



AAFCO

Association of American Feed Control Officials

Feed Inspector's Manual

Eighth Edition

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Table of Contents

Chapter 1	Introduction	1
Chapter 2	Safety	3
Chapter 3	Sampling.....	12
Chapter 4	Labeling.....	34
Chapter 5	Feed Investigation	63
Chapter 6	CGMP.....	66
Chapter 7	Feed Ingredients	70
Chapter 8	VFD.....	72
Chapter 9	BSE.....	76
Chapter 10	Enforcement	78
Chapter 11	Drug Carryover Control and Prevention	83
Chapter 12	Feed Manufacturing Techniques	87
Chapter 13	Toxins	92
Chapter 14	Field Glossary	107
Appendix A	Conversion Tables	142
Appendix B	Laboratories that Analyze Feed.....	152

This manual is the compilation of many hours of work and effort by many people. Several states have shared their own manuals and resources for this project to reach completion. AAFCO, and especially the committee, wish to thank all those who have helped in updating and publishing this edition.

LIMITATIONS OF USE

No one manual could be the end all resource for performing inspections in the field. If one were able to be produced, it would be so large, that back support would be needed to even lift it!

This manual is designed to be used as a resource by field inspectors both in the field and when preparing for inspections and regulatory work. It still must be taken only as a guide.

States may have varying laws, rules, and regulations that will not be addressed by this manual. This manual was designed with the AAFCO Model Bill and rules, not one particular state's program. Therefore, you must be sure how this manual and your state's laws, rules, policies, and programs agree or disagree.

OFFICIAL AAFCO POLICY

This manual is not intended to be or replace Official AAFCO Policy. Many of the items in this manual will be consistent with wording in the AAFCO Official Publication and many will not. The only Official Policy adopted by AAFCO is contained in the Official Publication. If anything in this manual disagrees with policies outlined in that publication, the Official Publication should take precedence.

SPECIAL THANKS TO:

- The entire Inspection and Sampling Committee
- Our Industry Liaisons
- The Communication Committee for publishing the Manual
- Kansas State University
- AFIA
- NGFA
- FDA

Other Valuable Resources

AAFCO Official Publication

AAFCO Professional Inspector Manual

Feed Additive Compendium

AFIA Feed Manufacturing Technology

Title 21 of Code of Federal Regulations

FSPCA

FDA ORAU/Pathlore Online Course

CHAPTER 1 INTRODUCTION

THIS MANUAL

This manual is a compilation of many sources. The Inspection and Sampling Committee of AAFCO gratefully acknowledges the hard work and contributions from many states and others in preparing this manual. While it cannot be an end all to inspection, it is a valuable resource and should be referenced whenever possible.

INTENT

This manual is designed to provide inspectors with a comprehensive explanation of the regulatory and enforcement functions of a feed inspection program. While industry is ultimately responsible for the quality of the products they manufacture, your agency and the U.S. Food & Drug Administration (FDA) are responsible for safeguarding the human food supply, animal and plant health and to facilitate national and international trade.

The FDA Food Safety Modernization Act (FSMA) was signed into law by President Obama on January 4, 2011. Although this is federal regulation, it will most likely impact feed regulations in your state, especially if you have a contract with the FDA that requires inspections with the new FSMA rules. The AAFCO Feed Inspection Manual will not be guidance for FSMA, but a small group has reviewed and edited the portions that were not compliant with the new rule. The FDA will have training and guidance documents to assist the inspector with FSMA.

INSPECTOR'S MISSION

To assure that feed manufacturing facilities produce unadulterated and properly labeled feed products;

To provide effective and uniform administration of the laws and rules within the agency's jurisdiction;

To promote compliance by the regulated industry through education.

OBJECTIVES

The objectives of a feed regulatory program are many. First and foremost is to protect the human food supply. Products must be manufactured properly, free of adulterants or contaminants, and labeled properly so that they may be used effectively and safely. Labeling is critical so that the consumer can safely, effectively and efficiently use the feed.

Inspections must be performed that are representative of the activities performed by the mill and samples must be collected properly to represent the feeds that were manufactured. Education is a vital part of all regulatory programs.

An inspector must also be trained to respond to consumer complaints and toxic response situations.

PROGRAM EMPHASIS

An effective program must reflect current concerns with the safety of animal products entering the human diet, while continuing to protect the producer and their livestock. Recognition that quality ingredients make quality feed has focused more attention on feed components and less on complete feed. Current activities are designed to support the goal that the livestock producer receives a quality product to prevent contaminant problems in milk, eggs and meat purchased by the consumer.

The prime focus is on uniformity and product safety (i.e. drug, chemical and biological residues/contaminants). Programs are designed to monitor compliance with established standards through planned inspections and sampling activities to minimize potential hazards. Even in unconventional feed ingredient/feed additive areas such as pulp and paper waste, single cell proteins, poultry waste, and facilitating agents, evaluations are primarily concerned with chemical contaminants, mycotoxins and drug residues which may affect animal and human health.

Directed investigations are carried out when livestock illness, death or loss of performance may be attributable to the feed, or when contaminants occurring in meat, milk and eggs may be linked to feed. (In addition, investigations are carried out when other government agencies detect problems such as salmonella contamination, mycotoxins or drug residues in foods, which might be feed related.)

THE INSPECTOR'S ROLE

As an inspector, you are a member of a regulatory team. The administrative function, the laboratory, and the work you perform, all tie together to assure compliance with the law and a safe product for the consumer. As such, you are the agency's front-line representative. The way you prepare yourself and conduct yourself will either aid or hinder your mission.

Inspectors are professionals. Please refer to the AAFCO Professional Agricultural Inspector's Manual to address the professional skills necessary for efficient and effective inspection.

CHAPTER 2 SAFETY

Elevators, mills, and warehouses may be potentially hazardous work environments. The sampling and inspection of commercial feed involves working in many potential hazardous situations. Since an Inspector works alone much of the time, you must assure your personal safety. Safety equipment must be on hand and used to insure maximum protection under any conditions. Be aware of the potential dangers and possible peculiarities of each establishment. A feed inspector should exercise care and use common sense at all times.

Accidents may be caused by physical hazards, such as faulty equipment, or by human factors, such as complacency or haste. Accidents can be prevented by eliminating these causes and safety depends on the willingness of everyone to conform to safe practices. In addition to your established safety procedures, follow safety requirements of the facility, if more stringent. Ignorance of safety instructions is no excuse for their violation.

Remember, your personal safety is more important than any sample!

If you do not know the safe way to do your job, ask your supervisor for instructions!

ENTERING THE PLANT

Safety hazards found at elevators, mills, and warehouses are many and varied. Caution should start at the main entrance. Vehicular traffic within the plant grounds may not follow normal movement patterns nor obey usual traffic rules.

Personal Protective Equipment

- Use all safety devices and protective equipment provided.
- Hard hats should be worn at all times on elevator, mill and warehouse premises.
- Safety shoes with non-slip soles and heels should be worn. Clothing should be close fitting.
- Flashlights should be carried, especially when work assignments involve the upper floors or basements of elevators.
- Goggles and appropriate respirators should be worn in dust laden environments.

Use all other safety equipment as required.

NOTIFY MILL PERSONNEL OF YOUR PRESENCE

- Do not enter an elevator, mill, or warehouse before alerting the facility's supervisory personnel of your presence and where you will be working.
- Be sure the workers in the area know who you are and what you will be doing and where.
- Do not enter areas where you have no official purpose.

KNOW YOUR SURROUNDINGS

Determine the location of exits, telephones, showers, emergency evacuation routes and procedures. Read and follow all warning signs.

Construction and maintenance work is common in all plants. This activity may increase hazards. Keep a safe distance from it.

When entering an elevator, mill, or warehouse from bright outside light, your vision may be impaired temporarily. Stop and let your eyes adjust, or you may walk into floor openings or machinery. Be aware of your surroundings. Avoid stepping on manhole covers since they may slide from underfoot.

The Inspector should be conscious of the machinery being used. Observe conditions surrounding the various products to be sampled, with emphasis on the danger of front-end loaders, hopper and tank cars, forklifts, conveyor belts, motor drives, welding and cutting, drag and screw conveyors, falls from heights and electrical equipment. Stay away from machinery, whether it is operating or not. The "dead" machinery may be started by a remote control switch located in another part of the plant. Do not sit or step on a motionless conveyor belt. Cross over conveyors only on cross bridges or walk around the belt end.

Watch for wet floors due to condensation. Dust caused by loading or unloading products can mix with the moisture on the floors, making them slippery and hazardous.

When the air is dust laden, your ability to see is diminished. This is not an unusual condition and can be dangerous.

High pressure lines should be not used to blow dust from clothing or body. Foreign matter such as metal fragments, oil, or water can be blown under the skin or into the eyes, causing a painful or infectious injury.

Grain dust is extremely dangerous, because it is highly explosive. The grain industry has had many damaging explosions with loss of life and property. There should be **NO SMOKING** at any time in the elevator, or within fifty feet of unloading pits.

PHYSICAL HAZARDS

Inspect the trucks, rail cars or storage areas and assess their condition. Check for fumigant odor. It is possible for fumigants to have no odor and continue to be toxic. Rather than take any chances, check with management to eliminate any risk of exposure. DOT regulations and pesticide labels require that warning signs be placed on rail-cars containing fumigated commodities. If you find a fumigant notice on the car, especially if it has a recent date, (3 days or less), or if you detect a fumigant odor, "**DO NOT OPEN.**" Notify the firm management to have a qualified person determine if it is safe to open the car. The firm's qualified person should open the doors on both sides of the car and allow the car to air out for a prescribed length of time before allowing anyone to enter. Remember, some fumigants may not have an detectable odor by you, but may still present a hazard.

You should not enter trucks, rail cars or storage areas during the application of these materials, nor should you enter where the materials have been applied unless the atmosphere has been certified safe by a competent person.

TRUCKS

Sampling around moving trucks and trailers may increase the hazard of the work environment. The key factor to prevention of accidents in this area is alertness. Remain alert and constantly aware of moving vehicles and the fact drivers may not see you. Safe guidelines for sampling trucks and trailers are:

Be sure that the driver knows you are sampling their load so that they will not move the truck until you have completed the sampling. You may want to have the driver block the wheels of the truck.

- Use a ladder to get into or out of trailers.
- Always carry or lift sampling equipment into trucks, trailers and between units. Never toss or throw them!
- Don't ride on running boards or crawl under trucks or trailers.
- Always be alert and watch for moving vehicles.
- Request the driver to open and secure doors on the side of van-type trailers before entering.

When probing, always be alert for hidden obstructions such as cross braces and bars as well as the side and bottom of the trailers. Hitting such obstructions with a sudden force can cause serious injuries to your ribs, shoulder, face, or teeth as well as damage to the trailer and probe. To prevent such occurrences, avoid throwing all your weight from a standing or running position onto the probe.

BOXCARS AND HOPPER CARS

Sampling personnel performing duties on boxcars and hopper cars should be extra careful. This practice will minimize the possibility of an accident or injury if you know and observe the rules of safety.

If part of a team or by yourself, be certain someone is aware you are there and the length of time you expect to remain. Persons to be notified should be: The manager of the plant, and the person in charge of unloading.

Keep in contact when entering any boxcar or hopper car in a railroad yard.

The person(s) notified prior to sampling of boxcars or hopper cars should also be notified when you are done.

Elevators and mills utilize winches or car pullers to move cars. Stay clear of cables or ropes used for this purpose. Watch for electric wires and other overhead obstructions when sampling hopper cars at elevators. Mount hopper cars and enter boxcars only when cars are not to be moved. When possible, have someone standing by to watch. Many elevators have alarm systems that sound when cars are being moved. Do not attempt to get off a hopper car or into or out of boxcars when an alarm is sounding or when cars are moving. Debris removed from empty cars can contain nails or steel strapping. Use care when walking over such materials.

Cars to be sampled are classified as either BOXCARS or HOPPER CARS. Since the physical characteristics of the two are completely different, there are hazards that are unique to both, therefore, each will be covered separately.

Boxcars

See Physical Hazards (page 4) for fumigant precautions.

If a seal must be broken, precautions must be taken to prevent hand injury from sharp edges. A cutting tool, such as a side cutter, should be used to cut the seal. Protect your eyes by use of safety glasses. Seal locking mechanisms often fly apart as they are broken.

Open and closing car doors can be hazardous. When using a pry bar, push the door away from you; never stand beside the door. It may come free of its track and fall.

Note the condition of grain door and watch for protruding nails and steel strapping. Place sampling equipment on door sill and climb into the car. Never throw sampling equipment into car ahead of you.

Check inside car roof for protruding nails, bolt heads, etc. Older boxcars may be wire, rods, or wooden cross braces. Use care avoiding physical contact.

When probing, do not throw all of your weight on the probe from a standing or running position. If the feed is shallow and the end of the probe should strike the floor, you may sustain possible rib or shoulder injury.

Use the same care in dismounting from the car as you did when entering. Do not throw your sample or equipment from the car. It could hit someone below or damage the equipment or sample.

Hopper Cars

See Physical Hazards (page 4) for fumigant precautions.

The hopper car is a special purpose type carrier that requires sampling from the top either through individual hatches or a continuous opening down the center of the car. Because of its unique construction and the longer and heavier equipment required for sampling, it is probably more dangerous to sample than a boxcar.

The first thing to look for when approaching a hopper car is electric power lines above or close to the car. Serious injury to sampling personnel has occurred as a result of the sampling probe coming in contact with electric lines. If lines are present, extreme care should be used during the sampling operation.

Check the condition of the car's ladders. If a ladder is damaged, loose, or bent, go to the other end of the car and check for a more secure ladder. Ascend the ladder carefully.

While atop hopper cars, you should be especially alert to slippery conditions such as spilled, loose, or wet feed. In winter, there may be ice, frost, or snow.

You should watch for the approach of a fast engine or switched car while working atop hopper cars. If, during sampling, the car is moved or you do not have time to get down from the car, kneel or sit down to lessen the possibility of falling from the car.

High winds can blow you or your equipment off of the car. If conditions are considered too hazardous, delay or forego sampling activities.

Care should be used in breaking seals. Many lids and hatch covers are quite heavy and require proper lifting techniques. As you start to probe the hopper car, care should be taken not to probe into the sides of the hopper bottoms causing the probe to stop suddenly.

Safety belts are required by O.S.H.A. regulations to enter a hopper car. It is considered a confined space, therefore you should request a second person to handle a lifeline. It is your responsibility to decide whether or not the condition presents such a hazard as to deem the car too dangerous for sampling at that time.

Never sample a hopper car from above during unloading or when a partial unload has occurred. Hopper bins may bridge presenting a false "skin" through which you may fall and become trapped.

Notify the person in charge of unloading when you are finished sampling.

Bin or Tank Entry

Be alert and take proper safety precautions in plants, silos, bins, pits and any closed areas where bulk products are stored and asphyxiation hazards exist. Certain products can produce dangerous amounts of carbon dioxide, or other gases, or may deplete the oxygen supply in these areas. Fumigated/treated bins or tanks, or Confined Spaces should not be entered until a "Gas Free Certificate" or an "Entry Permit" has been issued by the facility's qualified personnel. **STAY OUT.**

When it is necessary to enter a bin, advise the facility's supervisor(s) and worker(s) in the bin area before entering, and again when the bin is closed. Turn-heads, spouts and trippers must not be set for that bin. Before entering a bin, it must be inspected first from the top to make sure that no grain is hung up. Do not jump down on top of grain. There may be a cavity caused by crusted grain which could break

and result in you being buried in grain or being in an atmosphere of fumigating gas. Do not enter bins without proper safety equipment and following all required safety rules. You could become trapped in the bin.

SAMPLING SAFETY

Cup-Type Samplers (Stream Cutters)

Cup-type samplers (stream cutters) should be used with care. Be cautious of reaching too far across the stream. Keep a firm footing. Sampling should be restricted to areas where sufficient room is available to properly swing the device through the feed stream without the possibility of the cup hitting or becoming entangled in spouting.

Sampling Bagged or Packed Products

Obtaining samples during the bagging or packaging process requires the Inspector to be constantly alert. Loose fitting jewelry should be removed and kept in your pockets. Check-weighing requiring the removal of bags or packages from the line can cause injury. Be alert for the movement of forklifts used to move the commodity. Stacked paper or polypropylene bags are slick and fall easily. When sampling stacked or containers on pallets and a ladder is required, check the condition of the ladder.

Note Special Handling Precautions

Concentrated sources of medications, vitamins, minerals or other products may have precautions and warnings included on the product label. Review all labeling prior to beginning your sampling procedure. Follow ALL precautions indicated on the label.

Sampling concentrated sources may result in airborne dust. Also, grains may have mycotoxins present causing exposure through dust. Even if no “toxins” are present, there may be potential harm from inhalation of mold spores or from allergic response to inhaled dust.

Use proper safety precautions. If you have questions, contact your supervisor prior to obtaining samples.

MAN LIFTS & CAGE ELEVATORS

Most mills and elevators have elevating devices to transport personnel from lower to upper working levels. They are normally cage-type or continuous vertical belt-types.

Man-lifts

Never attempt to ride a man-lift until you have had instructions in its operation.

When riding an endless belt man-lift always:

- Face the belt
- Keep your feet firmly on the steps
- Hold on to the hand holds with both hands

No freight, packaged goods or sampling equipment should be carried or handled on any man-lift. Only tools which fit entirely within a pocket or tool belt should be carried on any man-lift.

Cage-Type Elevators

The cage-type is similar to a passenger elevator, except much smaller. When using the cage-type lift, use care to keep door closed, and operate it as per posted instructions. If there are no posted instructions, request instructions from elevator or plant personnel. The maximum load capacity must be posted in the elevators and the capacity observed by all persons using the elevators.

Neither man-lift nor elevator should be used for emergency evacuation of the plant. Power failure or shutdown will cause the equipment to stop, possibly trapping occupants.

GENERAL SAFETY

Ladders

- Never use a ladder that has cracked rails or rungs or has splinters on rails.
- Never use a portable straight ladder that is not equipped with safety feet, unless the ladder is securely fastened in place.
- Always climb and descend a ladder facing the rungs and rails.
- Movable straight ladders should be climbed only when the foot of the ladder is about one-quarter of the ladder length away from the wall.

- Use only a ladder for climbing; use of chairs, boxes or other makeshift ladders is prohibited.
- Always use a ladder with safety feet to enter a boxcar or truck. Do not jump from a boxcar or truck.

Lifting

Never attempt to lift an object that is too heavy for you to handle alone. **GET HELP.**

When lifting an object:

- Get close to the load.
- Keep your back vertical, bend your legs.
- Lift slowly, feel the load react through your legs.

Machines and Equipment

- Do not attempt to operate a machine or equipment.
 - Equipment must be operated by trained employees only.
- Never remove a guard or shield on a piece of equipment while it is running.
- If you need to observe a machine in operation, request plant personnel to operate it.
- Never tamper with electrical equipment.
 - Electricity can KILL—and fast.

CHEMICAL HAZARDS

Chemical compounds are commonly used to control or eliminate insect infestation in agricultural products or in containers destined to store or transport these products. Such chemical compounds can present a safety hazard to man when used in an indiscriminate manner or when individuals disregard necessary safety precautions through ignorance or poor judgment. No individual is immune to the toxicity of these chemicals. There may be many different reactions to exposure to these toxic chemicals, such as a reduction in the body's natural resistance that can compound the effect of exposure.

Chemical applications to agricultural products or to containers destined to store or transport these products may be separated into three categories, each offering a different degree of hazard. When describing a chemical application of a commodity or container, proper terminology should be used, as it can indicate the degree of hazard involved with the application.

Respect all safety signs in the plant. They are posted for your safety and failure to obey them can cause injury to you or your fellow employee. Whenever the exposure to noise exceeds allowable levels, ear protection equipment should be worn by Inspectors.

CONTACT TYPE PESTICIDES

Malathion and Pyrethrum I are contact types; that is, their effectiveness depends upon the insects coming in contact with the material.

Malathion and Pyrethrum can be applied directly to the commodity or used to eliminate an infestation within a container. Inspectors should not enter or remain in an area while either of these materials are being applied as sprays to empty containers. Nor should they enter a treated area until all vapors or mists have settled from the atmosphere. These chemicals typically have a disagreeable odor. Vapor contact and absorption through the skin and the vapor or mist entering the respiratory system can cause ill effects.

SMOKE AND FOG TYPE PESTICIDES

Vapona I falls in the category of smokes and fogs. Normally, the use of these compounds is restricted to empty infested containers. However, Vapona has been used in filled containers. Vapona is also known as DDVP or Dichlorovous and is commonly available as "Shell Strips". This compound offers a better penetrating quality than the "Contacts" and also leave residues which are toxic to insects as well as man.

You should not enter storage areas during the application of these materials nor should you enter areas where the materials have been applied unless the atmosphere within the areas has been certified safe by a competent person.

Residues remaining on container surfaces, after the application of either of these materials, are more toxic than the "Contact" residues. Inspectors performing vessel storage examinations may pick up residue on their hands while climbing or descending ladders. No food or smoking material should be handled until hands are thoroughly washed with soap and water.

FUMIGANT PESTICIDES

The use of fumigants in elevators, mills, and warehouses is not unusual. If a fumigant or unidentifiable odor is detected, check with plant personnel and determine source of odor. Fumigants are hazardous to breathe, even at low concentrations. Treatments of grain and storage areas within elevators and mills are common. Avoid breathing vapors. If accidental contact is made, wash area of body contacted with mild soap and water. Remove and thoroughly wash clothing, including shoes. Report mishap to supervisor and seek recommendation of a physician.

Fumigants are normally liquid or solid chemical compounds which, when released into the atmosphere, readily turn to the gaseous state. These products are extremely toxic to man and should be handled or dealt with using extreme caution.

Methyl Bromide is an odorless gas used to fumigate loaded trucks, rail cars, and tarped warehouse lots. It may be applied as a gas or a liquid which will vaporize immediately upon exposure to the atmosphere. This gas is approximately twice as heavy as air and penetrates well. Entry into areas fumigated with Methyl Bromide should not be made unless a competent person has tested with a monitor to ascertain that the atmosphere within the container is safe for human habitation or unless the container has been under constant aeration for a minimum of eight hours, and it can be determined that a good circulation of air has been maintained in the container during the aeration period. Methyl Bromide will cause skin burns if contact is made with the liquid fumigant. Clothing or footwear contaminated with Methyl Bromide should be immediately removed, aired, and washed before being worn again.

Phostoxin (Phosphine) is a solid fumigant manufactured in the form of tablets or pellets which, when allowed to contact the humidity in the atmosphere or in the commodity, generate the highly toxic phosphine gas. The gas has an odor similar to garlic or fishmeal and, at an extremely low level, can be detected by the nose. When detected, Inspectors should immediately leave the area until the atmosphere is determined safe by a competent person.

Phostoxin tablets or pellets are designed to generate gas for a 72-hour period after exposure to the atmosphere containing a normal humidity and temperature of 65E to 70E F. Warmer temperatures will speed the rate of gas generation, and colder temperatures will retard the gas generation, and extend the active period of the tablets or pellets for several additional days. Where it can be determined that a good circulation of air has been maintained during the eight-hour aeration period, all traces of the fumigant will normally be removed. Before aeration can be attempted, it must be ascertained when the tablets or pellets were exposed to the atmosphere and that the minimum 72-hour period of gas generation under normal weather conditions has passed. Do not enter the fumigated container if the tablet or pellet application date and time cannot be accurately determined or if the garlic or fishmeal odor persists. If the gas concentration is tested with a monitor determining to be below the published threshold limit by a competent person, you may enter the container.

When a commodity has been fumigated, a percentage of the fumigant is absorbed by the commodity. This fumigant will be released during the aeration process at a retarded rate. When a container has been fumigated, aerated, and resealed, it is possible for a dangerous concentration of the fumigant to build up within the container. When a "Gas Free" certificate is issued by a competent person, you should perform your inspection duties within a two-hour period after testing and issuance of the certificate, providing that the fumigated area has remained open to the atmosphere. In the event the two-hour time period has been exceeded or the container sealed, a new test and certificate by the competent person is required.

Danger Signs

Indications of exposure to a chemical compound include, but may not be limited to, the following symptoms:

1. Skin irritation (rash, burning sensation, dryness, and sensitivity)
2. Watering of the eyes (also burning sensation)
3. Dryness of the nasal passages
4. Coughing
5. Shortness of breath
6. Congestion in the chest
7. Nausea and vomiting
8. Light-headedness
9. Intoxication
10. Ashen (gray) complexion
11. Agitation



CAUTION

All Inspectors should have easy access to the emergency telephone numbers such as police, fire department, medical doctor or hospital, rescue service, or State or local poison control center. Be alert to your physical condition and aware of your surroundings. Horseplay, in any form, is dangerous and prohibited.

Do not take chances where chemical compounds are involved.

Check and seek advice from a competent individual before risking a harmful or fatal exposure.

Report all injuries, however small, as well as unsafe conditions and unsafe acts which might be the cause of an accident.

