

MANUFACTURING PRACTICE - EQUIPMENT CLEAN OUT PROCEDURES

I Proposed Regulatory Text

17 (1) Subject to subsection (3), the making of medicated feed by a licensed operator must be by sequential production.

(2) Every licensed operator must have written procedures respecting sequential production, flushing and the cleaning of equipment used in the making of medicated feed.

(3) Medicated feed may be made by means other than by sequential production if, between lots of medicated feed or lots of medicated feed and other animal food, all equipment, including any equipment used for making, storing, processing, conveying or packing animal food, that comes in contact with the medicated feed is vacuumed, swept, washed, flushed or subject to other equally effective procedures in a manner that prevents contamination.

II Rationale for Regulatory Requirement

Caution is required when handling medications because the amount of medicated feed required to contaminate subsequent batches of non-medicated feeds is minimal. There can be serious ramifications when small quantities of medications are unintentionally carried over from one batch of feed to another. For example, even the smallest quantity of arsenicals can produce problems if they accidentally end up in dairy feeds. Similarly, should monensin sodium from beef rations end up in a horse ration, the results can be fatal. The presence of sulfamethazine in non-medicated finisher rations can lead to condemnation of hog carcasses.

The potential for carryover of drugs from one batch of feed to another is recognized as a challenge in feed manufacturing. However, thorough cleaning of manufacturing and distribution equipment following every batch of medicated feed is impractical and may not be required if appropriate precautions are taken.

Drug carryover can take place anywhere in the feed manufacturing and distribution system. Therefore, effective procedures to prevent the unsafe contamination of feed is required for all equipment, including that used for receiving, storing, processing, mixing, conveying, packaging and distribution.

III Items to Consider When Developing Procedures to Meet Regulatory Objectives

General

To ensure feed safety, feed manufacturers must develop and use appropriate equipment clean out and production sequencing procedures. The purpose of this module is to provide information on:

- general principles respecting production sequences; and
- methods which can be used to verify the effectiveness of flushing and/or other clean out procedures in reducing drug residues to acceptable levels.

Production Sequences

An appropriately designed production sequence is an effective means of preventing the unsafe contamination of medicated and non-medicated feeds. The intent of production sequencing with respect to medications is twofold: prevention of unsafe drug residues in foods produced from animals; and, prevention of injury to the animals themselves. Sequencing procedures and practices should be clearly understood by all personnel responsible for feed production and scheduling. Written procedures should be readily available for their use as needed. The following are principles to use in designing appropriate production sequences:

- When a medication has a withdrawal established for any use level, feeds containing those medications should **not** be directly followed by feeds for animals producing milk for human consumption, laying hens, finisher animals or other “market-ready” animals (e.g., treated animals may not be shipped for use in food until the withdrawal period is complete) **unless validated cleaning procedures are used** (e.g. flushing, physical clean out) **or unless otherwise authorized**; (e.g., use in “market-ready” animals of this species or class of animals is approved in the Compendium of Medicating Ingredient Brochures (CMIB) or pursuant to a veterinary prescription).
- When a medication is not approved at any level for a particular species or class of animals (i.e., the medicating ingredient is not approved for use in that species or class of animals), feeds containing those medications should **not** be directly followed by feeds intended for that species or class of animals **unless validated cleaning procedures are used** (eg. flushing, physical clean out) **or unless otherwise authorized**; (e.g., a veterinary prescription is available for the batch of feed directly following the medication which authorizes this off-label use).
- When a medication is toxic to a particular species or class of animals (i.e., the CMIB or label indicates that it should be not given to that species or class of animals), feeds containing those medications should never be directly followed by feeds intended for the susceptible species a particular species or class of animals **unless validated cleaning procedures are used.**
- In addition to medications, sequencing procedures must take into account other regulatory requirements such as ingredients included in the mammalian to ruminant feeding ban, e.g., Feeds containing “prohibited material” should **never** be directly followed by feeds intended for ruminants **unless validated cleaning procedures are used.**
- Medicated feeds containing the same medication at different levels should be grouped together and sequenced such that the feed containing the highest level is manufactured first and the feed with the lowest level is manufactured last.
- When sequencing multiple batches of feeds containing different medications, group compatible medications together. Medications that are compatible with the medication in question are listed in the acceptable compatibility section of each medicating ingredient brochure (available from the CFIA web site, www.inspection.gc.ca)

- Since supplements, premixes or minerals are intended for further mixing, any residual medication when these feeds directly follow a medicated feed, in an appropriate sequence, will be further diluted in the complete feed. As such, these feeds may provide a “lower risk” option for directly following medicated feeds.

