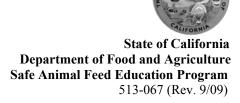


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6.



SAFE FEED QUALITY ASSURANCE AUDIT CHECKLIST

D	ate of	Inspection	Firm#	Current FDA License #	Total Time of Inspection		
F	Firm Name Address			Owner/Parent Firm (If Different) Address			
A							
C	ity & S	State		City & State			
Т	Telephone			Telephone	Telephone		
R	espons	sible Individual &	Γitle:	Type of Commercial Feed Manufacturer:			
	olume ulk =	of Business: Sacked =	% Medicated =	Commercial Feed mill			
			rcentage of feed distributed in CA)	Custom Formula Mixer			
Ir	ngredie	ents =	Premixes =	Premix Mineral facility			
C	Concentrates = Complete Feed = List Species and Class of Animal for which Commercial Feed M			Other			
L				Manufactured or Distributed.			
I)	⊠ FE	facility are not in	accordance with that statement of follow-up actions or recommenda	on this Checklist. Use the Safe Fo	nditions or practices observed at the eed Quality Assurance Summary to		
A)	PRC	TEIN PRODUC	TS PROHIBITED IN RUMINA	NT FEED			
	1.	. Does this firm receive any mammalian protein prohibited in ruminant feed other than sacked pet food. Yes No					
	2.	Does this firm ha	andle feed ingredients or feeds that	are intended for the feeding of rum	inant animals. Yes \(\square\) No \(\square\)		
3)	DR	UG ROOM AND	OR CONCENTRATE HAND-A	ADD AREA			
	1.	Drugs & high-ris	sk minerals (i.e. concentrated - selen	nium, copper, iodine etc.) are stored	d in a discrete location.		
\Box	2.	Drug room and/o	or concentrate hand-add area can be	secured and access is limited to tra	nined personnel.		
	3.	=	or concentrate hand-add area is clea	-			
5	4.	Drugs are labele indications for u	d and approved for use in commerc se.	ial feed including appropriate speci	es, drug levels, and proper		
5	5.	Drugs & high-ris	sk minerals are stored in original co	ntainers with lot integrity is preserv	ved, and have not expired.		

Inventory and usage records are maintained for each drug and/or high-risk minerals.



	7.	The firms drug inventory system: 1 A. Makes a daily comparison between actual amount of drug used and theoretical drug usage. 1 B. Have drug inventory records that agree with actual drug inventory on hand. 1 C. Includes a working definition of what it considers as constituting a significant discrepancy in the drug inventory. 1 D. Includes procedures for holding feeds on the premises until a significant discrepancy is reconciled.			
5	8.	Scale used to weigh drugs, high-risk and other hand-adds is accurate and calibration is checked regularly. (Certified to be accurate annually)			
3	9.	Scale sensitivity is appropriate for the demands of the feed formulas being utilized.			
3□	10.	Identity and security of weighed material is maintained from the scale to the mixer.			
3□	11.	Firm maintains receipt records for each lot of drugs received.			
	12.	List drugs & high-risk minerals present:			
	DI II	RCHASING AND RECEIVING FEED INGREDIENTS			
C) 3□	1.	All ingredient manufacturers have agreements with the firm that they are in compliance with the provisions of the ruminan			
الا	1.	feeding ban. (FDA's BSE-prevention regulation 21CFR 589.2000)			
5□	2.	All ingredients are manufactured by firms that are on an existing approved supplier list, that has been established by			
У П	2.	manufacturing plant inspections, supplier certification, purchase contract specifications, and monitoring product quality.			
3□	3.	All ingredients are delivered by firms (i.e. trucking companies) that have agreed not to cross-contaminate or adulterate the			
		product and that all the required labeling accompanies each delivery.			
5	4.	All ingredients are approved for use in commercial feed and are properly labeled.			
D)	WAI	REHOUSING OF ALL SACKED FEED INGREDIENTS			
1	1.	Ingredients are stored in a separate location from finished feeds and are clearly identified.			
5□	2.	Ingredients are stored apart from hazardous materials and unapproved feed additives.			
		(i.e. pesticides, lubricants, petroleum products, caustic chemicals and cleaning agents)			
1	3.	Ingredients are stored in a manner that promotes "first in/first out" usage.			
1	4.	Sacks are examined for evidence of adulteration upon receipt and before use.			
1	5.	Sacks are stored on pallets and are not in contact with walls or the floor.			
5□	6.	Prohibited materials, such as meat & bone meal, are handled and stored separately from ruminant feed ingredients.			
3□	7.	Open or torn bags are not present and cleanup procedures for ingredients such as prohibited materials are in place.			
5□	8.	Expired, damaged, moldy or otherwise adulterated material is not observed.			
3□	9.	Pest infestation is not apparent.			
1	10.	Storage area is reasonably clean and orderly.			
E)	BUI	K FEED INGREDIENT STORAGE			
1	1.	All ingredients are protected from weather damage or environmental adulteration.			
1	2.	Silos/bins/stalls are clearly identified and designated for specific commodities.			