CONFINED SPACE ENTRY

29 CFR § 1910.146 (Confined Spaces) has established minimum occupational safety and health standards for public employees who may enter into or work in confined spaces.

A confined space:

- Is large enough and so configured that an employee can readily enter and perform assigned work; and
- Has limited or restricted means for entry or exit (for example: tanks, vessels, silos, storage bins, hoppers, vaults and pits)
- Is not designed for continuous employee occupancy; and must contain one or more of the following:
 - Contains or has a potential to contain a hazardous atmosphere
 - Contains a material that has the potential for engulfing an entrant
 - Has an internal configuration such that an entrant could be trapped or asphyxiated by inwardly converging walls or by a floor which slopes downward and tapers to a smaller cross-section;
 - Contains any other recognized serious safety or health hazard.

In addition, in any space which meets the above criteria, and has a depth of 4.5 feet or more from the plane of entry to the plane upon which the worker will perform his/her work or when a person's head or feet pass the plane of entry or any other opening shall be considered a confined space.

Confined Space Hazards

Accidents, occupational illness and a substantial number of fatalities can occur through asphyxiation, fire and explosion, exposure to substances, falls, electrocution and a host of other specific hazards. Since confined space entry has resulted in more deaths and injury than any other source in the industry, it is essential to recognize and carefully evaluate the situation prior to entry.

Flammable Atmospheres

This condition can result from an enriched oxygen atmosphere, vaporization of flammable liquids, concentrations of combustible dust, work byproducts or desorption of chemicals from surface coatings.

Too much oxygen, even several percent above the 20.9% normally found in our atmosphere will cause an increase in the range of flammability. A flammable atmosphere is created when the oxygen-combustibility mixture is neither too rich nor too lean for combustion to occur. If inadequate ventilation occurs, flammable gases such as propane, methane or hydrocarbons can be trapped in a confined space.

Since a number of these vapors or gases are heavier than air, they sink to the lower level of the confined space. Combustible dust concentrations can often be found in grain elevators and silo storage areas.

Entry and Exit

The size of the entry orifice must be taken into account in considering rescue actions. Barriers to entry, and ladders or the lack thereof must also be considered. Workers may fall off ladders, develop claustrophobia or become lodged in the entry orifice.

Your Responsibilities

Inspectors shall report any hazardous conditions in connection with confined space entry or any safety equipment defects to the facility manager immediately.

No Inspector Shall Enter a Confined Space, Without First:

- Passing a Confined Space safety training course,
- Informing company officials of your intent to enter a confined space,
- Utilizing ALL required confined space entry equipment, AND
- Obtaining an entry permit, if required.

AAFCO MINIMUM BIOSECURITY PROCEDURES

The farm biosecurity procedures identified in this manual are a minimum standard; if your Agency's are more stringent, use them. These procedures described may appear to be simple and tedious, but persistence and attention to detail is vital for the successful elimination of disease agents. You do not want to be the reason the disease spread to another farm.

Preparation for inspection is very critical; you need to keep your visits to the infected area at a minimum. If you have more than one area to visit, the highest risk area should be your last.

Before you leave:

- Obtain as much information as possible from your supervisor, the veterinarian, the farm manager to ensure you will be prepared for your visit.
 - Check to see if the farm has biosecurity procedures. If so, ensure that you comply with the farm or facility's procedures.
- Designate a clean and dirty area in your vehicle.
 - Dirty area means items that may come in contact with animal secretions and excretions including blood, saliva, milk, semen, manure, urine, mucus, or other discharges. The plastic lined trunk of your car would be a good example.
 - Clean area means items free from any visible dirt, mud, manure, etc. At the beginning of the day, your entire vehicle including tools and clothing should be clean.
- Rubber floor mats in your car should be used for the driver and each passenger. Floor mats will need to be cleaned and disinfected between visits.
 - Heavy plastic can be used to lay over your floor mats and trunk, but make sure the plastic will not interfere with the safe operation of your vehicle.
- Items can be stored in a plastic sealable container or garbage bag in your trunk in case of an emergency. When possible, you should leave all of your disposable items at the farm before you leave.
 - Disposable coveralls
 - Disposable rubber boot covers without deep cleats
 - Rubber gloves
 - Dust mask
 - Safety goggles
- Bring a micro/virucidal disinfectant for on-site disinfecting.
 - A pail and brush will be necessary to clean your boots if disposable covers are not available.
 - Rubber boots should have a pattern of the indentations on the soles that allows easy cleaning.
 - Also bring an equipment pail for cleaning and disinfection of your tools.
 - There are wipes that can also be used in place of the pail of disinfectant.

At the farm:

- On arrival at the farm, park the vehicle in a clean or designated parking area with no obvious manure accumulation. Avoid exhaust fans from livestock areas. Close all windows to prevent insects from entering the car. It is best to park on an impermeable surface, which might require you to park on the road in front of the farm.
 - At a minimum, avoid driving through manure, puddles, or wasted water.
- Ensure farm personnel are aware of your arrival before exiting the vehicle to avoid contamination or breach of the farm's biosecurity plan.
- Put on clean coveralls and boots in an area that avoids potential contamination, such as beside the vehicle.
- Prepare the approved disinfectant solution in the boot pail using the amounts of water indicated on the manufacturer's label.
- Make sure you have all the equipment you will need for your inspection, but try not to overcompensate and take too much. Anything brought back will need to be disinfected or disposed of.
- Rinse your boots with the disinfectant before entering the farm. Even when the risk is negligible, producers may perceive a risk from inspection staff who have visited other sites.
- Leave the boot pail, brush, and disinfectant in a protected area to avoid contact with livestock, children, and pets when necessary.

Leaving the premises:

- Follow biosecurity procedures for the farm, if applicable.
- Before leaving the barn, remove manure and debris from your boots.
- Remove your rubber gloves, wash your hands and the exposed portion of your arms with hand disinfectant, and scrub under the nails. Wipe your hands with a damp paper towel.
- Do the preliminary cleaning of equipment and then prepare a disinfectant solution in the equipment pail or use your disposable wipes. If a pail is used, equipment should soak for a few minutes.
- At the vehicle, wipe down equipment that has been soaking. Open the equipment box and clean any extraneous material from taggers, blood samples, etc. used for livestock activities.
- Clean and disinfect the exterior of the equipment box.
- Brush and rinse your boots in the boot pail or remove your disposable boot covers and place them in the garbage bag.
- Using a brush, wipe the sides and bottom of the equipment pail. Place it in the trunk, and put cleaning and disinfecting equipment back in the equipment pail.
- Remove (inside out) soiled coveralls without contaminating street clothing, and place them in dirty compartment, preferably in a heavy-duty polyethylene bag or plastic carrier.
 - If these are disposable coveralls, put them in your trash bag with boot covers, rubber gloves, dusk mask, or any other disposable item to be left at the farm.
- If you cannot dispose of clothing, consider the interior of the vehicle contaminated, and it will be necessary to clean and disinfect it.
- **Do not travel to another farm or feed mill until all is clean and disinfected.**

Return to the office:

- On your way to the office, a commercial carwash or a power washer should be used to facilitate clean-up.
 - Pay special attention to tires and wheel wells.
- All plastic equipment, carriers, etc. should be replaced regularly to avoid deep scratches, which cannot be readily cleaned and disinfected.
- When necessary, do a more in-depth cleaning of the interior of the vehicle.
 - Clean and soak the floor mats.
- Taking a shower at the office or at home will also help remove any infectious particles.

Safety First

You are the primary person responsible for your safety.

Inspectors have been seriously hurt while performing their jobs.

Make sure you take the time to safely perform yours.

Safety is NO accident!

CHAPTER 3 SAMPLING

WHY SAMPLE?

Sampling is one of the most effective methods for the agency to:

- Check that feeds meet the requirements of State and Federal feed laws and regulations;
- Verify inspectional observations;
- Verify that ingredients, pesticides, drugs and medications are used safely; and
- Evaluate new products and feed processes.

Samples are collected in feed mills, distribution points, and on farms then are forwarded to the State, Food and Drug Administration (FDA) or contracted laboratories services for analysis. The sample collected must be representative of the product sampled to provide a meaningful result upon analysis. The technique of sample collecting is crucial to the accuracy of the laboratory findings along with any possible administrative actions based upon the results.

Always remember that any official sample taken may serve as a basis for legal action. It is important to always follow sampling protocol and procedures to collect the best representative sample available. By doing so, you are being equally fair to your represented agency, the industry and the consumer.

A feed sample may also be collected to ensure that:

- The feed is of composition, quantity, or quality as represented by the label;
- The feed is not moldy, sour, heated, or contains a poisonous or deleterious substance that may render it injurious to animals under ordinary conditions of use;
- An ingredient has not been omitted or extracted in whole or in part;
- The product is not concealing a diseased, filthy, putrid, or decomposed substance, unless the substance has been rendered harmless by sterilization or other effective process;
- Substances have not been added, mixed or packed to deceptively increase its bulk or weight, reduce its quality or strength, or make it appear of greater value than it is;
- The documentation of distribution;
- Part of a survey of products for a specific issue such as checking for levels of a particular ingredient, checking for levels of pesticides or mycotoxins;
- Confirm a suspected violation;
- Help determine or eliminate a suspected cause of an injury or death.
- Evidence to support a regulatory action; and
- Information to develop, enhance or revise a regulatory program.

WHAT IS A SAMPLE?

A sample consists of material and information representing products found at feed mills, distribution points, transportation vehicles, and farms or illustrating conditions found in association with that product and is collected and submitted for evaluation and used in making determinations or supporting violations.

SAMPLE TYPES

Physical Sample

Collection of actual product

Documentary

Collection of records related to a product but no physical product is collected. Records can include labeling: invoices: production records: shipping documents; photographs of conditions, equipment, or environment; and, statements from individuals involved in production, storage, distribution and use of the product.

TYPES OF SAMPLE CATEGORIES

Laboratory analysis of samples is primarily used to obtain information that is not readily available to the Inspector in the field. Samples are usually categorized into either routine surveillance or investigational.

Routine surveillance samples are collected at firms selected at random, or they can be targeted toward specific firms or types of products with a history of compliance problems. Adequate procedures must be followed so samples may be used as prima facie evidence in enforcing the law.

Considerations for selection of products to be sampled:

- Lot size.
- Type of products moving at the particular location.
- The agency's sampling schedule.
- Products with a high violation rate.
- Products on enforcement list(s) (e.g. Stop Sale/Holding Order).
- Follow-up of previous products in violation.
- Coverage of classes of feed.
- Ability of your laboratory to analyze the product or its ingredients.

Investigational samples are obtained for gathering information to be used in enforcement work, and are usually generated by a complaint, toxic incident or an inquiry.

SELECTION OF SAMPLING EQUIPMENT

Official samples must be documented completely, accurately and legibly to be able to withstand legal scrutiny. They must be obtained by a procedure which yields a representative sample using procedures of AOAC International or procedures that are determined to be dependable through research and/or investigation.

There is an array of sampling equipment available on the market. Some sampling equipment may be locally manufactured as long as design specifications are maintained. The type of sampling equipment chosen is highly dependent on the sampling media. Is it a liquid? Is it in block or tub form, hard or soft? Is it packaged or bulk? Is it free flowing or is it not? Inspectors will likely face many different products types and should be properly equipped for such situations.

Not only will inspectors have to select the proper sampling tool for sample collection it is also important to select the proper container to store and ship samples. Do samples need to be stored in a glass jar or can it be plastic? Can I use a paper bag or plastic Ziploc? Does it need to be sterile or does it not? How large do the containers need to be? Is the sample temperature sensitive? How samples are collected, stored and shipped need serious consideration to maintain the representation, integrity and security of the sample.

PRE-SAMPLING PREPARATION

Always be prepared for sample collection and submission.

Sample Kit

Maintain a sample kit that includes basic materials for general sample collection. The kit should include but is not limited to sample tools such as flashlight, spoons, scoops, ruler or measuring tape, scissors, knife, permanent markers, inspection stickers; sample containers such as whirl pak bags, glass jars, vials, zip-lock plastic bags, paper bags; tape such as packing tape, duct tape; materials for aseptic sampling such as sterile containers, sterile gloves, mask; and forms which may include sample receipt forms, affidavit forms, or other forms required by your state when collecting samples or entering premises for regulatory work. There may be additional sampling equipment such as probes, triers, black light that may not fit in your "kit" but should be available if needed.

WHAT TO WEAR WHEN SAMPLING?

Sampling is a physical activity that can require you to climb, move large containers and will often be in areas that are dusty or exposed to the elements. Wear protective clothing that is easy to brush off. You need to dress accordingly which can include coveralls, safety shoes, booties, or safety glasses. Make sure you have included all of the firm's mandatory personal protective equipment. Some feed ingredients in concentrated form can be irritants.

SAMPLE EQUIPMENT SHOULD ALWAYS BE CLEAN

Always clean your equipment after sample collection AND check equipment for cleanliness before starting out on a sampling assignment or investigation that may lead to sampling. Equipment should be stored in a location that maintains cleanliness and prevents damage. Hands should be clean and, if appropriate, gloved. Clean sampling instruments with detergent and water, or other means. Inspectors should wash their hands (and face, if necessary) after sampling as a measure of self-protection.

If you make a mess during the collection of a sample, clean it up.

SAMPLING PROCEDURE AND EQUIPMENT

Pre-Sample Evaluation

Surveillance and investigational sampling should be confined to unopened containers, except when an investigation is underway or a sample is needed for evidence. All bags must be of the same product and production or lot code. Note: While sampling, observe the feed in the trier for any difference in appearance.

If more than one production or lot code is evident on a target product, take a second or third sample. Select bags from all portions of the lots at random, not all from one pallet, one row or one pile. Read the label for any safety warnings and cautions prior to handling the material.

Labeling

Whenever possible request a label from the lot being sampled. If other means of obtaining the label data are used, other than photography or photocopying, the data should be compared with the labels on the lot to make sure the sampled product labels in use are identical. Document this fact.

Sample Identification

Every container of an official sample shall be identified. Follow your agency's established policy of marking and sealing the sample. If a sample can't meet the litmus test of chain-of-custody, it can't be entered as evidence and may be of no use for anything. Never place paperwork in with the sample. Paper can be an absorbent or may be torn, thereby adulterating the sample. When sampling a dated product, the expiration date must be taken from the label to alert the laboratory.

Samples must be identified and handled by you, in a manner that maintains sample integrity for a proper chain-of-custody by being: In your possession, within sight, sealed with a tamper proof seal or locked up.

Mark the sample to inform those handling it of any hazards or special precautions associated with it.

Be certain a collected sample is identified and sealed, before taking another sample.

Selection of Sampling Equipment

Section 965.16 of the 18th Edition of AOAC "Sampling of Animal Feed - Procedure" suggests: Use slotted single or double tube, or slotted tube and rod, all with pointed ends take a 500 grams sample (most labs prefer a 1 kilogram sample). Lay bag horizontally and remove core diagonally from end to end. Determine number of cores as follows: From lots 1-10 bags, sample all bags; from a lot of ≥ 11 bags, sample 10 bags. Take 1 core from each bag sampled, except that for lots of 1-4 bags take enough diagonal cores from each bag to total 5 cores. A sample from less than these number of bags may be declared an official sample if the labeler or guarantor agrees. For bulk feeds draw ≥ 10 cores from different regions or steam cut a sample as the product is moving; when sampling small containers (10 lb. or less), 1 package is enough.

- **Sleeved Probes**

When proper care is given a sleeved probe will give trouble-free service for a long time. When these probes leave the factory, they are adjusted to the proper clearance, fit and tolerance between inner and outer tubes. Since some grains contain more grit or foreign materials than others the probe should be pulled apart and cleaned after every probing. If the probe becomes tight, sticks, or freezes, do not attempt to force the probe to turn. Never use a pipe wrench. This will cause particles of grit to embed into both the inner and outer tubes, causing damage to the probe which can only be repaired and corrected at the factory.

To loosen a frozen probe, place the probe in a horizontal position on a bench, table or any flat surface, with openings down. A second person should tap the probe gently with a flat object of wood, such as a small board or flat stick. This will cause the grit to dislodge and fall toward openings. At the same time, the other person should gently turn the handle on the collar. The probe can then be gently pulled apart. Do not strike the probe hard enough to dent or damage.

The particles of grit will usually lodge near the point within 1/4th of the probe length from the point. Aluminum probes are more prone to sticking and freezing than probes of any other metal.

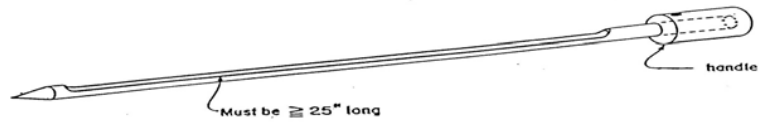
- **Sampling Triers**

The correct trier and its proper use are of major importance in collecting a representative sample.

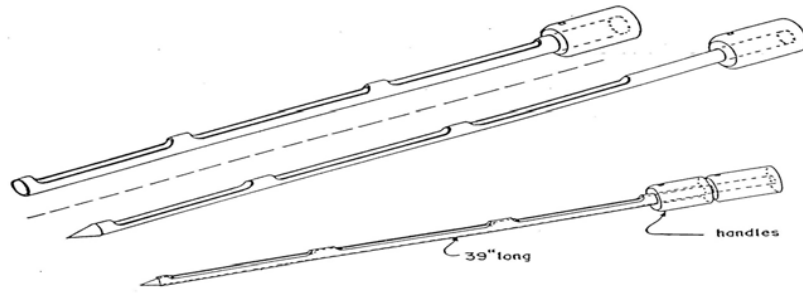
A sampling trier must have a slot equal to or larger than the largest particle, grain, or pellet in the material being sampled.

Make sure sampling instruments are cleaned before each sample is taken. Pay particular attention that no residues remain in or on the barrel or the bulkhead separating the nose cone from the barrel.

Single and Double Tube Trier

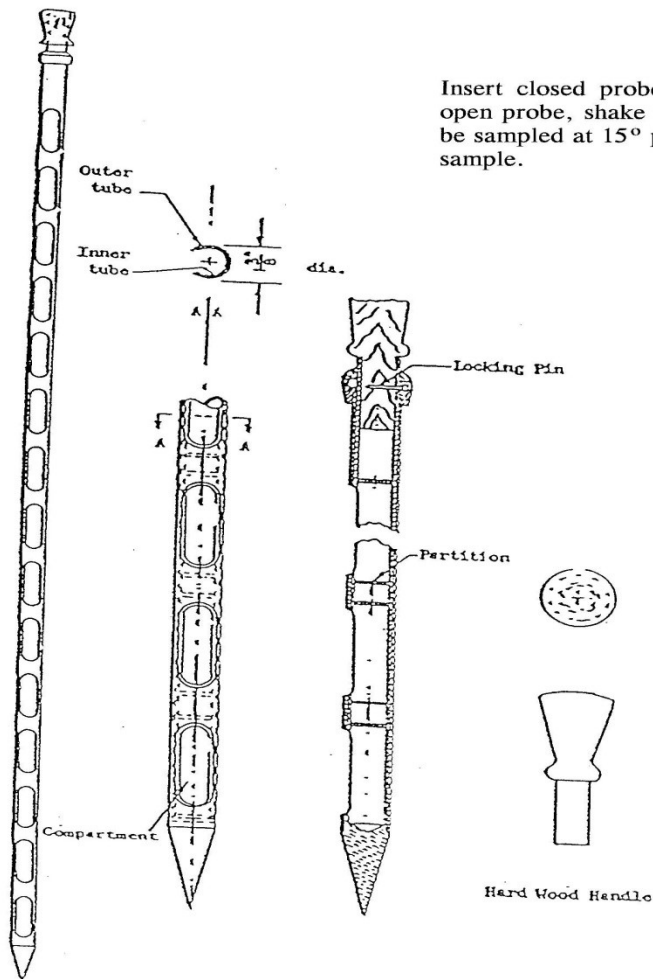


SINGLE TUBE TRIER



DOUBLE TUBE TRIER

7 Foot Probe - Closed Compartment



For samples that cannot be representatively taken with the probes described above, use other sampling means.

Sampling Methodology

The following outlines the sampling techniques, containers and sample size for samples to be taken. The sampling procedures expressed below are minimum sample sizes given for laboratories to perform basic methodologies in sample analysis. Some toxic investigative samples may require bio-assays to be done by the laboratory, greatly increasing the sample size requirement.

For each sampling method outline, combine the samples into a suitable container for sample reduction at the laboratory. Do not split samples in the field unless instructed so by your supervisor.

For certain non-routine circumstances, creating a sampling scheme may be necessary based upon manipulation of other proven sampling methods, sampling knowledge and past experience. You should consult with your supervisor in such cases.

- **Specialty Small Packaged Dry Feeds**

The lots for sampling small packages must be closely examined to ascertain that all units of the sample are of the same production code. If all units are not of the same code, select a code or product which has adequate numbers for sampling. This may be foregone if sampling is based on a consumer complaint.

For pet and specialty pet foods, powders, pellets and packages of crumbles or grains in containers of ten (10) lbs. or less, purchase one unbroken package. This may require the purchase of more than one package to meet the sampling size requirement.

For capsule, tablet or other single dosage range of package sizes, purchase three to six unbroken packages of the smallest size available.

Often times a small packaged item price can be very expensive. Check with your supervisor to insure that the product should be sampled and that the amount is large enough for the laboratory to run.

For canned dog and cat foods, purchase 3 cans of the same production code. This will assure the laboratory has enough sample to process and a reserve can if needed

- **Bagged Dry Feed**

Sometimes it is impossible to use any type of trier for sampling feeds. Examples of these are high molasses feeds, range pellets or hay wafers (cubes). An Inspector may have to resort to other methods of sampling, such as hand or cup sampling.

After sampling is completed, all bags shall be sealed and returned to their position in the pallet or stack. Leave the lot in good saleable condition.

- **Free Flowing Materials**

Includes fine ground material, well mixed, completely homogenous, non-separating, including: mineral mixes, solvent process soybean meal, urea, fine ground poultry mash, pig feed and similar substances. Fine particle feeds should be sampled by probing the bags after being sewn, tied or sealed.

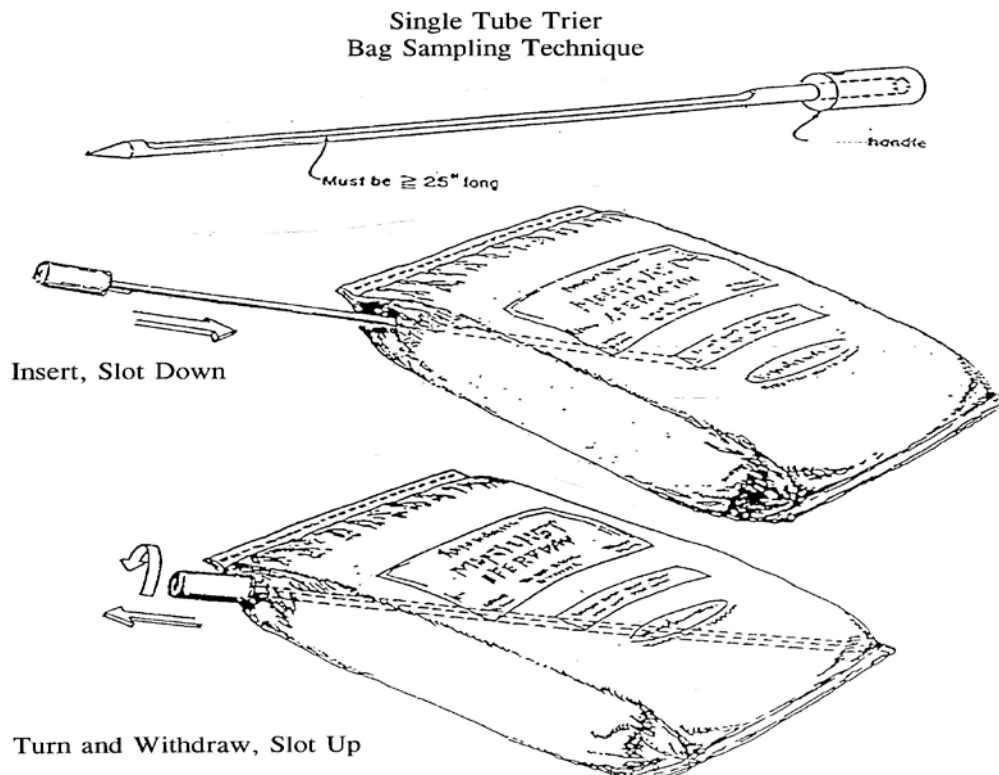
When sampling bags of free flowing material, the Inspector should insert the trier in the upper sections of the bag. Leakage is less likely to occur from the trier holes. A standard bag trier should be used.

When sampling bags with a slotted trier, insert the trier length-wise to the opposite corner of the bag with the slot in the downward position the trier should then be turned until the slot is on the upper side of the trier, before withdrawing. This compensates for any differences in segregation during the filling of the bag.

When sampling with a trier that cannot span the length of the bag, sample the same number of bags from the top and from the bottom of the bag. This is to compensate for any differences in sifting during the filling of the bag.

