QUALITY ASSURANCE IN MANUFACTURING RENDERED PRODUCTS

"A SUPPLIERS PERSPECTIVE"

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C. Ross Hamilton, Ph.D.
VP Government Affairs, Technology & Biosecurity
Darling International Inc.

Acknowledgement

- Tom Dobbs, Director Quality Assurance for Darling International Inc., has spent his career in Quality Assurance in the pet food and rendering industries. Tom prepared the bulk of this presentation, but was unable to be present.

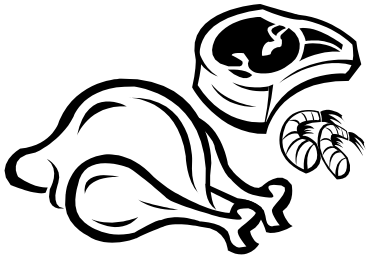
Key Topics for Discussion

- *Providing Safe, Quality Ingredients to Customers for use in Pet Food and Animal Feed.*

- *Raw material considerations in preventing hazards in front of the process*
- *Rendering Plant Biosecurity for prevention of intentional and accidental adulteration*

Raw Materials

- Slaughtered Byproducts (cattle, poultry, pork, sheep, deer)
- Fat and Bone Scrap (grocery stores)
- Processing Waste (lockers, meat shops)
- Meats beyond sale-by date (grocery stores; food processors)
- Recovered cooking oil (restaurants)
- Mortalities at certain facilities (farms, slaughter plants, diagnostic labs)



What is available to the rendering industry to recycle?

Wastes generated by the meat and food industries in US.

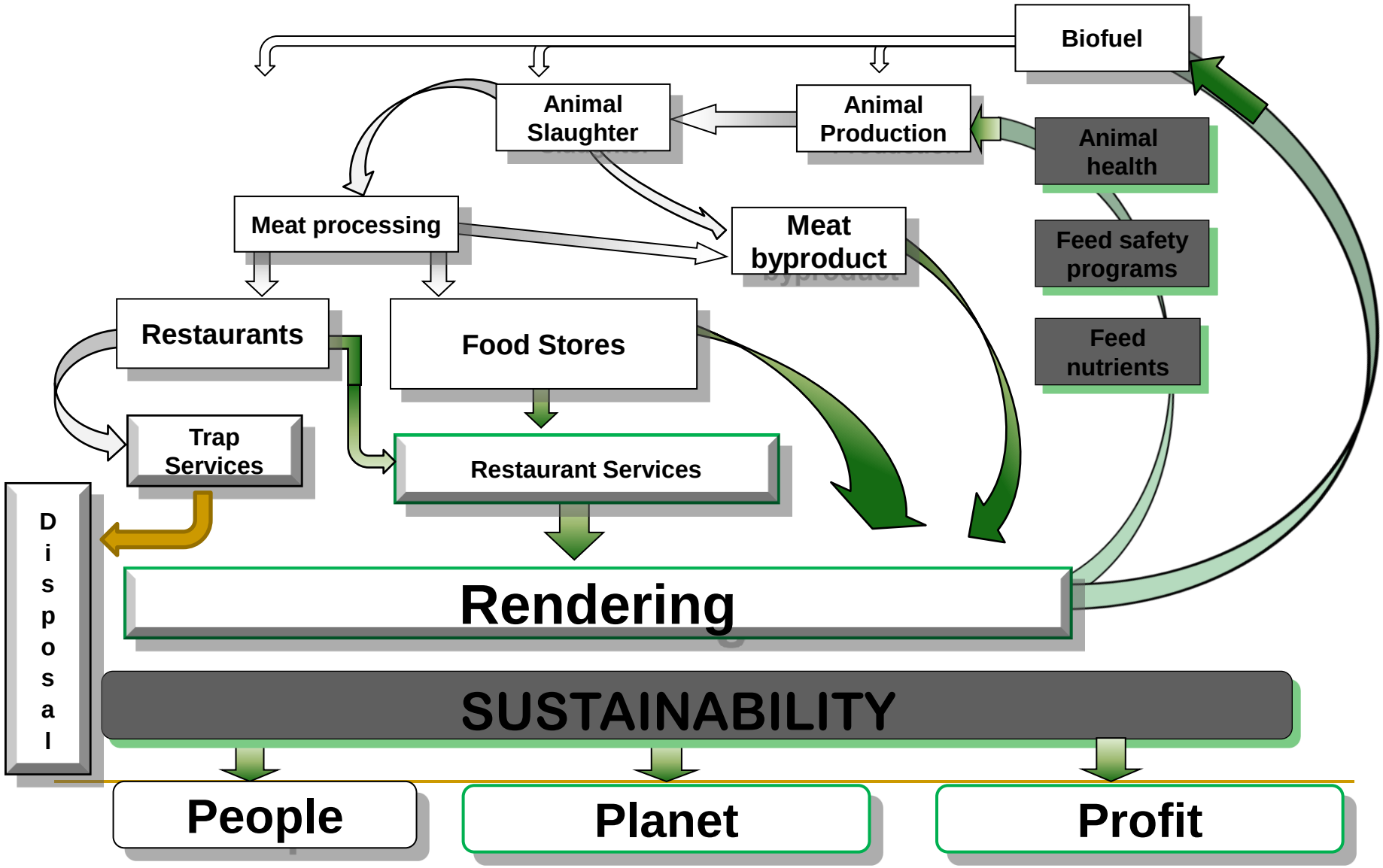
Source	Amount (million pounds)
On-farm and pre-slaughter	3,702.4
Inedible byproducts removed at slaughter	39,047.6
Downstream	
Fat, bone and trim from processing	23,850.7
Expired meat from retail stores	3,960.4
Used cooking (frying) oil	5,629.4
Total	76,190.2

