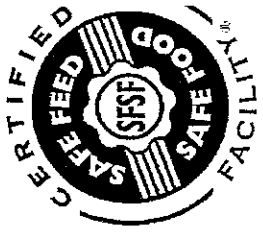


AFIA SAFE FEED/SAFE FOOD GUIDELINES AUDIT



Facility Company Name	MERCER MILLING CO.					
Date of Audit	6-8-70					
Facility Address	7698 CROSSROADS PARK DRIVE					
Facility City/State/ZIP	LIVERPOOL, NY 13088					
Person conducting audit	DICK CHASE					
Product Line	DAIRY, POULTRY, EQUINE, SWINE, SHEEP					
A. Safe Feed/Safe Food Policy, Management, Control of Documents and Records, Communication and Review						
1	A Food/Feed safety policy has been defined, reviewed and implemented by top management. Has the policy been communicated to each employee? Comments: 9-17-09 MEETING HELD + POLICY IMPLEMENTED. ALL EMPLOYEES PRESENT FOR MEETING.			X		
2	Document control procedures are in place, and documents are accessible to appropriate personnel. Comments:			X		
3	The physical and chemical feed safety hazards in the AFIA Hazard Guide have been identified, reviewed and have control procedures, where applicable. Comments:			X		
4	Records retention procedures are defined and followed. Records must be maintained for one year from the date of manufacture of the finished product or the receipt of ingredients. Comments:			X		
5	The following records are maintained as appropriate to the product: BSE feed rule, medicated feed, formula/mixing instructions, production records, drug assays, and label files.			X		

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	Comments:			
6	Responsible personnel review the following: audit results, customer feedback, process performance and product conformity, status of preventative and corrective actions, follow-up action from previous management reviews, planned changes that could affect the food/feed system and recommendations for improvement. Comments: UPPER MGT MEETINGS TWICE MONTHLY.	X		
	B. Human Resources /Training			
1	Personnel are competent for assigned tasks and received initial training and at least annual recertification. Comments: MEETINGS HELD REGULARLY WITH VARIOUS EMPLOYEES ADDRESSING SOP'S, ETC.	X		
2	Job descriptions are maintained that include the responsibility and skills required by the employee to complete the job. The employee is evaluated to determine knowledge of the required skill. Comments:	X		
3	Personnel are properly trained in SOPs for restricted areas, and where appropriate, to avoid contamination or carry-over from internal or external sources. Comments:	X		
	C. Facility Planning and Control			
1	A team has been formed to identify, evaluate, and control feed and food safety hazards. Comments: WAREHOUSE MGR. (ED WASILEWSKI) RICK LANGTAX JEFF MATUSZCZAK (PURCHASING AGENT) (PRODUCTION MGR.) ROBERTA WOLF (QUALITY ASSURANCE MGR.) RENE LAYOIE (GENERAL MGR.)	X		
2	Checkpoints where hazards may enter the facility are identified and controlled.	X		

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	Comments:			
3	Verification, monitoring, inspection and test activities have been determined specific to the need of the product.	X		
	Comments:			
D. Manufacturing and Processing				
1	Records are maintained for each product which includes the supplier approval process, product specifications, formulation, label, and special manufacturing instructions.	X		
	Comments:			
2	Procedures exist to monitor and measure the manufacturing processes.	X		
	Comments: VISUAL CHECK-OFF SYSTEM IMPLEMENTED LAST MONTH TO ORGANIZE RUNNING MAINTENANCE LOG.			
3	Procedures exist and are implemented to compare expected and theoretical results and to reconcile any differences. [see section J]	X		
	Comments:			
4	Review all literature and publications that include the seal and ensure that they are using the current seal, and such use conforms to the licensing agreement in regard to use and proper placement			
	Comments: NEW SF/SF APPLICANT			
E. Monitoring Devices				
1	Monitoring procedures have been established to evaluate incoming raw materials and finished products, where appropriate.	X		

