

# IMPLEMENTING A SUCCESSFUL ANIMAL FOOD SAFETY PLAN

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Animal Food Quality Assurance Program



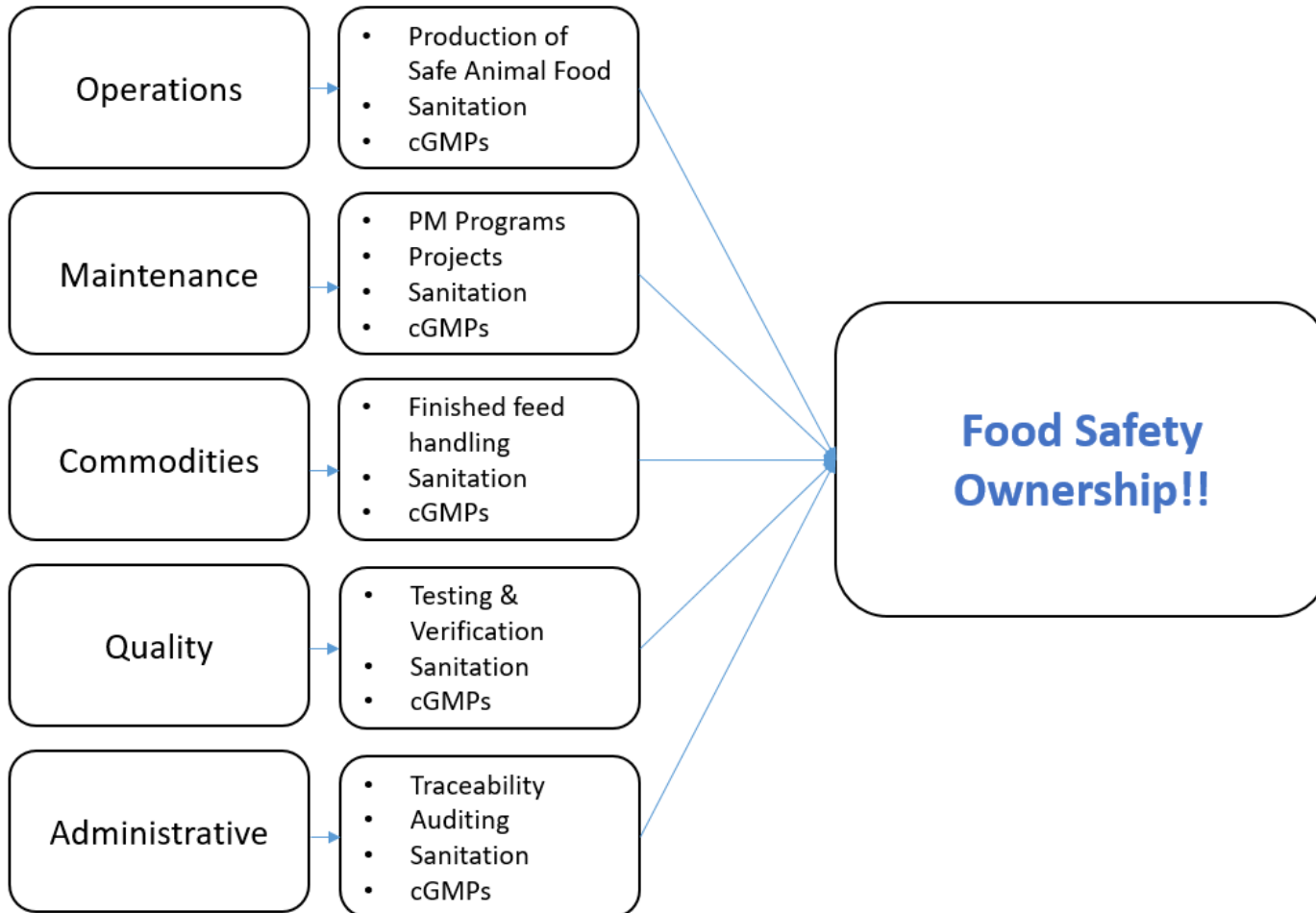
# ANIMAL FOOD SAFETY

- 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



# 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

Annex C Hazard Analysis Dried Distillers Grain with Solubles

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|   |  |   |                                     |  |                |                          |                 |  |                            |  |
|---|--|---|-------------------------------------|--|----------------|--------------------------|-----------------|--|----------------------------|--|
|  | Distillers Dried Grains with Solubles (DDGS) | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2" style="text-align: center;"><b>AFQA ANNEX C HAZARD ANALYSIS</b></td> </tr> <tr> <td style="width: 50%;">Facility Name:</td> <td>POET Biorefining- Groton</td> </tr> <tr> <td colspan="2" style="text-align: right;">VERSION: 16.7.0</td> </tr> <tr> <td colspan="2" style="text-align: right;">EFFECTIVE DATE: 11/16/2018</td> </tr> </table> | <b>AFQA ANNEX C HAZARD ANALYSIS</b> |  | Facility Name: | POET Biorefining- Groton | VERSION: 16.7.0 |  | EFFECTIVE DATE: 11/16/2018 |  |
| <b>AFQA ANNEX C HAZARD ANALYSIS</b>   |  |   |                                     |  |                |                          |                 |  |                            |  |
| Facility Name:  | POET Biorefining- Groton                     |   |                                     |  |                |                          |                 |  |                            |  |
| VERSION: 16.7.0   |  |   |                                     |  |                |                          |                 |  |                            |  |
| EFFECTIVE DATE: 11/16/2018  |  |   |                                     |  |                |                          |                 |  |                            |  |


| Food For Animals Hazard Analysis Matrix   |  |                         |                            |                             | Hazard Ranking Key   |       |         |       |
|---|--|-------------------------|----------------------------|-----------------------------|--|-------|---------|-------|
| Increasing Likelihood of Hazard Occurring | 4<br>Common Occurrence                       | 3<br>Known to Occur     | 2<br>Not Expected to Occur | 1<br>Practically Impossible |  |       |         |       |
| 4   | 2.5  | 3.0                     | 3.5                        | 4.0                         | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center; background-color: #f8d7da;">≥ 3.0</td> </tr> <tr> <td style="text-align: center; background-color: #fff3cd;">2.0-2.5</td> </tr> <tr> <td style="text-align: center; background-color: #d4edda;">≤ 1.5</td> </tr> </table> | ≥ 3.0 | 2.0-2.5 | ≤ 1.5 |