The opening made by the trier in the plastic weave or burlap bags may be closed by simply drawing the point of the trier over the hole. Holes in paper bags shall be sealed by the use of inspection stickers.

The following illustration demonstrates the proper technique to use when sampling bagged feed with a single slot tube trier.



- **Coarse/Textured Feeds**

For material that does not flow freely, including high variation material having different compositions and/or particle size, non-ground material and coarse grinds, a slotted trier, stream sampling cup, Barley Trier or Bulk Probe should be used.

When sampling bags, the bags should be rolled prior to sampling to loosen up material, then with a slotted trier, insert the trier lengthwise to the opposite corner of the bag with the slot in a downward position. The trier should then be turned until the slot is on the upper side of the trier, before withdrawing.

Liquid molasses feeds bind finer particles, preventing product separation. There are, however, sampling problems using a standard bag trier if pellets are in the mixture or during cold temperatures. Pellet products, that could be the primary source of protein or drug in the feed, tend to fall off the probe before extraction.

The Inspector may sample by hand or cup. This is done by sampling at least 10 bags after they have dropped from the scale-filler, prior to sewing.

Due to non-uniformity in these products, larger samples should be submitted for analysis.

- **Pellets, Cubes and Wafers**

Use one of the standard bag triers with openings larger than the diameter of the pellets being sampled. The Inspector may sample pellets, cubes or wafer feed by hand or cup. Make sure to collect the same amount from each container. If the manufacturer is producing the feed, sample at least 10 bags after they have dropped from the scale-filler, prior to sewing.

Large cubes may be sampled by cutting a three-cornered hole in the bag and hand removing individual pellets, cubes or wafers from the bag.

- **Powdered Feeds**

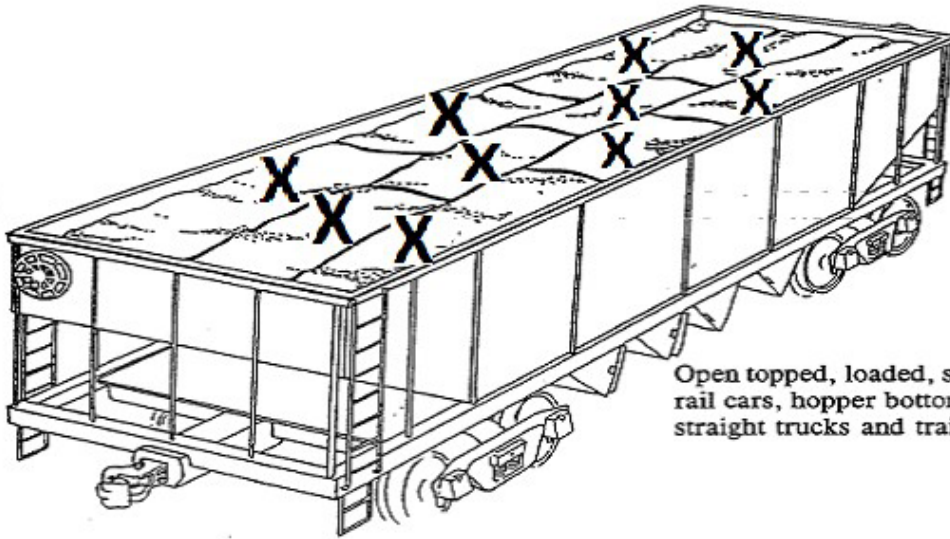
For fatty based, fine textured feeds, including powdered milk products, a Flour Trier or slotted trier should be used. High humidity can cause increased difficulty in sampling.

- **Bulk Dry Feeds and Ingredients**

The slot of the sample probe must be larger than the largest particle of material being sampled.

- **Loaded Stationary Rail Cars, Hopper Bottom Trucks, Straight Trucks, and Trailers**

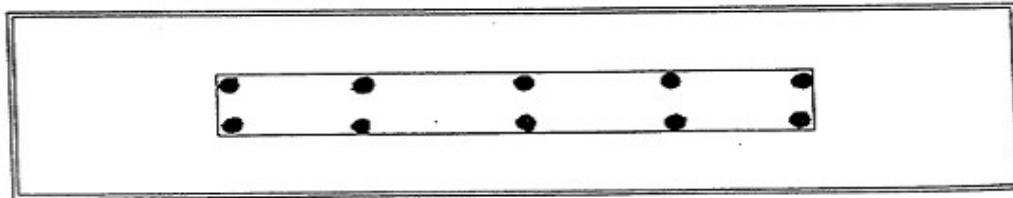
For open topped vehicles, the preferred method of sampling is by collecting (10) full probes in the pattern illustrated below. The probes DO NOT have to be taken in numerical order.



Open topped, loaded, stationary rail cars, hopper bottom trucks, straight trucks and trailers

Sampling Pattern

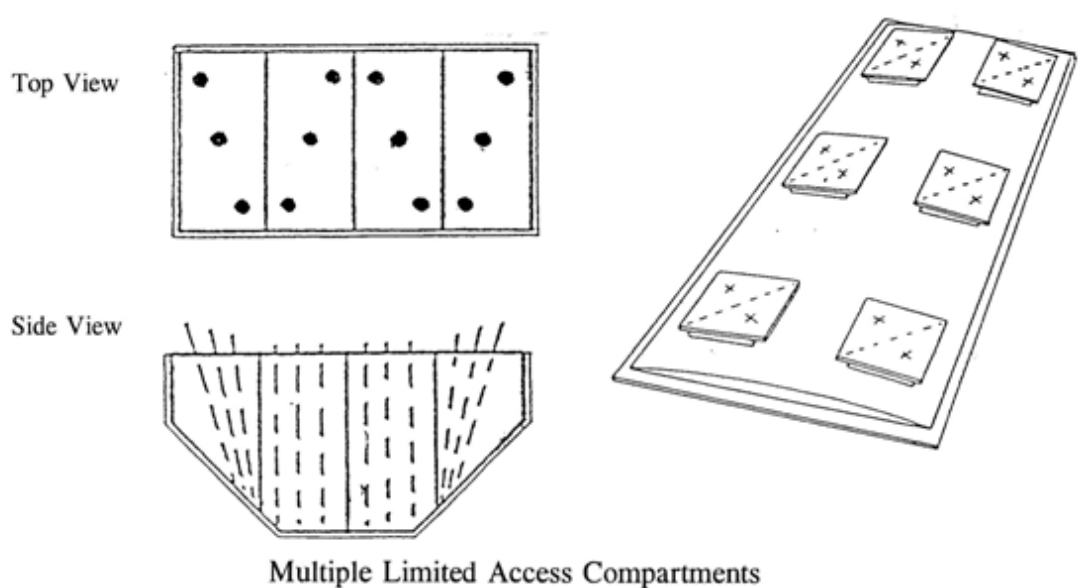
- c. For limited access vehicles, with one compartment, the preferred method of sampling is by collecting (10) full probes, accessing as much feed as you safely can. For coarse textured feeds, hand grabs or cups may be used in lieu of probing. The probes, hand grabs or cups should be evenly spaced to represent the entire lot of feed.. (See illustration below)



Single Limited Access Compartment

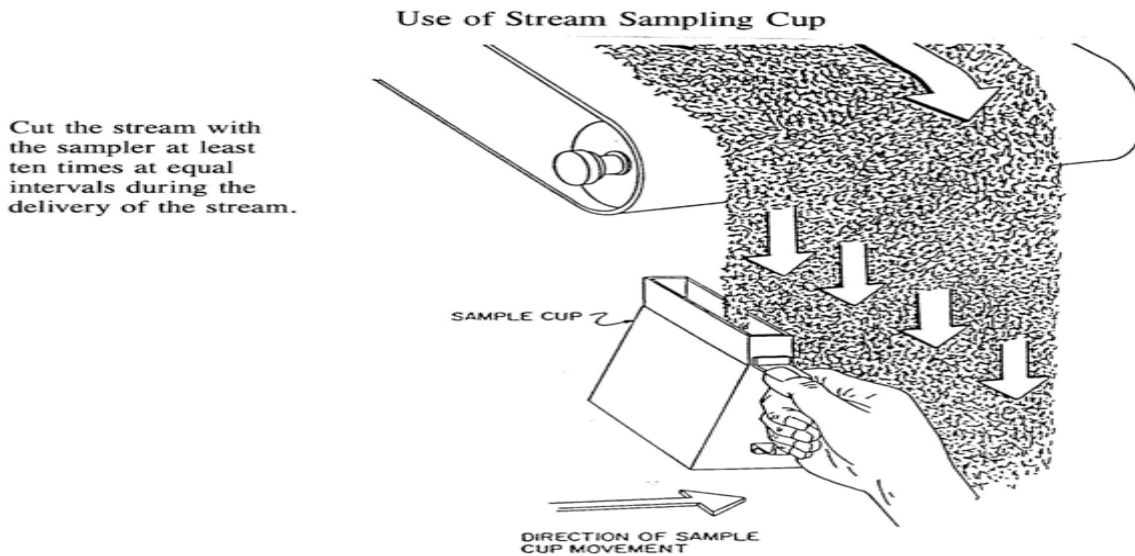
- **Multiple Compartments, Limited Access, Loaded Stationary Rail Cars, Hopper Bottom Trucks, Straight Trucks and Trailers.** Sample each compartment evenly to a total of at least (10) or greater probes.

Probes Per Compartment	
Compartments	Probes
1	10
2	5
3	4
4	3
5	2
6	2
7	2
8	2
9	2
10	1



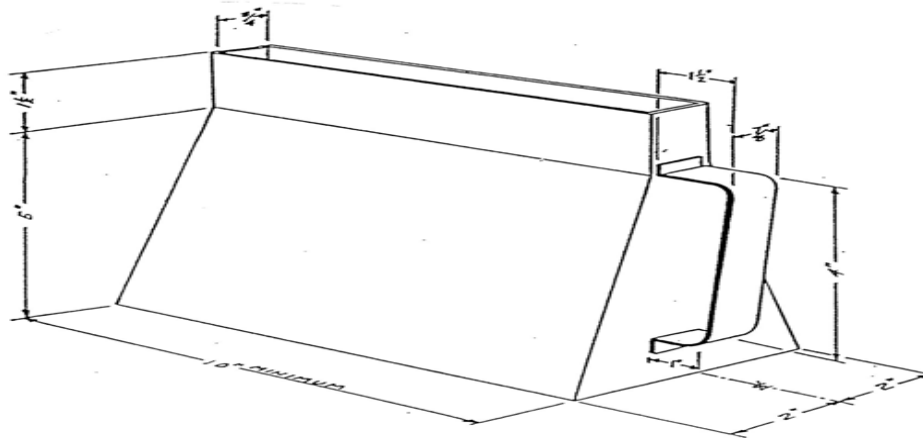
• **Cut Stream Sampling**

Stationary rail cars, hopper bottom trucks, straight trucks and trailers, while transferring feed, depending on accessibility, can be probed or sampled by a stream cutting device.

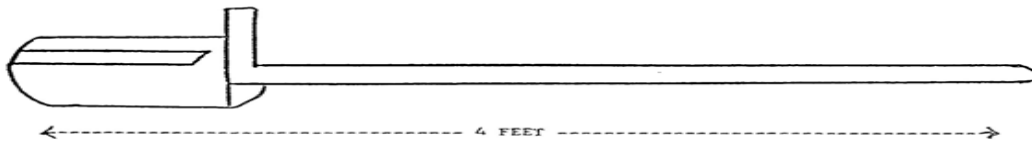


- a. **Minimum sample size: 18 oz. (500 grams) or 2.2 lbs. (1 kg.) preferred.**
- b. **Sample the moving cone under a hopper bottom rail car or hopper bottom truck. Insert the probe horizontally, full depth, in the inverted position through the cone, then turn, remove and empty into the sample bag. Repeat 10 times at equal intervals over the entire unloading process. If only one compartment is sampled, the sample report must so indicate.**

Cup Sampler (Stream Cutter)



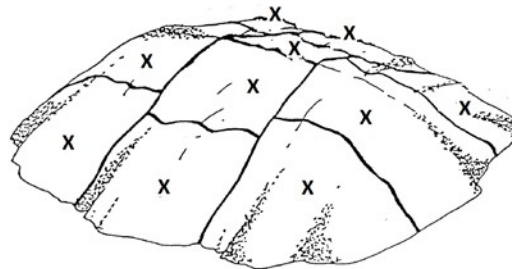
Fabricate from: 16 GA. GALVANIZED IRON
OR 18-20 GA. STAINLESS
STEEL, TYPE 304



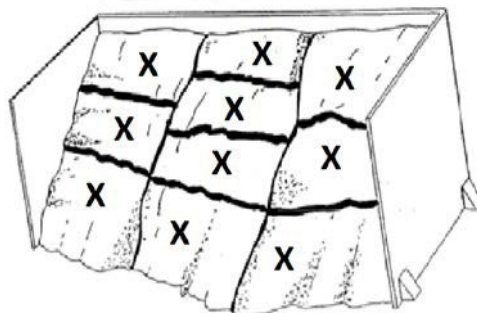
Examples of Stream cutting devices

• **Bin Sampling**

The preferred method of sampling is by collecting (10) full probes, accessing as much feed as you safely can. For coarse textured feeds, hand grabs or cups may be used in lieu of probing. The probes, hand grabs or cups should be evenly spaced to represent the entire lot of feed. For safe access, open bins (See Chapter 2 “Safety”).



For center filled, coned, ridged or level filled bins, take (10) probes, hand grabs or cups using the illustrated pattern. The probes DO NOT have to be taken in numerical order.



For side filled bins, (material slopes away from one wall), take (10) probes, hand grabs or cups using the half-pile illustrated pattern. The probes DO NOT have to be taken in numerical order.

For closed bins (See Section 2 “Safety”) **Stay Out**

A sample may be taken from a closed bin, at a limited access point, by one of the following methods:

- Ten sweeps with a Stream Sampling Cup while emptying into a weigh-buggy or front-end loader;
or
- Ten probes, hand grabs or sample cups, evenly distributed, from a weigh-buggy, front-end loader, or opening to the bin.

• **High Fiber Products**

Includes cottonseed hulls, whole almond hulls and gin trash. Use the corkscrew cottonseed probe or almond hull probe. The probe shall be used before resorting to hand grab samples.

Take a minimum of three (3) probes per carrier, in a staggered pattern.

A car-lot should be sampled with a minimum of four (4) probes per car or one (1) probe per section of the car.

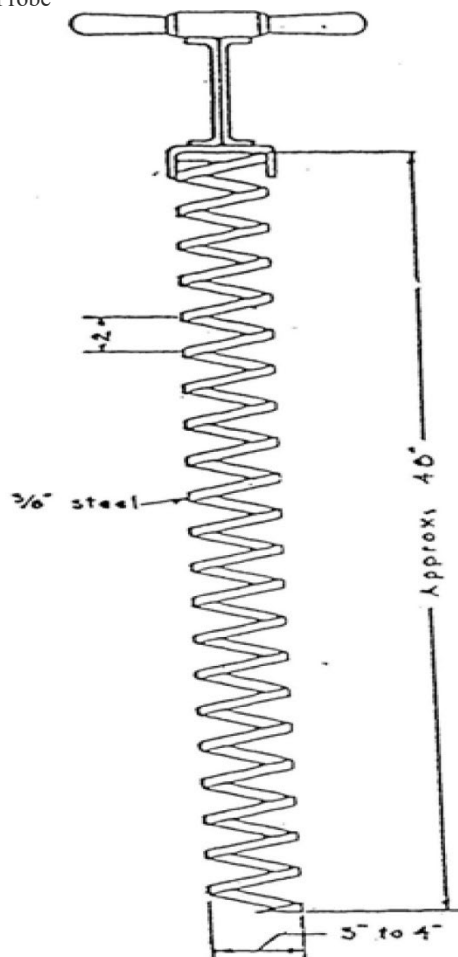
Hand grab sampling during loading or unloading operations shall be used if the almond hull probe or cottonseed corkscrew probe is not satisfactory. Take a minimum of ten (10) grab samples evenly time- spaced during the loading and unloading operation.

Combine the samples into a suitable container and submit to the laboratory. A minimum sample size of ten (10) pounds of high fiber products should be taken.

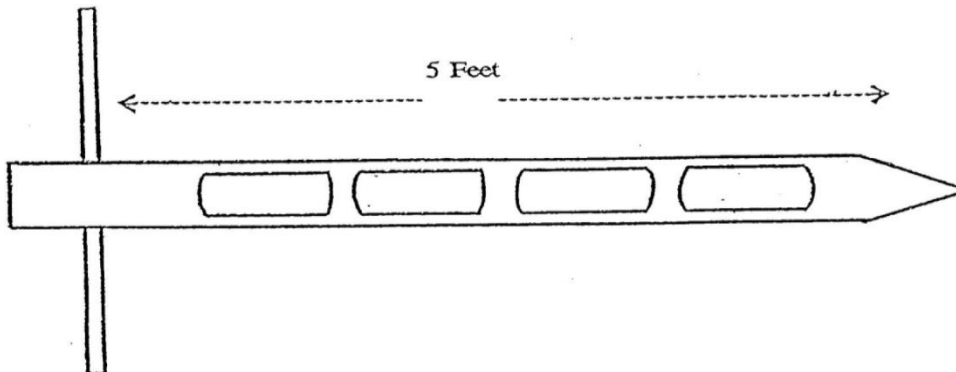
Sampling devices used to sample high fiber products:

Corkscrew Cottonseed Probe

Trier takes 4 lbs. of cottonseed at a single probe. Made of band steel 7/16 x 5/32 inches and bent to form an open cylinder 3 inches in diameter. The pitch of the twist is 2 inches and the screw portion 42 inches long. A single slight twist will cut the walls so that the trier may be readily withdrawn.



Almond Hull Probe



Insert, compartment side down, turn so compartment side is up, shake to full and withdraw sample.

- **Liquid Products**

Agitated versus Non-Agitated Products—If the label specifies agitation, make sure the feed is agitated by the facility representative before sampling. If feed requiring agitation is being sold without agitation, sample & document “no agitation”. If agitation is not required, inform facility representative of your intentions to open valve and completely flush out the line before sampling and they can decide what to do with the flush, before sampling begins.

- **Liquid Bulk**

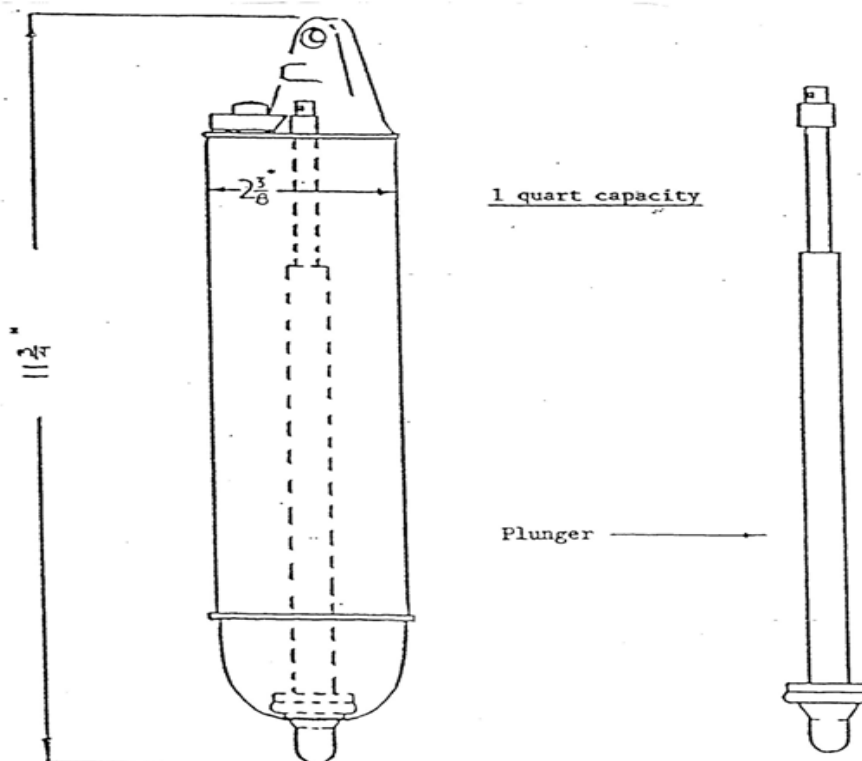
Liquid sample may include clear liquids, semi solids, or suspension type products. In collecting a sample, fill the plastic or glass container about three quarters full and close with a neoprene or Teflon lined cap. The container should only be two thirds to three fourths full so the product may be shaken or agitated prior to laboratory preparation. Properly identified and officially seal the container. If necessary, refrigerate or place the sample on ice. Liquid feeds may be sampled in various places in the manufacturing or distribution channel. Some common places to collect samples include mixers, delivery lines, delivery tanks or trailers, or storage tanks.

- **Mixers**

Liquid feeds may be sampled at the manufacturer directly from the mixer, immediately following or after recirculation, from a valve on the mix vat. Flush at least one quart of material through the valve before collecting the sample. Be sure to collect the flush material and recycle or dispose of it accordingly.

After manufacturing has occurred, the Missouri suspension bottle may be used to collect a core sample through the mixing vat. Simply lower the bottle slowly into the vat and wait for it to fill. Make sure there are no moving parts or mechanisms in the mix vat when you are collecting a sample in this fashion. A liquid sampling bomb or liquid zone sampler may also be used.

Liquid Bomb Sampler



Full horizontal cylindrical or spherical tanks may be sampled by lowering the liquid bomb sampler just below the surface and allowing the sampler to fill. This process is repeated twice at the center level of the tank and once at the bottom. All four aliquots are mixed and tested; or sent to the laboratory for testing.

Vertical cylindrical, cubic, or rectangular shaped tanks are sampled by the same method except one aliquot is taken from the center level rather than taking two.

- **Delivery Lines (Closed System)**

A closed system entails manufacturers that have devoted lines for certain commodities. This would include fixed plumbing running from a storage container to a mixing vat. The line will always carry a certain material. It will never have another ingredient transported through the line.

Often manufacturers will have sampling valves or drip valves built into a delivery line within their plant. Flush this valve with at least a quart of material prior to collecting your sample.

- **Delivery Lines (Open System)**

This would include lines that are common carriers for various products. Great care must be exercised to flush these lines with enough material to remove all traces of any previous product. Care must also be exercised to collect the flush material and recycle or dispose of it properly.

A good rule of thumb is to flush the line with at least twice the volume of the line prior to collecting the sample. The following table lists approximate line volumes in gallons per foot and gallons per ten feet.

Line Diameter	Gallons per foot	Gallons per 10 feet
½ inch	.0102	.102
1 inch	.0408	.408
1 ½ inch	.0918	.918
2 inch	.1632	1.632
3 inch	.3670	3.670
4 inch	.6528	6.528
5 inch	1.020	10.200
6 inch	1.4688	14.688

○ **Delivery Tankers or Storage Containers**

When a product is stored at a manufacturing or delivery facility, it may need to be agitated before sampling. Check with management and review the product's label to ascertain whether agitation is required. If agitation is suggested, make sure you collect your sample after proper agitation has occurred. If the label specifies agitation and the facility does not have the proper equipment to agitate or recirculate the product, obtain a sample and document *no agitation available* in the comment area of the collection report.

Samples may be collected at the load out valve. Once again, make sure the valve has been properly flushed with at least a gallon of product prior to collecting the sample. Often valve lines will extend well into the tank and will need to be flushed with more than a gallon of product.

Some storage tanks will have "sight" gauges on them to indicate the volume of the tank. The plastic tubing may be removed and a sample collected from the sight gauge valve. Do not collect the material in the sight gauge. Flush the sight gauge valve with at least a quart of flush prior to collecting the sample. Be certain to collect the valve flush material as well as the material in the plastic tube for disposal or recycling.

If the top of the tank is accessible, the Missouri bottle, liquid sampling bomb, or liquid zone sampler may be used. When ascending a tank or trailer, please use caution. The tank may be slippery or in poor condition. Refer to Chapter 2 on safety.

○ **Liquid Samples from Small Drums or Barrels**

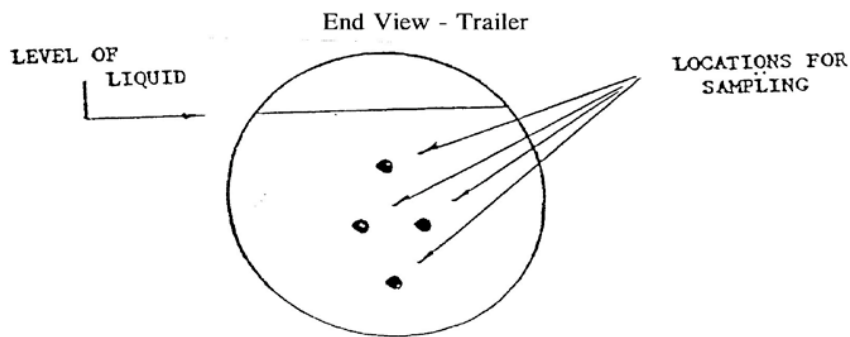
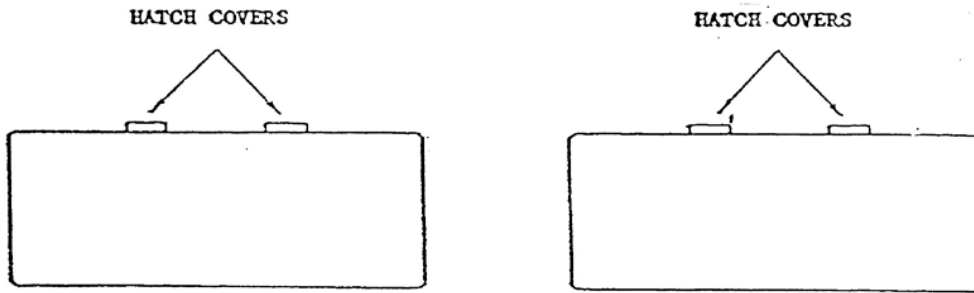
Shake the container thoroughly before sampling solutions that are in small drums or barrels.