Flushing/Other Equipment Clean Out Procedures

The use of appropriate production sequences is the preferred method of managing drug residues because it is the least disruptive to the manufacturing process and does not generate flush material. However, there will be situations as described above when production sequencing will not be suitable. In these situations, flushing with an appropriate amount of an approved feed ingredient or other equipment clean out procedures may be required to ensure that the subsequent batches of feed do not contain unsafe drug residues. To ensure that flush materials do not contribute to feed contamination, they must be disposed of in accordance with local environmental regulations or used as an ingredient in feeds intended to contain the same medication.

The amount of flush material required to adequately clean out equipment can vary considerably for the different types of manufacturing systems. The Department of Grain Science and Industry, Kansas State University recommends ground grain be used as the flush material, at a quantity of about 5 to 10% of the mixer capacity, (minimum 100 kg). Most feed manufacturing systems will have “dead spots” where feed accumulates which must be taken care of effectively. The availability of other cleaning methods will depend on the type of system. **As a result, the effectiveness of all written cleaning procedures (other than production sequencing) must be validated for each establishment prior to licensing.** Validation will be required prior to the issuance of the initial license and again when there are “significant” changes to manufacturing equipment, amount and type of flush material or manufacturing practices. The required validation is for the manufacturing system and does not have to be completed for each medication used in a facility. To ensure that drug residues are adequately controlled, the “worst-case” scenario should be evaluated if possible. “Worst-case” scenarios include drugs where there are known manufacturing or toxicity issues. The following principles should be used when assessing the effectiveness of equipment clean out procedures:

- A detailed description of the cleaning method for each piece of manufacturing and distribution equipment or each production stream and the data supporting their effectiveness **must** be kept at the establishment for future reference.
- Appropriate sampling methodologies including random monitoring of finished products at various steps in the manufacturing process for drug residues, tracers or other indicators of inadequate clean out. For simpler operations, with a single process flow, such as many on farm feed manufacturing facilities, testing the end product for drug residues or the chosen test substance should provide sufficient information on the effectiveness of equipment clean out procedures. Refer to Appendix II for information on drug interferences which should be taken into consideration when choosing feeds to sample for drug residue testing.

- Composite samples representing the entire batch manufactured after equipment clean out procedures have been used will not be accepted as evidence that clean out procedures were effective. Rather, samples to validate equipment clean out procedures must be obtained from the initial portion (first 50 - 100 kg) of the batch immediately following the clean out procedure.
- Appropriate analytical methodologies for determination of the level of drug residues present must be used. Samples should be sent to an accredited laboratory for analysis where available. The laboratory must use an approved method which has a detection limit at least as low as that indicated in the Device Performance Verification List for that drug. In some situations, there may be test kits which could be used on farm that meet these requirements. Where indirect measures are used, evidence supporting the correlation of the selected test substance with drug carryover will be required.
- Unless other information is available to support the safety of a higher residue level, the critical limit will be the limit of detection as indicated in the Device Performance Verification List.
- In addition to medications, equipment clean out procedures should take into account other regulatory requirements such as ingredients included in the mammalian to ruminant feeding ban or where equipment is used for multiple purposes, e.g., treating seed and mixing feed.