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5□	3.	Prohibited materials, such as meat & bone meal and mammalian blood, are not conveyed in common equipment and are			
		stored separately from ruminant feed ingredients.			
1	4.	Trucks and railcars are examined for labeling and fumigation notices prior to unloading.			
1	5.	Trucks and railcars are examined for gross adulteration before/during unloading.			
5□	6.	Damaged, moldy or otherwise adulterated material is not observed.			
3□	7.	Pest infestation is not apparent.			
5□	8.	Ingredients are stored apart from hazardous materials and unapproved feed additives.			
		(i.e. pesticides, lubricants, petroleum products, caustic chemicals and cleaning agents)			
F)	PES	ST CONTROL			
1	1.	A routine pest control program is in place for rodents, insects and birds.			
5□	2.	Pesticides are stored and used in a manner to prevent the adulteration of commercial feed.			
1	3.	Only trained personnel apply pesticides.			
1	4.	Pesticide applications are recorded.			
	5.	List pesticides that are present or in use:			
II)	PR	ROCESSING AND EQUIPMENT			
A)	MA	IAINTENANCE			
5□	1.	Equipment is constructed and maintained to prevent contamination from lubricants or cleaning agents.			
3□	2.	Magnets and screens are routinely checked for proper operation and cleaning.			
1	3.	Receiving pits, elevators, silos, bins and commodity stalls are under a routine cleaning schedule.			
1	4.	Conveyors, augers, mixers, grinders, grain rollers, pellet mills, etc. are under a routine maintenance and cleaning			
		schedule, including monitoring allowable tolerances for moving parts.			
3□	5.	Hand-add areas are constructed and maintained to prevent adulteration of feed by drugs and high-risk minerals.			
5□	6.	All scales and metering devices are accurate and calibration is checked regularly.			
		(Certified to be accurate at least annually.)			
1	7.	Maintenance activity, repairs, cleanings and calibrations are recorded.			
3	8.	All computerized and/or automated equipment has been verified to be able to perform as intended.			
B)	ΕO	UIPMENT			
Δ)	1.	Mixers are used according to manufacturer's specifications			
		1 ☐ A. Minimum and maximum capacity limits are known and observed.			
		1 ☐ B. Mixing times have been established and adhered to (Note – timing device).			
		1 ☐ C. Limitations on minimum inclusion rates are known and observed.			
3□	2.	Sampling and analysis validate mixing specifications.			
3□	3.	Sequencing protocols are utilized for the addition of drugs and concentrated ingredients insure uniform distribution.			
5□	4.	Since installation, the firm has determined the mixers ability to produce a uniformly mixed feed. (mixer study/mixer profile)			
1	5.	Equipment is constructed to allow inspection and use of clean-out procedures.			
1	6.	All equipment is reasonably clean and properly maintained.			

All equipment is of suitable size, design, construction, and precision f or the intended purpose.