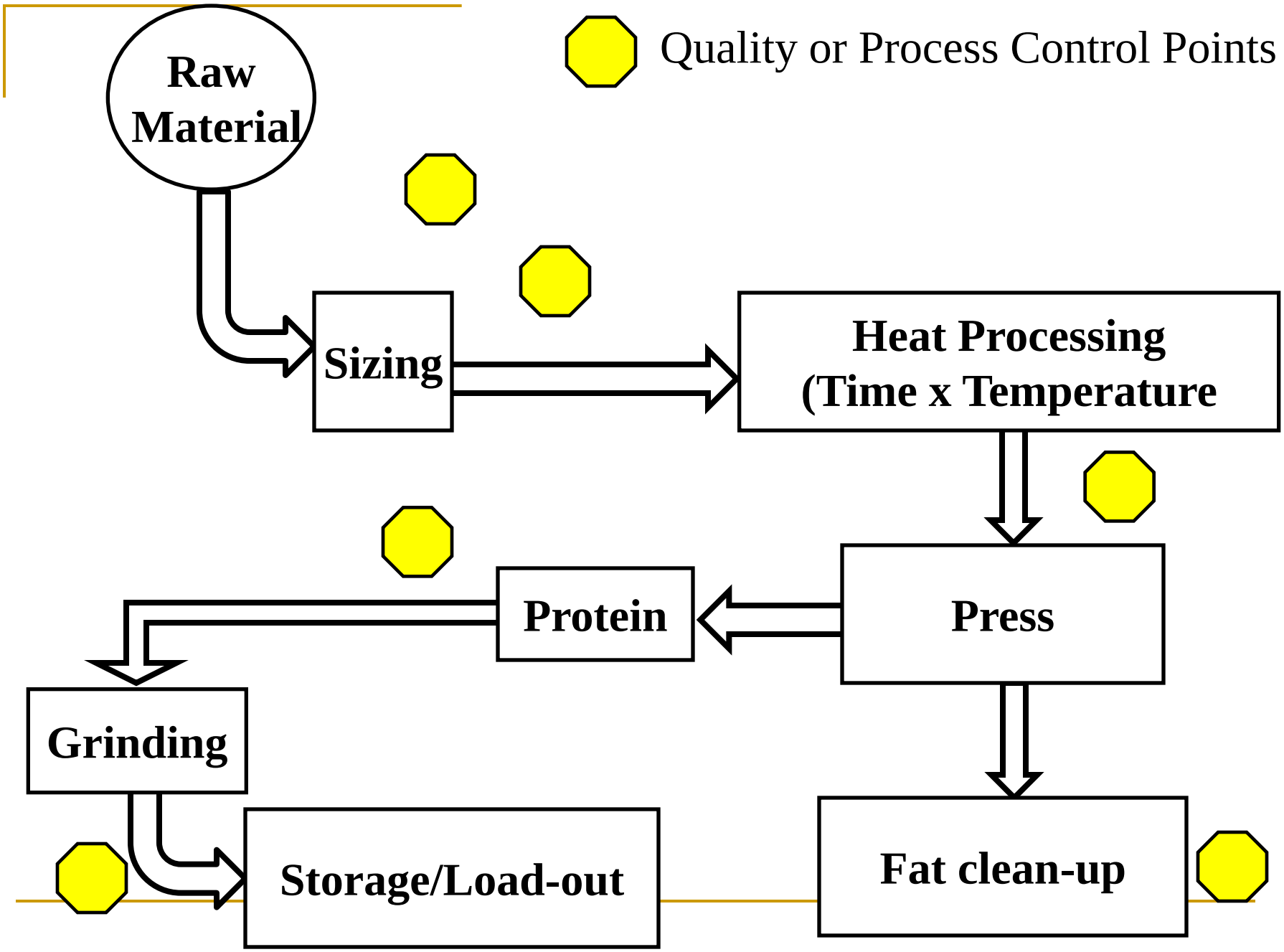
What does rendering do?

