Model Animal Food Safety Plan for Vitamin and Mineral Premix

Table of Contents

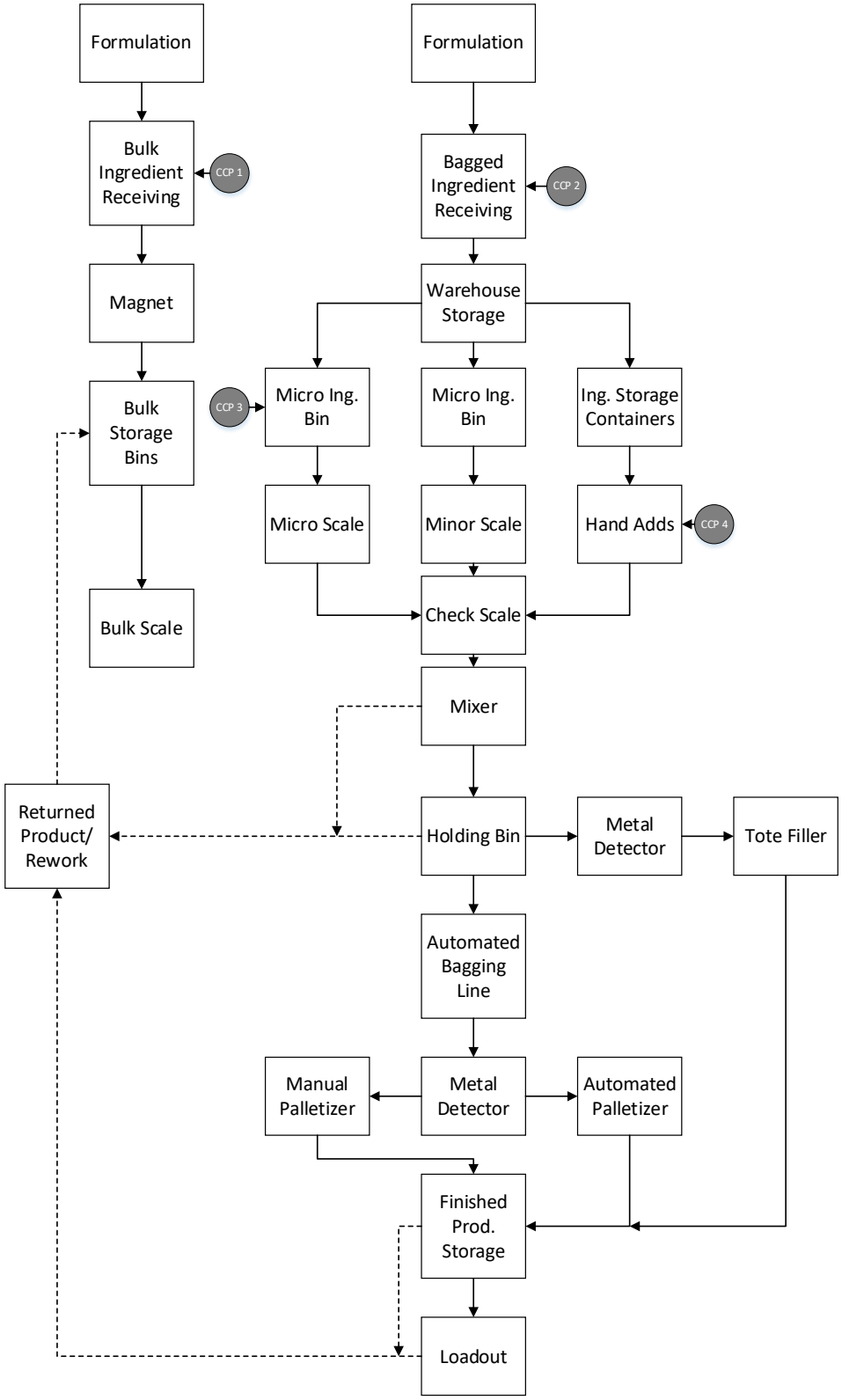
List of Product Ingredients and Incoming Materials Form

