**Example Prerequisite Programs**

**Some City Feed Mill**

# Prerequisite Program for Metal

## A. Purpose

Metal would have a very low severity overall. It could be hazardous to the health of swine, poultry, equine, beef, dairy, sheep, or goats that are intended to consume our feed, but would not cause large quantities of animal illness or deaths. There is no potential impact to human health because the feed is not intended to be stored in the home or come in contact with humans. Metal in feed cannot be passed to humans through their consumption of animal products like meat, milk, or eggs. Metal has a moderate probability of occurrence from bulk ingredients and the many moving metal parts within the manufacturing process. The intent of this prerequisite program is to further reduce the probability of metal in finished feed.

## B. Responsibilities

The owner, operator, or agent-in-charge of the facility and the Preventive Controls Qualified Individual have determined that this prerequisite program is necessary to reduce the occurrence of metal. The mill manager is responsible for its implementation by all parties. Qualified individuals involved in manufacturing, processing, packing, or holding ingredients and feed are responsible for implementing these activities as appropriate for their roles. Specifically, the Receiving Operators, Day Shift Supervisor, and Maintenance Supervisor have responsibilities for this program’s implementation.

## C. Actions and documentation to control metal

1. All bulk ingredients are received through a bulk receiving pit with the width between grates being a maximum of 2.5 inches to prevent large metal objects from entering with ingredients or from vehicles.
2. The entire receiving process is visually observed by a Receiving Operator. If metal is observed in ingredients during the unloading process, the conveyor from the pit to the bucket elevator is immediately stopped. The contaminant is removed and eliminated before receiving restarts. In the case that the contaminant cannot be removed, the material is immediately diverted to an empty loadout bin and is removed from the facility and not used to make animal feed.
3. There are magnets present prior to the hammer mill, pellet mill, and in the finished feed leg. These magnets are checked and cleaned weekly by the Day Shift Supervisor and documentation of this is logged using the Magnet Log, which is maintained in the yellow binder labeled Prerequisite Programs in the Control Room.
4. The facility has a written preventive maintenance program managed by the Maintenance Supervisor to reduce the likelihood of equipment failures that may lead to metal from the manufacturing process. This program is available for review in the Maintenance Office, as well as the maintenance schedule for the previous year and next six weeks.

## D. Magnet Log

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| --- | --- | --- | --- |
| Date Checked | Summary of Material Found | Summary of Investigation | Day Shift Supervisor Initials |
| Hammermill | Pellet Mill | Finished Feed Leg |
| **1/4/2021** | **3/16” washer** | **None** | **Approximately 5 g of tram metal** | **Washer appears to be from bucket elevator. Maintenance called to inspect it. Tram metal likely because we changed the pellet mill die on Sunday.** | **HSJ** |
| **1/11/2021** | **None** | **None** | **None** | **n/a** | **HSJ** |
| **1/18/2021** | **None** | **Screen fragments** | **None** | **Maintenance called to replace hammermill screen.** | **HSJ** |
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# Prerequisite Program for Aflatoxin, Fumonisin, & Vomitoxin

## A. Purpose

Mycotoxins would have a moderate severity overall. All three could be hazardous to the health of swine, poultry, equine, beef, dairy, sheep, or goats that are intended to consume our feed, and are capable of causing large quantities of animal illness or deaths. Aflatoxin has the potential impact to human health because it can be passed to humans through their consumption of animal products like milk. Mycotoxins have a low probability of occurrence from bulk ingredients and their storage within the facility. The intent of this prerequisite program is to further reduce the probability of mycotoxins in finished feed. This process is relevant for the following ingredients susceptible to mycotoxin:

* Corn (Aflatoxin and fumonisin)
* Corn DDGS (Aflatoxin and fumonisin)
* Corn Gluten Feed (Aflatoxin and fumonisin)
* Corn Gluten Meal (Aflatoxin and fumonisin)
* Wheat (Deoxynilvalenol, also known as vomitoxin)
* Wheat Midds (Deoxynilvalenol, also known as vomitoxin)

## B. Responsibilities

The owner, operator, or agent-in-charge of the facility and the Preventive Controls Qualified Individual have determined that this prerequisite program is necessary to reduce the occurrence of aflatoxin, fumonisin, and vomitoxin. The mill manager is responsible for its implementation by all parties. Qualified individuals involved in manufacturing, processing, packing, or holding ingredients and feed are responsible for implementing these activities as appropriate for their roles. Specifically, the Scale House and Receiving Operators have responsibilities for this program’s implementation.

