IMPLEMENTING A SUCCESSFUL ANIMAL FOOD SAFETY PLAN

Animal Food Quality Assurance Program
ANIMAL FOOD SAFETY

- What is AFQA?
- Implementation and Best Practices
- Documentation
- Preparing for an FDA inspection
- FDA inspection feedback
WHAT IS AFQA?

- Animal Food Quality Assurance Program
  + Managed by an advisory board
    - AFQA is a program by the producers for the producers
  + An Animal Food Safety Program for the fuel ethanol industry
    - Outlines the requirements in 21 CFR 507
    - Completely customizable to each facility
  + Forms for easy documentation
  + Hazard Analysis with identified industry standard hazards. Additional hazards can be added at facility discretion
TEAM WORK FOR SUCCESS

- **Operations**
  - Production of Safe Animal Food
  - Sanitation
  - cGMPs

- **Maintenance**
  - PM Programs
  - Projects
  - Sanitation
  - cGMPs

- **Commodities**
  - Finished feed handling
  - Sanitation
  - cGMPs

- **Quality**
  - Testing & Verification
  - Sanitation
  - cGMPs

- **Administrative**
  - Traceability
  - Auditing
  - Sanitation
  - cGMPs

Food Safety Ownership!!
MEAT AND POTATOES: WHAT MAKES UP AFQA?

- Hazard Analysis
  + An in depth look at your facility and process
    • Best Practice: Develop a food safety team and include members from each department and the facility leadership team
  + AFQA requires a reanalysis every 3 years or when significant process changes are made
MEAT AND POTATOES: WHAT MAKES UP AFQA?

- cGMPs
- Personnel
- Plant, Grounds, and Sanitation
- Water Supply and Plumbing
- Equipment and Utensils
- Plant Operations
- Mycotoxins
- Holding and Distribution
- Training Program
PERSONNEL

▪ All team members must conform to hygienic practices that protect against the contamination of animal food. These include:
  + Personal cleanliness
  + Clean and damage free uniforms
  + Clean boots
  + Clean hardhats (with no loose stickers)
  + Clean gloves
  + Defined jewelry policy is clearly stated
PLANT, GROUNDS, AND SANITATION

- **Pest Control**
  - **Rodents**
    - Provide documentation on traps, trap locations, catch counts, etc.
      - Best practice: use a test pest to check pest controller
    - Chemical controls: have SDS and labels handy. Pick chemicals that are already approved for use in feed facilities
    - Clear procedures if managed in house. Third party pest control makes documentation easier
  - **Birds**
    - Know your options. Investigate third party and use available state and federal resources
    - Hazing and deterrent methods
    - Best practice: Use netting to eliminate roosting hazards over open animal food storage
PLANT, GROUNDS, AND SANITATION

- Pest Control continued..
  - Insects
    - Raw materials contamination
    - Finished product contamination
    - Insect control in process areas
    - Standing water elimination
  - Weeds
    - Pest harborage
    - Third Party Provider based on local regulations
      - Provide chemical use and consumption reports
      - Targeting problem areas
PLANT, GROUNDS, AND SANITATION

- Facility Maintenance and Sanitation
  + Shatter resistant fixtures
  + Condensation
    • Wet cake storage concerns
  + Chemical Storage
    • Best practice: Store of non-food grade and food grade lubricants in separate areas to avoid cross contamination. Include proper lubricant in preventative maintenance plans
  + Documentation of preventative maintenance
    • Including frequency, completion dates, and relevant notes
EQUIPMENT AND UTENSILS

- Utensils must be clean and in good repair
  + Spot check utensils for wear during cGMPs
    • Best Practice: Have an SOP or guidelines on how to conduct a cGMP inspection. This will increase consistency in corrective actions and documentation.
  + Have separate animal food utensils
  + Address utensil materials in Hazard Analysis
    • Ex. Wooden handles on shovels

- Equipment Maintenance and Sanitation
  + Loading Equipment
    • Best Practice: Have separate pay loader/ skid steer buckets for feed and general use
WATER SUPPLY AND PLUMBING

- Bathrooms and handwashing facilities must be readily available
  - FDA inspectors have checked for ‘warm’ water at handwashing stations and bathrooms
- Sewage disposal
- Adequate water for operations
  - Provide documentation that the water used for production and cleaning is adequate
    - It is up to the facility to define adequate water. Have defensible data!
      - Example: POET Groton uses city water and pulls the consumer confidence report from supplier. We also provide coliform and e coli results from a storage tank sample
PLANT OPERATIONS

- Sanitation schedule is owned by all departments!
  - Best Practice: Rotate cGMP completion through multiple people from various departments.