Bulk Ingredients	**Bag, and Hand Add Ingredients**	**Medications/Drugs**
Rice hulls Cottonseed meal DDG's NPN	Vitamin D3 Vitamin AD&E Vitamin B1 Selenium Salt Copper	None
Liquids	**Packaging Materials**	**Other Additives**
None	Poly bags	N/A

Product Description Form

1. Product name(s)	Vitamin Premix
2. Product safety properties (Moisture, Temperature, NPN, etc.)	NPN, Copper, Vitamin D3, Vitamin AD&E, Vitamin B1, Selenium
3. Intended use and customer	Cattle, horse, sheep, goat, dog, and cat food
4. Type of packaging	Poly Bags
5. Shelf life	12 months
6. Where will the product be sold?	Distributors
7. Labeling instructions	If copper added in ingredients then put copper statement about not feeding to sheep.
8. Special distribution control	None

Process Flow Diagram



Hazard Analysis Form

Ingredient or Process Step	Known or reasonably foreseeable hazards introduced, increased or controlled at this step	Do known or reasonably foreseeable hazards require a preventive control based on Severity and Probability (Yes/No)	Explanation/Justification	Preventive Control Measures Applied	Is the Preventive Control Applied at this Step? "Yes" or "No"
Formulation Procurement	**Biological** None identified at this time				
	Chemical NPN, Copper, Selenium, Vitamin AD&E, Vitamin D3, Vitamin B1	Yes	Supply chain applied control for vitamins and minerals, verification of formulation accuracy	Supply chain control	No
	Physical None identified at this time				
Bulk Receiving	**Biological** None identified at this time				
	Chemical Aflatoxin Fumonisin	Yes	DDG's, Rice Hulls and Cottonseed Meal possess a medium to high probability of aflatoxin contamination. TX corn has a high probability of fumonsin that also may occur in distillers dried grains and solubles (DDGS).	Process Control Testing for aflatoxin and fumonisin upon receipt.	Yes CCP1
	Physical Metal, Glass, Plastic, Wood, Stone	No	Foreign materials are managed at the next process step and includes magnets to control metal and screens to remove stones, glass, plastic and wood. Likelihood is low resulting from SOP – Magnets and Screens		
Bagged Receiving	**Biological** None identified at this time				
	Chemical Incorrect ingredient concentration from unapproved supplier	Yes	Bagged ingredients may contain excess or deficiency of critical nutrients	Supply chain control	Yes CCP2
	Physical None identified at this time				
Magnet & Screens	**Biological** None identified at this time				
	Chemical None identified at this time				
	Physical Metal, Glass, Plastic, Wood, Stone	No	SOP will include magnets and screens control metal, glass, plastic, stones, & wood. Likelihood is low.		
Bulk Storage	**Biological** None identified at this time				
	Chemical Aflatoxin	No	Aflatoxin can increase in storage. Control of storage length and temperature through aeration and monitor reduce the likelihood of this hazard following bulk storage SOP.		

Ingredient or Process Step	Known or reasonably foreseeable hazards introduced, increased or controlled at this step	Do known or reasonably foreseeable hazards require a preventive control based on Severity and Probability (Yes/No)	Explanation/Justification	Preventive Control Measures Applied	Is the Preventive Control Applied at this Step? "Yes" or "No"
	Physical None identified at this time				
Warehouse storage	**Biological** *Salmonella*	No	Potential contamination by rodent and bird excrement reduced through sanitation and pest control SOPs.		
	Chemical None identified at this time				
	Physical Wood	No	Wood pallets are not used.		
Micro-ingredient Bins, Minor and Micro Scales	**Biological** None identified at this time	No	Salmonella is of low likelihood in poultry fat.		
	Chemical Copper, Selenium, Vitamin AD&E, Vitamin D3, Vitamin B1, Vitamin E	Yes	Weighing errors and use of incorrect ingredients are managed at this critical control point.	Process Control Ingredient use is recorded for each batch and reconciliation of ingredients at the end of every shift.	Yes CCP3
	Physical None identified at this time				
Hand Adds	**Biological** None identified at this time				
	Chemical Copper, Selenium, Vitamin AD&E, Vitamin D3, Vitamin B1	Yes	Weighing errors and use of incorrect ingredients are managed at this critical control point.	Process Control Ingredient use is recorded for each batch and reconciliation of ingredients at the end of every shift.	Yes CCP4
	Physical None identified at this time				
Bulk Scale	**Biological** None identified at this time				
	Chemical None identified at this time				
	Physical None identified at this time				
Check Scale	**Biological** None identified at this time				
	Chemical None identified at this time				
	Physical None identified at this				