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	Comments:			
2	Scheduled monitoring activities have been established and should include incoming raw material evaluation and finished product evaluation. Comments:	X		
3	Ingredient and finished product assays are performed on a scheduled basis, where appropriate. Comments:	X		
	F. Infrastructure - Building, Equipment and Grounds			
1	Procedures exist for the review and evaluation by the feed safety team of feed and food safety hazards in the event of new or changed facilities or equipment. Comments:	X		
2	Buildings, equipment and grounds are adequately and routinely maintained. Comments: WEEKLY AUDIT (IN-HOUSE) CONDUCTED BY DIRECTOR OF Q.A.	X		
3	Scales and liquid metering devices are tested/calibrated upon installation and at least annually thereafter. Comments:	X		
4	Buildings are of suitable construction to minimize access by pests. A written pest-control program exists and a record of pest-control products used in the facility is maintained. Comments:	X		
5	Buildings provide adequate space and lighting.	X		

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	Comments:			
6	Equipment possesses the capability to produce a homogenous product that prevents, eliminates or reduces identified food/feed safety hazards. A procedure to test the mixer has been developed and includes corrective action to be taken when necessary. Mixers are tested/calibrated upon installation and annually thereafter.	X		
	Comments:			
7	All equipment is of suitable size, design, construction, precision and accuracy for its intended use.	X		
	Comments:			
8	All equipment is maintained to prevent lubricants and coolants introduction as unapproved additives to finished products. Where contact may be possible, food-grade products are used.	X		
	Comments:			
9	All equipment is designed, constructed and maintained to facilitate inspection by the operator and the use of clean-out procedures when required.	X		
	Comments:			
10	Work areas and equipment used for the manufacture and storage of ingredients and feed are kept separate from agrichemicals.	X		
	Comments:			
11	Procedures exist and are implemented to ensure all equipment is routinely and properly cleaned to prevent contamination of feed and ingredients.	X		
	Comments:			
12	Adequate procedures are established and used for all equipment in the production and distribution of ingredients and products to avoid contamination of feed and ingredients.	X		

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	Comments:				Meets Requirements	Does not meet requirements	Requires Follow-up
13	Procedures are established to ensure a biosecure workplace and the firm is following the AFIA "Guide to Biosecurity Awareness" program.				X		
	Comments:						
1	G. Ingredient Purchasing Process and Controls				X		
	Certification for compliance to 21 CFR 589.2000 is provided by suppliers where appropriate.						
	Comments:						
2	Procedures are in place to monitor, qualify and disqualify suppliers on a scheduled basis and an approved supplier list exists.				X		
	Comments:						
3	Procedures for conveyance of raw materials to plant are in place to ensure identification of food/feed safety hazards. Suppliers and transportation companies have agreed to clean-out procedure requirements for transportation vehicles. A truck receiving log is maintained, documenting clean-out and prior cargo in the truck.				X		
	Comments: 8-31-09 STARTED RUPP CLEANOUT LOG.						
4	Suppliers are required to place a safety seal on incoming rail cars or trucks. A policy to handle broken bags has been developed and is being followed.						
	Comments: RAILCARS ARE SEALED + SEAL NUMBERS + CONDITION RECORDED. BULK TRUCKS (LIME, SALT, DICAL, MAG OX, D.D.S) MOST SAME DAY DELIVERY ARE NOT SEALED.						
	H. Identification and Traceability						
1	Finished product is properly packaged and labeled for traceability (e.g. production codes), and other				X		