Lower a Texas molasses sampler completely to the bottom of the container and examine the withdrawn portion to detect sediment, crystallization, or lack of uniformity in the material.

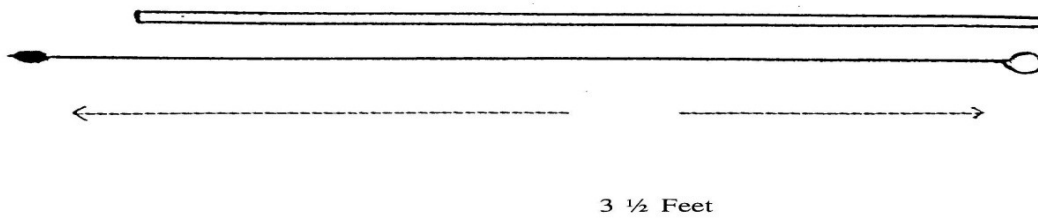
Remove the large bung. Use a disposable pump or a clean pipette to draw off sample. Place an inspection sticker on the drum. If total number containers is 1-10, sample 1-3; 1-25, sample 2-4; 26-50, sample 3-6; 51-75, sample 6-8; 76-100, sample 8-10. Place a sampling sticker on the drum after replacing bung. Sample size should be at least 500 milliliters (17 oz.).

Sampling Bulk Liquid Feed

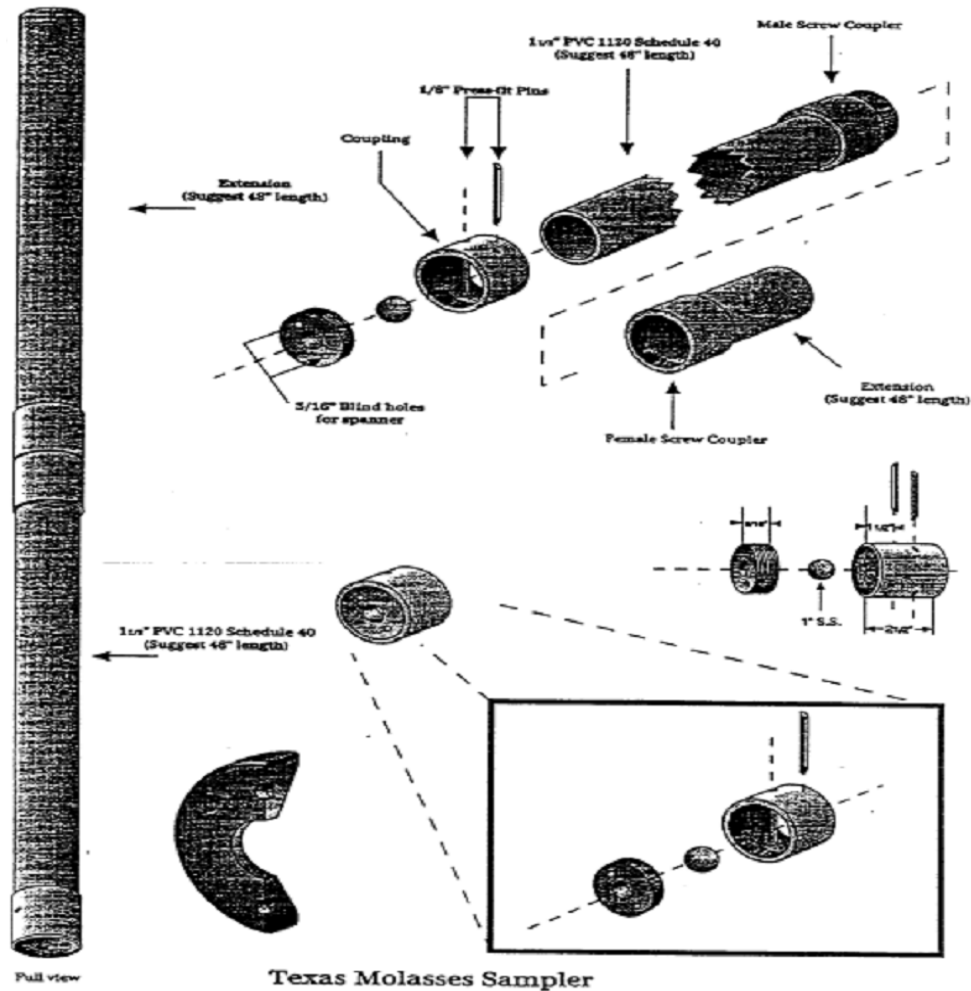
Side View - Set of Doubles



Liquid Tube Sampler



The tube sampler (above) is used to sample liquids in tanks or drums. The cone end of rod is a snug fit inside the tube by use of 1/4L washer. By manipulation, either liquids or thick emulsions can be sampled.



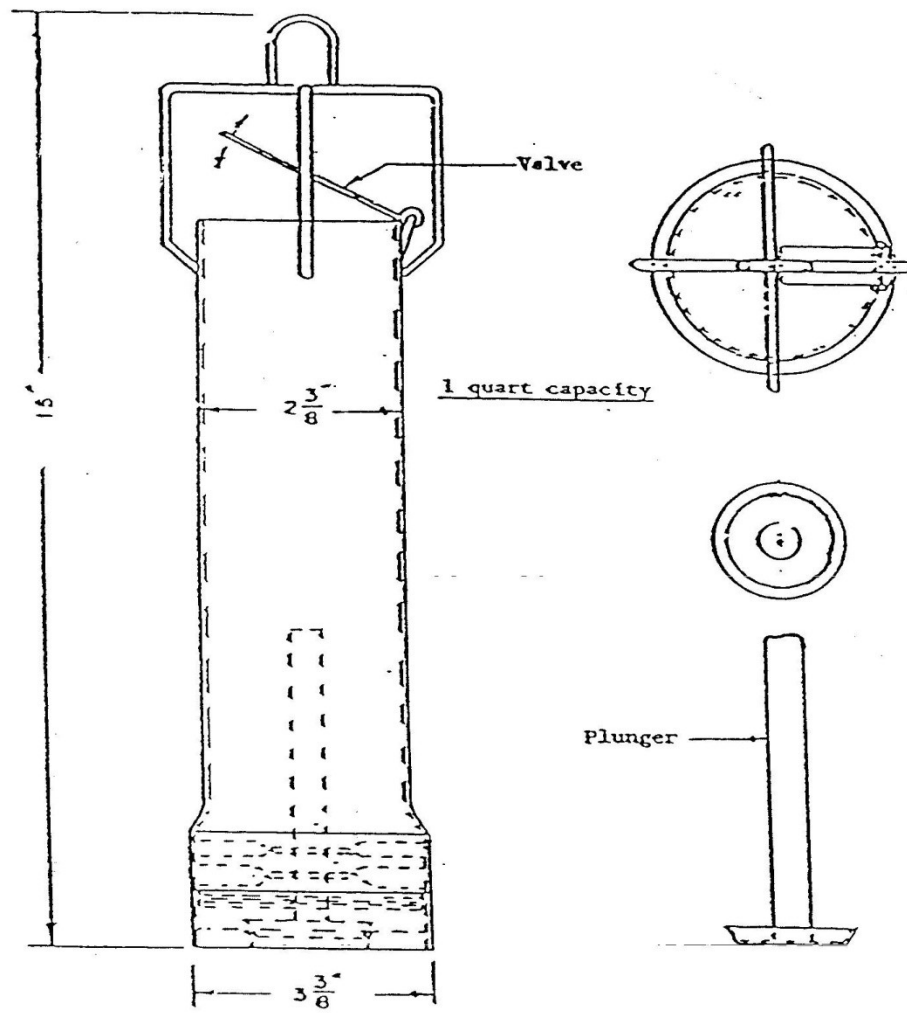
The Texas Tube (above) is used to sample liquids in tanks, drums or vehicles. The valve end of the sampler is slowly lowered into the contained material. A core sample is supplied. Extensions allow for sampling of large tanks and vehicles. Molasses, liquid feeds, suspension feeds, liquid fats and oils (less than 140 degrees) can be sampled.

○ **Fats**

These products are frequently difficult to sample due to the heat necessary to maintain the liquid state and inaccessibility of the holding vessels. The liquid sampler will distort when inserted into a very hot fat (above 140 F). Be very careful sampling near moving, hot equipment. Fat burns can be extremely painful.

Take a one quart sample from manufacturer's fat blender equipment nozzles or valves on the mixer, or take a one quart sample from a valve of the blender's delivery vehicle at time of delivery.

Liquid Zone Sampler (Fats and Greases)



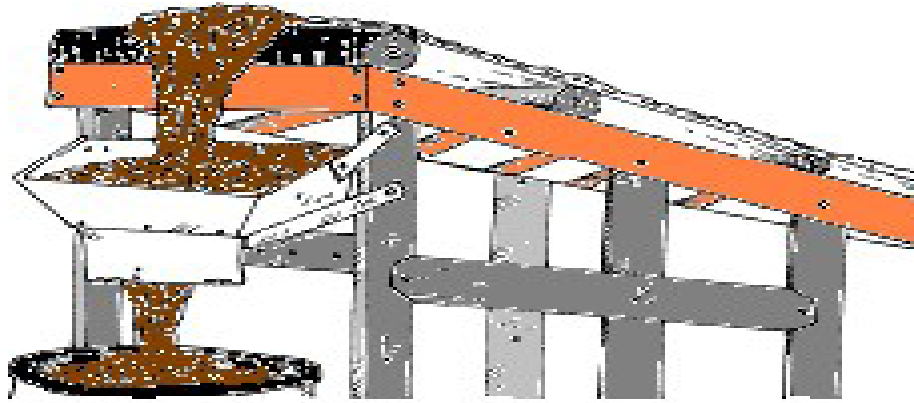
Full horizontal cylindrical or spherical tanks are sampled by lowering the liquid zone sampler just below the surface and allowing the sampler to fill. This process is repeated twice at the center level of the tank and once at the bottom. All four aliquots are mixed and tested; or sent to the laboratory for testing. Vertical cylindrical, cubic, or rectangular shaped tanks are sampled by the same method except one aliquot is taken from the center level.

- **Protein Tub Sampling**

- **Manufacturer**

Use a lined container/bag as a stream cutting device or secure a grab sample from each of at least ten tubs at equal time intervals and place into a lined container/bag. Collect a 2 lb. minimum composite sample.

Be very careful sampling near moving equipment, hot equipment, and hot tubs. Please wear the proper personal safety equipment for sampling this product.



- **Dealer and Consumer**

There are three approved methods for sampling hardened poured tubs: Chipping from the edge, chisel from the center, and drilling from the center of tub.

Caution should be used when using a chisel and hammer. These sampling methods can cause shattering of material; proper personal protective should be used at all times when collecting samples.

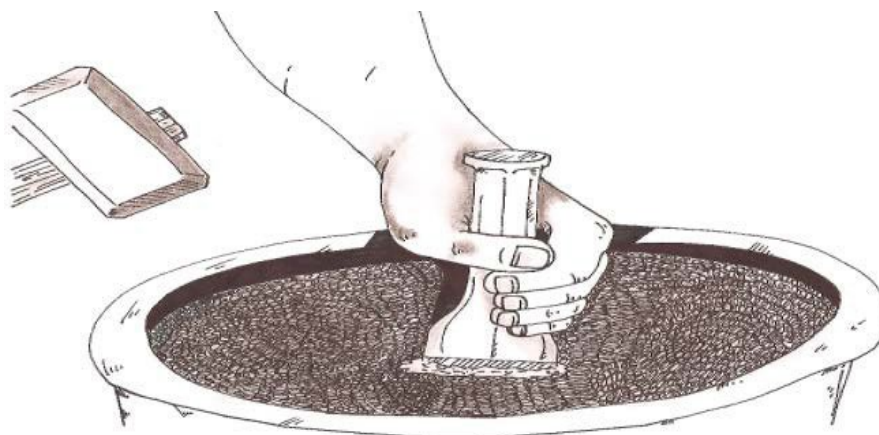
- **Chipping from the edge**

Using a chisel and hammer, holding the chisel at an angle, strike the chisel with the hammer to produce a cone shaped sample. A total of 10 samples from ten separate tubs should be taken with a minimum total sample size of two pounds.



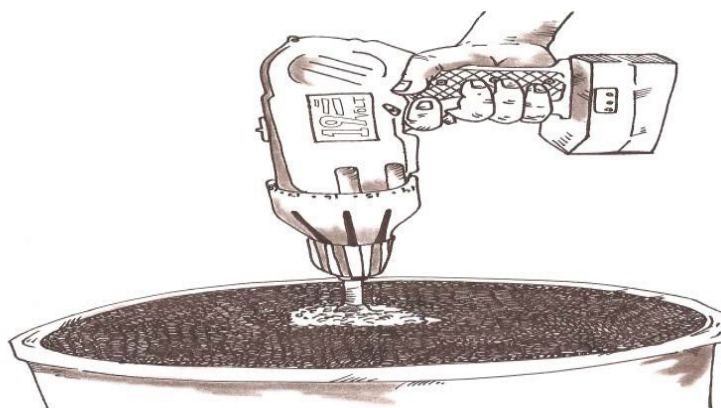
- **Chiseling from the center**

Using a chisel and hammer, holding the chisel at an angle and strike the chisel with the hammer just off center of the tub, repeat on opposite side to form a pyramid shape sample. A total of 10 samples from ten separate tubs should be taken with a minimum total sample size of two pounds.



□ **Drilling from the center**

Using a bit and drill, drill the center of the tub approximately three inches deep with a 1" drill bit. A total of 10 samples from ten separate tubs should be taken with a minimum total sample size of two pounds.



• **Soft Mineral and Protein Block**

○ **Manufacturer**

If not hot, take 10 grab samples of the meal prior to blocking. Sampling should take place during the period of blocking of at least 50 blocks. Using a 3/8 drill and 1" drill bit, drill at least 10 cores from separate blocks selected at random. Carefully check the codes of the blocks to ascertain lot number.

○ **Dealer and Consumer**

Sample by drilling at least 10 cores from separate blocks selected at random. Carefully check codes of selected blocks to ascertain lot fidelity.

• **Hard Mineral and Salt Blocks**

○ **Manufacturer**

Ten grab samples of the mix prior to blocking, over the manufacture of at least 50 blocks.

○ **Dealer**

Break the corners of 10 blocks selected at random. Take only a small portion from each corner for the sample. The total sample should be a minimum of two pounds in size.

• **Molasses Blocks**

When sampling at the manufacturer use a stream-cutting method to secure the sample. Place at least a two pound sample in a lined bag or container which may be removed from the sample bag.

• **Haylage/Silage**

Because of the non-uniformity and high moisture content, silage is best sampled by hand. Avoid sampling from moldy or spoiled areas in the tower or bunker silo unless you are specifically sampling for that material. The sample also needs to be larger than most other product sample requirements - a minimum of five (5) pounds.

• **Tower Silos**

Secure ten grab samples at equal intervals while the unloader is operating.

DO NOT GO UP INTO THE SILO. IT MAY BE OXYGEN DEFICIENT.

- **Bunker Silos**

Scrape away surface material to get to fresh material; this is especially important if materials has not been disturbed for 1-2 weeks. If material is generally uniform, take 10 separate equal grab samples across the working face, making sure to get a representative sample of what is fed. If the material is not uniform; take a total of 2 samples in the above-described manner (5 sub-samples each): one of better the quality and one from the poorer. Combine all grab samples into a plastic bag or other suitable moisture-tight container and identify. Pack silage tightly and reduce air space to the minimum. Keep sample as cool as possible. Submit to laboratory as soon as possible.

Note: While sampling bunker silos, safety must be taken as entrapment and suffocation can be a major hazard, sample only when the sampling area is safe.
- **Sample for Insects and Rodent Droppings**

To sample for insects and rodent droppings in stored feed, a large sample is needed for lab examination. Wear clean disposable gloves and hand grab and place into sample bag.

Obtain a minimum sample of 2.2 pounds (1 kg) in large polyethylene bag.
- **Sampling for Mycotoxins (i.e. aflatoxin, fumonisin)**
 - **Packages**

Open packages in such a manner that sample can be withdrawn without contacting packaging material to avoid possible contamination of sample. Use a clean instrument to take approximately equal samples from a minimum of 5 packages in the lot to avoid taking too large a quantity from any one package.
 - **Bulk**

Take sample directly by scooping from the lot with the clean sampling cup or by passing the sampling cup through the stream of a lot being transferred into or out of a storage bin. Close sample immediately. Collect a sample of a minimum of 11 pounds (5 kg).

Sampling of dry materials may result in airborne dust. Even if no toxin is present, there is potential harm from inhalations of mold spores or from allergic response to inhaled dust. **Use protective mask and/or dust collector.**

Do not package in polyethylene due to the possibility of continued mold growth. Use large paper bag.
- **Aseptic Sampling for Salmonella and other bacterial contaminants**

Aseptic sampling is a technique used to collect a sample without contamination by your sampling method, using sterile sampling implements and containers. The intent of aseptic sampling is to provide a sanitary sample for microbiological testing. Taking steps to minimize exposure of sample material, sampling equipment and the interior of sampling containers to the environment is vital to maintaining the integrity of an aseptic sample. Performed correctly, samples collected using aseptic techniques will permit testimony that the microbiological findings accurately represent the condition of the product at the time of sampling.

Before initiating aseptic sampling, it is essential to properly plan and evaluate biosecurity precautions. Always follow the biosecurity and safety plan for the facility. Additional steps listed below can be incorporated into sampling protocol to reduce the likelihood of becoming a potential source of contamination:

 - Plan your work so you do not carry contaminants from one location to another.
 - Ensure shoes, clothes and additional equipment are clean and appropriate for task at hand.
 - Practice good personal hygiene.
 - Change or clean shoes between inspection sites if they become dirty.
 - Wear disposable shoe coverings or other personal protective equipment when necessary.
 - Be cognizant of recent contact with animals and livestock.

NOTE - *There are many methods/procedures that can be utilized to collect samples in an aseptic manner. The following information is intended to provide basic examples. When collecting aseptic samples, always consult with the appropriate agency/organization for specific sampling protocols.*

General Procedures

Whenever possible collect intact, unopened containers. When it is not possible to collect unopened containers, proper steps and equipment must be used to collect an appropriate aseptic sample. All equipment, supplies and containers should be sterile and made of nonporous, easily cleanable materials. If sterile equipment is not available, supplies should be adequately sterilized using an appropriate method immediately prior to use. Wooden tools should be avoided as they are particularly susceptible to bacterial contamination and are difficult to sterilize. Sample collectors should consult with their laboratories, compliance staff, etc. to determine the appropriate tools and methods to collect samples aseptically. Once appropriate equipment has been selected, don sterile disposable gloves (Figure 1) and sample as follows:

- **Packaged Products**

Before initiating sampling, prepare in accordance with the product being sampled. Select a representative number of packages from the lot of feed to be sampled. One sample will consist of a sufficient number of smaller increments/sub-samples collected from each of the selected packages; typically, one scoop per package is a sufficient sub-sample. Numbers of packages to sample from, and number of increments/sub-samples from each package, should be determined by consulting with your agency, program or division.

If product is bagged, bags should be opened (preferably by firm employees) and product made accessible for sampling. Alternatively, samples can be collected from packaged products by surface sterilizing the package, cutting the package open in a “V” or “H/I” shape utilizing sterile equipment and creating a flap opening. Packages should be opened in such a manner to permit the withdrawal of sample without contacting packaging material. Label Whirl-pack bags with sample information and prepare sampling area by having sampling tools and equipment in place.

- **Bulk Products**

Before sampling, assess where and how the sample will be obtained (in-line sampling, at load-out, etc.). Clean or sanitize sampling port, if available. If no sampling port is available, sanitize any adjacent surface the bulk product may contact during sampling. Utilize sterile sampling equipment to collect product. Sample collectors should consult with their laboratories, compliance staff, etc. to determine the appropriate tools and methods to collect samples aseptically. Determine the approximate length of time of the product run and collect samples at equal intervals throughout the run. For sampling bulk piles, consider sampling area, pattern and the firm's biosecurity policies prior to beginning sample collection.

One sample will consist of a sufficient number of smaller increments/sub-samples collected from equal intervals over the course of the production run. Again, to determine number of increments/sub-samples, and interval at which to collect, please consult with your agency, program or division. Label Whirl-pak bags with sample information and prepare sampling area by having sampling tools and equipment in place.

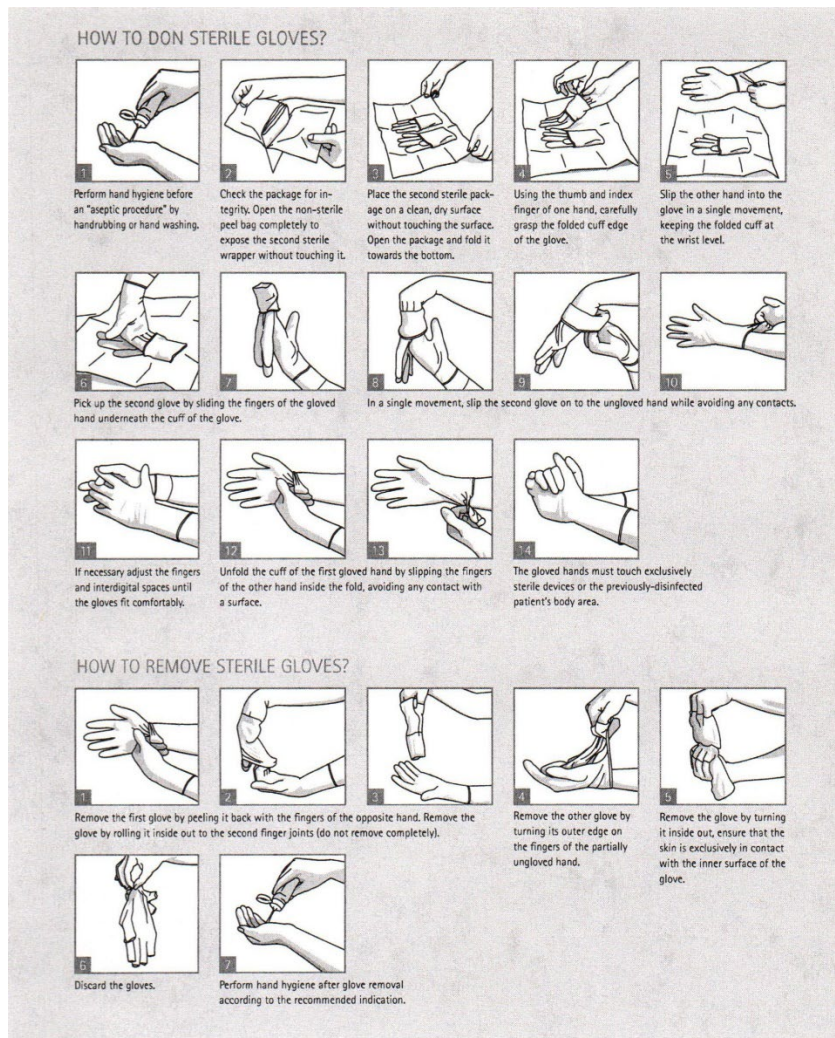
Technique

When collecting any sample, safety should always be first priority. Exercise extreme caution when using sterilization techniques and/or solvents. Always use adequate PPE. Samplers must use sterile gloves during sampling and change gloves between each sampling in an aseptic manner. If your hands or any other material contacts the sample, sampling tool or container in such a way the sample integrity may have been compromised, discard that sample and collect a new one. When available, attempt to employ two individuals when collecting aseptic samples: one designated as the sampler; one designated as a helper.

Inspector uses aseptic techniques to collect the sample:

- Verify attire is appropriate for sampling process and/or materials being collected (ex. clean, long sleeve shirt, clean pants, required PPE, dust-mask for fine powders, hairnet, etc.).
- Ensure all needed equipment is available, prepared for use and in good condition (ex. scoops, cups, probe, Whirl-pak bags, marker/pen, trash bag for waste, etc.).
- Wash hands with soap and water to mid-forearm and dry with clean disposable paper towel.
- Using aseptic technique, unwrap and don sterile gloves (Figure 1). Do not touch any non-sterile surface (i.e. clothes, skin, floor, etc.) with the sterile surface of the glove.
- Using aseptic technique, unwrap and utilize sterile scoop to collect the sample.
- Place sample into a sterile Whirl-pak bag that has been properly labeled and seal by rolling top of the Whirl-pak bag tightly and sealing with yellow wire tabs.
- Place sub samples into a clean kraft paper bag or larger Whirl-pak bag and seal.