| ≥ 3.0                                     |  |                         |                            |                             |  |       |         |       |
| 2.0-2.5                                   |  |                         |                            |                             |  |       |         |       |
| ≤ 1.5                                     |  |                         |                            |                             |  |       |         |       |
| 3   | 2.0  | 2.5                     | 3.0                        | 3.5                         |  |       |         |       |
| 2   | 1.5  | 2.0                     | 2.5                        | 3.0                         |  |       |         |       |
| 1   | 1.0  | 1.5                     | 2.0                        | 2.5                         |  |       |         |       |
|   | 1<br>Insignificant                           | 2<br>Customer Complaint | 3<br>Serious Illness       | 4<br>Fatality               |  |       |         |       |
|   | Severity of Harm Caused to Animals or Humans |                         |                            |                             |  |       |         |       |
|   | Increasing Severity →                        |                         |                            |                             |  |       |         |       |

**Hazard Analysis Instructions:**

List all known possible hazards that are specific to your production facility in Table 2 below. Also taken into consideration is the hazard's potential to pass through and impact human health. If the hazard is already listed in Table 1 you should not list it again. Rank each of the hazards by giving them a ranking of 1, 2, 3, or 4; with 1 being not likely to occur or will not cause severe harm to animals, and 4 being very likely to occur or causing severe harm to animals. The resulting Hazard Ranking will be calculated in Column N. Any hazard having a score of 3.0 or greater is considered a hazard needing a Preventive Control. You must also fill out Table 2a for each hazard providing a justification for the ranking.

# 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



**AFQA**  
ANIMAL FOOD QUALITY  
ASSURANCE PROGRAM

AFQA Annex B Forms  
VERSION: 16.7.0  
EFFECTIVE DATE: 11/16/2018

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**Form B2F - cGMP Inspection Form**

Facility Name: \_\_\_\_\_  
 Inspection Date(s): \_\_\_\_\_  
 Inspector Name(s) and Initials: \_\_\_\_\_  
By entering your full name you are electronically signing this document

