</tr>
<tr>
<td>Listeria species</td>
</tr>
<tr>
<td>Lysteria monocytogenes</td>
</tr>
<tr>
<td>Campylobacter species</td>
</tr>
<tr>
<td>Campylobacter jejuni</td>
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<tr>
<td>Salmonella species</td>
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The chart above lists the pathogens found in the tissue of unprocessed animal by-products when tested at 17 of Darling’s rendering facilities (Before), and the presence of the same pathogens found when tested After processing. The pathogens were undetectable in the cooked proteins. (Trout et al. 2001 FPRF)
Avoiding Cross Contamination

A critical step in the rendering process is to limit cross contamination of the animal by-products brought into facilities for processing with the products produced after processing. This control reduces opportunities for the contamination of feed and food ingredients.

Federal regulations and biosecurity safeguards established independently by each renderer dictate operational practices. For example:

- Diseased animals are prohibited from entering the rendering raw material processing stream
- Certain organs and tissues from cattle of identified ages are prohibited from being processed into animal feed ingredients (in compliance with regulations to prevent bovine spongiform encephalopathy (BSE))
- Meat recalled from retailers, untraceable raw material, or by-products contaminated with chemicals, must be processed separately from any material intended to be used in animal feed
- Some facilities are dedicated to processing only the by-products generated from a single species; such as poultry-only or beef-only processing plants; this ensures ruminant animals are not consuming ruminant material, and also facilitates requests from customers for species-specific protein ingredients

Following federal regulations and developing, implementing, and monitoring biosecurity process controls are among the basic components for a biosecurity program in the rendering industry. Compliance with these procedures and safeguards prevent the spread of transmissible spongiform encephalopathy (TSE) diseases such as BSE in cattle.

“My grandfather raised beef cattle when I was growing up. He lived in an area where he didn’t have the option of deadstock removal by a rendering service whenever one of his cattle died. The best stewardship practice he could make at that time was to bury the deceased animal, not fully knowing the impact his actions may have on soil and groundwater contamination. Nevertheless, he wanted to protect his family and his other livestock from any potential health risks the dead animal might pose. Some of the neighboring farmers would simply allow their dead cattle to decompose where they lay or drag the carcasses off into the woods where birds and varmints would spread potentially diseased animal waste from farm to farm. Rendering would have been a much better alternative for disposing of the cattle carcasses, protecting the environment and the health of both humans and livestock.”

-Kerry Courchaine, Director of Technical Services, Darling Ingredients
The rendering industry works alongside federal- and state-level agencies to practice and produce quality outputs in a safe, environmentally-friendly fashion. Rendering facilities follow an array of regulatory codes enforced by the rendering industry itself and related associations, including the:

- Environmental Protection Agency (EPA)
- Food and Drug Administration (FDA)
- U.S. Department of Agriculture (USDA)
- Occupational Safety and Health Administration (OSHA)

The FDA is an agency involved with the regulation of animal feed and food for human consumption. This agency places an emphasis on identifying and developing limits for hazardous contaminants within feed and developing process controls with audited oversight to ensure compliance with regulations.

The FDA recently enacted the Food Safety Modernization Act (FSMA). This legislation put forth seven major rules aimed to help regulate the production of rendered ingredients used for animal and human goods. This new system transformed the previous system of reacting to food safety crises to a culture of prevention and education. It focuses on training employees on personal hygiene and food safety principles, educating suppliers on safeguarding the raw material stream, and informing the industry’s customers on quality and safety standards to expect in the ingredients they purchase.

The United States Department of Agriculture (USDA) plays a role in regulating dedicated edible rendering facilities (producing ingredients used in human food, such as gelatin, collagens, meat binders and texturizers) and has a tangential regulatory role over material intended for animal feed.