Figure 1



Source: B. Braun Medical Inc.

• **Forages**

○ **All Baled Hay**

Use a hay coring device, rather than hand sampling, whenever possible.

For sampling baled hay at least 20 cores (one core per bale) should be taken then combined to develop one composite sample per lot. Bales within a lot should be randomly sampled. Use a coring device that has an inside diameter = > 3/8". When sampling round bales drill horizontally to a depth of 12 to 24 inches into the curved side of the bale aiming towards the center of the bale. To sample rectangular bales center the coring device on the end of the bale then drill horizontally into the bale to a depth of 12 to 18 inches. If sampling by hand sample by pulling material from round bales. Take equal amounts from surface & interior. Avoid stripping off leafy or tender materials. Obtain a large enough sample to ensure sample is representative of lot. Close container immediately.

○ **Loose Hay in Mows/Stacks**

If sampling by hand secure 10 individual grab samples from evenly spaced locations on the face being fed out. If a coring device can be used, it is the preferred method. In loose hay, use a probe at least 30" long with an inner diameter =>3/4". Drill at any angle from the side of the stack to the probe's full depth. When sampling in a hay mow, probe vertically and drill at the spot where the hay is compressed by the operator. Take samples from 20 random locations throughout the stack or mow.

Quick Reference Sampling Guide

SAMPLING DEVICE(S)	SAMPLING MEDIA	SAMPLING PROCEDURE *maintain integrity of lot*	SAMPLE SIZE
Single / Double Tube Trier	Bagged Feed: free flowing / coarse / textured / small to medium sized pellets	= > 11 bags - sample 10 bags (= 10 cores) 1 to 10 bags - sample all bags (= 10 cores) = < 4 bags - sample all bags (= > 5 cores)	Min - 18oz (500 grams) Preferred - 2.2 lbs. (1 kg)

SAMPLING DEVICE(S)	SAMPLING MEDIA	SAMPLING PROCEDURE *maintain integrity of lot*	SAMPLE SIZE
Flour / Slotted Trier	Bagged Feed: Powdered	= > 11 bags - sample 10 bags (= 10 cores) 1 to 10 bags - sample all bags (= 10 cores) = < 4 bags - sample all bags (= > 5 cores)	Min - 18oz (500 grams) Preferred – 2.2 lbs. (1 kg)
Hand Grab	Bagged Feed: Cubes / Wafers / Large pellets	= > 11 bags - sample 10 bags (= 10 cores) 1 to 10 bags - sample all bags (= 10 cores) = < 4 bags - sample all bags (= > 5 cores) Take equal amounts from each bag	Min - 18oz (500 grams) Preferred – 2.2 lbs. (1 kg)
Single or Double Tube Trier / Closed Compartment / Grain Probe/ Stream Sampler / Hand Grab	Bulk Feed: free flowing / coarse / textured / small to medium sized pellets / Cubes / Wafers / Large pellets	10 Cores/Probes Or Cut stream 10 x's @ = intervals over the duration of loading / unloading Or 10 grabs	Min - 18oz (500 grams) Preferred – 2.2 lbs. (1 kg)
Specialty Probes Or Hand Grab	High Fiber Products: Cottonseed hulls / Almond hulls / Gin trash	4 probes per car or 1 probe per section of car Or 10 grabs, @ = intervals during load /unloading	10 lbs.
Scoop	Wet Brewers / Distillers Grain	Collect @ = intervals a composite sample totaling 25-30 lbs. then mix and quarter until sample is reduced to desired sample size	3-4 lbs.
N/A	Packaged Feed in containers = < 10 lbs.	Purchase sample	1 unopened package
N/A	Canned Pet foods	Purchase sample	Minimum of 3 cans
N/A	Capsules / Tablets / Other single dose products	Purchase sample	3-6 sealed packages containing the least number of product
Liquid Bomb / Liquid Zone / Texas Tube / Liquid Tube / Delivery Lines-Valves / Site Gauge	Liquid Products	Collect sample per device directions Or Properly flush delivery line(s) and/or valve then collect sample Or If equipped, remove site gauge, flush then collect sample	**Min - 17oz. (500 ml) For sampling <i>Drums</i> and <i>Barrels</i> refer to page 23 for the number of containers to sample
Approved container for hot liquids Danger: Possible Burn Hazard	Fats & Oils	Sample from fat blender equipment Or Valve/nozzle on Mixer Or Valve on delivery vehicle	32oz. (946 ml)
Stream Cutter (lined bag or container) / Hand Grab/ Hammer & Chisel / Drill & 1" bit	Protein Tub Protein Tub	Cut stream or hand grab from contents from at least 10 tubs @ = intervals during manufacture Or Chisel center or edge of 10 separate tubs Or Drill 1" core at a ~3" depth from center of 10 separate tubs	Min - 2 lb. (0.9 kg)

SAMPLING DEVICE(S)	SAMPLING MEDIA	SAMPLING PROCEDURE *maintain integrity of lot*	SAMPLE SIZE
Hand Grab / Drill & 1” bit	Soft Mineral and Protein Blocks	10 grab samples of the meal prior to blocking Or Drill 1” core at a ~3” depth from center of 10 separate blocks	Min - 2 lb. (0.9 kg)
Hand Grab - Stream Cutter / Hammer & chisel	Hard Mineral and Salt Blocks	<i>At the manufacturer</i> - 10 grabs of mix prior to blocking; for molasses products use a stream- cutting method prior to blocking Or <i>At the Dealer</i> - Break corners of 10 randomly selected blocks	Min - 2 lb. (0.9 kg)
Hand Grab Danger: Do not enter Tower Silos (possible oxygen deficiencies)	Haylage and Silage	<i>Tower Silo</i> – 10 grabs @ = intervals while unloading <i>Bunker silo</i> – 10 grabs off fresh face @ = intervals across material being fed (Only enter a bunker silo if the area is secure and the sample can be taken safely.	5 lbs. (2.3 kg) (tightly packed and keep cool)
Hay Coring device Hand Grab	Forages	<i>Baled Hay</i> – hay corer is preferred to hand grab <i>Loose Hay</i> – sample from fresh face at equal intervals across material being fed	<i>baled hay</i> -20 randomly selected cores <i>loose hay</i> -20 cores or 10 grab samples

Notes:

*For bagged feed, a sample taken from 4 or fewer bags of may be declared an official sample, if the guarantor agrees.

**Some liquid products require agitation prior to sampling – review label and/or check with facility management or guarantor.

CHAPTER 4 LABELING

LABELING

One major emphasis of all feed laws and regulatory programs centers on a properly manufactured product being distributed to the ultimate consumer with proper instructions detailing nutritional claims, ingredients being used, cautions, warnings and directions for use.

The vehicle to accomplish the task is the label. If a feed is properly formulated for swine yet fed to cattle, disastrous results may be expected. Similarly, if a feed contains medications for use in a swine starter or grower, then you would not want to use it to finish the animals for market because of residues unless you are certain it is acceptable to do so.

The importance of adequate labeling cannot be overemphasized. The label is the communication device connecting the producer of the feed to the consumer.

With labeling being an important part of the total feed distribution process, AAFCO has spent several years evaluating and studying labeling. Years of hard work between AAFCO, academia, and the feed industry produced a new expanded labeling concept. New labeling requirements were established by AAFCO and adopted by the general membership. States began to adopt these model labeling regulations after 1995.

In using this manual, you need to fully understand what labeling requirements are in force under your law and administrative program. AAFCO's new labeling requirements may or may not be adopted or enforced in your state. However, since this manual is devoted to all feed inspectors, it is important that current and future versions of labeling and label reviews be presented.

In using this section, current labeling requirements have been broken out and explained. For example, the regulations require that there shall be a drug purpose statement on all medicated feed labels. Yet, the regulations do not necessarily state why that statement is important.

Explanations have been added to better foster an understanding of the various parts of the label.

The second section deals with AAFCO's model labeling concepts. These guidelines are placed in this guide for use, not as enforcement tools, but as education material for field staff. As states adopt these guidelines into their laws, rules, and regulations, the first section on labeling will be replaced and combined with the new protocol.

Make sure you reference your State law and current regulations

The Food Safety and Modernization Act requires facilities to ensure all animal food, which includes ingredients, and raw materials, to be accurately identified. Animal food ready for distribution must contain, when applicable, information and instructions for safely using the animal food for the intended animal species.

While using this section, make sure you reference your State law and current regulations. It is also important to realize that the label may include more than just the printed placard attached to the bag. It may include information printed on the bag, stenciled on the bag, or otherwise supplied to the customer. Information otherwise supplied to the customer could include brochures and other handouts, internet media and TV commercials. Labeling is not solely defined by what is on the bag.

UNDERSTANDING A FEED'S LABEL: COMMERCIAL FEED LABELING (EXCEPT CUSTOMER-FORMULA FEED)

The feed label serves as a communication system between the manufacturer and the purchaser of the feed. Effective, meaningful labeling is essential to inform the purchaser of the purpose of the feed, its composition and how to use it. The following is an explanation of the eight principle components of a label.

Product Name

Each feed has its own unique name to identify it. The name may also indicate the purpose of the product. For example: Pig Starter #302. If the feed is medicated, then the word "**medicated**" shall appear directly following and below the product name in type size, no smaller than one-half the type size of the product name.

Drug Purpose Statement (Medicated Feeds Only)

If a medication is included in a feed, the drug purpose statement will follow the product name. More than 50 different medications are approved for mixing in feed at several hundred levels and combinations. Each drug use has been researched and proven safe and effective for its claimed purpose. *All unapproved drug use is prohibited.*

Livestock producers need to know what drug purpose is desired, such as prevention or treatment of a specific disease, then select the drug and level that is approved for that purpose.

Active Drug Statement (Medicated Feeds Only)

Labeling for a medicated feed shall also include the active drug statement, which identifies the drug(s) present in the feed and the level. Normally, the amount is stated in grams per ton or percentage for complete and mineral feeds and grams per pound or percentage for drug premixes.

Some feeds may have drug approvals based on the animal receiving a specific drug intake per head per day. In these instances, the drug may be guaranteed in milligrams per pound of feed. This information and the feeding directions enable the livestock producer to determine the correct level of feed intake to deliver a safe and effective drug dosage.

Guaranteed Analysis

The law requires every feed to have a guaranteed analysis to advise the user of the composition of the feed and to support claims. Guarantees must be determinable by recognized laboratory methods. Most complete and mineral feeds are labeled with the minimum level of crude protein and crude fat and the maximum level of crude fiber.

- **Crude Protein**
Crude protein is an expression of the minimum percentage of nitrogen in a feed, multiplied by a factor of 6.25. Crude protein includes nitrogen from both natural protein and any added non-protein nitrogen. Protein is a high cost component and is essential for maintenance, growth and other animal functions such as milk and wool production. Selection of the proper protein level by the livestock producer depends upon many factors including species of livestock, the life stage and production level. Producers must know their animals' protein and other nutritional requirements in order to properly evaluate feeds. This information is available from several sources such as extension publications, National Research Council (NRC) recommendations and popular and scientific publications. Some species can be intolerant to overages or shortages of protein in their feed.
- **Non-Protein Nitrogen (NPN) Equivalent Protein**
Ruminant feeds that contain urea or other NPN sources must guarantee the maximum units of equivalent crude protein from non-protein nitrogen. This statement will immediately follow the crude protein guarantee. The NPN guarantee reflects the total protein units which are derived from non-protein nitrogen. A 16% dairy feed that contains 4 units of equivalent crude protein from the non-protein nitrogen also contains 12 units of natural protein. In this example, twenty-five percent of the total protein is from NPN and would include the following statement in the guaranteed analysis: "This includes not more than 4% equivalent crude protein from non-protein nitrogen".
- **Crude Fat**
One indicator of the energy content of feeds and is expressed as a minimum percentage on the label. Fat contains 2.25 times more energy than carbohydrates per weight. A 16% protein mix of corn and soybean meal contains approximately 3% crude fat. Many feeds now contain ingredients which add considerable fat such as distiller's grains, meat & bone meal, whole cottonseed and extruded soybeans or have added vegetable or animal fat. Fat guarantees above 3% generally indicate these ingredients are included in the feed. Review the ingredient listing to determine fat sources.
- **Crude Fiber**
Also indicates the energy content. The general rule is the higher the fiber guarantee, the lower the energy content and feeding value. That is why crude fiber is a maximum guarantee. Like all rules, there are exceptions. Certain high fiber ingredients, such as soybean hulls, are a good energy source for ruminants. Evaluate the crude fiber guarantee in conjunction with the crude fat guarantee and list of ingredients. For reference, the following are typical crude fiber contents of several commonly used ingredients:
- **Mineral & Vitamin Guarantees**
Feeds which contain more than 6.5 % total mineral elements must guarantee the minimum and maximum calcium, minimum phosphorus and minimum and maximum salt levels, when added.
- **Voluntary Guarantees**
Voluntary guarantees may be made if a recognized assay method exists. Feed manufacturers may provide additional nutrient information on voluntary guarantees to inform the purchaser of the nutritional value of their feeds. This information can assist the producer in obtaining the best use and production from the feed. The voluntary nutritional information provided varies extensively among manufacturers and also according to the type of product.

Ingredient Statement

Federal and State laws require the label to list each ingredient used to manufacture the feed. Each ingredient is listed in predominance by weight by its official name as defined by the Association of American Feed Control Officials or its common or usual name if no official name exists.

Manufacturers may choose to identify certain ingredients used with a collective term. Most ingredients fall into one of the seven collective term classifications based on similarity of ingredient origin or function; Animal Protein Products, Forage Products, Grain Products, Plant Protein Products, Processed Grain By-Products, Roughage Products and Molasses Products.

Mineral and vitamin ingredients must be listed individually since no collective term exists.

Ingredients in the same collective term are not nutritionally equivalent and are quite variable.

The principle of collective terms is to allow feed manufacturers to make ingredient substitutions depending on cost and availability without requiring a label change, while still producing a feed with the same nutrient composition.

Directions for Use

The directions for use are to inform the purchaser of how the manufacturer intends for the feed to be used. The use of certain feeds is commonly understood and no directions are required. The product name may adequately acquaint the user with the purpose of the feed, eliminating the necessity for usage directions. Feeds that require mixing, special feeding or that are formulated for a particular production stage or dietary use require directions to inform the user of the manufacturer's recommendation for use. This may require the manufacturer to state explicit instructions for mixing and feeding. Instructions may indicate the amounts of all other ingredients to mix in a ration, the type of forage to be fed with the feed, the weight range of the animal or other information necessary to convey to the user the intended purpose and use of the feed. Usage directions communicate to the user the manufacturer's recommended use for the feed.

Medicated feeds containing drugs or antibiotics must be labeled with the appropriate directions to provide only for drug usage approved as safe and effective by the Food & Drug Administration. When reviewing a medicated feed's directions for use, close attention should be paid to the level of added selenium if included. The recommended feeding rate of a complete feed containing a medication should allow for the amount of added selenium to continue to meet the regulation 21 CFR 573.920.

Warning & Caution Statements

These statements are for customers to safely and effectively use the feed under normal conditions. They primarily advise of pre-slaughter withdrawal times, specific limitations and usage conditions for the medications, feeds containing more than 8.75 equivalent crude protein units from non-protein nitrogen or other special purpose additives which require special feeding or use.

Manufacturer Identification

Identifies the name and principle mailing address of the manufacturer or the person responsible for distributing the commercial feed.

Quantity Statement

Tells the purchaser the net weight (mass), net volume (liquid or dry), count, or other form of measurement of the feed in the package, bag, can or bulk shipment. The net quantity statement must be expressed in both avoirdupois and metric units.

UNDERSTANDING A FEED'S LABEL: CUSTOMER-FORMULA FEED

A customer-formula feed is a mixture of two or more ingredients which is manufactured according to the specific instructions of the final purchaser.

Customer-formula feeds may only be sold to the final purchaser who provided the formula to the manufacturer of the feed.

A customer-formula feed has specific labeling requirements that obligate the manufacturer to state on the invoice, delivery ticket, or other document that accompanies the feed the following information:

<p>The name and address of the manufacturer.</p> <p>The name and address of the purchaser.</p> <p>The date of sale or delivery.</p> <p>The customer-formula feed name and brand name if any. Any guarantees requested by the customer.</p> <p>The product name and net quantity of each commercial feed and each other ingredient used in the mixture.</p> <p>The direction for use and precautionary statements.</p> <p><u>If a product containing a drug is used:</u></p> <p>The purpose of the medication (claim statement).</p> <p>The established name of each active drug statement and the level of each drug used in the final mixture.</p>
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AAFCO COMMERCIAL FEED LABELING REQUIREMENTS

AAFCO adopted revised labeling requirements for most livestock feeds in August 1993. Some states have adopted these regulations while others have not. Know what your state commercial feed law enforces regarding labeling requirements. Also, note that under these rules, a purpose statement is now required following the product name or the active ingredient statement for medicated feed.

REGULATION 2. LABEL FORMAT

Commercial feed, other than customer-formula feed, must be labeled with the information on the principal display panel of the product and in the following format:

- **Product Name and Brand Name, if any**
If a drug is used the word “medicated” must appear directly after or following the name.
- **Purpose statement**
The statement of purpose shall contain the specific species of animal class(es) for which the feed is intended. The purpose statement may be excluded from the label if the product name includes a description of the species and animal class(es) for which the product is manufactured.
- **Guaranteed analysis**
Crude Protein, Equivalent Crude Protein from NPN, Amino Acids, Crude Fat, Crude Fiber, Acid Detergent Fiber, Calcium, Phosphorous, Salt, and Sodium shall be the sequence of nutritional guarantees for all species and class of animal when such guarantee is stated. The regulation also requires additional guarantees based on species and class of animal. Both AAFCO members and industry liaisons worked with nutritionists to determine what minimal guarantees would be necessary.
- **Ingredient Statement**
The label is required to list each ingredient used to manufacture the feed. Each ingredient is listed by its official name as defined by the Association of American Feed Control Officials or its common or usual name if no official name exists. Manufacturers may choose to identify certain ingredients used with a collective term.
- **Directions for use and precautionary statements**
The consumer must be able to know how to safely use the feed and be aware of any warnings or cautions necessary with the feed. A reference to their location must be included if the detailed feeding directions and precautionary statements appear elsewhere on the label.
- **Name and principal mailing address of**
the manufacturer or person responsible for distributing the feed.
- **Quantity Statement**
Net quantity shall be declared in terms of weight, liquid measure or count. Please see Regulation 3(8) which details the appropriate units in which the weight should be declared.

CUSTOMER FORMULA FEED LABEL-REGULATION 2(D)

With some medications, the directions and warnings are too complicated to simply write them on the invoice or delivery ticket. Therefore, many manufacturers will use preprinted supplemental labels for medications to attach to the invoice or delivery ticket serving as the label for the customer formula feed. It is critical that these supplemental labels be thoroughly completed. An example follows:

<p>CUSTOMER-FORMULA MEDICATED</p> <p>Customer _____ Inv. No. _____</p> <p>Medication (shown below) has been added to this feed at customer request</p> <p>ACTIVE DRUG INGREDIENT</p> <p>MONENSIN (Rumensin) as Monensin Sodium _____ g/ton</p>		
TYPE OF ANIMAL	INDICATION FOR USE	USE LEVEL
Cattle (Confinement for slaughter)	Improved feed efficiency	(Complete Feed) 5-40 g/ton Feed continuously in complete feed at a rate of 50 to 480 mg of monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 g/ton (360 mg monensin per head per day).
Growing Cattle on pasture or in dry lot (stocker and feeder, and dairy and beef replacement heifers)	For increased rate of weight gain	Feed at the rate of not less than 50 nor more than 200 mg. per head per day in not less than 1 lb. of feed or after the fifth day, feed at the rate of 400 mg per head per day every other day in not less than 2 lb. of feed. During the first 5 days of feeding cattle should receive no more than 100 mg per day in not less than 1 lb. of feed.
DIRECTIONS FOR USE		
Feed this mixture at the rate of _____ lb. per head daily to provide _____ mg of monensin per head daily.		
WARNING: A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.		
CAUTION: Do not allow horses or other equines access to feed containing monensin. Ingestion of monensin by horses has been fatal. Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions. Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result. If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin over dosing.		

Some manufacturers will also “custom medicate” a branded feed. As such, they will attach a copy of the required medicated labeling information in addition to the existing branded feed labeling. Some states consider this a new customer-formula feed while others may still view it as a branded feed. Be sure of your state’s guidelines on how to handle these types of feeds.

<p>CUSTOMER-FORMULA MEDICATED</p> <p>Customer _____ Inv. No. _____</p> <p>Medication (shown below) has been added to this feed at customer request</p> <p>ACTIVE DRUG INGREDIENT</p> <p>LASALOCID (Bovatec) _____ g/ton</p>		
TYPE OF ANIMAL	INDICATION FOR USE	USE LEVEL
Beef Cattle (Confinement for slaughter)	Improved feed efficiency	(Complete Feed) 1030 g/ton Feed continuously in complete feed to provide not less than 100 mg nor more than 360 mg/head/day.
Beef Cattle (Confinement for slaughter)	Improved feed efficiency and increased rate of weight gain	(Complete Feed) 2530 g/ton Feed continuously in complete feed to provide not less than 250 mg nor more than 360 mg/head/day.
Pasture Cattle (slaughter, stocker and feeder cattle and dairy and beef replacement heifers)	For increased rate of weight gain	Feed continuously at a rate of not less than 60 nor more than 300 mg. per head per day. Hand fed: The drug must be contained in at least 1 lb. of feed. Free Choice: Formulation must be manufactured under a feed mill license utilizing an FDA- approved formula, unless manufactured according to published formula.
Cattle (up to 800 lb.)	For control of coccidiosis caused by Eimeria bovis and Eimeria zuernii	Hand feed continuously to provide 1 mg per 2.2 lbs. of body weight per day to cattle weighing up to 800 lbs. with a maximum of 360 mg. of lasalocid per head per day.
DIRECTIONS FOR USE		
Feed this mixture at the rate of _____ lb. per head daily to provide _____ mg of monensin per head daily.		
<p>WARNING: A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.</p> <p>CAUTION: The safety of Lasalocid for use in unapproved species has not been established. Do not allow horses or other equines access to feeds containing Lasalocid as ingestion may be fatal. For Type B feeds: Mix thoroughly with grain and/or roughage prior to feeding. Feeding undiluted or mixing errors may result in an excess Lasalocid concentration that could be fatal to cattle.</p>		

Some feeds may be treated with a pesticide. Pesticides are not medications. Medications are used to treat and destroy diseases, and are regulated on the federal level by the Food and Drug Administration while pesticides are regulated by the Environmental Protection Agency. However, the feed still needs to be properly labeled to provide the appropriate directions for use and warnings to the customer.

Example of a customer-formula feed mixed with a pesticide.

CUSTOMER-FORMULA RABON/LARVADEX		
Customer _____ Inv.No. _____		
Pesticide (shown below) has been added to this feed at customer request.		
ACTIVE INGREDIENT NAME Rabon/Larvadex		
TYPE OF ANIMAL	INDICATION FOR USE	USE LEVEL & DIRECTIONS FOR USE
Cattle (beef & dairy) <input type="checkbox"/>	Control of fecal flies in manure of treated cattle. Prevents development of face flies, horn flies, house flies, & stable flies in the manure of treated cattle.	70 milligrams per 100 lbs. body weight per day (0.07 g/cwt/day). Feed at the rate of _____ pounds per 100 lbs. body weight.
Horses <input type="checkbox"/>	Control of fecal flies in manure of treated horses. Prevents development of house flies and stable flies in the manure of treated horses.	70 milligrams per 100 lb. body weight per day (0.07 g/cwt/day). Feed at the rate of _____ pounds per 100 lbs. body weight.
Swine <input type="checkbox"/>	Control of fecal flies in manure of treated swine. Prevents development of house flies in the manure of treated swine.	50 milligrams per 100 lb. body weight per day (0.05 g/cwt/day). Feed at the rate of _____ pounds per 100 lbs. body weight.
Chickens <input type="checkbox"/>	For housefly, soldier fly and lesser housefly control in and around (1) caged or slatted flooring layer chicken operations and (2) breeder chicken operations.	1 lb./ton (5.0 ppm)
(Provide complete labeling as contained on the Rabon or Larvadex label. This includes E.P.A. Registration Number, E.P.A. Establishment Number, use directions, disposal, and any precautionary statements on the label, i.e. withdrawal).		

REGULATION 3. LABEL INFORMATION

Brand and Product Name

The brand or product name must be appropriate for the intended use of the feed and must not be misleading. If the name indicates the feed is made for a specific use, the character of the feed must conform therewith. A commercial feed for a particular animal class must be suitable for that purpose.