**Inspection Findings**

| #  | Inspect | Inspection | Acceptable<br>(AY) | Description   |
|----|---------|------------|--------------------|---|
| 1  | _____   | _____      | _____              | Employees maintain adequate personal cleanliness.   |
| 2  | _____   | _____      | _____              | Employees wash hands and/or are wearing clean gloves prior to directly handling animal food.  |
| 3  | _____   | _____      | _____              | Employees' work wear is maintained in a clean, damage-free state.   |
| 4  | _____   | _____      | _____              | Employees' hardhats are clean of debris, dirt, loose or damaged stickers, and any other   |
| 5  | _____   | _____      | _____              | Employees' boots are clean of debris, dirt, and any other contaminants.   |
| 6  | _____   | _____      | _____              | Any jewelry or other accessories are properly secured or removed.   |
| 7  | _____   | _____      | _____              | All trash, litter and waste is stored properly and regularly removed.   |
| 8  | _____   | _____      | _____              | Grounds in the immediate vicinity of the animal food production are properly maintained and weeds   |
| 9  | _____   | _____      | _____              | No standing water, for extended periods of time, in the immediate vicinity of the animal food   |
| 10 | _____   | _____      | _____              | All pest control devices are undamaged and in working order or otherwise reported to Pest Control Program Manager or replaced.  |
| 11 | _____   | _____      | _____              | Areas of exposed animal food storage are free of condensation, broken fixtures or other possible contaminants of the animal food.   |
| 12 | _____   | _____      | _____              | Building, structures, fixtures and other physical facilities of the food production are clean and in  |
| 13 | _____   | _____      | _____              | Cleaning compounds, sanitization agents, and toxic chemicals properly labeled and stored to protect against the contamination of animal food.   |
| 14 | _____   | _____      | _____              | All plant equipment and utensils that may come in contact with animal food are clean, maintained and properly stored.   |
| 15 | _____   | _____      | _____              | Equipment and utensils used appropriately to avoid adulteration of animal food with non-food grade lubricants, fuel, metal fragments, contaminated water or another contaminate.                        |
| 16 | _____   | _____      | _____              | Animal food storage locations are properly labeled.   |
| 17 | _____   | _____      | _____              | Potentially adulterated animal food segregated and dispositioned in appropriate manner.   |
| 18 | _____   | _____      | _____              | Every load of raw material is probed or otherwise adequately sampled for testing. (Corn, small grains or other fermentable products)  |
| 19 | _____   | _____      | _____              | Mycotoxin testing is conducted at the required frequency.   |
| 20 | _____   | _____      | _____              | Shipping containers (e.g., totes, drums, and tubs) and bulk vehicles used to distribute animal food are examined prior to use to protect against the contamination of animal food from the container or |
| 21 | _____   | _____      | _____              | Carrier Acknowledgement signed for any necessary pre-load examinations.   |

**Required Frequency**  
Bi-weekly (every other week) and within two days of any process shutdowns or significant maintenance activities

All "Unacceptable" answers require a corrective action to be supplied.  
 A representative of the management team must sign off if any corrective actions are noted.

**Corrective Actions:**  
 Describe the corrective action implemented for any "Unacceptable" line items above:

Corrective Action Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
By entering your full name you are electronically signing this document

# 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, ect
  - 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
  - + 3<sup>rd</sup> party cross validation results

# AFQA MYCOTOXIN MANAGEMENT

Table 1 Raw Materials Mycotoxin Testing Frequency Levels

| Toxin      | Aflatoxin  | Fumonisin   | DON        | Zearalenone |
|------------|------------|-------------|------------|-------------|
| Units      | ppb        | ppm         | ppm        | ppb         |
| Ultra-Safe | < 2.0      | < 5.0       | < 0.5      | < 200       |
| Safe       | 2.0 - 8.0  | 5.1 - 15.0  | 0.51 - 2.0 | 200 - 400   |
| Caution    | 8.1 - 16.0 | 15.1 – 30.0 | 2.1 - 4.0  | 401 - 800   |
| Alert      | > 16.0     | > 30.0      | > 4.0      | > 800       |

Table 2 Raw Materials Mycotoxin Testing Frequency

|            |  |
|------------|--|
| Ultra-Safe | Daily Composite Samples for the week are combined to create a Weekly Composite Sample. The <b>Weekly Composite Samples</b> are to be <b>tested monthly</b> . |
| Safe       | Daily Composite Samples for the week are combined to create a Weekly Composite Sample. The <b>Weekly Composite Samples</b> are to be <b>tested weekly</b> .  |
| Caution    | <b>Daily Composite Samples</b> are to be <b>tested weekly</b> .  |
| Alert      | <b>Daily Composite Samples</b> are to be <b>tested daily</b> (i.e. every day animal food is released for sale).  |

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