Ingredient or Process Step	Known or reasonably foreseeable hazards introduced, increased or controlled at this step	Do known or reasonably foreseeable hazards require a preventive control based on Severity and Probability (Yes/No)	Explanation/Justification	Preventive Control Measures Applied	Is the Preventive Control Applied at this Step? "Yes" or "No"
	time				
Mixer	**Biological** None identified at this time				
	Chemical NPN, Copper, Selenium, Vitamin AD&E, Vitamin D3, Vitamin B1		High copper in Sheep Feed, high non-protein nitrogen selenium in horse feed, vitamin D toxicity in dog food, low vitamin B1 in cat food that can result in immediate health effects. Hazard controlled at micro scale and hand add process steps through SOP. Sequencing, flushing and cleanout are practiced. Low likelihood		
	Physical None identified at this time				
Holding Bin	**Biological** None identified at this time				
	Chemical None identified at this time				
	Physical None identified at this time				
Metal Detectors	**Biological** None identified at this time				
	Chemical None identified at this time				
	Physical Metal	No	SOPs include magnet to control metal. Likelihood is low.		
Tote Filler	**Biological** None identified at this time				
	Chemical None identified at this time				
	Physical None identified at this time				
Automated Bagging	**Biological** None identified at this time				
	Chemical None identified at this time				
	Physical None identified at this time				
Manual & Automatic Palletizer	**Biological** None identified at this time				
	Chemical None identified at this				

Ingredient or Process Step	Known or reasonably foreseeable hazards introduced, increased or controlled at this step	Do known or reasonably foreseeable hazards require a preventive control based on Severity and Probability (Yes/No)	Explanation/Justification	Preventive Control Measures Applied	Is the Preventive Control Applied at this Step? "Yes" or "No"
	time				
	Physical None identified at this time				
Finished Product Storage/ Loadout	**Biological** None identified at this time				
	Chemical None identified at this time				
	Physical None identified at this time				

Identifying Critical Limits, Monitoring and Corrective Actions Form

Process Step/CCP	Critical Limit	Monitoring Procedures	Corrective Action
Bulk Receiving CCP1	Aflatoxin: 20 ppb Fumonisin: 5ppm	**What will be measured?** Aflatoxin $\leq$ 20ppb Fumonisin $\leq$ 20	**Cause of the deviation?** Incorrect test result, failure to test.
		Where will the CL be measured? Receiving.	**How will the process be corrected?** Use of reference material and participation in proficient testing program to ensure accurate testing, retain employee or dismiss if repeat failures.
		How will the CL be measured? Use of USDA FGIS performance verified test kit.	**Product disposition?** Product rejected.
		Who will monitor the CL? Receiving employee.	**Measure to prevent recurrence?** Testing of every load accurately following mycotoxin testing SOP. Annual qualification of mycotoxin analysts. Annual review of bulk ingredients receiving and mycotoxin testing SOPs.
		How often will the CL be measured? Every load received into facility.	**Who is responsible for implementing the CA?** Quality Control/ Assurance Manager