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	label regulatory requirements.			
	Comments:			
2	Procedures for product traceability as required by the AFIA Safe Feed/Safe Food guidelines are documented and implemented, and the firm is complying with the FDA's Bioterrorism Act record-keeping rules.	X		
	Comments:			
3	Bagged ingredients are stored in either original containers or containers with lot numbers for traceability and identification and controlled in mixing areas. Bulk ingredients are controlled in a similar manner, as appropriate.	X		
	Comments:			
4	A sample retention program is defined and implemented. Retained samples are stored in an area away from production that minimizes the potential for contamination.	X		
	Comments:			
5	Daily inventories of drugs are maintained.	X		
	Comments:			
6	Procedures for proper storage to avoid contamination are established for both raw materials, ingredients and finished products.	X		
	Comments: 10/2009 - DISCONTINUED ACCEPTANCE OF RETURNED EMPTY TOTES.			
	I. Customer-Related Processes			
1	Product specifications are defined within customer and regulatory requirements.	X		
	Comments:			

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2	Procedures for customers' feedback and complaints are in place. <i>Comments:</i>		X	
J. Control of Non-conforming Product				
1	Procedures to control non-conforming product have been established and implemented. <i>Comments:</i>		X	

Auditor Recommendation. (Final Certification Decisions will be made by AFIA after reviewing this audit and notations.) All items should be checked "OK" to be in compliance. If items are not applicable to the facility or products produced, mark N/A and explain in the box or on a separate sheet. Auditor returns this form to FCI office for processing.

- Facility Passed Audit
- Facility Passed Audit (with plant management agreeing to minor corrections noted within 10 business days)
- Facility Failed Audit

Name of person conducting this audit DICK CHASE Signature Dick Chase Date 6-8-10
(please print legibly)

Name of management confirming this audit Rene L. Lavoie II Signature Rene L. Lavoie II Date 6/8/10
(please print legibly)

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FACILITY CERTIFICATION INSTITUTE
(For Certifying Agent Use Only)
FACILITY CERTIFICATION AUDIT FORM
Restricted Use Protein Program (RUPP)

Facility Name: MERCER MILLING CO. Date Inspected: 6-8-10
Facility Address: 4698 CROSSROADS PARK DRIVE Auditor: DICK CHASE
Facility City and State: LIVERPOOL, NY
FCI Facility Number 10085-001

1. Type of Facility Audit? [Check all that apply]

- a. FDA Licensed Feed Facility
- b. Non-FDA Licensed Feed Facility
- c. Premix Manufacturer Facility
- d. Liquid Feed Facility
- e. Drug Manufacturer/Blender
- f. Ingredient Supplier
- g. Feed Supplement Manufacturer
- h. Hauler/Distributor

Describe Other:

2. The facility has a copy of AFIA/FDA's 21 CFR 589.2000 and 589.2001 Regulation? YES NO (Circle one)
3. The facility has a written statement, SOP or QA Bulletin that prohibits the use of "Cattle Materials Prohibited in Animal Feed" (CMPAF)? YES NO (Circle one)
4. The company has a written statement, SOP or QA bulletin regarding the use of beef tallow in animal feeds?
YES NO (Circle one)
- (Attach a copy of the facility's statement, SOP or QA bulletin regarding compliance with 21 CFR 589.2001)*
(Attach a copy of the facility's statement regarding use of tallow derived from cattle.)
(Attach 1 copy showing beef tallow test results (if used). Results should be no more than .15% insoluble impurities)
(Attach 1 copy of beef tallow supplier statement that their product in compliance with 21 CFR 589.2001)
5. Does the facility receive and manufacture or use or distribute products that contain or may contain restricted use protein products? YES NO (Circle one)
- 5a. If the answer to #5 is "YES," is the facility only receiving packaged products (e.g. pet food products) containing restricted use protein products? YES NO (Circle one)

This audit is intended only for the named facility's RUPP program and its policies and procedures as they pertain only to those questions asked on this form. This audit is not intended to imply that all feed safety hazards are in compliance with cGMPs, ISO or HACCP programs. This audit does not imply that this plant is free of RUPP or CMPAF. This audit only certifies that written procedures and documentation are in place that makes the facility in compliance with FDA CFR 21-589.2000 and 589.2001.