The USDA role is seen during periods of meat recalls, when contaminated meat is deemed inedible for human consumption because of the presence of microbial pathogens. These recalls are often handled by the rendering industry, where the high temperature of the rendering process decontaminates the material and stops the spread of the pathogen. Once renderers pick up recalled meat in dedicated, raw-material service vehicles, the USDA follows the process to ensure that the contaminated product does not re-enter the food chain as either human or animal food.

Rendering plants are also regulated by state-level environmental agencies, the Environmental Protection Agency (EPA), and the Occupational Safety and Health Administration (OSHA). The EPA ensures that all processes affecting the air and water follow environmentally considerate practices. And by regulating animal by-products, OSHA takes on a role that focuses on both the safety of employees and consumers.
Today, biosecurity programs in the rendering industry address numerous processing and procedural controls. These controls are designed to minimize potential food safety hazards and to prevent accidental or intentional contamination of rendered products.

At the operational level, renderers have flexibility in how they set their own criteria for conforming to regulations and best practices. Darling Ingredients, the largest independent renderer across the globe, adheres to regulations and serves as a model of excellence for others in the industry. Darling’s components of a biosecurity program include:

- Registration of facilities with the FDA
- Implementing facility security and access measures, such as property fencing and employee I.D. cards
- Placing control plans in place for animal disease outbreaks
- Developing supplier approval programs
- Monitoring finished products for quality and safety
- Implementing control points to prevent or mitigate potential raw material and finished product hazards

**Internal and Third-Party Audits Monitor Darling’s Safety Controls**

Transparency is maintained through training, record keeping, auditing, recalls, the establishment of non-compliance standards, and corrective action validation. Well-trained employees are critical to the oversight and implementation of these programs. Regular audits of Darling’s biosecurity processes are conducted by both qualified internal staff and independent third-parties, and have become one of the critical requirements to monitor compliance and success.

Third-party audits most common to the U.S. rendering industry align with:

- The APPI Code of Practice (COP)
- AFIA Safe Feed/Safe Food (SF/SF)
- Hazard Analysis Critical Control Point (HACCP) plans
- Global Food Safety Institute (GFSI) accreditation or benchmarking
FSMA, signed into law on January 4, 2011, grants the FDA new authorities, including a mandate that requires science-based preventative controls that affect the entire food supply chain, including:

- Inspection
- Compliance
- Response to hazards
- Recall requirements

The importance of a clearly-defined biosecurity program and the need for internal and external compliance audits is further reinforced under FSMA.

PRODUCT SAFETY

There are unique challenges to produce sufficient meat-based fats and proteins to satisfy the growing global food and feed demand. Fortunately, the rendering industry plays a major role in safeguarding this food supply, meeting these challenges with effective and efficient solutions.

As stated earlier in this paper, Darling’s commitment to producing ingredients of the highest safety and quality standards is central to Darling Ingredients’ growth and reputation. This is why we have developed comprehensive programs to monitor and test both the raw and the finished product at company and third-party laboratories.

Rendering provides full traceability and produces safe, bio-secure ingredients that comply with all federal and state regulations.

CONCLUSION

Rendering has proven to be the most efficient and effective way to handle animal by-products and mortalities. While maintaining public and animal health and well-being, rendering simultaneously creates sustainable products for consumers across numerous industries. By using a carefully planned and controlled infrastructure, following local and federal guidelines, and processing animal by-products and carcasses in a timely and efficient manner, the rendering industry protects the planet’s environment and living inhabitants by providing the most effective and sustainable method for handling the discarded remnants of a meat-based diet.
REFERENCES


7. FDA, BSE Feed Ban Enhancement Q&A. https://www.fda.gov/animal-veterinary/bovine-spongiform-encephalopathy/feed-ban-enhancement-implementation-questions-and-answers


Other greenpapers in our Gatekeeper of the Food Chain series take closer looks at the environmental protection role of the rendering industry; how the industry handles select food waste and repurposes it to its best use; and how Darling Ingredients has been a pioneer and innovator for the rendering’s industry growth and critical position in the world today. The Gatekeeper series can be viewed at www.darlingii.com/OurCompany/Sustainability as they are published.