



# **Cleanout Procedures**

NOTE: Safe Animal Feed Education Program (SAFE) guidance materials are provided for educational purposes only and do not guarantee adequacy of procedures or compliance with regulations.

\*This SOP is an example based on a scenario for "ABC Feedmill". The key to forming appropriate sequencing and flushing procedures is testing to verify effectiveness within a specific facility. \*

# Scheduling Sequence and Flushing

### Objective:

To minimize the possibility of non-medicated feed being adulterated with a drug residue, and to minimize the possibility of nutrient toxicities due to residues.

### Responsible Person:

Plant Manager and Trained Mixer Operator

Daily and weekly sequencing of the production schedule is approved by the Plant Manager (See Table 2 for example).

### Procedure:

**Background:** "ABC Feed Mill" manufactures finished feed and complete feed <u>for beef and</u> <u>dairy cattle, calves, horses, poultry (layers and meat birds), swine, and sheep</u> including medicated feed for cattle, poultry, swine and sheep, and premixes, concentrates, supplements and Type B medicated feeds for cattle. This feed mill only has <u>1 mixer</u> with a 2-ton capacity.

The following ingredients require proper scheduling of sequence in manufacturing, adequate flushing procedures when necessary, and special considerations when applicable **(Table 1)**:

- Monensin (Category I, Type A)
- Chlortetracycline (CTC) (VFD drug) (Category I, Type A)
- Sodium
- Selenium (any premixes over 600 ppm)
- Non-protein nitrogen (NPN)
- > Copper

Both flushing and sequencing procedures are used together to prevent possible carryover in non-medicated and non-target feeds. A single flush does not negate the need for proper





# **Cleanout Procedures**

sequencing, and sequencing rules cannot be utilized without flushing when necessary. ABC Feed Mill follows several procedures for proper sequencing and flushing.

Definitions:

ABC Feed Mill utilizes the following definitions from American Feed Control Officials (AAFCO) Official Publication, with slight modifications for specific use within ABC Feed Mill.

"Complete Feeds" a nutritionally adequate feed that is intended to be fed as the sole ration without any additional substance besides water. This includes swine and poultry feeds.

"Concentrates" a feed used to improve the nutritive balance of the total diet and intended to be further diluted and mixed to produce a supplement or a complete feed (i.e., protein pellet for component fed dairy herds).

"Supplements" a feed used to improve the nutritive balance or performance of the total ration and intended to be fed undiluted as a supplement to other feeds, offered free-choice with other parts of the ration separately available, or further diluted and mixed to produce a complete feed.

"Premix" is a uniform mixture of one or more micro-ingredients with diluent and/or carrier.

"Grains" includes any rolled grains singly or mixed together as well as grain screenings.

"Finished Feeds" are intended to be fed without further manufacturing except for the addition of forage, hay, silage, or other roughage. This includes horse feeds and ruminant feeds such as pellet/grain mixtures.

### **Sequencing Instructions**

Sequencing is the preplanned order of production, storage, and distribution of feeds designed to prevent unsafe drug carryover into subsequent feeds. ABC Feed Mill sequencing procedures consists of 3 practices (See Table 1):

- 1. Rules for types of feeds to use in sequence, *as practical,* regardless of flushing.
- 2. Strict policies for when a flush is required.
- 3. Strict policies for minimum tons between certain types of feeds.

### Sequencing Rules

Begin sequence with highest concentration of drug and move to lowest concentration before beginning non-medicated feeds.





# **Cleanout Procedures**

- After flushing when appropriate, transition from medicated feeds to non-medicated feeds beginning with supplements, premixes or concentrates (products that will be fed in smaller portions) intended for growing animals of the same species which are under market weight and <u>avoid</u> complete feeds for lactating, egg producing, and market ready animals.
- > Special requirements for: (See Table 1 and Table 2)
  - Horse feed following monensin
  - Lactating dairy and egg producing poultry feed following CTC
  - Sheep feed following copper
  - Poultry, swine, and "close-up" dairy feed following sodium

# **Flushing Instructions**

Flushes consist of 10% of the mixer capacity (a 2-ton mixer requires 400 lbs of flush material) of the primary feed ingredient or an effective alternative. Three types of flushes are performed at this facility: Hold-Back Flush, Clean-Out Flush, and Truck Flush. Hold-Back Flushes are preferred, however when not feasible or adequate, and anytime the product is going to sack-off, a Clean-Out Flush must be performed instead. A flush is performed anytime sequencing procedures cannot be adequately followed, and anytime switching from: (See Table 1 and Table 2).