5b. If the answer to #5 is "YES" and the facility is only receiving packaged products (e.g. pet food products) containing restricted use protein products, does the facility have written procedures in place to prevent such products or "salvage" products from entering the manufacturing area of the plant? YES NO (Circle one)

(Attach 1 copy of the facility's SOP or QA Bulletin as it relates to 5b)

6. Could the facility produce a written policy that assures it does not utilize restricted use protein products and CMPAF in manufacturing feed? YES NO (Circle one)

(Attach 1 copy of the facility's SOP or QA Bulletin)

7. Does the facility have written agreements with transporters and ingredient suppliers (including renderers and protein blenders) that they comply with the FDA's carry-over prevention procedures? YES NO (Circle one)

(Attach 1 copy of a supplier's agreement that indicates that they are in compliance with 589.2000 and 589.2001)

8. Does the facility have written agreements from livestock renderers, protein blenders and beef tallow suppliers that their product is in compliance with the newly revised 21 CFR 589.2001? YES NO (Circle one)

(Attach 1 copy of tallow supplier agreement regarding 21 CFR 589.2001)

For applicants that handle restricted use protein products complete questions #9 through #14

NA

9. Does the facility maintain records sufficient to track restricted use materials throughout their receipt, processing, and distribution including:

- Date of receipt or purchase; sale or delivery YES NO (Circle one)
- Name and address of the renderer/supplier YES NO (Circle one)
- Name and address of the carrier YES NO (Circle one)
- Name and address of the consignee YES NO (Circle one)
- Identification of the product YES NO (Circle one)
- Quantities in pounds or tons YES NO (Circle one)
- Copies are available for inspection and copying YES NO (Circle one)

10. Is the facility processing or manufacturing and distributing both products containing restricted use protein products and products containing non-restricted use products? YES NO (Circle one)

11. If the answer to #10 is "YES," does the facility have written procedures in place to avoid commingling and cross contamination? YES NO (Circle one)

(Review and describe the separation procedures or clean-out processes and any procedures to avoid commingling and cross contamination. List SOP or QA manual reference sources for the procedures below.)

12. If the answer to #10 is "YES," does the facility have written procedures in place to ensure proper labeling of restricted and non-restricted use protein products? YES NO (Circle one)

(Attach SOP or QA bulletin reference sources for these procedures)

13. Are all products containing restricted use proteins prominently labeled with the caution statement "Do not feed to cattle or other ruminants?" YES NO (Circle one)

14. Does the facility have any safeguards in place to assure that outgoing products containing restricted use protein products are not shipped to ruminant feeders for feeding to ruminants? YES NO (Circle one)

(Attach SOP or QA bulletin source for these safeguards)

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15. Does the facility have an adequate product lot numbering system to facilitate recalls? **YES** NO (Circle one)

(List Recall SOP or QA Bulletin number regarding recall policy and procedure SOP 26)

16. Briefly describe any discrepancies or concerns that would disqualify certification:

NO DISCREPANCIES NOTED.

17. Did the facility's representatives make any commitments to correct these deficiencies? YES NO NA
If "YES," briefly describe those corrections below: (use deficiencies form if additional space is required)

NA

18. Did the facility's representatives provide a date at which the deficiencies would be corrected? YES NO NA
If "YES," provide expected date of corrections for each deficiency:

NA

19. Name(s) and title(s) of person(s) interviewed during walkthrough of the facility:

20. Is the FCI RUPP seal being used as described in licensing agreement? **YES** NO
If "NO", please explain licensing infringement below:

21. Auditor's Conclusion: (check all that apply)
Recommend Certification **X**
Requires re-audited to confirm corrections
Needs additional educational materials
Next scheduled date for re-inspection: _____

Auditor's Signature Dick Chap Date of this Audit 6-8-10

Plant Representative's Signature: Rene L. Lova Date of this Audit: 6/8/10

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