## C. Actions and documentation to control mycotoxins

1. The following products may only be received from these suppliers:
* Corn: Company X, Broker Y, Farmer John Doe, Farmer Joe Smith, Farmer Jane Jones
* Corn DDGS: Company Y, Broker Z
* Corn Gluten Feed: Company M, Company O, Broker Z
* Corn Gluten Meal: Company M, Company O, Broker Z
* Wheat: Company X, Broker Y, Farmer Joe Smith, Farmer Jane Jones
* Wheat Midds: Company B, Company F
1. The entire receiving process is visually observed by a Receiving Operator. If black or moldy material is observed in susceptible ingredients during the unloading process, the conveyor from the pit to the bucket elevator is immediately stopped. The contaminated material manually probed, ground, and analyzed for the relevant mycotoxin given the type of ingredient. Based on the result, the ingredient is either received or diverted to an empty loadout bin and is removed from the facility and not used to make feed.
2. A mycotoxin testing program is active for aflatoxin and fumonisin in corn and corn co-products and deoxynilvalenol (DON)/vomitoxin in wheat and wheat co-products. Samples are collected and analyzed by the Scale House Operator and documentation of this is logged using the Mycotoxin Log, which is maintained in the yellow binder labeled Mycotoxin Records in the Scale House.

**Stage 1 Strategy** ⌂

**Geographical-Based Risk Assessment Plan**

Weekly third party surveillance reports of grain grown in various geographical locations will be reviewed, and used to develop the risk level of ingredient that is known to be sourced from a specific geographic region. If the weekly surveillance shows limited prevalence, then no further action is necessary.

**Stage 2 Strategy** ⌂

**General Daily Composite Plan**

If the geographic source location of ingredient is not known, or from an area where the risk assessment suggested moderate risk, additional surveillance will be developed to complete a General Daily Composite Plan. Daily composite is built at the scale house and tested once per day and recorded. Once per week these data are rolled up into a weekly weighted average. The weekly weighted average indicator is used to make decisions regarding mycotoxin strategy. If the weekly composite number is below 20 ppb for aflatoxin, 5 ppm fumonisin, and 5 ppm DON, then no further action is necessary.

**Stage 3 Strategy** ⌂

**Composite by Supplier Plan**

If weekly results generated during Strategy 2 are above threshold levels listed, then additional surveillance must be put in place to identify and mitigate the source of the mycotoxin. A daily composite for each corn, wheat, and co-product supplier is built at the scale house and tested once per day and recorded. Once per week these data are summarized into weekly weighted averages by supplier. The weekly weighted average by supplier indicator is used to make decisions regarding mycotoxin strategy. Suppliers identified as having mycotoxin levels above the threshold levels listed in Stage 2 but below 300 ppb for aflatoxin, 60 ppm fumonisin, and 10 ppm DON will be either sent to another feed mill for use in feeds for finishing beef cattle or have their ingredient segregated at the feed mill into bins specifically used for finishing beef cattle. In this case, the problematic ingredient cannot exceed 30% of the finished diet.

**Stage 4 Strategy** ⌂

**High Aflatoxin Corn Supplier Mitigation Plan**

If weekly composite results generated for an individual supplier are consistently above threshold levels listed in Stage 3, then additional mitigation steps will be employed to reduce the risk of accepting high mycotoxin corn. These steps can include, but are not limited to, movement of specific supplier corn to other destinations of less risk, cleaning, more intensive segregation strategies, consultation with regulatory authorities, or rejection of high threshold loads.

## D. Mycotoxin Log

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Date and Time****of Analysis** | **Ingredient** **Type** | **Ingredient Supplier** | **Program****Stage** | **Tested Level** | **Product Used or Rejected?** | **Notes** | **Initials** |
| **1/4/2021****8:46 AM** | **Wheat midds** | **Company B** | **4** | **Vomitoxin: 12 ppm** | **Rejected** | **Supplier remains Stage 4**  | **TPB** |
| **1/4/2021****4:15 PM** | **Corn DDGS****(Composite)** | **Company Y** | **3** | **Aflatoxin:< 5 ppb****Fumonisin: 4 ppm** | **Used** | **n/a** | **TPB** |
| **1/4/2021****4:24 PM** | **Corn DDGS****Composite)** | **Broker Z** | **3** | **Aflatoxin: 16 ppb****Fumonisin: 2 ppm** | **Used** | **n/a** | **TPB** |
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# Prerequisite Program for Animal Drug Contamination

## A. Purpose

Contamination of feeds with unapproved drugs would have a moderate severity overall. Depending upon the drug and its concentration, contamination may be hazardous to the health of swine, poultry, equine, beef, dairy, sheep, or goats that are intended to consume our feed, and certain drugs may cause large quantities of animal illness or deaths. In rare instances, high levels of certain drugs may impact human health due to residues in meat, milk, or eggs. Animal drug contamination has a low probability of occurrence because the facility is a registered feed mill that follows the medicated feed cGMP requirements described in 21 CFR 225. The intent of this prerequisite program is to further reduce the probability of unsafe animal drug contamination in finished feed.