C)	CLE	ANOUT PROCEDURES			
5	1.	Clean out procedures in use are adequate to prevent adulteration of feed. Describe procedures in use. (sequencing, flushing, and physical).			
1	2.	Clean out procedures following mixes containing drugs or high-risk minerals are posted and utilized.			
5	3.	There is documentation that equipment cleanout procedures are actually being performed.			
5	4.	Flush material is identified, stored and utilized in a manner that prevents contamination of other feed.			
3	5.	Sampling and laboratory testing have verified effectiveness of clean out procedures.			
3	6.	Mixers and conveyors do not contain excessive buildup of old material.			
III)	FOI	RMULAS, LABELS AND PRODUCTION RECORDS			
A)	FOR	FORMULAS			
5	1.	Formulas are reviewed for safety, regulatory compliance, and suitability for the intended species and specific class of Animal.			
1	2.	Formulas are reviewed for compatibility with equipment limitations.			
1	3.	A clear chain of custody and control of formulas exists between formulators and mixers.			
3□	4.	Formulas are clearly identified and maintained to ensure correspondence with current labeling.			
5□	5.	Formulas are accurate to produce commercial feed as indicated by its labeling.			
		(Note – check several formulas and labels for accuracy)			
	6.	List person(s) responsible for formulation.			
B)	LAB	BELS			
1	1.	Feed labels are reviewed prior to use and initialed by responsible individual.			
1	2.	Responsibility for the use of new labels and destruction of outdated labels is clearly allocated.			
5□	3.	A label is affixed to, or accompanies, all commercial feeds being distributed.			
5□	4.	Labels contain a list of ingredients and all guarantees required by law.			
5	5.	Medicated feeds are clearly identified.			
5 <u></u>	6.	Drug levels are guaranteed at Federally approved levels and are approved for the intended species/class of animal.			
5	7.	Applicable warning statements as required by law are present and prominent (i.e. BSE, drugs, NPN, and selenium).			
5□	8.	Feeding and/or mixing directions are adequate for the safe, approved and intended use of the commercial feed.			
	9.	List person(s) responsible for designing feed labels.			
C)	PRODUCTION RECORDS				
	1.	Mixing records are maintained to chronicle sequence and quantity of batches produced daily.			
		1 ☐ A. Provide a complete and traceable history of the production of a batch or production run.			
		1 ☐ B. Written endorsement by a responsible person.			
		1 □ C. Name and quantity of drug or high-risk components used.			
5∐	2.	Acceptable deviations of actual from theoretical batch weights have been determined.			



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5□	3.	A comparison of theoretical versus actual batch weights is recorded.
5□	4.	A comparison of actual production versus final load weight or bag count is documented.
1	5.	Production records identify specific equipment and bins used in that batch of formula feed.
1	6.	Steps are in place to minimize mix-ups, such as running feeds into the wrong bins.
3	7.	Production records include a code or lot number that identifies every load of feed manufactured for at least one year.
3	8.	Production records are reviewed daily and management is immediately notified of any discrepancies.
3	9.	Do the records include alarms or error messages that occurred during production and any actions taken to clear the error.
5□	10.	Significant discrepancies are investigated and the production records show the corrective actions taken.
5□	11.	The production formula agrees with the formula in the master record file.
D)	MA	STER RECORD FILE
	1.	The firm has a mater record file for each formula feed
		1 ☐ A. An accurate formula including appropriate levels of drugs and lbs/%/both of each ingredient.
		1 ☐B. A copy of the label that is affixed to or accompanies all formula feeds.
		1 ☐ C. Manufacturing procedures including mixing steps, mixing times, assay requirements and appropriate control directions.
		1 □ D. Procedures for estimating quantity produced for bulk formula feeds.
		1 ☐ E. Each master record file is prepared checked and signed or initialed by a qualified person .
		(Note: calculate drug levels in a representative number of feeds and compare to master record file)
IV)		ISHED PRODUCT CONTROLS
A)	STO	RAGE OF SACKED AND BULK FEED
3□	1.	Sacks are stored on pallets in a clean environment free of pesticides, fuels or other contaminants.
5□	2.	Damaged, moldy or otherwise adulterated products are not present.
3	3.	Pest infestation is not apparent.
1	4.	Medicated products are stored separately from non-medicated.
5□	5.	Products containing prohibited materials, such as meat & bone meal and mammalian blood, are processed, conveyed and
		stored separately from ruminant feeds and written cleanup procedures are in place for bulk, sacks and pet food.
5□	6.	Ingredients are stored apart from hazardous materials and unapproved feed additives.
		(i.e. pesticides, lubricants, petroleum products, caustic chemicals and cleaning agents)
B)	SHIF	PMENT AND DISTRIBUTION
3	1.	Return and/or reworked feed is identified with a label and stored to prevent commingling with other feed.
1	2.	Load-out and sack off bins are designated only for medicated feeds, or validated clean-out procedures are in place.
1	3.	Identity and integrity of finished bulk feeds are maintained from the mixer to the truck.
1	4.	Trucks are inspected for cleanliness and integrity prior to bulk loading.
1	5.	Trucks are loaded and unloaded to prevent the commingling of feeds and eliminate residues from drugs, high-risk

minerals or prohibited materials.