Identifying Critical Limits, Monitoring and Corrective Actions Form

Process Step/CCP	Critical Limit	Monitoring Procedures	Corrective Action
Bag Receiving PC 2	Zero tolerance,	**What will be measured?** Product must be part of supply chain control program – approved supplier **Where will the CL be measured?** Receiving. **How will the CL be measured?** Compare list of approved suppliers with bill of lading **Who will monitor the CL?** Receiving employee. **How often will the CL be measured?** Every load received into facility.	**Cause of the deviation?** Incorrect supplier Failure to check if product was from an approved supplier **How will the process be corrected?** Retrain receiving and purchasing employee **Product disposition?** Product rejected. **Measure to prevent recurrence?** Annual review of bulk ingredients receiving and mycotoxin testing SOPs. Employee training or termination **Who is responsible for implementing the CA?** Quality Control/ Assurance Manager

Identifying Critical Limits, Monitoring and Corrective Actions Form

Process Step/CCP	Critical Limit	Monitoring Procedures	Corrective Action
Minor Scales CCP3	Actual versus theoretical variance of 2% based on formulation procurement.	**What will be measured?** Products controlled by automated minor scales.	**Cause of the deviation?** Scales out of calibration obstructions. Incorrect data transmitted to system.
		Where will the CL be measured? Minor scales	**How will the process be corrected?** Product separated to rework or disposed of.
		How will the CL be measured? Daily reconciliation paperwork of used versus actual ingredients.	**Product disposition?** Potentially product return to rework or disposed of.
		Who will monitor the CL? Production supervisor	**Measure to prevent recurrence?** Preventative maintenance to insure proper operation. SOPs provide schedules calibration of scales. System design to prevent incorrect data entry.
		How often will the CL be measured? Every batch.	**Who is responsible for implementing the CA?** Quality control manager.

Identifying Critical Limits, Monitoring and Corrective Actions Form

Process Step/CCP	Critical Limit	Monitoring Procedures	Corrective Action
Hand Add Scale CCP4	Actual versus theoretical variance of 2% based on formulation procurement.	**What will be measured?** Hand add products	**Cause of the deviation?** Employee error Scales out of calibration
		Where will the CL be measured? Hand add station	**How will the process be corrected?** Product separated for rework or disposed of.
		How will the CL be measured? Daily reconciliation paperwork of used versus actual ingredients.	**Product disposition?** Potentially product returned to rework or disposed of.
		Who will monitor the CL? Production employee	**Measure to prevent recurrence?** Preventative maintenance to insure proper operation. SOPs provide scheduled calibration of scales. Proper employee training/retraining
		How often will the CL be measured? Every batch and end of shift.	**Who is responsible for implementing the CA?** Quality control manager.

Record Keeping and Verification Form

Process Step/ CCP	Hazard	Records	Responsibility	CCP Verification?
Bulk Ingredient Receiving CCP1	Aflatoxin Fumonisin	Bulk receiving records, reference material, and testing records. Training records Corrective action	Receiving employee Quality Manager	**Short term** Production supervisor verifies tests were performed on every load and that reference material tests results were in control and that no product was received above specified control limit. Quality control manager weekly checks of receiving records, receiving employee signature and signs off. **Long term** Annual qualification of analysts. Participation in proficiency testing program.
Bag Ingredient Receiving PC2	NPN, Copper, Selenium, Vitamin AD&E, Vitamin D3, Vitamin B1	Bag receiving records, Training records Corrective action	Receiving employee Quality Manager	**Short term** Production supervisor verifies correct receiving Quarterly analytical review by reference laboratory Onsite inspection of supplier or review of FDA/State PC inspection report **Long term** Annual qualification of analysts. Participation in proficiency testing program.