IV Documentation and Records

- Written procedures describing production sequences.
- Where applicable, written procedures describing flushing protocols which include information on the type and amount of flush.
- Evidence that the flushing procedures have been validated including, sampling dates, sampling methods and laboratory results, etc.
- Where applicable, written procedures describing the handling and disposition of flush materials. These procedures must indicate that the flush materials are disposed of in accordance with local environmental regulations or used as an ingredient in feeds intended to contain the same medication. Furthermore, the procedures should indicate that if the flush material is stored it must be properly identified and labelled.
- Evidence that written procedures respecting handling and disposition of flush materials have been followed.
- Where applicable, written procedures describing other protocols for equipment clean out.
- Evidence that the clean out procedures have been validated including, sampling dates, sampling methods and laboratory results, etc.

- Daily production records which demonstrate that the establishment is following their written procedures for each piece of manufacturing equipment used to manufacture both medicated and unmedicated feeds. The daily production records should include the following information:
 - the name of the piece of equipment to which the production record refers;
 - the manufacturing date(s) for the feed;
 - the name of the feeds in the order which they passed through the equipment;
 - the information used to identify each lot of feed;
 - the amount of each feed;
 - information as to whether the feed contains any medicating ingredient; and
 - details of any feed safety precautions taken between batches of feed, e.g., production sequence, flushing including the amount and type of flush material or description of other equipment clean out procedures used.
- Written procedures describing investigations to be undertaken when sample results contain drug residues or the chosen test substance is above the critical limit. These follow up investigations must include a review of all critical control points in the manufacturing process. Refer to Appendix III for the approved CFIA protocol for sample follow up.
- Evidence that investigations are carried out and appropriate corrective actions are implemented.

V Appendices

Appendix I	Substances Causing Interference for Drug Residue Testing
Appendix II	Guide to Conducting Follow Up Inspections of Non-Compliant Samples
Appendix III	Trouble Shooting - Sources of Carryover
Appendix IV	Checklist for Equipment Clean out Procedures
Appendix V	References

Substances Causing Interference for Drug Residue Testing

Interactions between medicating ingredients often affect the capability of Laboratories to accurately analyze the feed to determine if drug residues are present. To help clarify which tests cannot be done due to interferences the following table has been prepared by the Laboratory Services Division of the Canadian Food Inspection Agency.

Drug Residue Analysis Requested	Interference
Arsanilic acid) 3-nitro) 4-hydroxyphenyl) arsonic acid)	Any combination of arsenicals. The analysis is by total arsenic; so is not specific.
Bacitracin	Nicarbazine, monensin
Chlortetracycline	Any other tetracycline
Lincomycin	Tylosin, and virginiamycin
Oxytetracycline	Any other tetracycline
Penicillin	Lincomycin, tylosin and virginiamycin
Tylosin	Lincomycin, urea, virginiamycin
Virginiamycin	All drugs except monensin, salinomycin, and narasin.
Low level antibiotics	Mineral premixes and high levels of other antibiotics.

Guide to Conducting Follow Up Inspections of Non-Compliant Samples

I Samples for Drug Guarantee Verification

Assessing Compliance of Analytical Results

All samples not within the analytical tolerances set forth in Table 2 of the Feeds Regulations are to be considered non-compliant. **The establishment who manufactured the noncompliant feed must conduct a follow up inspection for ALL noncompliant results.**

Follow Up Inspection

A follow up inspection should be undertaken by the establishment within thirty days of their being notified of the noncompliant sample result. The objective of the follow up inspection is to determine and/or confirm the cause(s) of the noncompliance. The follow up inspection should include a review of all critical control points in the manufacture of the noncompliant lot of medicated feed, including verification of the following:

- A.**
- Do the product formula and mixing sheet, for the noncompliant lot, correspond to the product label, i.e., do the product formula/mixing sheet stipulate the inclusion of the amount of medicating ingredient required to provide the drug level guaranteed on the label? If not, the product is non-compliant as it was improperly labelled and the label and/or formula must be changed to achieve compliance.
 - Does the mixing sheet, for the noncompliant lot, indicate that the correct amount of all ingredients, in accordance with the product formula, were used in the manufacture of this lot of feed?
 - Do the production records indicate that the feed immediately preceding the noncompliant lot contained a higher level of the same drug which may have caused an elevated drug level in the noncompliant lot?
 - Is the labelled potency of the source of medicating ingredient that was used in the manufacture of the noncompliant lot of feed the same as that indicated on the product formula and mixing sheet?
- B.**
- Is the source of medicating ingredient used in the manufacture of the noncompliant lot in compliance with the *Food and Drugs Act* and Regulations and/or the *Feeds Act* and Regulations, e.g., if the product is a medicating ingredient, does it have a valid DIN or is it covered by an emergency drug release, or if the product is a medicated feed is it properly labelled?
 - Was the source of medicating ingredient used in the manufacture of the noncompliant lot within its expiry date?
 - Are all medicating ingredients (e.g., those with DINs) stored in this establishment within their expiry dates?