- Disposition records

- Raw Ingredients
  - Specification sheets for Raw Materials (production feedstock)
  - Grading SOPs and training certifications for scale master and commodities team
  - Segregation SOPs
  - Sampling and compositing SOPs
PLANT OPERATIONS

- **Other ingredients**
  - Defining ‘other ingredients’
  - Approval pathways for use in your process
    - Documentation of approvals
    - Chemical certificates of analysis and records

- **Auxiliary chemicals**
  - Defining auxiliary chemicals
MYCOTOXINS

- Mycotoxin Management
  + AFQA program limits and step-up, step down procedures
    • Raw materials and finished feed
  + Communication with customers
  + Lab SOPs
  + Data management and record keeping
  + Proficiency Testing
  + 3rd party cross validation results
AFQA MYCOTOXIN MANAGEMENT

Table 1 Raw Materials Mycotoxin Testing Frequency Levels

<table>
<thead>
<tr>
<th>Toxin</th>
<th>Aflatoxin</th>
<th>Fumonisin</th>
<th>DON</th>
<th>Zearalenone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Units</td>
<td>ppb</td>
<td>ppm</td>
<td>ppm</td>
<td>ppb</td>
</tr>
<tr>
<td>Ultra-Safe</td>
<td>&lt; 2.0</td>
<td>&lt; 5.0</td>
<td>&lt; 0.5</td>
<td>&lt; 200</td>
</tr>
<tr>
<td>Safe</td>
<td>2.0 - 8.0</td>
<td>5.1 - 15.0</td>
<td>0.51 - 2.0</td>
<td>200 - 400</td>
</tr>
<tr>
<td>Caution</td>
<td>8.1 - 16.0</td>
<td>15.1 – 30.0</td>
<td>2.1 - 4.0</td>
<td>401 - 800</td>
</tr>
<tr>
<td>Alert</td>
<td>&gt; 16.0</td>
<td>&gt; 30.0</td>
<td>&gt; 4.0</td>
<td>&gt; 800</td>
</tr>
</tbody>
</table>

Table 2 Raw Materials Mycotoxin Testing Frequency

<table>
<thead>
<tr>
<th>Level</th>
<th>Testing Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultra-Safe</td>
<td>Daily Composite Samples for the week are combined to create a Weekly Composite Sample. The <strong>Weekly Composite Samples</strong> are to be tested monthly.</td>
</tr>
<tr>
<td>Safe</td>
<td>Daily Composite Samples for the week are combined to create a Weekly Composite Sample. The <strong>Weekly Composite Samples</strong> are to be tested weekly.</td>
</tr>
<tr>
<td>Caution</td>
<td><strong>Daily Composite Samples</strong> are to be tested weekly.</td>
</tr>
<tr>
<td>Alert</td>
<td><strong>Daily Composite Samples</strong> are to be tested daily (i.e. every day animal food is released for sale).</td>
</tr>
</tbody>
</table>

Footnote 1: To move to a lower testing frequency level (see Table 1) three (3) consecutive test results must be obtained in the lower level. Once three consecutive test results are obtained in a certain lower testing level the facility can move to that respective lower testing frequency level.
HOLDING AND DISTRIBUTION

- Sanitary Transportation
  - Pre-Load Inspections: AFQA form B11F
    - Trailer inspections
    - Prior load documentation
    - Prohibited item list with carrier acknowledgement
  - Feed tags
  - Seals

- Animal food storage
  - Controlled Access
    - Best Practice: Barriers to prevent access to storage area
  - Hygienic Practices
    - Best Practice: Boot scrapers outside of flat storage
    - Best Practice: Covered trash cans for producers and drivers in flat storage
AFQA DOCUMENTATION

- Facility Management Sign Off Form
- cGMP Form
- Management cGMP Confirmation Form (quarterly review of cGMPs and related action items)
  - Best Practice: Completed by site PCQI
- Pre-load Examination & Carrier Acknowledgement Form
- Employee Training Documentation Form
- Verification Form (quarterly form complete to verify preventative controls are working)
- Reanalysis Form
PREPARING FOR AN AUDIT

▪ AFQA annual audits
▪ Internal audits
  • Best Practice: Completed shipments and retain reconciliation
▪ Reviewing FDA Guidance Documents
▪ Participate in mycotoxin proficiency testing
▪ Conduct regular SPOT Checks of your animal food safety plan
  + Example spot checks: in progress mycotoxin testing or load inspections
FDA FEEDBACK

- Feedback from FDA audits at POET facilities
- Recent discussion points
  - Magnets
  - Utensils
  - Mock Recalls
  - Refresher Training