Commercial, registered brand or trade names are not permitted in guarantees or ingredient listings and only in the product name of feeds produced by or for the firm holding the rights to such a name.

The name of a commercial feed shall not be derived from one or more ingredients of a mixture to the exclusion of other ingredients and shall not be one representing any components of a mixture unless all components are included in the name: Provided, that if any ingredient or combination of ingredients is intended to impart a distinctive characteristic to the product which is of significance to the purchaser, the name of that ingredient or combination of ingredients may be used as part of the brand name or product name if the ingredients or combination of ingredients is quantitatively guaranteed in the guaranteed analysis, and the brand or product name is not otherwise false or misleading.

The word "protein" shall not be permitted in the product name of a feed that contains added non-protein nitrogen.

When the name carries a percentage value, it shall be understood to signify protein and/or equivalent protein only, even though it may not explicitly modify the percentage of the word "protein": Provided that other percentage values may be permitted if they are followed by the proper description and conform to good labeling practice. Digital numbers shall not be used in such a manner as to be misleading or confusing to the customer.

Single ingredient feeds shall have a product name in accordance with the designated definition of feed ingredients as recognized by the Association of American Feed Control Officials unless certain states designate otherwise.

The word “vitamin”, or a contraction thereof, or any word suggesting vitamin can be used only in the name of a feed which is represented to be a vitamin supplement, and which is labeled with the minimum content of each vitamin declared.

The term “mineralized” shall not be used in the name of a feed except for “TRACE MINERALIZED SALT”. When so used, the product must contain significant amounts of trace minerals which are recognized as essential for animal nutrition.

The term “meat” and “meat by-products” shall be qualified to designate the animal from which the meat and meat by-products is derived unless the meat and meat by-products are made from cattle, swine, sheep and goats.

If the commercial feed consists of raw milk, the words, “Raw (blank) Milk” shall appear conspicuously on the principal display panel. (Blank is to be completed by using the species of animal from which the raw milk is collected.)

If a drug is used, the word “medicated” shall appear directly following and below the product name in type size, no smaller than one-half the type size of the product name.

Purpose Statement as required in Regulation 3(a) (3). The purpose of medication (claim statement).

An active ingredient statement listing the active drug ingredients by their established name and the amounts.

Purpose Statement

The statement of purpose shall contain the specific species and animal class(es) for which the feed is intended.

The manufacturer shall have flexibility in describing in more specific and common language the defined animal class, species and purpose while being consistent with the category of animal class defined in Regulation 3(a)(4) which may include, but is not limited to including the weight range(s), sex, or ages of the animal(s) for which the feed is manufactured.

The purpose statement may be excluded from the label if the product name includes a description of the species and animal class(es) for which the product is intended.

The purpose statement of a premix for the manufacture of feed may exclude the animal class and species and state “For Further Manufacture of Feed” if the nutrients contained in the premix are guaranteed and sufficient for formulation into various animal species feeds and premix specifications are provided by the end user of the premix.

The purpose statement of a single purpose ingredient blend, such as a blend of animal protein products, milk products, fat products, roughage products or molasses products may exclude the animal class and species and state “For Further Manufacture of Feed” if the label guarantees of the nutrients contained in the single purpose nutrient blend are sufficient to provide for formulation into various animal species feeds.

The purpose statement of a product shall include a statement of enzyme functionality if enzymatic activity is represented in any manner.

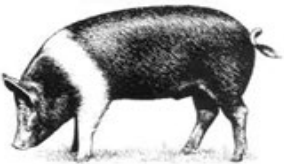
Guarantees

Crude Protein, Non-Protein Nitrogen, Amino Acids, Crude Fat, Crude Fiber, Acid Detergent Fiber, Calcium, Phosphorus, Salt and Sodium shall be the sequence of nutritional guarantees when such guarantee is required. Other required and voluntary guarantees should follow in a general format such that the units of measure used to express guarantees (percentage, parts per million, International Units, etc.) are listed in a sequence which provides a consistent grouping of the units of measure.

• Swine formula feeds

- a. Animal Classes
 - (1) Pre-Starter - 2 to 11 pounds
 - (2) Starter - 11 to 44 pounds
 - (3) Grower - 44 to 110 pounds
 - (4) Finisher - 110 to 242 pounds (market)
 - (5) Gilts, Sows and Adult Boars
 - (6) Lactating Gilts and Sows
- b. Guaranteed Analysis for Swine complete Feeds and Supplements (all animal classes)
 - (1) Minimum percentage of Crude Protein
 - (2) Minimum percentage of Lysine
 - (3) Minimum percentage of Crude Fat
 - (4) Maximum percentage of Crude Fiber
 - (5) Minimum and maximum percentage of Calcium
 - (6) Minimum percentage of Phosphorus

- (7) Minimum and maximum percentage of Salt (if added)
- (8) Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee
- (9) Minimum Selenium in parts per million (ppm)
- (10) Minimum Zinc in parts per million (ppm)

Blue Bird Feed Mill Sow & Pig Feed	
 <p style="margin-top: 10px;">Complete feed for lactating sows and starter feed for piglets.</p>	
Guaranteed Analysis	
Crude Protein, minimum	20.0%
Lysine, minimum	1.2%
Crude Fat, minimum	4.0%
Crude Fiber, maximum	4.0%
Calcium, minimum	0.8%
Calcium, maximum	1.3%
Phosphorus, minimum	0.65%
Salt, minimum	0.35%
Salt, maximum	0.85%
Selenium, minimum	0.1 ppm
Zinc, minimum	150 ppm
Ingredient Statement	
<p>Grain Products, Plant Protein Products, Processed Grain By-Products, Dried Whey, Calcium Lignin Sulfonate, Animal Fat, Vitamin A Supplement, D-Activated Animal Sterol (source of Vitamin D₃), L-Lysine, Riboflavin Supplement, Choline Chloride, Biotin, Thiamine Mononitrate, Pyridoxine Hydrochloride, Vitamin E Supplement, Folic Acid, Ethoxyquin (a preservative), Ground Limestone, Dicalcium Phosphate, Salt, Copper Sulfate, Manganous Oxide, Zinc Oxide, Ferrous Sulfate, Cobalt Carbonate, Calcium Iodate, Sodium Selenite.</p>	
FEEDING DIRECTIONS	
Feed as the complete ration to sows and piglets from birth to wean.	
Manufactured by	
Blue Bird Feed Mill, Inc.	
1000 Feed Mill Road	
Anytown, Any State 12345	
NET WT 50 LB (22.67 kg)	

BLUE BIRD SUPER PIG FEED

FOR STARTER PIGS WEIGHING 11 TO 44 POUNDS

Guaranteed Analysis

Crude Protein (Min)	20%
Lysine (Min)	1.2%
Crude Fat (Min)	4%
Crude Fiber (Max)	4%
Calcium (Min)	0.8%
Calcium (Max)	1.3%
Phosphorus (Min)	0.65%
Salt (Min)	0.35%
Salt (Max)	0.5%
Selenium (Min)	0.3 ppm
Zinc (Min)	150 ppm

Ingredient Statement

Grain Products, Plant Protein Products, Processed Grain By-Products, Dried Whey, Calcium Lignin Sulfonate, Animal Fat, Vitamin A Supplement, D-Activated Animal Sterol (source of Vitamin D₃), L-Lysine, Riboflavin Supplement, Choline Chloride, Biotin, Thiamine Mononitrate, Pyridoxine Hydrochloride, Vitamin E Supplement, Menadione Sodium Bisulfite Complex (source of Vitamin K activity), Folic Acid, Ethoxyquin (a preservative), Ground Limestone, Dicalcium Phosphate, Salt, Copper Sulfate, Manganous Oxide, Zinc Oxide, Iron Sulfate, Cobalt Carbonate, Calcium Iodate, Sodium Selenite.

FEEDING DIRECTIONS:
Feed as the complete ration to starter pigs weighing 11 to 44 pounds.

Manufactured by
Blue Bird Feed Mill
Anytown, Texas 77777
50 lb (22.6 kg)

- **Poultry Feeds (Broilers, Layers and Turkeys)**
 - a. Animal Classes
 - (1) Layer - Chickens that are grown to produce eggs for food, i.e. table eggs
 - (a) Starting/Growing - From day of hatch to approximately 10 weeks of age.
 - (b) Finisher - From approximately 10 weeks of age to time first egg is produced (Approximately 20 weeks of age).
 - (c) Laying - From time first egg is laid throughout the time of egg production.
 - (d) Breeders - Chickens that produce fertile eggs for hatch replacement layers to produce eggs for food, table eggs, from time first egg is laid throughout their productive cycle.
 - (2) Broilers - Chickens that are grown for human food.
 - (a) Starting/Growing - From day of hatch to approximately 5 weeks of age.
 - (b) Finisher - From approximately 5 weeks of age to market, (42 - 52 days of age).
 - (c) Breeders - Hybrid strains of chickens whose offspring are grown for human food, (broilers), any age and either sex.
 - (3) Broiler Breeders - Chickens whose offspring are grown for human food (broilers).
 - (a) Starting/Growing - From day of hatch until approximately 10 weeks of age.
 - (b) Finishing - From approximately 10 weeks of age to time first egg is produced, approximately 20 weeks of age.
 - (c) Laying - Fertile egg producing chickens (broilers/roasters) from day of first egg throughout the time fertile eggs are produced.
 - (4) Turkeys
 - (a) Starting/Growing - Turkeys that are grown for human food from day of hatch to approximately 13 weeks of age (females) and 16 weeks of age (male).
 - (b) Finisher - Turkeys that are grown for human food, females from approximately 13 weeks of age to approximately 17 weeks of age; males from 16 weeks of age to 20 weeks of age, (or desired market weight).
 - (c) Laying - female turkeys that are producing eggs; from time first egg is produced, throughout the time they are producing eggs.

- (d) Breeder - Turkeys that are grown to produce fertile eggs, from day of hatch to time first egg is produced (approximately 30 weeks of age), both sexes.
- b. Guaranteed analysis for Poultry Complete Feeds and Supplements (all animal classes)
 - (1) Minimum percentage of Crude Protein
 - (2) Minimum percentage of Lysine
 - (3) Minimum percentage of Methionine
 - (4) Minimum percentage of Crude Fat
 - (5) Maximum percentage of Crude Fiber
 - (6) Minimum and maximum percentage of Calcium
 - (7) Minimum percentage of Phosphorus
 - (8) Minimum and maximum percentage of Salt (if added)
 - (9) Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee

BLUE BIRD LAYER FEED

COMPLETE FEED FOR LAYING CHICKENS

Guaranteed Analysis

Crude Protein (min)	15.0 %
Lysine (min)	0.65 %
Methionine (min)	0.35 %
Crude Fat (min)	3.0 %
Crude Fiber (max)	3.5 %
Calcium (min)	3.4 %
Calcium (max)	4.4 %
Phosphorus (min)	0.6 %
Salt (min)	0.35 %
Salt (max)	0.50 %

Ingredient Statement

Grain Products, Plant Protein Products, Processed Grain By-Products, Animal Protein Products, Vitamin A Supplement, Vitamin D3 Supplement, Vitamin E Supplement, Riboflavin Supplement, Niacin Supplement, Calcium Pantothenate, Choline Chloride, Folic Acid, Menadione Sodium Bisulfite Complex (Source of Vitamin K Activity), Methionine Supplement, Potassium Sulfate, Calcium Carbonate, Salt, Manganous Oxide, Ferrous Sulfate, Copper Oxide, Zinc Oxide, Ethylenediamine Dihydriodide, Sodium Selenite

FEEDING DIRECTIONS:
 This is a complete and balanced ration. Feed Blue Bird Layer Feed from time first egg is laid throughout the time of egg production. Always provide plenty of fresh water.

Guaranteed By:
 BlueBird Feed Mill
 Anytown, Texas 77777

50 lb (22.6 kg)

BLUE BIRD SCRATCH FEED	
A GRAIN MIXTURE FOR POULTRY	
Crude Protein (min)	9.0%
Crude Fat (min)	3.0%
Crude Fiber (max)	5.0%
Ingredient Statement	
Corn, Wheat, Grain Sorghum	
FEEDING DIRECTIONS:	
Feed free choice as a source of grain to chickens. This feed is not a complete feed and additional supplementation is required.	
Guaranteed By: Blue Bird Feed Mill Anytown, Texas 77777	
50 lb (22.6 kg)	

- **Beef Cattle Formula Feeds**
 - a. Animal Classes
 - (1) Calves (birth to weaning)
 - (2) Cattle on Pasture (may be specific as to production stage; e.g. stocker, feeder, replacement heifers, brood cows, bulls, etc.)
 - (3) Feedlot Cattle
 - b. Guaranteed analysis for Beef Complete Feeds and Supplements (all animal classes)
 - (1) Minimum percentage of Crude Protein
 - (2) Maximum percentage of equivalent crude protein from Non-Protein Nitrogen (NPN) when added
 - (3) Minimum percentage of Crude Fat
 - (4) Maximum percentage of Crude Fiber
 - (5) Minimum and maximum percentage of Calcium
 - (6) Minimum percentage of Phosphorus
 - (7) Minimum and maximum percentage of Salt (if added)
 - (8) Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee.
 - (9) Minimum percentage of Potassium
 - (10) Minimum Vitamin A, other than precursors of Vitamin A, in International Units per pound (if added)
 - c. Beef Mineral Feeds (if added)
 - (1) Minimum and maximum percentage of Calcium
 - (2) Minimum percentage of Phosphorus
 - (3) Minimum and maximum percentage of Salt
 - (4) Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee
 - (5) Minimum percentage of Magnesium
 - (6) Minimum percentage of Potassium
 - (7) Minimum Copper in parts per million (ppm)
 - (8) Minimum Selenium in parts per million (ppm)
 - (9) Minimum Zinc in parts per million (ppm)
 - (10) Minimum Vitamin A, other than precursors of Vitamin A, in International Units per pound

BLUEBIRD BEEF MINERAL
FOR BEEF CATTLE ON PASTURE

Guaranteed Analysis

Calcium (Min)	11.0%
Calcium (Max)	13.0%
Phosphorus (Min)	6.0%
Salt (Min)	20.0%
Salt (Max)	22.0%
Magnesium (Min)	1.0%
Potassium (Min)	2.0%
Copper (Min)	460 ppm
Selenium (Min)	9 ppm
Zinc (Min)	2300 ppm
Vitamin A (Min)	100,000 IU/Lb

Ingredient Statement

Dicalcium Phosphate, Monocalcium Phosphate, Salt, Calcium Carbonate, Magnesium Mica, Distillers Dried Grains with Solubles, Cane Molasses, Manganous Oxide, Ferrous Sulfate, Copper Oxide, Magnesium Oxide, Zinc Oxide, Ethylenediamine Dihydriodide, Cobalt Carbonate, Iron Oxide, Sodium Selenite, Animal Fat, Vitamin A supplement, Vitamin D3 Supplement, Vitamin E Supplement, Copper Sulfate, Manganese Sulfate, Perolatium, Mineral Oil.

Feeding Directions:
This mineral should be fed in dry, wind-free, rain-protected feeders. Place near a water source where animals gather. Provide fresh, clean water at all times. Also, provide salt free-choice at all times.

Feed to beef cattle on pasture at the rate of 4 oz/hd/day.

Manufactured by
BlueBird Feed Mill
Anytown, Texas 77777

50 lb (22.6 kg)

• **Dairy Formula Feeds**

- a. Animal Classes
 - (1) Veal Milk Replacer
 - (2) Herd Milk Replacer
 - (3) Starter
 - (4) Non-Lactating Dairy Cattle: replacement Dairy Heifers, Dairy Bulls
 - (5) Lactating Dairy Cattle
 - (6) Dry Dairy Cows
- b. Guaranteed Analysis for Veal and Herd Replacement Milk Replacer
 - (1) Minimum percentage of Crude Protein
 - (2) Minimum percentage of Crude Fat
 - (3) Maximum percentage of Crude Fiber
 - (4) Minimum and maximum percentage of Calcium
 - (5) Minimum percentage of Phosphorus
 - (6) Minimum Vitamin A, other than precursors of Vitamin A, in International Units per pound (if added)
- c. Guaranteed Analysis for Dairy Cattle Complete Feeds and Supplements
 - (1) Minimum percentage of Crude Protein
 - (2) Maximum percentage of Non-Protein Nitrogen (NPN) when added
 - (3) Minimum percentage of Crude Fat
 - (4) Maximum percentage of Crude Fiber
 - (5) Maximum percentage of Acid Detergent Fiber (ADF)
 - (6) Minimum and maximum percentage of Calcium
 - (7) Minimum percentage of Phosphorus
 - (8) Minimum Selenium in parts per million (ppm)
 - (9) Minimum Vitamin A, other than precursors of Vitamin A, in International Units per pound (if added)
- d. Required Guaranteed Analysis for Dairy Mixing and Pasture Mineral with Vitamins (if added)
 - (1) Minimum and maximum percentage of Calcium
 - (2) Minimum percentage of Phosphorus
 - (3) Minimum and maximum percentage of Salt
 - (4) Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee

- (5) Minimum percentage of Magnesium
- (6) Minimum percentage of Potassium
- (7) Minimum Selenium in parts per million (ppm)
- (8) Minimum Vitamin A, other than the precursors of Vitamin A, in International Units per pound

BLUE BIRD DAIRY FEED

GRAIN RATION FOR LACTATING DAIRY CATTLE

Guaranteed Analysis

Crude Protein (min)	16.0%
(This includes not more than 3.5% equivalent crude protein from non-protein nitrogen)	
Crude Fat (min)	2.5%
Crude Fiber (max)	8.0%
Acid Detergent Fiber (ADF) (max)	14.0%
Calcium (min)	1.0%
Calcium (max)	1.5%
Phosphorus (min)	0.75%
Selenium (min)	0.2 ppm
Vitamin A (min)	7000 IU/lb

Ingredient Statement

Grain Products, Plant Protein Products, Processed Grain By-Products, Animal Protein Products, Forage Products, Molasses Products, Urea, Mineral Oil, Vitamin A Supplement, Vitamin D₃ Supplement, Vitamin E Supplement, Ethoxyquin (a preservative), Hemicellulose Extract, Methionine Supplement, Calcium Carbonate, Salt, Manganous Oxide, Magnesium Oxide, Ferrous Sulfate, Copper Oxide, Zinc Oxide, Potassium Chloride, Calcium Sulfate, Ethylenediamine Dihydroiodide, Potassium Sulfate, Sodium Selenite, Natural and Artificial Flavors.

FEEDING DIRECTIONS:

Feed 16 pounds per head per day to a 1200 pound cow. Feed 18.6 pounds per head per day to a 1400 pound cow. Do not exceed 50% of the total dry matter intake from this feed.

Guaranteed by:
 Blue Bird Feed Mill
 Anytown, Texas 77777
 50 lb (22.6 kg)

BLUE BIRD DAIRY MIXING MINERAL
MIXING MINERAL FOR LACTATING DAIRY CATTLE

Guaranteed Analysis

Calcium (min)	9.1%
Calcium (max)	10.9%
Phosphorus (min)	3.2%
Salt (min)	11.2%
Salt (max)	13.4%
Sodium (min)	12.0%
Sodium (max)	13.0%
Magnesium (min)	4.0%
Potassium (min)	1.0%
Selenium (min)4 ppm
Vitamin A (min)	100,000 IU/lb

Ingredient Statement

Ground Limestone, Dicalcium Phosphate, Magnesium-Mica, Salt, Sodium Bicarbonate, Magnesium Oxide, Corn Distillers Dried Grains, Potassium Chloride, Potassium Sulfate, Magnesium Sulfate, Animal Fat, Sulfur, Dried Extracted Streptomyces Meal Fermentation Solubles, Zinc Oxide, Manganous Oxide, Active Dry Yeast, Ferrous Carbonate, Vitamin A Supplement, Vitamin D₃ Supplement, Vitamin E Supplement, Calcium Carbonate, Ferrous Sulfate, Copper Oxide, Calcium Sulfate, Ethylenediamine Dihydroiodide, Potassium Sulfate, Sodium Selenite

FEEDING DIRECTIONS:

Feed at a rate of 8 ounces per lactating cow mixed with concentrate or total ration when the roughage is a combination of alfalfa hay and corn or small grain silage. Mix 50 lbs. per ton of grain for animals consuming 20 pounds of grain per day.

Guaranteed by:
 Blue Bird Feed Mill
 Anytown, Texas 77777

50 lb (22.6 kg)

BLUE BIRD DAIRY MIXING MINERAL

MIXING MINERAL FOR LACTATING DAIRY CATTLE

Guaranteed Analysis

Calcium (min)	16.5%
Calcium (max)	17.0%
Phosphorus (min)	4.5%
Salt (min)	5.5%
Salt (max)	6.5%
Magnesium (min)	5.5%
Potassium (min)	6.6%
Selenium (min)	3.0 ppm
Vitamin A (min)	115,000 IU/lb

Ingredient Statement

Dicalcium Phosphate, Monocalcium Phosphate, Calcium Carbonate, Sodium Bicarbonate, Potassium Chloride, Salt, Cane Molasses, Vitamin A Supplement, Vitamin D₃ Supplement, Vitamin E Supplement, Vitamin B₁₂ Supplement, Riboflavin Supplement, Niacin Supplement, Choline Chloride, Folic Acid, Ethoxyquin (a preservative), Calcium Pantothenate, Menadione Sodium Bisulfate Complex, Zinc Oxide, Manganous Oxide, Magnesium Oxide, Potassium Chloride, Iron Oxide, Copper Oxide, Ferrous Sulfate, Cobalt Carbonate, Ethylenediamine Dihydroiodide, Sodium Selenite, Yeast Culture, Natural and Artificial Flavors added.

FEEDING DIRECTIONS:

Mix this product with grains, sources of proteins, and other concentrates to prepare complete concentrated mixes for lactating dairy cows. Feed approximately 1.5 lb. of Dairy Mineral on a daily basis. A minimum of 1.5 lb. of forage dry matter per 100 lb. body weight should be fed per cow per day. Provide plain white stock salt on a free-choice basis.

Guaranteed by:
Blue Bird Feed Mill
Anytown, Texas 77777

50 lb (22.6 kg)

- **Equine Formula Feeds**

- a. Animal Classes

- (1) Growing
- (2) Broodmare
- (3) Maintenance
- (4) Performance (Including Stallions)

- b. Guaranteed Analysis for Equine Complete Feeds and Supplements (all animal classes)

- (1) Minimum percentage of Crude Protein
- (2) Minimum percentage of Crude Fat
- (3) Maximum percentage of Crude Fiber
- (4) Maximum percentage of Acid Detergent Fiber (ADF)
- (5) Maximum percentage of Neutral Detergent Fiber (NDF)
- (6) Minimum and maximum percentage of Calcium
- (7) Minimum percentage of Phosphorus
- (8) Minimum Copper in parts per million (ppm)
- (9) Minimum Selenium in parts per million (ppm)
- (10) Minimum Zinc in parts per million (ppm)
- (11) Minimum Vitamin A, other than the precursors of Vitamin A, in International Units per pound (if added)

BLUE BIRD 12% TEXTURED HORSE FEED

FOR MAINTENANCE OF MATURE HORSES

Guaranteed Analysis

Crude Protein (min)	12.0%
Crude Fat (min)	3.0%
Crude Fiber (max)	11.0%
Acid Detergent Fiber (max)	13.0%
Neutral Detergent Fiber (max)	28.0%
Calcium (min)	0.7%
Calcium (max)	1.2%
Phosphorus (min)	0.7%
Copper (min)45 ppm
Selenium (min)	0.3 ppm
Zinc (min)	115 ppm
Vitamin A (min)	4,000 IU/lb

Ingredient Statement

Grain Products, Plant Protein Products, Processed Grain By-Products, Molasses Products, Roughage Products, Vitamin A Supplement, Vitamin D₃ Supplement, Vitamin E Supplement, Vitamin B₁₂ Supplement, Riboflavin Supplement, Pyridoxine Hydrochloride, Folic Acid, Biotin, Thiamine Hydrochloride, Calcium Carbonate, Salt, Dicalcium Phosphate, Sodium Selenite, Manganous Oxide, Ferrous Sulfate, Copper Oxide, Magnesium Oxide, Zinc Oxide, Cobalt Carbonate Potassium Chloride.

FEEDING DIRECTIONS:

Feed 1/2 lb. of feed per 100 lb. of body weight for the maintenance of mature horses. Feed good, clean hay at the rate of 1 to 1-1/2 lbs. per 100 lbs. body weight daily. Provide fresh, clean water at all times, except to hot, tired horses.

Important: Feed hay along with this ration, as per directions.