## B. Responsibilities

The owner, operator, or agent-in-charge of the facility and the Preventive Controls Qualified Individual have determined that this prerequisite program is necessary to reduce the occurrence of unsafe animal drug contamination. The mill manager is responsible for its implementation by all parties. Qualified individuals involved in manufacturing, processing, packing, or holding ingredients and feed are responsible for implementing these activities as appropriate for their roles. Specifically, the Warehouse Manager, Batching Operator, and Load-out Operator have responsibilities for this program’s implementation.

## C. Actions and documentation to control animal drug contamination

1. The buildings and equipment within the feed mill must be of adequate construction, cleanliness, and maintenance to prevent unsafe cross-contamination.
2. Only packaged animal drugs will be received. Upon receipt, the Warehouse Manager will examine them for damage and, if accepted, will document their arrival in the Drug Receiving Log. These drugs will be stored in their original, closed containers until used.
3. When drugs are used to manufacture feed, they will be moved to their specified bin in the microtable that is labeled with the drug name. The quantity placed in the microtable bin will be recorded in the Drug Use Log.
4. The Batching Operator will confirm that batching records generated during the manufacture of medicated feed are accurate and reflect the drugs used in each batch. These batching records will be maintained for at least one year.
5. The quantity of each drug used daily will be recorded in the Daily Drug Reconciliation Log. This information will be tracked as theoretical use and compared daily to the daily drug inventory in the log to determine the percentage deviation. Any deviation greater than 1% of the drug’s daily use or 0.2 lb will be reported to the PCQI and investigated.
6. A sample of feed manufactured with each drug will be obtained three times annually (ideally during Weeks 1, 16, and 30 of the calendar year) and analyzed for quantity to confirm its accuracy. If a new drug is brought into the mill, the first feed manufactured with that drug will also be assayed. If the results are greater than the allowable analytical variance, the PCQI will conduct an investigation to determine the root cause and implement a corrective action.
7. The Batching Operator will follow an approved Flushing/Sequencing Schedule, which is posted in the Control Room. This schedule will be developed by the mill manager and approved by the PCQI.
8. The Load-Out Operator will document the distribution of all medicated feeds in distribution records that will be maintained for at least one year.
9. The Load-Out operator will also ensure each load of feed distributed in accompanied by a placard or label that the feed is MEDICATED and will include directions for use. Labels will be maintained for at least 1 year in the Master Record File.
10. The Mill Manager will maintain a complaint file of any oral or written complaints relating to the safety or efficacy of medicated feeds. When a complaint is received, he will coordinate with the PCQI to conduct an investigation to determine the root cause and implement a corrective action, if necessary.

## D. Drug Receiving Log

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Date and Time Received | Supplier | Drug | Lot # | Strength | QuantityReceived | Condition | Initials |
| **1/7/2021****9:05 AM** | **ABC Drug Company** | **Drug X** | **10001001** |  **50 g Drug X per pound of premix** | **Ten****50-lb bags****(500 lb. total)** | **Good** | **SJB** |
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## E. Drug Use Log

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| --- | --- | --- | --- | --- |
| Date and Time Used | Drug | Lot # | Quantity Used | Initials |
| **1/8/2021****2:45 PM** | **Drug X** | **10001001** | **1 50-lb bag** | **TCH** |
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## F. Daily Drug Reconciliation Log

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Date | Beginning Time | Drug | Beginning Drug Inventory | EndingTime | Ending Drug Inventory | Change in Drug Inventory | Theoretical Daily Use | Deviation | Investigation Necessary? | Initials |
| **1/6/21** | **7:20 AM** | **Drug X** | **500 lb** | **4:52 PM** | **442 lb** | **-8.0 lb** | **8.0 lb** | **0.0%** | **No** | **TCH** |
| **1/6/21** | **7:20 AM** | **Drug Y** | **52.6 lb** | **4:52 PM** | **52.6 lb** | **0 lb** | **0 lb** | **0.0%** | **No** | **TCH** |
| **1/6/21** | **7:20 AM** | **Drug Z** | **122.4 lb** | **4:52 PM** | **106.5 lb** | **-15.9 lb** | **16.0 lb** | **0.6%** | **No** | **TCH** |
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## G. Flushing and Sequencing Schedule