- ***Kills pathogenic organisms***
- ***Protects (sustains) the environment***
- ***Recycles carbon***
- ***Recycles energy***
- ***Provides control, verification and traceability that condemned or expired meat products are not re-used as human food.***

The industry does all of this within hours of receiving raw materials, rather than taking weeks or months as some popular alternative methods do.

The rendering industry has been the gatekeepers of food safety and the environment for decades, offering a sanitary and eco-friendly way to dispose of the massive amount of meat and food by-products produced every year.




Quality or Process Control Points
Raw Material
Sizing
Heat Processing (Time x Temperature
Press
Protein
Grinding
Storage/Load-out
Fat clean-up

Rendered Products

- Meat and Bone Meal
- Tallow
- Poultry Grease
- Recovered Cooking Oil
- Poultry Byproduct Meal
- Blood Meal
- Feather Meal
- Chicken Meal

Rendering Industry Provides Products for Domestic and International Customers

- Animal Feed
- Pet Food
- Bio-Fuels
- Industrial Products
- Fertilizers

Customer Expectations of Renderers

- Food-safe ingredients!!!
- No foreign material or contamination -(NO metal, wood, plastic, rubber, glass, chemicals, picking fingers, rubber gloves, ear tags, leg bands or other unspecified materials!)
- Pest-free ingredients.
- Consistently meet ingredient quality and nutritional specifications.
- Sourced from traceable and sustainable raw materials.
- Fresh (not rancid) ingredients (Antioxidant Application)

Safe Feed!

Primary objectives and challenges of Rendering:

- To convert animal tissue and recovered cooking oil into safe animal feed products and ingredients which meet customers specifications and regulatory requirements
- To protect products from accidental or intentional contamination
- To design processes to minimize hazards