- > Any VFD feeds to non-medicated feed or a different medication.
- > Formulas over 50 g/ton monensin to non-medicated or a different medication.
- > Formula over 5% sodium to complete feed or close-up dairy feed.
- > Formula over 30 ppm selenium to complete feed or finished feed.
- > Formula containing added copper to sheep feed.
- Formula over 8.75% equivalent crude protein from NPN to complete feed or finished feed.

# Flushing Procedure

<u>Hold-back Flush</u>: The amount of flush material (10% of mixer capacity) of the primary feed ingredient (largest inclusion rate) in that formula is "held back" in the last batch of medicated/ concentrated mineral feed. Once all the product from the last batch is discharged from the mixer, the hold-back flush material is added to mixer and mixed for 30 seconds and then discharged. The hold-back flush follows medicated feed from the mixer to the medicated feed load out bin, and through all common equipment and is finally loaded out on top of the medicated/ mineral feed.





### **Cleanout Procedures**

A Hold-back flush CANNOT be used in the following circumstances:

- When the feed is going to the sack-off line since it may impact consistency of the formula in a 50 lb bag.
- When the feed is a small batch (less than 6 tons) and holding back may impact consistency of the formula.

<u>Clean-out Flush:</u> (*When a Hold-back Flush is not appropriate*): After the last batch of medicated/ concentrated mineral feed is discharged from the mixer, 10% mixer capacity of additional material is placed in the mixer and the mixer runs for 30 seconds, then the flush material follows the medicated feed to the load-out bin, and through all common equipment. Flush material is NOT placed on top of medicated feed, but is captured in a bin, tote, or sacked off. Flush material is labeled with the formula # and date and may be re-used in similar formulas with the same drug or concentrated ingredient or disposed of in the dumpster.

<u>Truck Flush</u>: The **same sequencing principles apply to hauling and unloading bulk feed** for delivery. The 6 scenarios which requires flushing will also prompt a truck flush. Further, all "special requirements" listed under Sequencing Rules and in Table 1 must be applied to trucking.

For example, if a feed with 400 g/ton monensin is loaded to a truck and delivered to a dairy; before that truck is loaded with a non-medicated feed a truck flush must be performed. Further, at least 10 tons of non-medicated feed must be delivered through that truck, utilizing all compartments which held medicated feed, before horse feed would be loaded to the same truck.

When a split load of medicated or high-risk mineral feed and a non-medicated feed is hauled in the same truck, the non-medicated feed or high-risk mineral feed must always be unloaded first.

# ABC Feed Mill has 2 designated trucks for hauling medicated feeds which will never haul horse feed.

Scheduling of sequence in trucking and designated trucks are used to avoid the necessity of truck flushes, however on occasion it is not feasible to avoid a truck flush. After using the auger to unload the medicated feed there will be non-medicated feed or a flush material that is loaded into the compartment closest to tractor (farthest from the stinger load-out) and used for the flush. The flush will consist of unloading the non-medicated feed or flush material for 15 seconds. Depending on the situation, the non-medicated feed or flush material can be emptied on top of the medicated feed or captured in a bin or tote for disposal or rework.

# Frequency:

Daily.





### **Cleanout Procedures**

### Validation:

1. Sequencing and flushing procedures for drugs based on FDA Compliance Policy Guide Sec. 680.600 "Sequencing as a Means to Prevent Unsafe Drug Contamination in the Production, Storage, and Distribution of Feeds".

2. Sequencing rules for copper, selenium, and sodium are based on the maximum tolerable levels of minerals for livestock, according to National Research Council "Mineral Tolerance of Animals". Based on this value, a carryover rate of 10% is assumed, using an <u>abundance of caution</u>, (400 lbs out of a 2 -ton batch left in the mixer/conveyance) to determine the formula concentration at which special consideration or flushing is needed prior to manufacturing feed for that species.

3. Guidelines for NPN are based on the California Code of Regulations requirement that feeds over 8.75% equivalent crude protein from NPN are a concern and require a caution statement.