Manufactured by:
 Blue Bird Feed Mill
 Anytown, Texas 77777

50 lb (22.6 kg)

BLUE BIRD SOUTH TEXAS CUBE

FOR BEEF CATTLE ON PASTURE
FOR MAINTENANCE OF MATURE HORSES

Guaranteed Analysis

Crude Protein (min)	20.0%
Crude Fat (min)	3.0%
Crude Fiber (max)	18.0%
Acid Detergent Fiber (max)	23.0%
Neutral Detergent Fiber (max)	34.0%
Calcium (min)	0.7%
Calcium (max)	1.2%
Phosphorus (min)	0.7%
Copper (min)45 ppm
Selenium (min)	0.3 ppm
Zinc (min)	115 ppm
Vitamin A (min)	4,000 IU/lb

Ingredient Statement

Plant Protein Products, Processed Grain By-Products, Cane Molasses, Animal Protein Products, Ground Limestone, Grain Products, Salt, Vitamin A Supplement, Vitamin D₃ Supplement, Vitamin E Supplement, Dicalcium Phosphate, Copper Oxide, Cobalt Carbonate, Manganous Oxide, Iron Carbonate, Ethylenediamine Dihydroiodide, Sodium Selenite, Zinc Oxide, Iron Oxide, Iron Sulfate, Copper Sulfate, Cobalt Sulfate, Zinc Sulfate, Magnesium Sulfate, Manganese Sulfate, Potassium Chloride.

FEEDING DIRECTIONS:

Cattle: Feed from 1 to 4 pounds per head per day depending on condition of roughage fed.
Horses: For horses on pasture, feed 1 to 2 pounds per head per day.

Manufactured by:
Blue Bird Feed Mill
Anytown, Texas 77777

50 lb (22.6 kg)

- **Goat Formula Feeds**

- a. Animal Classes
 - (1) Starter
 - (2) Grower
 - (3) Finisher
 - (4) Breeder
 - (5) Lactating
- b. Guaranteed Analysis for Goat Complete Feeds and Supplements (all animal classes)
 - (1) Minimum percentage of Crude Protein
 - (2) Maximum percentage of equivalent crude protein from Non-Protein Nitrogen (NPN) when added
 - (3) Minimum percentage of Crude Fat
 - (4) Maximum percentage of Crude Fiber
 - (5) Maximum percentage of Acid Detergent Fiber
 - (6) Minimum and maximum percentage of Calcium
 - (7) Minimum percentage of Phosphorus
 - (8) Minimum and maximum percentage of Salt (if added)
 - (9) Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee
 - (10) Minimum and maximum Copper in parts per million (ppm) (if added or if total copper exceeds 20 ppm)
 - (11) Minimum Selenium in parts per million (ppm)
 - (12) Minimum Vitamin A, other than precursors of Vitamin A, in International Units per pound (if added)

- **Sheep Formula Feeds**
 - a. Animal Classes
 - (1) Starter
 - (2) Grower
 - (3) Finisher
 - (4) Breeder
 - (5) Lactating
 - b. Guaranteed Analysis for Sheep Complete Feeds and Supplements (all animal classes)
 - (1) Minimum percentage of Crude Protein
 - (2) Maximum percentage of equivalent crude protein from Non-Protein Nitrogen (NPN) when added
 - (3) Minimum percentage of Crude Fat
 - (4) Maximum percentage of Crude Fiber
 - (5) Minimum and maximum percentage of Calcium
 - (6) Minimum percentage of Phosphorus
 - (7) Minimum and maximum percentage of Salt (if added)
 - (8) Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee
 - (9) Minimum and maximum Copper in parts per million (ppm) (if added or if total copper exceeds 20 ppm)
 - (10) Minimum Selenium in parts per million (ppm)
 - (11) Minimum Vitamin A, other than precursors of Vitamin A, in International Units per pound (if added)
- **Duck and Geese Formula Feeds**
 - a. Animal Classes
 - (1) Ducks
 - (a) Starter - 0 to 3 weeks of age
 - (b) Grower - 3 to 6 weeks of age
 - (c) Finisher - 6 weeks to market
 - (d) Breeder Developer - 8 to 19 weeks of age
 - (e) Breeder - 22 weeks to end of lay
 - (2) Geese
 - (a) Starter - 0 to 4 weeks of age
 - (b) Grower - 4 to 8 weeks of age
 - (c) Finisher - 8 weeks to market
 - (d) Breeder Developer - 10 to 22 weeks of age
 - (e) Breeder - 22 weeks to end of lay
 - b. Guaranteed Analysis for Duck and Geese Complete Feeds and Supplements (for all animal classes)
 - (1) Minimum percentage of Crude Protein
 - (2) Minimum percentage of Crude Fat
 - (3) Maximum percentage of Crude Fiber
 - (4) Minimum and maximum percentage of Calcium
 - (5) Minimum percentage of Phosphorus
 - (6) Minimum and maximum percentage of Salt (if added)
 - (7) Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee
- **Fish Complete Feeds and Supplements**
 - a. Animal Species shall be declared in lieu of animal class
 - (1) Trout
 - (2) Catfish
 - (3) Species other than trout or catfish
 - b. Guaranteed analysis for all Fish Complete Feeds and Supplements
 - (1) Minimum percentage of Crude Protein
 - (2) Minimum percentage of Crude Fat
 - (3) Maximum percentage of Crude Fiber
 - (4) Minimum percentage of Phosphorus
- **Rabbit Complete Feeds and Supplements**
 - a. Animal Classes
 - (1) Grower - 4 to 12 weeks of age
 - (2) Breeder - 12 weeks of age and over
 - b. Guaranteed Analysis for Rabbit Complete Feeds and Supplements (all animal classes)
 - (1) Minimum percentage of Crude Protein
 - (2) Minimum percentage of Crude Fat
 - (3) Minimum and maximum percentage of Crude Fiber (the maximum crude fiber shall not exceed the minimum by more than 5.0 units)
 - (4) Minimum and maximum percentage of Calcium

- (5) Minimum percentage of Phosphorus
- (6) Minimum and maximum percentage of Salt (if added)
- (7) Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee
- (8) Minimum Vitamin A, other than precursors of Vitamin A, in International Units per pound (if added)
- **Grain mixtures with or without molasses and feeds other than those previously described shall include the following items in the order listed:**
 - a. Animal class(es) and species for which the product is intended.
 - b. Guaranteed analysis
 - (1) Minimum percentage of Crude Protein
 - (2) Maximum or minimum percentage of equivalent Crude Protein from non-protein nitrogen as required in Regulation 4(e)
 - (3) Minimum percentage of Crude Fat
 - (4) Maximum percentage of Crude Fiber
 - (5) Minerals in formula feeds, to include in the following order:
 - (a) Minimum and maximum percentages of Calcium
 - (b) Minimum percentage of Phosphorus
 - (c) Minimum and Maximum percentage of salt (if added)
 - (d) Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee
 - (e) Other Minerals
 - (6) Minerals in feed ingredients - as specified by the official definitions of the Association of American Feed Control Officials
 - (7) Vitamins in such terms as specified in Regulation 4(c)
 - (8) Total sugars as invert on dried molasses products or products being sold primarily for their sugar content
 - (9) Viable lactic acid producing microorganisms for use in silage in terms specified in Regulation 4(g)
 - (10) A commercial feed (e.g. vitamin/mineral premix, base mix, etc.) intended to provide a specialized nutritional source for use in the manufacture of other feeds, must state its intended purpose and guarantee those nutrients relevant to such stated purpose. Article II of AAFCO's "Criteria for Labeling Nutritional Indicators" is not applicable to the label guarantees for these specialized commercial feeds.
- **Exemptions:**

A mineral guarantee is not required when the feed or feed ingredient is not intended or represented or does not serve as a principal source of that mineral to the animal or if it is intended for non-food producing animals and contains less than 6.5% total mineral. Guarantees for vitamins are not required when the commercial feed is neither formulated for nor represented in any manner as a vitamin supplement.

Guarantees for crude protein, crude fat, and crude fiber are not required when the commercial feed is intended for purposes other than to furnish these substances or they are of minor significance relating to the primary purpose of the product, such as drug premixes, mineral or vitamin supplements, and molasses.

Guarantees for microorganisms are not required when the commercial feed is intended for a purpose other than to furnish these substances or they are of minor significance relating to the primary purpose of the product, and no specific label claims are made. The indication for animal class(es) and species is not required on single ingredient products if the ingredient is not intended, represented, or defined for a specific animal class(es) or species.

BLUEBIRD RATITE STANDARD
A RATION FOR OSTRICH, EMU & CASSOWARY

Guaranteed Analysis

Crude Protein (Min)	17.0%
Crude Fat (Min)	3.0%
Crude Fiber (Max)	15.0%
Calcium (Min)	0.8%
Calcium (Max)	1.0%
Phosphorus (Min)	0.8%
Salt (Min)	0.2%
Salt (Max)	0.5%

Ingredient Statement

Dehydrated Alfalfa Meal, Ground Corn, Soybean Meal, Whole Extruded Soybeans, Fish Meal, Meat & Bone Meal, Corn Gluten Meal, Corn Chops, Wheat Middlings, Dried Whey, Brewers Dried Yeast, Yeast Culture, Rice Bran, Dried Streptococcus Faecium Fermentation Product, Dried Lactobacillus Acidophilus Fermentation Product, Dried Lactobacillus Bulgaricus Fermentation Product, Dried Bacillus Subtilis Fermentation Product, Dried Aspergillus Oryzae Fermentation Extract, Dried Milk Protein, Lecithin, Wheat Germ Oil, Soybean Oil, DL-Methionine, L-Lysine, Beta Carotene, Citrus Bioflavonoids, Vitamin A Supplement, Vitamin D₃ Supplement, Vitamin E Supplement, Choline Chloride, Riboflavin Supplement, Niacin, Calcium Pantothenate, Thiamine Mononitrate, Folic Acid, Pyridoxine Hydrochloride, Vitamin B12 Supplement, Menadione Sodium Bisulfite Complex (source of Vitamin K Activity), Sodium Tripolyphosphate, Monosodium Phosphate, Dicalcium Phosphate, Calcium Carbonate, Potassium Sulfate, Salt, Magnesium Oxide, Magnesium Sulfate.

FEEDING DIRECTIONS:
 Feed BlueBird Ratite Standard free choice to adult birds. Average Daily Consumption: Ostrich (1 lb. per 40 lbs. body weight); Rhea (1 lb. per 50 lbs. body weight); Emu (1 lb. per 45 lbs. body weight); Cassowary (1 lb. per 40 lbs. body weight)
NOTE: Provide plenty of fresh, clean water at all times. Keep feed fresh in cool, dry storage. DO NOT use feed that is old, molded or insect contaminated.

Manufactured by
 BlueBird Feed Mills
 Anytown, Texas 77777

50 lb (22.6 kg)

Feed Ingredients

The name of each ingredient as defined in the Official Publication of the Association of American Feed Control Officials, common or usual name, or one approved by the state.

Collective terms for the grouping of feed ingredients as defined in the Official Definitions of Feed Ingredients published in the Official Publication of the Association of American Feed Control Officials in lieu of the individual ingredients; provided that:

- When a collective term for a group of ingredients is used on the label, individual ingredients within that group shall not be listed on the label.
- The manufacturer shall provide the feed control official, upon request, with a list of individual ingredients, within a defined group, that are or have been used at manufacturing facilities distributing in or into the state.

Manufacturer Information

The name and principal mailing address of the manufacturer or person responsible for distributing the feed. The principal mailing address shall include the street address, city, state, zip code; however, the street address may be omitted if it is shown in the current city directory or telephone directory.

REGULATION 4. EXPRESSION OF GUARANTEES

The guarantees for crude protein, equivalent crude protein from non-protein nitrogen, lysine, methionine, crude fat, crude fiber and acid detergent fiber shall be in terms of percentage.

Mineral Guarantees

When the calcium and salt guarantees are given in the guaranteed analysis such shall be stated and conform to the following:

- When the minimum is below 2.5%, the maximum shall not exceed the minimum by more than 0.5 percentage point.
- When the minimum is 2.5% but less than 5.0%, the maximum shall not exceed the minimum by more than one percentage point.
- When the minimum is above 5.0% or greater the maximum shall not exceed the minimum by more than 20% of the minimum and in no case shall the maximum exceed the minimum by more than five percentage points.

- When required, guarantees for minimum and maximum total sodium, and salt: minimum potassium, magnesium, sulfur, phosphorus and maximum fluoride shall be stated in terms of percentage. Other minimum mineral guarantees shall be stated in parts per million (ppm) when the concentration is less than 10,000 ppm and in percentage when the concentration is 10,000 ppm (1%) or greater.
- Products labeled with a quantity statement (e.g., tablets, capsules, granules, or liquid) shall state mineral guarantees in milligrams (mg) per unit (e.g., tablets, capsules, granules, or liquids) consistent with the quantity statement and directions for use.

Vitamin Guarantees

Guarantees for minimum vitamin content of commercial feeds shall be listed in the order specified and are stated in mg/lb or in units consistent with those employed for the quantity statement unless otherwise specified.

- Vitamin A, other than precursors of vitamin A, in International Units per pound
- Vitamin D-3 in products offered for poultry feeding, in International Chick Units per pound
- Vitamin D for other uses, International Units per pound
- Vitamin E, in International Units per pound
- Concentrated oils and feed additive premixes containing vitamins A, D and/or E may, at the option of the distributor, be stated in units per gram instead of units per pound
- Vitamin B-12, in milligrams or micrograms per pound
- All other vitamin guarantees shall express the vitamin activity in milligrams per pound in terms of the following: menadione; riboflavin; d-pantothenic acid; thiamine; niacin; vitamin B-6; folic acid; choline, biotin, inositol; p-amino benzoic acid; ascorbic acid; and carotene.

Drug Guarantees

Guarantees for drugs shall be stated in terms of percent by weight, except:

- Antibiotics, present at less than 2,000 grams per ton (total) of commercial feed shall be stated in grams per ton of commercial feed.
- Antibiotics present at 2,000 or more grams per ton (total) of commercial feed shall be stated in grams per pound of commercial feed.
- Labels for commercial feeds containing growth promotion and/or feed efficiency levels of antibiotics, which are to be fed continuously as the sole ration, are not required to make quantitative guarantees except as specifically noted in the Federal Food Additive Regulations for certain antibiotics, wherein, quantitative guarantees are required regardless of the level or purpose of the antibiotic.
- The term “milligrams per pound” may be used for drugs or antibiotics in those cases where a dosage is given in “milligrams” in the feeding directions.

NPN Guarantees

Commercial feeds containing any added non-protein nitrogen shall be labeled as follows:

- For ruminants
 - Complete feeds, supplements, and concentrates containing added non-protein nitrogen and containing more than 5% protein from natural sources shall be guaranteed as follows:
Crude Protein, minimum _____ %
(This includes not more than _____ % equivalent crude protein from non-protein nitrogen).
 - Mixed feed concentrates and supplements containing less than 5% protein from natural sources may be guaranteed as follows:
Equivalent Crude Protein from Non-Protein Nitrogen, minimum _____ %
 - Ingredient sources of non-protein nitrogen such as Urea, Diammonium Phosphate, Ammonium Polyphosphate Solution, Ammoniated Rice Hulls, or other basic non-protein nitrogen ingredients defined by the Association of American Feed Control Officials shall be guaranteed as follows:
Nitrogen, minimum, _____ %
Equivalent Crude Protein from Non-Protein Nitrogen, minimum, _____ %
- For non-ruminants
 - Complete feeds, supplements and concentrates containing crude protein from all forms of non- protein nitrogen, added as such, shall be labeled as follows:
Crude protein, minimum, _____ %
(This includes not more than _____ % equivalent crude protein which is not nutritionally available to (species of animal for which feed is intended).
 - Premixes, concentrates or supplements intended for non-ruminants containing more than 1.25% equivalent crude protein from all forms of non-protein nitrogen, added as such, must contain adequate directions for use and a prominent statement:

WARNING: This feed must be used only in accordance with directions furnished on the label.

Mineral phosphatic materials

For feeding purposes shall be labeled with the guarantee for minimum and maximum percentage of calcium (when present), the minimum percentage of phosphorus, and the maximum percentage of fluorine.

Guarantees for microorganisms

Shall be stated in colony forming units per gram (CFU/g) when directions are for using the product in grams, or in colony forming units per pound (CFU/lb) when directions are for using the product in pounds. A parenthetical statement following the guarantee shall list each species in order of predominance.

Guarantees for enzymes

Shall be stated in units of enzymatic activity per unit weight or volume, consistent with label directions. The source organism for wash type of enzymatic activity shall be specified, such as: Protease (*Bacillus subtilis*) 5.5 mg amino acids liberated/min./milligram. If two or more sources have the same type of activity they shall be listed in order of predominance based on the amount of enzymatic activity provided.

Guarantees for dietary starch, sugars, and fructans

For Commercial Feeds, other than customer-formula feed, Pet Food and Specialty Pet Food Products:

- A commercial feed which bears on its labeling a claim in any manner for levels of “dietary starch,” “sugars,” “fructans,” or words of similar designation, shall include on the label:
 - Guarantees for maximum percentage of dietary starch and maximum percentage sugars, in the Guaranteed Analysis section immediately following the Crude Fiber guarantee.
 - A maximum percentage guarantee for fructans immediately following sugars, if the feed contains forage products.
- When such guarantees for dietary starch, sugars or fructans for commercial feeds appear on the label, feeding directions shall indicate the proper use of the feed product and a recommendation to consult with a veterinarian or nutritionist for a recommended diet.

REGULATION 5. SUBSTANTIATION OF NUTRITIONAL SUITABILITY

A commercial feed, other than a customer-formula feed, shall be nutritionally suitable for its intended purpose as represented by its labeling.

If the _____ has reasonable cause to believe a commercial feed is not nutritionally suitable, the _____ may request the feed manufacturer to either submit an “Affidavit of Suitability” or an alternative procedure acceptable to the _____, certifying the nutritional adequacy of the feed. The Affidavit of Suitability or alternate procedure of suitability shall serve as substantiation of the suitability of the feed.

If an Affidavit of Suitability or alternative procedure acceptable to the _____ is not submitted by the feed manufacturer within 30 days of written notification the _____ may deem the feed adulterated under section 7(c) of the Model Bill and order the feed removed from the marketplace.

The Affidavit of Suitability shall contain the following information:

- The feed company’s name;
- The feed’s product name;
- The name and title of the affiant submitting the document;
- The statement that the affiant has knowledge of the nutritional content of the listed feed product and is familiar with the nutritional requirements for the animal species and animal class(es) for which the product is intended as established by the National Research Council of the National Academy of Science;
- The statement that the affiant has knowledge of valid scientific evidence that supports the suitability of the product for the intended animal species and animal class(es) for which the feed is intended;
- The date of submission; and
- The signature of the affiant notarized by a certified Notary Public.

REGULATION 6. INGREDIENTS

The name of each ingredient or collective term for the grouping of ingredients, when required to be listed, shall be the name as defined in the Official Definitions of Feed Ingredients as published in the Official Publication of the Association of American Feed Control Officials, the common or usual name, or one approved by the state

The name of each ingredient must be shown in letters or type of the same size.

No reference to quality or grade of an ingredient shall appear in the ingredient statement of a feed. The term “dehydrated” may precede the name of any product that has been artificially dried.

A single ingredient product defined by the Association of American Feed Control Officials is not required to have an ingredient name.

Tentative definitions for ingredients shall not be used until adopted as official, unless no official definition exists or the ingredient has a common accepted name that requires no definition, (i.e. sugar).

When the word “iodized” is used in connection with a feed ingredient, the feed ingredient shall contain not less than 0.007% iodine, uniformly distributed.

REGULATION 7. DIRECTIONS FOR USE AND PRECAUTIONARY STATEMENTS

Directions for use and precautionary statements on the labeling of all commercial feeds and customer-formula feeds containing additives (including drugs, special purpose additives, or nonnutritive additives) shall:

- Be adequate to enable safe and effective use for the intended purpose by users with no special knowledge of the purpose and use of such articles; and
- Include, but not be limited to, all information described by all applicable regulations under the Federal Food, Drug and Cosmetic Act.

Adequate directions for use and precautionary statements are required for feeds containing non-protein nitrogen as specified in Regulation 8.

Adequate directions for use and precautionary statements necessary for safe and effective use are required on commercial feeds distributed to supply particular dietary needs or for supplementing or fortifying the usual diet or ration with any vitamin, mineral, or other dietary nutrient or compound.

Raw milk distributed as commercial feed shall bear the following statement: **“WARNING: NOT FOR HUMAN CONSUMPTION – THIS PRODUCT HAS NOT BEEN PASTUERISED AND MAY CONTAIN HARMFUL BACTERIA.”** This statement shall be displayed in a conspicuous manner and shall not be smaller than the height of the minimum font required by the Federal Fair Packaging and Labeling Act for the quantity statement as shown in the following table:

Panel Size	Minimum Warning Statement Type Size
< 5 sq. in.	1/16 in.
5-25 sq. in.	1/8 in.
25-100 sq. in.	3/16 in.
100-400 sq. in.	1/4 in.
400 sq. in. +	1/2 in.

REGULATION 8. NON-PROTEIN NITROGEN

Urea and other non-protein nitrogen products defined in the Official Publication of the Association of American Feed Control Officials are acceptable ingredients only in commercial feeds for ruminant animals as a source of equivalent crude protein. If the commercial feed contains more than 8.75% of equivalent crude protein from all forms of non-protein nitrogen, added as such, or the equivalent crude protein from all forms of non-protein nitrogen, added as such, exceeds one-third of the total crude protein, the label shall bear adequate directions for the safe use of feeds and a precautionary statement: **“CAUTION: USE AS DIRECTED.”** The directions for use and the caution statement shall be in type of such size so placed on the label that they will be read and understood by ordinary persons under customary conditions of purchase and use.

Non-protein nitrogen defined in the Official Publication of the Association of American Feed Control Officials, when so indicated, are acceptable ingredients in commercial feeds distributed to non-ruminant animals as a source of nutrients other than equivalent crude protein. The maximum equivalent crude protein from non-protein nitrogen sources when used in non-ruminant rations shall not exceed 1.25% of the total daily ration.

On labels such as those for medicated feeds which bear adequate feeding directions and/or warning statements, the presence of added non-protein nitrogen shall not require a duplication of the feeding directions or the precautionary statements as long as those statements include sufficient information to ensure the safe and effective use of this product due to the presence of non-protein nitrogen.

REGULATION 9. DRUG AND FEED ADDITIVES

Prior to approval of a registration application and/or approval of a label for commercial feed which contains additives (including drugs, other special purpose additives, or non-nutritive additives) the distributor may be required to submit evidence to prove the safety and efficacy of the commercial feed when used according to the directions furnished on the label.

Satisfactory evidence of safety and efficacy of a commercial feed may be:

- When the commercial feed contains such additives, the use of which conforms to the requirements of the applicable regulation in the Code of Federal Regulations, Title 21, or which are “prior sanctioned” or “informal review sanctioned” or “generally recognized as safe” for such use, or
- When the commercial feed is itself a drug as defined in Section 3(g) of the Act and is generally recognized as safe and effective for the labeled use or is marketed subject to an application approved by the Food and Drug Administration under Title 21 U.S.C. 360(b), or
- When one of the purposes for feeding a commercial feed is to impart immunity (that is to act through some immunological process) the constituents imparting immunity have been approved for the purpose through the Federal Virus, Serum and Toxins Act of 1913, as amended, or
- When the commercial feed is a direct-fed microbial product and:
 - The product meets the particular fermentation product definition; and
 - The microbial content statement, as expressed in the labeling, is limited to the following: “Contains a source of live (viable) naturally occurring microorganisms.” This statement shall appear on the label; and
 - The source is stated with a corresponding guarantee expressed in accordance with Regulation 4(g).
- When the commercial feed is an enzyme product and:
 - The product meets the particular enzyme definition defined by the Association of American Feed Control Officials; and
 - The enzyme is stated with a corresponding guarantee expressed in accordance with Regulation 4(h).

REGULATION 10. ADULTERANTS

For the purpose of Section 7(a) (1) of the Act, the terms “poisonous and deleterious substances” include, but are not limited to, the following:

- Fluorine and any mineral or mineral mixture which is to be used directly for the feeding of domestic animals and in which the fluorine exceeds 0.20% for breeding and dairy cattle; 0.30% for slaughter cattle; 0.30% for sheep; 0.35% for lambs; 0.45% for swine; and 0.60% for poultry.
- Fluorine bearing ingredients when used in such amounts that they raise the fluorine content of the total ration (exclusive of roughage) above the following amounts: 0.004% for breeding and dairy cattle; 0.009% for slaughter cattle; 0.006% for sheep; 0.01% for lambs; 0.015% for swine and 0.03% for poultry.
- Fluorine bearing ingredients incorporated in any feed that is fed directly to cattle, sheep or goats consuming roughage (with or without) limited amounts of grain, that results in daily fluorine intake in excess of 50 milligrams of Fluorine per 100 pounds of body weight.
- Soybean meal, flakes, or pellets or other vegetable meals, flakes or pellets which have been extracted with trichloroethylene or other chlorinated solvents.
- Sulfur dioxide, Sulfurous acid, and salts of Sulfurous acid when used in or on feeds or feed ingredients which are considered or reported to be a significant source of Vitamin B1 (Thiamine).