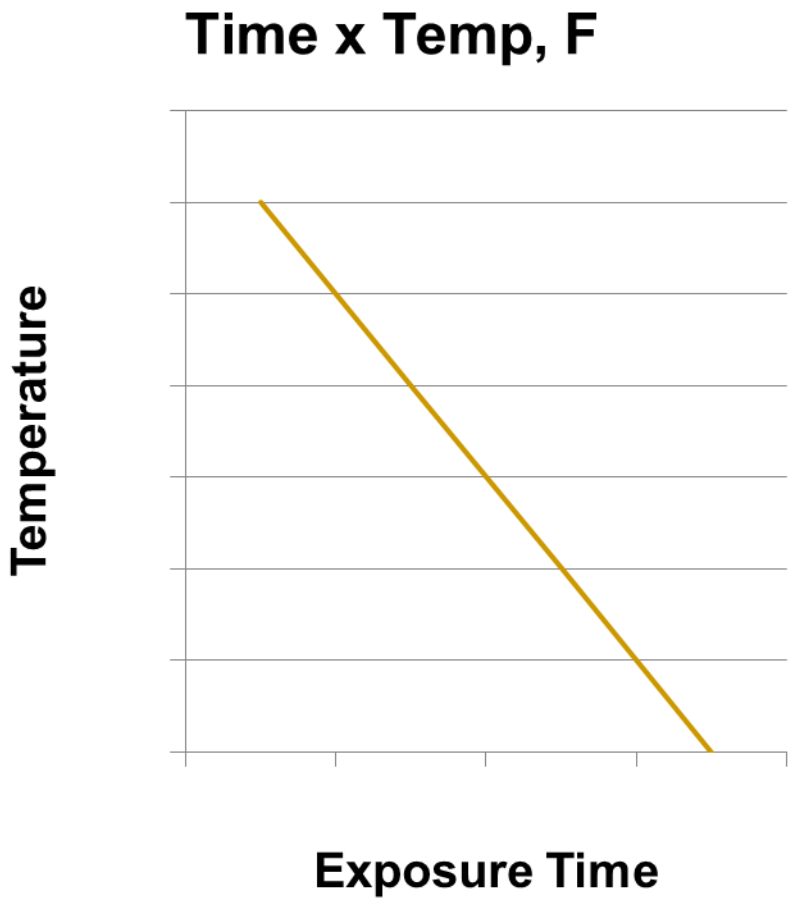
Potential Hazards

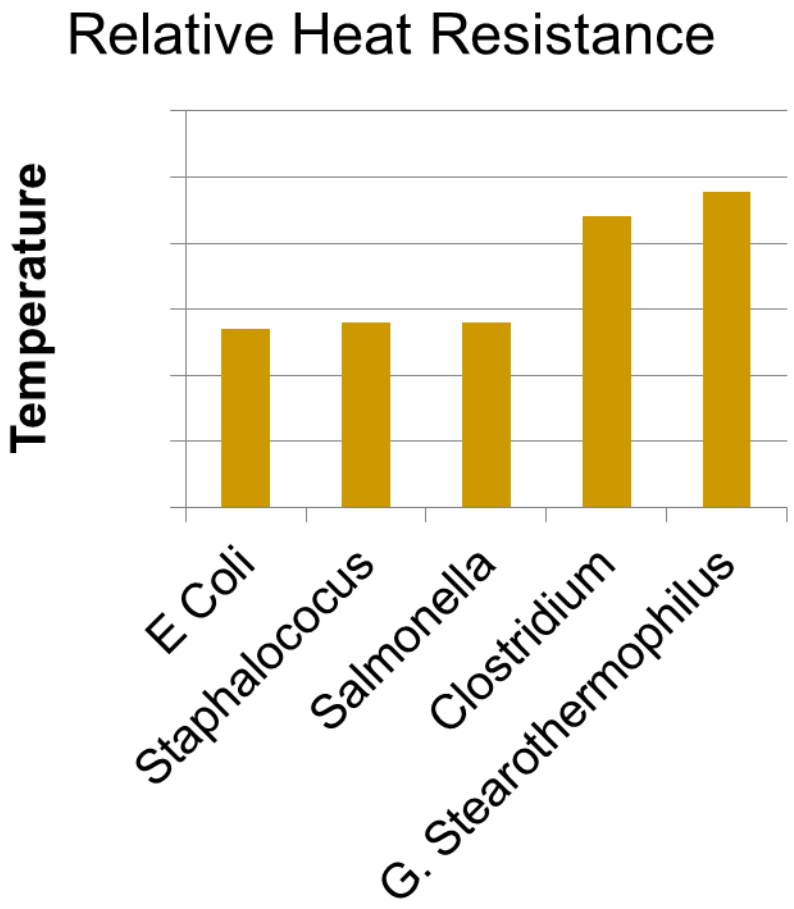
- Food Borne Pathogens (salmonella, clostridia perfringens, E. Coli), viruses
- Chemicals – Insecticides, PCBs, Rodenticides, Fungicides, Euthanizing Agents, Toxic chemicals (anti-freeze), Heavy Metals, i.e. lead and cadmium
- Physical – metal, glass, plastic, wood, rubber
- Regulated substances– CMPAF (cattle material prohibited in animal feed; brain and spinal cord of cattle aged 30 months or older)