513-067 (Rev. 9/09) $3\square$ Distribution records that include a code or lot numbers are maintained for all finished feed and feed ingredients. 6. RECALL PROCEDURES C) 5□ A written recall plan has been developed. 3□ 2. All feed can be traced back and traced forward by a code or lot number that identifies each load or production run. 1 All parties that may be impacted by adulterated, or unsafe feed are notified in a timely manner. 3. Investigation is initiated if existing criteria demands it. $1\square$ 4. $1\square$ 5. Recalled material is handled, used or disposed of in an appropriate manner. D) **COMPLAINT PROCEDURES** 5□ 1. A customer complaint form has been developed and a file is available on site for inspection. $1\square$ 2. All customer complaints are investigated and documented. 3. 1 Investigations involving animal health and/or food safety concerns are reported to regulatory officials immediately. 3□ 4. A complaint follow-up is documented and includes findings and resolution. V) **PERSONNEL TRAINING** A) 3□ 1. Mandatory training programs are in place for personnel assigned to critical areas of manufacturing. (i.e. drug room and/or hand-add area, mixing areas, bulk load out, and scale house) 3□ 2. Relief and back-up personnel in critical areas are adequately trained. $1 \square$ 3. All personnel in direct contact with feed and feed ingredients conform to good hygienic practices. 3□ 4. Quality assurance and feed safety training incorporating Standard Operating Procedures (SOP's) are documented and acknowledged by all personnel. 1 5. SOP's are posted at critical areas of feed manufacturing. **SUPERVISION** B) $3\square$ 1. Responsibility for monitoring adherence to the SOP's and/or quality assurance program is clearly assigned. 2. Supervisors are knowledgeable of all aspects of the firms SOP's and/or quality assurance program. 3□ $1\square$ 3. Employees are provided with ongoing evaluations and supervision. **BUILDINGS, GROUNDS AND BIO-SECURITY** A) HOUSEKEEPING 1. Separate and clearly identified trash receptacles are in place. $1\square$ Work areas are reasonably clean, orderly and well lit. 1□ 2.

Pallets are clean, and are examined for pests and contaminants prior to use.

Dust is controlled to prevent contamination of feed.

Packaging (i.e. sacks, buckets) is stored in a clean, contaminant free environment.

 $1 \square$

1

1

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B)	GROUNDS		
1	1.	Grounds are free of weeds and other debris (i.e. pallets, containers, etc.) that may harbor insects and other vermin.	
1	2.	Grounds have proper drainage to prevent the harboring of vermin and pathogens.	
1	3.	Excessive amounts of piled feed waste or spilled grains are not present.	
C)	BUI	LDINGS	
1	1.	Buildings are erected and maintained to prevent the entrance of vermin and other pests.	
1	2.	Buildings provide adequate space for equipment, processing and orderly receipt, shipping and storage of feed.	
1	3.	Buildings used for the manufacturing and storage of feed provide for ease of access to structures and equipment in need of routine cleaning and maintenance.	
D)	BIO-	-SECURITY	
3□	1.	Feed delivery trucks are disinfected after coming in contact with the ground where livestock are confined.	
1	2.	Sales staff and feed delivery truck drivers wear disposable boot covers when coming in contact with livestock on-farm.	
1	3.	Customers, and delivery vehicles are not allowed in areas where feed is stored or manufactured.	
3	4.	Entrances into feed manufacturing areas are secured and/or monitored at all times.	
VII)	Q U	ALITY CONTROL	
A)	SAN	IPLING PLAN FOR INGREDIENTS	
1	1.	Weight certificate numbers on bulk ingredients are recorded, then sampled and visually inspected by trained personnel.	
1	2.	Each lot number of sacked ingredients are recorded, visually inspected and sampled before use.	
1	3.	An assay schedule is developed according to the propensity for variation and potential risk.	
B)	SAN	IPLING PLAN FOR FINISHED FEED	
1	1.	All finished feed products are sampled and visually inspected by trained personnel.	
3□	2.	All samples are maintained by lot number in protected storage for at least three months.	
3	3.	Ruminant feed is tested to verify that there is no prohibited animal protein present.	
C)	LAB	SORATORY ANALYSES OF FINISHED FEED	
5□	1.	Medicated feeds are analyzed at least once per year for each drug in use, three times per year for Category II type A.	
1	2.	Non-medicated feeds are analyzed according to propensity for variation and potential risk.	
5□	3.	All out of tolerance assay results are investigated to verify that formulation and manufacturing processes are in control.	
1	4.	Corrective actions are documented.	