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| --- | --- |
| As of 1/1/2021 | Needed Action Before Next Making a Batch Containing |
| Diet A | Diet B | Diet C |
| Batch Made First | Diet A | None | None | Flush |
| Diet B | None | None | Flush |
| Diet C | None | None | None |

# Prerequisite Program for Copper Toxicity in Sheep Feed

## A. Purpose

Nutrient deficiencies and toxicities in feed would have a very low severity overall. Depending upon the nutrient and its concentration, contamination may be hazardous to the health of swine, poultry, equine, beef, dairy, sheep, or goats that are intended to consume our feed, and certain nutrient deficiencies or toxicities may cause large quantities of animal illness or deaths. This is especially the case with copper toxicity in sheep. Sheep are very sensitive to copper, and an incorrect concentration may lead to severe illness or death to multiple animals consuming the affected diet. Fortunately, there is no known impact to human health. Nutrient deficiencies and toxicities have a very low probability of occurrence, but the high severity of copper toxicity in sheep feed warrants special consideration. The intent of this prerequisite program is to further reduce the probability of copper toxicity in finished sheep feed.

## B. Responsibilities

The owner, operator, or agent-in-charge of the facility and the Preventive Controls Qualified Individual have determined that this prerequisite program is necessary to reduce the occurrence of unsafe animal drug contamination. The mill manager is responsible for its implementation by all parties. Qualified individuals involved in manufacturing, processing, packing, or holding ingredients and feed are responsible for implementing these activities as appropriate for their roles. Specifically, the Warehouse Manager, Batching Operator, and Load-Out Operator have responsibilities for this program’s implementation.

## C. Actions and documentation to control copper toxicity in sheep feed

1. The buildings and equipment within the feed mill must be of adequate construction, cleanliness, and maintenance to prevent unsafe cross-contamination.
2. Trace mineral premix intended for use in sheep diets will be received only in packaged form. Upon receipt, the Warehouse Manager will examine packages for damage. The premix will be stored in its original, closed container until used.
3. When sheep trace mineral premix is used to manufacture feed, it will be moved to the specified bin in the microtable that is ‘Sheep Trace Mineral Premix’.
4. The batching operator will confirm the quantity of sheep trace mineral premix to be batched by comparing the formula to the master record formulas provided by a Ph.D. nutritionist.
5. A mixer efficiency test will be conducted annually to confirm mixing time is adequate.
6. A sample of feed manufactured with sheep trace mineral premix will be obtained three times annually (ideally during Weeks 1, 16, and 30 of the calendar year) and analyzed for quantity to confirm its accuracy. If the results are greater than the allowable analytical variance, the PCQI will conduct an investigation to determine the root cause and implement a corrective action.
7. The Batching Operator and Load-Out Operators will follow an approved Flushing/Sequencing Schedule, which is posted in the Control Room. This schedule will be developed by the mill manager and approved by the PCQI.
8. If a customer complaint regarding high copper in sheep feed is verified or analytical results reveal that copper levels in finished sheep diets are more than 120% of the formulated level, the facility will implement a positive release program.
	1. All diets intended for sheep over the next 365 days will be analyzed for copper prior to release for distribution. At least ten samples will be collected at the port located at the pellet cooler discharge to create a total volume of 2 lbs. per batch of feed. The 2-lb. sample will be split using a riffle divider, with 1 lb. retained and 1 lb. submitted to Laboratory P to analyze for copper concentration. Resultant copper concentrations must be between 90-110% of formulated levels to be released for distribution. If it tests outside this range, the feed must be safely diverted to finishing beef cattle or finishing swine (upon consultation with a PhD nutritionist) or disposed of in a landfill with documentation of destruction. The PCQI will then lead an investigation to identify and correct the problem, as well as prevent its reoccurrence. Records of these decisions will be maintained by the PCQI.

## D. Flushing and Sequencing Schedule

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| --- | --- |
| As of 1/1/2021 | Needed Action Before Next Making a Batch Containing |
| Diet A | Diet B | Diet C |
| Batch Made First | Diet A | None | Flush | None |
| Diet B | None | None | None |
| Diet C | None | Flush | None |