4. Record of Flush Verifications for monensin, CTC, copper, sodium, selenium, and NPN (See Flush Verification Form: Example).

### **Corrective Actions:**

Corrective actions will be documented in the event that the sequence schedule or flushing procedure is not followed.

### Related Documents:

**Flush Verification** 

Ingredient	Sequence for feeds following:	Flush & Special Requirements	
Monensin (90.7 g/lb)	1. Other feeds containing monensin (begin sequence with highest level of drug and	10 tons of non-medicated feed prior to horse feed	
	move to lowest level). 2. Premixes, supplements and concentrates for growing animals of the same species.	5 tons of non-medicated feed prior to swine feed	
		Always flush when transitioning from a formula	

# Table 1. Sequencing Rules, Flushing and Special Requirements for "ABC Feed Mill"specific tonnages determined through flush verification testing and risk assessment.





# **Cleanout Procedures**

	3. Feeds for growing animals of the same species.	with over 50 g/ton monensin to a non-medicated feed or feed containing another drug.
Chlortetracycline (50 g/lb)	<ol> <li>Other feeds containing CTC (begin sequence with the highest level of drug and move to the lowest level).</li> <li>Premixes, supplements, and concentrates for growing animals of the same species.</li> <li>Feed for growing animals of the same species.</li> </ol>	Always flush when transitioning from CTC to non- medicated feed or feed containing another drug. 10 tons of non-CTC feed prior to lactating dairy feed or laying hen feed.
Sodium (over 5% in formula) Includes salt, sodium bicarbonate, etc.	<ol> <li>Premixes, supplements, concentrates</li> <li>Cattle feed</li> <li>Sheep feed</li> <li>Horse feed</li> </ol>	Always flush when transitioning from over 5% sodium formula to complete feed. At least 5 tons of finished feed prior to poultry, swine, or close-up dairy rations/ premixes.
Selenium (over 600 ppm)	<ol> <li>Premixes</li> <li>Concentrates</li> <li>Cattle feed</li> </ol>	Always flush when transitioning from a formula over 30 ppm to complete feed or finished feed.
Non-protein nitrogen (NPN) Includes urea, ammonium sulfate, etc.	1. Concentrate/ premixes that will be fed/ mixed in small quantities	Always flush when transitioning from a NPN supplement with over 8.75% equivalent crude protein from non-protein nitrogen to complete feed or finished feed.
Copper	<ol> <li>Cattle premixes and concentrate</li> <li>Horse feed</li> <li>Cattle Feed</li> </ol>	5 tons of feed without added copper prior to manufacturing sheep feed.





# **Cleanout Procedures**

# Table 2: Example of daily production schedule which is approved by the Plant Manager.

Date	Formula Name (Formula #)	Drug/ concentrated ingredient	Tons	Destination	Perform Flush?
Wednesday 1/5/22	Layer Pellet (#313)		18	Bulk # 1	NO
	Sweet Cob (#001)		16	Sack-off	NO
	Sheep Mix (#333)		8	Sack-off	NO
	Horse Mix (#888)	Copper	18	Sack-off	NO
	Beef Premix (#245)	Monensin 1200 g/ton, selenium, copper	12	Bulk #1	NO
	Dairy Pellet-B (#003)	Monensin 440 g/ton, copper	6	Bulk # 2	NO
	Calf Pellet-C (#657)	Monensin 30 g/ton	12	Bulk # 1	NO
	Range Salt (#101)	Sodium, copper, selenium, NPN	12	Sack-off	NO
	CTC Loose Salt (#123)	CTC 3000 g/ton, sodium, copper, selenium	14	Sack-off	YES
	CLEANOUT FLUSH	400 lbs ground corn		Sack-off	
	CTC Sow (765-3)	800 g/ton CTC	8	Bulk # 2	NO
	CTC Calf (#765)	400 g/ton CTC	10	Bulk # 1	YES
	HOLD-BACK FLUSH	400 lbs ground corn		Bulk # 1	
	Calf Grain (# 004)		10	Bulk # 1	NO
	Steer Mix (#005)		8	Bulk # 2	NO
	Corn Barley Mix (#11)		16	Bulk # 1	NO
	Close-up Dairy mix (#555)	selenium, copper	12	Bulk # 2	NO