How do we mitigate identified hazards?

- Physical: raw material inspection, magnets, sifters, grinders, screens, centrifuges, filters
- Regulated Substances – (CMPAF removal) supplier certifications and audits of suppliers to ensure SOPS are in place

Microbiological: Critical Control Limits established for cooking animal meat and byproducts; rendering effective in destroying pathogens (typical rendering temperature is 240 -270 F for 30 to 50 minutes).



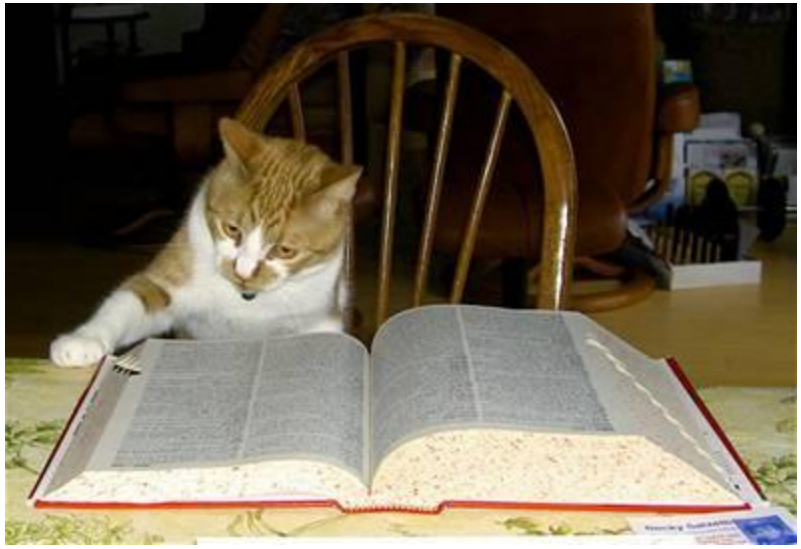


Chemical: raw material inspection; suppliers certifications; testing of fats for pesticides and PCBs; restrict access to non-feed chemicals and substances in plant

Finished Product Testing GMP

"Pathway to Feed Safety"

- The Pathway to Feed Safety begins with "GMPs" or Pre-requisite Programs.
- They are the "foundation" for producing safe and quality products.
- Essential for reducing the risk of product contamination in raw material and in the rendering plant



GMP's/Prerequisites

- GMP's/Prerequisite Programs include:

1. Sanitation and Pest Control
2. Trailer Load out Inspection for cleanliness
3. Employee Plant Practices
4. Magnet and Sifter Installations
5. CMPAF removal and disposal
6. Product Handling Practices
7. Building and Equipment Design and Maintenance
8. Routine Pesticide Testing (tallow and restaurant grease)

Biosecurity Programs in the Rendering Industry

Comprised of:

- Facility Security
- Human Resources
- Raw Material
- Finished Product
- Distribution Biosecurity & Traceability
- Housekeeping and Product Protection
- Emergency Response/Recall