- C.** Have the scales and metering devices, used to measure medicating ingredients, been verified for accuracy within 12 months of the manufacture of the noncompliant lot?
- Was the accuracy of scales and metering devices tested within prescribed limits?
- D.** Has a mixer efficiency test been conducted on the mixer within the 12 month period prior to the manufacture of the noncompliant lot?
- Was the coefficient of variation between the samples obtained for mixer performance verification $\leq 15\%$ for complete feeds or total mixed rations? $\leq 10\%$ for micro or macro premixes and supplements? $\leq 5\%$ for dilute drug premixes?
- Was the size/quantity of each batch of the noncompliant lot suitable given the operational capacity of the mixer indicated by the equipment manufacturer?
- Was the mixing time used in the manufacture of the noncompliant lot within the range recommended by the equipment manufacturer and/or set by the establishment for a lot of that size?
- For the day on which the noncompliant lot was manufactured, were there any mechanical problems with the mixer?
- Are mixer paddles or ribbons in good condition, e.g., not excessively worn?
- Is the mixer grounded?
- E.** Does the establishment maintain an adequate inventory system for medicating ingredients?
- For the day on which the noncompliant lot was manufactured, does the drug inventory verify that the theoretical and actual use of that medicating ingredient are within the limits set by that establishment?
- F.** Were there any customer complaints related to the noncompliant lot?

Contacting Responsible Inspector

Once establishment has completed their follow up inspection and identified the cause of the non-compliant sample, the responsible inspector should be contacted to schedule an appointment to review the findings and any proposed corrective actions.

Inspector Follow Up

The responsible inspector should:

- review the protocol used by the establishment in conducting the follow up inspection to verify that all critical elements have been considered;
- review the findings of the follow up inspection and the conclusions made;
- evaluate the proposed corrective actions including time lines; and
- where the establishment did not consider critical elements, inform management and have them complete the inspection tasks associated with those areas.

II Samples submitted for Drug Residue Testing

Assessing Compliance of Analytical Results

There is limited information on the exact quantity of specific medications that, if found in feeds, would be expected to result in an unsafe residue in food products produced from the animals consuming that feed, e.g., maximum residue limits (MRLs), or cause harm to animals. However, the presence of residues in feeds intended for animals producing milk for human consumption, laying hens, finisher animals or other “market-ready” animals or feeds for incompatible species may be an indicator of manufacturing errors or deviations from good manufacturing practices. Please refer to the table below for examples of when the presence of detectable residues of the target drug would be considered unacceptable for the specific classes/species of animals listed.

Target Drugs	Detectable residues unacceptable in feeds for the following food-producing livestock
Amprolium	Cattle (except calves), swine, sheep, goats, fish, horses
Chlortetracycline	Market ready cattle, lactating dairy, goats, fish, horses
Decoquinat	Lactating dairy, swine, layers, turkeys, sheep, goats, fish, horses
Lasalocid sodium	Horses, swine, layers, sheep, goats, fish
Lincomycin	Layers, cattle, sheep, goats, fish, horses
Maduramicin	Cattle, swine, finishing broiler chickens and turkeys, laying hens, sheep, goats, fish, horses
Monensin Sodium	Horses, swine, layers, sheep, goats, fish
Narasin	Cattle, layers, turkeys, sheep, goats, fish, horses
Oxytetracycline	Any finisher feed, market ready cattle and sheep, lactating dairy, goats, fish, horses
Penicillin	Layers, cattle, sheep, goats, fish, horses
Salinomycin Sodium	Layers, turkeys, dairy, breeding swine, sheep, goats, fish, horses

Target Drugs	Detectable residues unacceptable in feeds for the following food-producing livestock
Sulfamethazine	Poultry, finishing swine, finishing cattle, dairy, sheep, goats, fish, horses
Tylosin	Dairy, poultry, sheep, horses, goats, fish

The presence of a detectable amount of a residue of a target drug in a sample of one of these feeds results in the feed being considered non-compliant.