Process Step/ CCP	Hazard	Records	Responsibility	CCP Verification?
Minor Scales **CCP3**	Copper Selenium Vitamin A Vitamin E Vitamin D Vitamin B1	Product inventory Batches Records Minor scales calibration	Batching, mixing production employee Quality manager	**Short term** Production manager verifies inventory and sequencing of batches, signs off daily. Production manager daily checks of minor scales records. **Long term** Monthly review of records for production manager verification and completed records by production employee. Annual review and update of SOPs.
Hand Adds **CCP4**	Copper Selenium Vitamin A Vitamin E Vitamin D Vitamin B1	Product inventory and sequencing of batches records. Hand add scale, calibration records Training records, corrective action records	Production employee Production employee Quality manager	**Short term** Production manager verifies inventory and sequencing of batches, signs off daily. Production manager daily checks of minor scales records. **Long term** Monthly review of records for production manager verification and completed records by production employee. Annual review and update of SOPs.

SOPs for Vitamin Mineral Premix

1. **Personal Hygiene**
2. **Sanitation**
3. **Formulation**
4. **Sequential Scheduling**
5. **Receiving**
6. **Approved Supplier Program**
7. **Mycotoxin Testing**
8. **Scale Calibration**
9. **Minor Scales**
10. **Hand Adds**
11. **Magnets & Screens**
12. **Mixing**
13. **Rework**
14. **Recall**
15. **Finished Goods and Loadout**
16. **Pest Control**
17. **Bulk Storage**

Animal Food Safety Plan Summary Form

Process step and CCP	Hazard	Critical Limits for each CCP	Monitoring				Corrective Action	Verification Activities	Record-keeping Procedure
			What	How	Frequency	Who			
Bulk Receiving CCP1	Aflatoxin Fumonisin	Aflatoxin: 20ppb Fumonisin: 5ppm	Aflatoxin $\leq$ 20 ppb Fumonisin $\leq$ 5 ppm	Visual Use of USDA FGIS quick test	Every load received into the facility	Receiving employee	Reject load if test failure or non-approved supplier. Notify supplier grain contained aflatoxin excess of 20ppb or fumonisin excess of 5ppm. Potential removal of supplier from approved supplier list.	Daily review of receiving log and paperwork by QA/QC	Bulk receiving SOPs Receiving log Approved supplier list Record of testing Employee training log
Bag Receiving Supply Chain Control (PC2)	Nutrient deficiency or toxicity	Zero tolerance	Approved supplier	Visual	Every load and bag	Receiving employee	Reject load if test failure or non-approved supplier. Notify supplier grain contained aflatoxin excess of 20ppb or fumonisin excess of 5ppm. Potential removal of supplier from approved supplier list.	Daily review of receiving log and paperwork by QA/QC	Bulk receiving SOPs Receiving log Approved supplier list Record of testing Employee training log

Process step and CCP	Hazard	Critical Limits for each CCP	Monitoring				Corrective Action	Verification Activities	Record-keeping Procedure
			What	How	Frequency	Who			
Minor Scales	Hazards include over and under inclusion of an ingredient.	Actual versus theoretical variance of 3% based on formulation procurement.	Products controlled by automated minor scales.	Daily reconciliation paperwork of used versus actual.	Each batch	Production supervisor.	Product separated for rework or disposal. Preventative maintenance to insure proper operation. SOPs provide scheduled calibration of scales System design to prevent incorrect data entry.	Daily review of receiving log and paperwork by QA/QC.	Minor scales SOPs Production manager verifies inventory and sequencing of batches, signs off-daily. Quality control manager daily checks of minor scales records, product manager signature and signs off. Quality assurance manager daily review and sign off of minor scales records. Employee training log.
Hand Add Scale	Hazards include over and under inclusion of an ingredient.	Actual versus theoretical variance of 3% based on formulation procurement.	Hand add products.	Daily reconciliation paperwork of used versus actual.	Every batc h	Production Supervisor	Product separated for rework or disposal. Preventative maintenance to insure proper operation. SOPs provide scheduled calibration of scales. System design to prevent incorrect data entry.	Daily review of receiving log and paperwork by QA/QC.	Hand add products SOPs Production manager verifies inventory and sequencing of batches, signs off daily. Quality control manager daily checks of hand add records. Production manager signature and signs off. Quality assurance manager daily review and sign off of hand add records. Employee training logs.