Facility Security

- Plants registered with the FDA - requirement of Bioterrorism and Preparedness Act of 2002 and FSMA (every 2 years between Oct. and – Dec beginning 2012)

- Security cameras, gates/fencing used to control access to the plant and grounds

Facility Security

- Controlled access to plants, e.g. swipe cards issued to employees, sensitive areas secured
- Access to facilities is controlled by requiring visitors to sign in and wear ID badges
- Visitors are accompanied by company employees while on the property
- Know who is in the plant

Preventing Intentional Contamination

- Lock up and limit access to hazardous substances in the plant such as antifreeze, petroleum based solvents and cleaning chemicals that could be used for intentional contamination
- Limit access to finished product fat and meal storage areas. Lock them down if possible
- Inspect product at load out looking for physical and chemical contamination

Human Resources/Employee Selection and Training

- Employee background checks are conducted
- Employee probationary period observed
- Employees receive Feed Safety and GMP Training (new employees and annual refresher training)

Raw Materials

Feed Safety First Line of Defense

- Analyze raw material stream for risks likely to occur (the cleaner the raw material the cleaner the finished product)
- Know handling practices of your suppliers
- Let supplier know your expectations and why various types of potential contamination must be avoided
- Work with supplier on improvements by giving feed back on contaminants found and the quality of raw material

Raw Material

- Supplier approval procedures for evaluating raw material before purchase. Audit suppliers to evaluate their feed safety programs (focus on higher risk raw material streams)
- Supplier Agreements/Raw Material Contracts on specifications and avoidance of hazardous substances in raw material
- Suppliers required to provide certification of the integrity of raw materials on an annual basis (ruminant free; no PCBs, Pesticides, Rodenticides; no harmful levels of heavy metals or mycotoxins)
- Driver inspects raw material when picked up

Raw Material Inspection at Pickup

- Drivers look for:
  - Uncharacteristic odors
  - Suspicious raw material containers
  - Powder, pellets, granules
  - CMPAF material (brains/spinal cords)
  - Metal, wood, plastic
  - Cattle ear tags

- Provide a process to document and report possible contamination

Raw Material Inspection at Receipt

- Similar criteria as pickup inspection

- The inspection of raw materials of each receipt at the time of delivery to the plant is documented (feedback to suppliers; reject if contaminant cannot be removed)

Finished Product Biosecurity

- Documented risk based feed safety programs are implemented which includes cooking Critical Control Limit (240-255 F)
- Rendering temperatures kill conventional pathogens. Clostridia perfringens used as marker organism to validate cook. AI virus killed at 230 F. for 15 seconds
- Enterobacteriaceae testing of finished products confirms that thermal inactivation during cooking eliminates microbial hazards and that plant sanitation programs are effective
- Internal audits of the feed safety programs are conducted
- Fats are monitored for signs of pesticide and PCB contamination (primarily tallow and recovered cooking oil)

Finished Product Biosecurity

- Written procedures for compliance to the BSE Feed Rule/CMPAF (Cattle Material Prohibited from Animal Feed) are in place to prevent CMPAF from entering the plants and prevent the commingling of ruminant and non ruminant material (21 CFR 589.2000/2001)

- Non-feed chemicals and substances used in and around the plant are locked in a secure area with access limited to authorized personnel. Take routine inventories of these substances

- Food grade grease/oils are used on equipment that is above product zones where there is the potential of leaking into product

Finished Product Biosecurity

- Held Product procedures are in place to control non conforming product and document disposition.
- Customer complaints are reported and corrective action taken (monitor trends in types and frequency of complaints).
- Production samples are examined for signs of chemical and physical contaminants
- Product testing and retention sample programs in place