The establishment who manufactured the noncompliant feed conduct a follow up inspection for ALL noncompliant drug residue testing results.

Follow Up Inspection

A follow up inspection should be undertaken by the establishment within thirty days of the establishment being notified of the noncompliant sample results. The objective of the follow up inspection is to determine and/or confirm the cause(s) of the noncompliance. The follow up inspection should include a review of all critical control points in the manufacture of the noncompliant lot of feed, including verification of the following:

- A.** A review of the product formula and mixing sheet to verify that the label accurately reflects product composition, e.g., if the medication was added intentionally, the product is non-compliant because it was improperly labelled. In this situation, the label must be changed to achieve compliance.
- Does the product label accurately reflect the composition of the product?
- B.** A review of the written flushing and sequencing procedures for that establishment. In addition, a review of the flushing, sequencing and other cleanout procedures **used** in the production of the noncompliant feed.
1. Does the establishment have written flushing, sequencing or other cleanout procedures for the following equipment (where applicable)?
 - scales and metering devices used to measure medicating ingredients?
 - mixer?
 - pellet mill/extruder?
 - bagging equipment?
 - loadout bins?
 - bulk delivery vehicles?

Review the production sequence at the time of the manufacture of the contaminated batch of feed. Identify the three feeds manufactured immediately prior to the contaminated feed at each piece of equipment starting with the weighing of micro-ingredients into the mixer through to the loadout of the product (including the truck for bulk loads). Determine whether the documented flushing and sequencing procedures used at each process step were appropriate.

2. Were the written flushing, sequencing or other cleanout procedures **followed in the manufacture of the noncompliant lot** for the following equipment (where applicable)?
- scales and metering devices used to measure medicating ingredients?
 - mixer?
 - pellet mill/extruder?
 - bagging equipment?
 - loadout bins?
 - bulk delivery vehicles?
3. Do the written flushing, production sequencing or other cleanout procedures used in the manufacture of the noncompliant lot appear appropriate given known food safety and animal health concerns (look at target species, etc.)?
- Does the establishment have **written production sequence procedures** that are appropriate given known food safety and animal health concerns (look at target species)?
 - Did the establishment **follow** their **written production sequence procedures** in the manufacture of the noncompliant lot?
 - Does the establishment have **written flushing procedures** that are appropriate given known food safety and animal health concerns (look at target species, type and amount of flush material)?
 - Did the establishment **follow** their **written flushing procedures** in the manufacture of the noncompliant lot?
 - Does the establishment have **written procedures respecting proper storage, handling and identification of flush material** (e.g., identify type of medication in the flush on the label, store separately from other ingredients and finished feeds, use **only** as an ingredient in feeds containing the same medication)?
 - Did the establishment **follow** their **written procedures respecting proper storage, handling and identification of flush material** (e.g., identify type of medication in the flush on label, store separately from other ingredients and finished feeds, use **only** as an ingredient in feeds containing the same medication) in the manufacture of the noncompliant lot?
 - Does the establishment have **written procedures respecting storage, handling and use of returned feeds which contain medications** (e.g., identify type of medication in the returned feed, label and store separately from other ingredients and finished feeds, use **only** as an ingredient in feeds containing the same medication)?

- Did the establishment **follow** their **written procedures respecting storage, handling and use of returned feeds which contain medications** (e.g., identify type of medication in the returned feed, label and store separately from other ingredients and finished feeds, use **only** as an ingredient in feeds containing the same medication) in the manufacture of the non-compliant lot?
- Does the establishment have **written procedures respecting other cleanout procedures** which are appropriate given known food safety and animal health concerns (look at target species)?
- Did the establishment **follow** their **written procedures respecting other cleanout procedures** in the manufacture of the noncompliant lot?
- A review of written housekeeping procedures for the establishment and written medication storage and handling procedures to determine whether they may be a factor.
- Does the establishment have **written housekeeping procedures for the drug storage area** which are intended to ensure that the area is clean and orderly considering normal operating conditions?
- Determine whether the establishment is **following** their **written housekeeping procedures for the drug storage area** and whether they are effective in ensuring that the area is clean and orderly considering normal operating conditions.

Contacting Responsible Inspector

Once establishment has completed their follow up inspection and identified the cause of the non-compliant sample, the responsible inspector should be contacted to schedule an appointment to review the findings and any proposed corrective actions.

Inspector Follow Up

The responsible inspector should:

- review the protocol used by the establishment in conducting the follow up inspection to verify that all critical elements have been considered;
- review the findings of the follow up inspection and the conclusions made;
- evaluate the proposed corrective actions including time lines; and
- where the establishment did not consider critical elements, inform management and have them complete the inspection tasks associated with those areas.

Trouble Shooting- Sources of Carryover

Equipment	Mode
Dust Collection System	delayed return of dust to production line excessive pick-up of drug and carrier hang-up (electrostatic or moisture)
Mixer	residual feed remaining in mixer build-up on ribbon and walls hang-up on walls and top (electrostatic) leaking mixer gate (not fully closing)
Surge Bin	incomplete clean-out hang-up (electrostatic)
Conveyors	incomplete clean-out hang-up (electrostatic or moisture)
Elevators	residual feed remaining in buckets and boot hang-up (electrostatic or moisture)
Bins	bridging and hang-up residual feed from incomplete clean-out error in bin chart records
Bulk Trucks	incomplete clean-out bridging and hang-up

Based on information from, "Drug Carryover Control and Prevention" R. Wilcox and J. Balding, Kansas State University and "Feed Manufacturing Technology IV" by the American Feed Industry Association.

Notes

Mixers

- Horizontal drop-bottom mixers reduce feed additive carryover.
- The drag or screw conveyor in the surge hopper should be adjusted for minimum clearance.
- Horizontal mixers should have the ribbons adjusted periodically to maintain minimum clearance with the mixer shell.
- For horizontal mixers with discharge gates, be sure to allow adequate time for bulky feeds to clear the gates before closing.
- Vertical mixers are difficult to completely clean out and may be a source of cross-contamination if not properly managed.
- Another practice that has been proven effective in reducing drug residue levels is to hold back the first 25-50 kg of the batch immediately following a flush and use it as an ingredient in a subsequent batch of feed intended to contain the same medication.

Dust Collection System

The dust collection system should be designed to discharge the collected material back into the same feed from which it was removed. To determine if the dust collection system is the source of carryover, insert an easily identifiable material (i.e. coloured iron tracer) into a dust collection point. Monitor the point where the collected dust is returned to the production line (or where it is accumulated). Note the elapsed time from the time of introduction of the tracer into the system to the time of appearance at the point of dust return. Also note the time period that the tracer continues to be detectable in the returned dust. These measured times will be helpful in determining the amount of time that should elapse after batches of medicated feeds and whether improvements are needed in the dust collection and return system.

Fines Return

- Contamination can occur when finished feed is scalped and the cleanings are routed back to the hammermill in a closed system.
- Medicated feed removed in the cleaning process could contaminate the ground grain going into other feeds.
- If scalped fines are returned to the pellet mill, they should be added back to the same feed.

Feed Routing

- Screw and drag conveyors move feed in a horizontal plane or at slight inclines. Inspect these for wear, clearance, and build-up to minimize carryover.
- Check turnheads to be sure they are properly seated to prevent feed from getting into the incorrect bin.

Coolers

- With vertical coolers, do not switch feeds until all the previous pellets have cleared the cooler. Manually trip the cooler to empty the remaining feed at the end of a run.
- Allow adequate spacing in horizontal coolers between different runs. Be sure the delivery system is empty before switching destination bins.