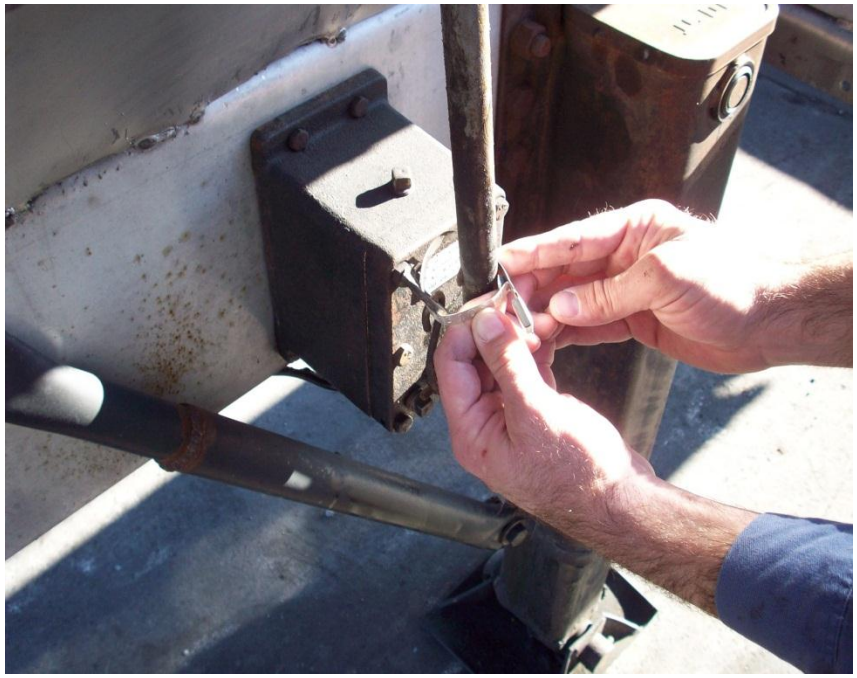
Quality Control Testing

- Typical test capabilities for customer specification compliance:

1. Protein
2. Fat
3. Ash
4. Moisture
5. Free Fatty Acid
6. Peroxide Value
7. Oxidative Stability
8. In-vitro indicators of digestibility

Distribution Biosecurity and Traceability

- Load out procedures are in place to document the cleanliness and condition of carriers and the inspection of product during loading (doors/hatches close tight?)
- Tamper evident seals are applied to carrier access and discharge points before they leave the premises



Distribution Biosecurity and Traceability

- Carriers are required to certify that trucks haul only feed grade materials. Verification of last product hauled can be required
- Product traceability procedures for raw material and finished products “one up – one back rule” are written and implemented
- Include the recording of lot numbers for ingredients such as antioxidants and antifoams in traceability process

Housekeeping and Sanitation

- Plants have written cleaning schedules and document the completion of cleaning as scheduled to ensure that we have a clean work place, free of debris and pests that could potentially contaminate our products
- Pest control is essential for ensuring product integrity and preventing contamination/infestation (i.e, eliminate rodents as a potential vector for salmonella contamination)
- Use color coded utensils (shovels, scoops, brooms etc.) to help avoid cross contamination issues from raw to finished product areas of the plants (“red for raw”, “green for finished product”)
- Avoid employee traffic from the raw material area to finished product areas of the plant
- Keep finished product areas of plant as dry as possible to prevent post-process microbial contamination

Emergency Response

- Emergency Response Plan to address the handling and management of biosecurity threats are written and implemented.
- Includes emergency contacts, action plan to respond to suspicious substances or threats and a recall plan
- Mock Recalls are conducted to test the process for the traceability and retrieval of product

Program Maintenance and Verification

- FDA inspections
- Department of Agriculture Audits
- Customer Audits
- 3rd Party Audits (APPI Code of Practice, AFIA Safe Feed/Safe Food)
- Internal Audits (HACCP, Sanitation, GMPs)

Conclusion

- *Analyze Raw Material Streams for Risks Likely to Occur*
- *Design processes and programs to minimize hazards and to prevent intentional and accidental contamination*
- *Maintain and Strengthen programs with employee training*
- *Verify programs are doing what they are designed to do*
  (i.e. internal/3rd party audits, mock recalls, customer complaint review)