Receiving Feed at the Farm

When receiving a load of non-medicated feed (or a feed with a medication that does not require a withdrawal), the producer should ensure that the farm storage bin is completely empty of any previously delivered feed requiring withdrawal and that any cross-utilized pieces of receiving equipment, e.g., augers have been cleaned between batches of medicated and unmedicated feeds.

Suggested Corrective Actions For Carryover

Mode of Carryover	Corrective Actions
1. Electrostatic Hang-up	Ground wire to affected equipment Use liquid ingredient to control dust Vibrators to shake hang-up loose
2. Delayed or extended dust return	Adjust air velocity at collection points Allow more time for dust to clear system Use liquid ingredient to reduce dustiness Collect and discard dust following production of medicated feeds (or retain for next run of like medicated feed) Remodel dust system
3. Mixer residues	Adjust ribbons or paddles Install plastic "wipers" on ribbons Install air sweep jets for cleaning Remodel discharge for more complete clean-out Add drug when mixer is $\frac{1}{2}$ to $\frac{3}{4}$ full (may affect mixing time required for good mix)
4. Surge bin, conveyor residues	Adjust for more complete clean-out Remodel bin or bin discharge
5. Elevator residues	Adjust bucket clearance in boot (if possible) Install air sweep jets Remodel boot for more complete clean-out
6. Bin residues	Manual inspection and cleaning when changing kind of feed stored Install vibrator or air sweep
7. Pellet mill & cooler residues	Flush blender and dies Adjust cooler for more complete clean-out
8. Entire system	Use production scheduling Allow time between kinds of feed for manual cleaning of system Use "flush" material – about 5% of mixer capacity but not less than 100 kg (should be established by actual tests)

Mode of Carryover	Corrective Actions
9. Bulk truck	Establish clean-out procedure for truck Require a sample from the first product discharged at point of delivery Analyze delivery samples randomly and let delivery person know that samples are being analyzed.

Checklist for Equipment Clean out Procedures

Task 1 Assess adequacy of daily production records

Rating Type Compliance Regulations Respecting the Making of Medicated Feeds Section (17)

All unsatisfactory ratings require a record of compliance action taken and/or a signed action plan for correction of noncompliance.

Standard This task should be repeated for each piece of cross-utilized manufacturing equipment

To receive a satisfactory rating, the establishment must maintain daily production records for any piece of manufacturing equipment used to manufacture both medicated and unmedicated feeds. To receive a satisfactory rating, the required daily production records must include the following information:

- the name of the piece of equipment to which the production record refers;
- the manufacturing date(s);
- the name of the feeds in the order which they pass through the equipment;
- the information used to identify each lot of feed;
- the amount of each feed;
- include information as to whether the feed contains any medicating ingredient;
- details of any feed safety precautions taken between batches of feed, e.g., equipment clean out procedures including the amount and type of flush; and
- copies of production records must be kept for a period of at least three years from the last date of manufacture of that feed.

Task 2 Assess adequacy of written clean out procedures

Rating Type Compliance Regulations Respecting the Making of Medicated Feeds Section (17)

All unsatisfactory ratings require a record of compliance action taken and/or a signed action plan for correction of noncompliance.

Standard This task should be repeated for each piece of cross-utilized manufacturing equipment

To receive a satisfactory rating, written cleanout procedures for any piece of manufacturing equipment used to manufacture both medicated and unmedicated feeds must detail practices which prevent unsafe contamination, including:

- feeds intended for animals producing milk for human consumption, laying hens, finisher animals or other “market-ready” animals (e.g., treated animals may not be shipped for use in food until the withdrawal period is complete) do not follow feeds containing a medication that has a withdrawal established for any use level **unless additional cleaning procedures are used** (e.g., flushing, physical clean out) **or unless otherwise authorized**; (e.g., use in “market-ready” animals of this species or class of animals is approved in the CMIB);
- feeds for a particular species or class of animals do not follow feeds containing medication that is not approved for that species or class of animals (i.e., the medicating ingredient is not approved for use in that species or class of animals), **unless validated cleaning procedures are used** (eg. flushing, physical cleanout) **or unless otherwise authorized**; (e.g., a veterinary prescription is available for the batch of feed directly following the medication which authorizes this off-label use);
- feeds for a particular species do not follow feeds containing medications that are toxic to that species or class of animals (i.e., the CMIB or label indicates that it should be not given to that species or class of animals), **unless additional validated cleaning procedures are used** (e.g., flushing, physical clean out); and
- the establishment must be following the written clean out procedures and have evidence which supports this, e.g., documentation.

Task 3	Assess adequacy of validation procedures used to demonstrate the adequacy of flushing or other additional cleanout procedures used and supporting documentation
Rating Type	<p>Compliance Regulations Respecting the Making of Medicated Feeds Section (17)</p> <p>All unsatisfactory ratings require a record of compliance action taken and/or a signed action plan for correction of noncompliance</p>
Standard	<p>To receive a satisfactory rating, the establishment must have written equipment clean out validation procedures which contain the following information:</p> <p>Validation records</p> <ul style="list-style-type: none"> <input type="checkbox"/> date of the validation testing; <input type="checkbox"/> production record for the validation test date (including sequence of feeds through equipment, type, amount and disposition of flush material (if applicable) or details of the clean out procedure being evaluated); <input type="checkbox"/> details of the sampling procedures used; <input type="checkbox"/> results of laboratory or other analytical testing; and <input type="checkbox"/> evidence that the validation of clean out procedures was conducted in accordance with their written procedures. <p>Equipment Cleanout Validation Procedures</p> <ul style="list-style-type: none"> <input type="checkbox"/> written equipment clean out validation procedures must indicate that flushing or other clean out procedures used for each piece of cross-utilized equipment or each processing stream must be been tested for their effectiveness prior to licensing and again when significant changes to manufacturing equipment, amount and type of flush material or manufacturing practices are made.

Task 4 **Assess disposition of flush or recovered* materials** (*materials recovered from spillage, dust collectors etc.)

Rating Type **Compliance** **Regulations Respecting the Making of Medicated Feeds Section (17)**

All unsatisfactory ratings require a record of compliance action taken and/or a signed action plan for correction of noncompliance.

Standard To receive a satisfactory rating, flush and recovered material must be handled as follows:

- disposal in accordance with local environmental regulations;

- if the feed contains a medication, it may only be used as an ingredient in feeds containing the same medication or fed to directly to animals for which the medication is permitted;

- when stored, the flush/recovered material must be labelled the name of the medication and any other pertinent information; and

- the establishment must have evidence documenting these procedures.

Task 5 Assess adequacy of written procedures for the management of medicated product storage and handling

Rating Type Compliance Regulations Respecting the Making of Medicated Feeds Section (17)

All unsatisfactory ratings require a record of compliance action taken and/or a signed action plan for correction of noncompliance.

Standard To receive a satisfactory rating:

- all medicated products must be handled and stored in a manner to prevent contamination and protect integrity, purity and potency;
- bulk medicated product storage procedures must include inspection and maintenance of turnheads or other equipment used to direct ingredients into specific bins;
- all bulk medicated products must be stored in clean, correctly identified bins or area;
- bulk medicated feeds must be sequenced such that
 - feeds intended for animals producing milk for human consumption, laying hens, finisher animals or other “market-ready” animals do not follow a feed containing a medication that has a withdrawal established for any use level **unless validated cleaning procedures are used or unless otherwise authorized.**
 - feeds for a particular species do not follow feeds containing medication not approved for that species **unless validated cleaning procedures are used.**
 - feeds for a particular species do not follow feeds containing medications that are toxic to that species **unless validated cleaning procedures are used.**; and
- the establishment must be following the written procedures and have evidence which supports this, e.g., documentation.

References

1. "Drug Carryover Control and Prevention" by R. Wilcox and J. Balding, Kansas State University
2. "Feed Manufacturing Technology IV" by the American Feed Industry Association