All screening or by-products of grains and seeds containing weed seeds, when used in commercial feed or sold as such to the ultimate consumer, shall be ground fine enough or otherwise treated to destroy the viability of such weed seeds so that the finished product contains no more than _____ viable prohibited weed seeds per pound and not more than _____ viable restricted weed seeds per pound.

REGULATION 11. GOOD MANUFACTURING PRACTICES

For the purposes of enforcement of Section 7(d) of the Act the _____ adopts the following as current good manufacturing practices:

- The regulations prescribing good manufacturing practices for Type B and Type C medicated feeds as published in the Code of Federal Regulations, Title 21, Part 225, Sections 225.1-225.202.
- The regulations prescribing good manufacturing practices for Type A Medicated Articles as published in the Code of Federal Regulations, Title 21, Part 226, Sections 226.1-226.115.

REGULATION 12. CERTAIN MAMMALIAN PROTEINS PROHIBITED IN RUMINANT FEED

Pursuant to Section 7(a) (1) or 7(a) (3) of the Act, the _____ adopts the requirements of Title 21, Code of Federal Regulations, 589.2000.

Pursuant to Section 7(a) (1) or 7(a) (3) of the Act, the _____ adopts the requirements of Title 21, Code of Federal Regulations, 589.2001.

SPECIAL CONSIDERATIONS FOR PET & SPECIALTY PET FOOD LABEL REVIEW- MODEL REGULATIONS

Pet foods follow the same general label format as other feeds, but there are important differences to watch for when you conduct a field review of the label. The Official AAFCO Pet Food Regulations are found in the AAFCO Official Publication as well as in the Pet Food and

Specialty Pet Food Labeling Guide. Notation, such as (PF2(c)) in this section, are references to the Pet Food Regulations in the AAFCO Official Publication.

BRAND NAMES AND PRODUCT NAMES (REGULATION PF3)

The pet food industry is highly competitive. It also relies heavily on labels and packaging to communicate to the purchaser. The label not only transmits nutrition information about the product, but is also used to create an image of the product in the marketplace. The brand name and product name, and other information and graphics on the label, are an important part of the developing of the product image. To help insure accurate information for customers and fair competition among manufacturers, the Pet Food Regulations contain specific requirements relating to product names and product content. For many of these regulations, it will be difficult to determine if violations are occurring during field review of labels. Compliance is often established by having the labeler submit affidavits to the feed control official demonstrating the ingredient content if the product meets the regulations.

Use of the designations “100%” or “All” (PF3 (a))

The designations “100%” or “All” cannot be used in the product name if it is made up of more than one ingredient, not including water for processing, decharacterizing agents, and trace amounts of the preservatives and condiments which are allowed in such a product and would need to appear in the ingredient statement.

Ingredients in the product name, 95% Rule (PF3 (b) (1))

When an ingredient or combination of ingredients derived from animal, poultry or fish constitute 95% or more of the total weight of the pet food, the names of those ingredients may appear in the product name without modification or qualification (i.e. Bowser Beef and Chicken Dog Food). When several ingredients are involved, all such ingredients must be in the product name and all must be in the same color, type and size of print. Water sufficient for processing is excluded when calculating the percentage of the name ingredients, but the named ingredients must make up at least 70% of the total product.

Ingredients in the product name, 25% Rule (PF3 (b) (2))

If an ingredient or group of ingredients is at least 25% but less than 95% of the total weight of a pet food, the name(s) of those ingredient(s) may form part of the product name of a pet food, provided that (1) each individual ingredient named is at least 10% of the total product, water sufficient for processing is excluded when calculating the total percent of the ingredient(s), and (2) the product name includes a primary descriptive term such as “dinner”, “entrée” or “platter” (i.e. Bowser Beef and Chicken Platter). The ingredient names must appear in the product name in order of their predominance by weight in the product and in the same type size, style, and color as the primary descriptive term.

Ingredients named on the label, 3% Rule (PF3(c))

When the name of any ingredient appears in the product name of a pet food or specialty pet food or elsewhere on the product label and includes a descriptor such as “with” or a similar term, i.e. “With Tuna and Chicken”, the each emphasized ingredient(s) must constitute at least 3% of the product (exclusive of water sufficient for processing.) Ingredient(s) should not be presented in such a way to create undue emphasis on the ingredient(s). If the names of more than one ingredient are shown, they shall appear in their respective order of predominance by weight in the product. The 3% minimum level shall not apply to claims for nutrients, such as, but not limited to, vitamins, minerals, fatty acids, as well as condiments.

Flavor designations (PF3 (d))

Flavor designations are often used on pet food labels, i.e. “Bowser Biscuits, Turkey and Chicken Flavored”. The flavor designation must be supported by the ingredient listing, i.e. a product that is “turkey and chicken flavored” must contain, both turkey and chicken, or turkey and/or chicken by-products as ingredients. The source of the flavor must be identified in the ingredients statement. The word “flavor” must be in the same size type and be as conspicuous as the flavor names. If a flavor is designated on the label, it must be detectable by a recognized test method or it must impart a characteristic to the pet food that is distinguishable by the pet.

Expression of Guaranteed Analysis (Regulation PF 4)

A pet food or specialty pet food label shall list the following required guarantees:

- Crude protein (minimum percentage)
- Crude fat (minimum percentage)
- Crude fat (maximum percentage), if required by Regulation PF10
- Crude fiber (maximum percentage)
- Moisture (maximum percentage). The moisture content of a pet food must not exceed 78%, with the exception of products that consist principally of stew, broth, gravy, sauce, juice, or milk replacer and is represented as such by the label (PF5(a)).
- Additional guarantees shall follow moisture

Additional guarantees are allowed and in some cases may be required (see below).

- A pet food that is formulated and represented as a mineral supplement must have guarantees for calcium (minimum and maximum), phosphorous (minimum) and salt (minimum and maximum) plus all other essential minerals recognized by the AAFCO Dog or Cat Food Nutrient Profiles (PF4(b)).
- A pet food that is formulated and represented as a vitamin supplement must have a minimum guarantee for all vitamins listed in the ingredient statement (PF4(c)). If the pet food is not represented as a vitamin or mineral supplement, but the labeling contains a table comparing the typical analysis of the product to nutrient levels recommended by a recognized animal nutrition authority, the statements in the comparison table are considered guarantees. They do not need to be repeated in the guaranteed analysis and may appear on the label separate from the guaranteed analysis (PF4 (f)).

Ingredient Statements (Regulation PF5)

All ingredients must be shown in the same type size in the statement, and ingredients should be listed by predominance in descending order. An ingredient which does not have an official AAFCO definition should be identified by the common or usual name of the ingredient.

Collective terms are not allowed on pet food labels. Brand names or trade names of ingredients should not be used, and no reference to the quality or grade of an ingredient shall appear in the ingredient statement. A reference to the quality, grade, or other attribute of an ingredient can be made in another area on the label as long as the designation is accurate, and the ingredient imparts a distinctive characteristic on the pet food because of the named attribute.

Statement of Nutritional Adequacy/Purpose and Feeding Directions (Regulation PF7 & PF 8)

The label of a dog or cat food (except those prominently labeled as “snack” or “treat”) must have a statement of nutritional adequacy or purpose on either the principle display panel or the information panel (PF2(a)(6)). The statement must be one of the following:

- A claim that the pet food is complete and balanced for one or more of the following life stages: gestation, lactation, growth, maintenance or all life stages;
- A dietary claim for a purpose other than (1) above (the claim must be scientifically substantiated);
- The statement “this product is intended for intermittent or supplemental feeding only” if the product is suitable only for that type of feeding and must be supplemented with other food;
- The statement “Use only as directed by your veterinarian” if the product is intended for use only under the supervision or direction of a veterinarian, as well as nutritional adequacy in accordance with (1) or (3) above.

Dog and cat foods, including snacks or treats, labeled as complete and balanced under (1) above for any and all life stages must have feeding directions on the product label (PF2(a)(7)). At a minimum, the feeding directions must state “feed (amount of product) per (bodyweight unit) of dog (or cat)”.

Statements of Caloric Content (Regulation PF9)

The label of a dog or cat food must bear a statement of caloric (energy) content and it must appear separate and be distinct from the “Guaranteed Analysis” and appear under the heading “Caloric Content”.

The statement must be expressed in terms of metabolizable energy on an “as fed” basis, and in units of “kilocalorie per kilogram”, often abbreviated as “kcal/kg”. It can additionally be expressed in units of a familiar household measure, such as cups, cans or pounds. An example of such a statement would be “This product contains 3,000 kcal of metabolizable energy per kg, or 300 kcal per “cup”.”

Comparative claims based on caloric content must not be false or misleading, and must be based on the same methodology for both products.

Descriptive Terms (Regulation PF10)

• **Calorie Terms**

A dog cat food product which bears on its label the terms “Light”, “lite”, or “low calorie” must include a calorie content statement on the label and be labeled in accordance with Regulation PF9. The feeding directions must reflect a reduction in calorie intake consistent with the intended use. These products can contain no more than the allowed maximum kcal ME/kg based on the percentage of moisture as outlined in the table listed below:

Dog		Cat	
Kcal ME/kg	Percentage Moisture	Kcal ME/kg	Percentage Moisture
3100	>20	3250	>20
2500	20-65	2650	20-65
900	<65	950	<65

A dog or cat food product which bears on its label the claims “Less Calories” or “Reduced Calories” shall include on the label the name of the product of comparison and the percentage of calorie reduction, a calorie content statement in accordance with the format provided in Regulation PF9, and feeding directions which reflect a reduction in calories compared to feeding directions for the product of comparison. A comparison between products in different categories of moisture content is misleading.

- **Fat Terms**

A dog or cat food product which bears on its label the terms “Lean” or “low fat” must include an additional maximum crude fat guarantee immediately following the minimum crude fat guarantee in the guaranteed analysis and can contain no more than the allowed maximum percentage of crude fat based on the percentage of moisture as outlined in the table listed below:

Dog		Cat	
Percentage Crude Fat	Percentage Moisture	Percentage Crude Fat	Percentage Moisture
9	>20	10	>20
7	20-65	8	20-65
4	<65	5	<65

A dog or cat food product which bears on its label the claims “Less Fat” or “Reduced Fat” shall include on the label the name of the product of comparison and the percentage of fat reduction, and a maximum crude fat guarantee in the Guaranteed Analysis immediately following the minimum crude fat guarantee in addition to the mandatory guaranteed analysis information as specified in Regulation PF4 (a) (1). A comparison between products in different categories of moisture content is misleading.

Guidelines for Tarter Control Claims

The AAFCO Pet Food Committee supports and recommends the following guidelines developed for dental health claims with respect to rawhides, biscuits, and other pet food products:

- Food bearing claims to cleanse, freshen, or whiten teeth by virtue of their abrasive or mechanical action are not objectionable
- Foods bearing claims for plaque or tarter reduction or prevention, or control of breath odor may be misbranded. If these claims are made only with respect to the products’ abrasive action, enforcement would be a low priority, thus CVM is not objecting to these types of claims at this time.
- Foods bearing expressed or implied drug claims to prevent or treat dental diseases are not permissible unless they are the subject of approved New Animal Drug Applications.
- Food Ingredients that are not GRAS for the intended purpose of affecting the teeth or gums may be unapproved food additives or unapproved drugs, depending on the nature of the claim.
- Foods bearing claims for plaque or tarter reduction, preventions, or control of breath odor that achieve their effect, in part or in total, by means other than mechanical action must have an approved New Animal Drug Application or a letter of no objection from the FDA prior to being marketed.

Guidelines for “Natural” Claims

AAFCO recommends and supports the following guidelines for use of the term “natural” in the labeling of commercial feeds, pet foods, and specialty pet foods:

- In the AAFCO-defined feed term “natural”, the use of the term “natural” is only acceptable in reference to the product as a whole when all of the ingredients and components of ingredients meet the definition
- The use of the term “natural” is false and misleading if any chemically synthesized ingredients are present in the product. Exceptions can be made if the product is not a dietary supplement and if a disclaimer is used to inform the consumer that chemically synthesized vitamins, minerals, or other trace minerals are present in the product
 - Acceptable use of the disclaimer:
 - “Natural with added vitamins, minerals, and other trace nutrients”
 - The disclaimer appears with the largest or most prominent use of the term “natural” on each panel of the label on which the term appears, in the same style and color print and at least one-half the size of the term “natural”
 - All other ingredients and components of ingredients in the product meet the definition of the AAFCO-approved feed term “natural”
 - If the disclaimer makes reference to a specific nutrient, guarantee would be warranted (i.e. “with added calcium”)
- Exceptions can be made when the term is used only in reference to a specific ingredient. The reference should not imply that the product as a whole is “natural” (i.e. “natural cheese flavor”).

Health Claims on Pet Food Labels

A new animal drug must go through an approval process with the Food and Drug Administration before it can be marketed. A pet food (**or any animal feed**) that claims to treat, prevent, or reduce the risk of disease is considered a “new animal drug” by FDA and is considered adulterated if it has not undergone the normal premarket testing required to determine safety and efficacy. A company must remove the health claim from the label if they want to market the product without going through the approval process.

The FDA takes a fairly broad view of what constitutes a “drug claim” on a label. In addition to specific wording that a product will “treat” or “prevent” a disease, implied claims that suggest a product will have therapeutic benefit are not allowed. For example, a discussion of a medical condition on a pet food label implies that the product will affect the condition and is not allowed. A claim on a label stating that the product may affect conditions of stress, dehydration, or allergens are also considered drug claims.

The term “label” is defined broadly to include any brochures, signs, flyers, or other promotional material that accompany the product at the point of sale. Advertising, websites, or oral representations that establish the intended use of the product are also considered part of labeling. For purposes of determining if drug claims are being made, all of the above are subject to regulatory action.

Under certain circumstances there are some types of “health claims” that are allowed on pet food labels. Generally these are for conditions that are well known to be related to diet and nutrition, and only specific wording is allowed. One example is related to Feline Urologic Syndrome (FUS) claims for cat foods. FDA does not allow claims that products will prevent or reduce the risk of FUS, cystitis or urinary problems in cats however they do recognize that diet does play a role in aiding the symptoms of FUS. FDA has decided to use regulatory discretion in not taking action against products that bear claims to “reduce urine pH to help maintain urinary tract health”, provided the company has conducted adequate controlled studies to demonstrate the product will produce the intended effect (acidic urine) without over acidifying the urine and causing metabolic problems, and that such studies have been previously reviewed by FDA. Cat foods may also claim to have “low magnesium levels” if they contain less than 0.12 % magnesium on a dry matter basis, however, the statement should not claim that low magnesium levels will prevent or treat FUS. Products formulated to be “low magnesium” should contain enough magnesium to meet the requirements of the type of cat it is intended for (0.08% for growth and reproduction, 0.04% for adult maintenance). Therefore, substantiating data must be sent to FDA for their prior review. Claims of a cat food being “low ash” are not allowed on labels. The ash content is not related to FUS (although it was once thought to be) and there is no reason to reference the ash content of the product, other than in the guaranteed analysis.

For a complete listing of the pet food regulations, please refer to the AAFCO Official Publication.

CHAPTER 5 FEED INVESTIGATION

COMPLAINTS

Inspectors are called upon by livestock producers, pet owners, feed mills and veterinarians to investigate whether an animal food problem may be feed-related. If within such a complaint, animals become ill or die from an adulterated animal food and the investigation must expand to coordinate with other regulating agencies in the food chain, the investigation may be considered a toxic response. (A toxin, as used here, includes pesticides, mycotoxins and other substances which may contaminate food or feed products and cause them to be illegal for sale or dangerous if allowed into the food chain). Animal food may also be considered adulterated if they do not follow the new Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals regulations found in 21 CFR Part 507. Compliance with the CGMPs should reduce the likelihood that animal food is adulterated due to contamination, or because it was produced under conditions that could result in contamination from other feed sources such as residues from feed ingredients, i.e. copper may cause a sheep feed to be considered adulterated.

INVESTIGATION CRITERIA

Inspectors are frequently requested to investigate either a feed manufacturer or supplier. Criteria that may exclude the inspector from being able to conduct or complete the investigation include, but are not limited to, the following:

- No veterinarian was involved in a complaint of animal sickness or death; (prime requisite). However, an example of an exception to this criterion might be that an investigation would take place without a veterinarian if the situation involved a caged bird with no other feed source. The complainant requests analysis for informational purposes only. Inspectors should provide names of commercial laboratories that can perform this service.
- No feed product is available to obtain an official sample.
- The complainant asks that the manufacturer not be informed of their complaint.
- The complainant has retained no documents which identify the source of product(s).
- The complaint was neither discussed nor authorized by the inspector's supervisor

THE INSPECTORS ROLE

Inspectors should serve as impartial fact-collectors and be non-biased in expressing views or opinions concerning the particular situation. (It is not the responsibility of the state to act as a claim adjuster, attorney or counselor).

It is the responsibility of the supervisor or feed specialists to assess the facts, put these together with any laboratory findings, and render a report to the parties involved. (Such procedure will avoid embarrassment to the state should there be legal proceedings between the complainant and the firm or firms involved).

It must be made clear to the complainant that the inspectors' role is that of a neutral observer and if the department initiates proceedings against the feed manufacturer, it will not result in any compensation to the complainant.

INVESTIGATION PROCEDURE

Upon notification of an investigation request, the inspector should first meet with their supervisor to discuss the merits of the complaint to determine if the proper criteria have been met by the complainant. Once given authorization the inspector should conduct a thorough investigation without bias or prejudice, following the below listed guidelines.

- **From the Veterinarian**
The usual first contact to be made is with the veterinarian that initiated the case. Normally the office staff furnishes the name, address and telephone number of the clinic and veterinarian. Attempt to set up an appointment to see him/her. Information that should be addressed:
 - All available information about the owner/lessee of the affected animals that would be relevant to the case.
 - Details on illness which led to the complaint which include the veterinarian's report, history of treatment provided, name, address, telephone number of veterinarian/clinic, results from autopsy, if conducted, lab reports from other sources.
 - Discuss details on what investigation and sampling the veterinarian has done to this point. (If sampled, determine if samples were already forwarded to "what" lab)?
- **From the Owner/Lessee/Farmer of Animals Affected**
Obtain all information he/she may have available. If this feed investigation is with animals in the food or feed chain of meat, milk or eggs, you should screen the following issues:
 - Has there been unusual herd or animal activity?
 - Have animals broken out of feeding areas lately?

- Have the animals had access to any disposed-of materials? (Empty bags, containers, spills, burn piles, etc.)
- Have you shipped any milk or cattle since noticing the cows were ill? If so, where, when and by whom?
- Who is your milk plant field person?
- Have you buried any animals? If so, where, how and when?
- If the animals are on pasture, are there any old dump sites?
- Were pastures fertilized or treated with pesticides?
- Were any animals posted and what were their results?
- **It May Not Be Feed Related**
 - Question where these animals have been. Did they get out? Where did they die? Inspect all areas; barns, feed lots, water sources, fields, fence lines and adjacent fields. Have they changed pastures lately?
 - Has there been a recent electrical storm? Could they have been struck by lightning? Could they have been electrocuted by an ungrounded circuit?
 - Could this have been an organophosphate poisoning or lead poisoning from a used battery?
 - Could the animals have licked an empty container, sprayer or even a planter? Could a sprayer have been filled from a water source without a back-flow device?
 - Could this have been caused by vandalism of a former employee, neighbor, or family member over some dispute?
 - Could this have happened through an unintentional mix-up, (i.e. pesticide rinse-ate stored in a silage preservative container)?
 - Obtain supportive evidence such as photographs, invoices, statements or affidavits substantiating suspected contamination sources and violations.
- **Information obtained on the feed(s):**
 - Name and type of all feeds, used, including lot numbers when available.
 - Name and address of the supplier and/or manufacturer. If products were custom-mixed, who mixed and furnished ingredients.
 - Description of type of container, amount purchased/on hand, invoice number, and purchase date.
 - Where have the manufactured or custom-mixed product(s) been stored? Where have the custom- mixed ingredients been stored? Were second-hand bags used?
 - Is there a possibility that this product was contaminated due to improper storage of chemicals and feeds? How about the vehicle that transported the feed?
 - Details of feeding history, amount fed, rate of feeding, details on other supplements, medications and length of time the product has been fed.
 - What was the source of water supply and condition of feeding area?
- **Feed Supplier and/or Manufacturer**
 - Many toxic response investigations involve the feed mill. Visit the manufacturing facilities to obtain a complete picture of the feed in question.
 - The establishment will have a food safety plan that contains at least their written hazard analysis. If they have identified a hazard requiring a preventive control, then the establishment will also have a recall plan. Some establishments may have a recall plan because of best practices. If the firm has been notified of the animal food in question, have they implemented their recall plan?
 - If available, sample ALL feed and feed ingredients supplied by the mill that was sold or custom- mixed relative to the investigation. All formula feeds sampled should have the same lot number as the feed samples on site. (All feeds and ingredients may not necessarily be analyzed at the lab, however, often the evidence may be short lived or cause you to return a second time to sample such feed).
 - Attempt to get more background information to confirm the issues given by the complainant. Obtain copies of the last several purchases done with the mill. Could this have been caused by a mineral deficiency, followed by free-feeding?
 - Tactfully question any outstanding bill(s) that may exist between the mill and the complainant. (It has happened that the complainant has adulterated the feed given to their own animals and sued the mill for exactly the amount owed the mill).

TOXIC RESPONSE

Chemical and other contaminant problems have pointed out the need for emergency preparedness procedures. (A toxin, as used here, includes pesticides and other substances which may contaminate human or animal food products and cause them to be illegal for sale, or dangerous if allowed into the food chain). Animal poisoning incidents are extremely costly in terms of direct and indirect economic losses attributable to the time and effort required to determine the cause and assure that contaminated products are destroyed.

Types of contaminants are:

- Natural (e.g. mycotoxins, molds, insects, bacteria, salmonella)
- Pesticides
- Heavy Metals
- Industrial chemicals (e.g. PCB's, oils)
- Animal drugs (carry-over, wrong drug, wrong amount)

Contain the problem

If possible:

- Hold milk, meat or eggs until determined to be safe.
- Hold dead animals until it's determined they're safe for rendering.
- Hold feed until it's determined to be safe.

Where to Get Help

- State Veterinarian
- State Toxicologist
- FDA
- National Animal Poison Control Center Hot-line: Tel# 217-333-3611

When Contamination Source is Identified

If needed, make sure that all contaminated feed, food, and animals are prevented from moving in the food chain.

Work out disposal plans for contaminated products.

CHAPTER 6 CGMP

CGMPs MEDICATED FEED & OTHER ANIMAL FOOD

There has been CGMP (Current Good Manufacturing Practices) requirements for animal food facilities which manufacture medicated animal food required by 21 CFR part 225. Now with the implementation of FSMA, we now have CGMPs for all animal food manufactured processed, packed and held in the US. This included any animal food manufactured animal food manufactured in foreign countries to be utilized in the US. These rules are regulated under 21 CFR part 507, (FSMA). In addition, each of your states may have certain CGMP requirement under your own state laws.

Before conducting any federal CGMP, an inspector must have the legal authority to do so e.g., current contract with the FDA for the particular CGMP you are performing, or your state has adopted the federal language into your state law. You should discuss this with your supervisor to see if you do have the needed authority and have been trained by the FDA.

MEDICATED ANIMAL FOOD

The passage of the Animal Drug Availability Act (ADAA) in October of 1996, abolished medicated feed applications (Form FDA 1900) and established medicated feed mill licenses, (Form FDA 3448). The ADAA amended the FFD&C Act to require a single medicated feed mill facility license to manufacture feeds that were previously covered by multiple Medicated Feed Applications (MFAs). New regulations, contained in 21 CFR Part 515, governing medicated feed mill licenses were published on November 19, 1999. Any new animal drug approved for use in animal feed is placed in one of two categories, Category I or II (see definitions below). Firms using Category II Type A Medicated Articles to make medicated feeds are required to register with FDA and hold an approved medicated feed mill license. FDA is required to inspect these firms once every two years. Regulations governing the manufacture of medicated feeds are published in 21 CFR Part 225.

On May 28, 2003 (68 FR 31645), in the Federal Register, CVM proposed changes to the regulations for liquid medicated feed and free-choice medicated feed. The final rule published on May 27, 2004 (69 FR 30194) with an effective date of June 28, 2004. The final rules adopted the proposed rules without change. For both the liquid and free-choice medicated feed final rules, FDA concluded that an approved medicated feed mill license is required for facilities that manufacture feeds using Category II drug(s) or manufacture those products using Category I drug(s) that must follow proprietary formulas or specifications. This means that certain liquid and free-choice medicated feeds will no longer require an approved medicated feed mill license for their manufacture.

For the most current information regarding the labeling of medicated feeds, please visit the following website:
<https://www.fda.gov/animalveterinary/products/animalfoodfeeds/medicatedfeed/bluebirdlabels/default.htm>

For the most current information regarding 21 CFR Part 558, New Animal Drugs for Use in Animal Feeds, please visit the following website:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=558>

CATEGORIES

Category I Drugs

Drugs that have no required withdrawal period at the lowest continuous feeding level for any approved animal species.

Category II Drugs

Drugs that either requires a withdrawal period at the lowest continuous feeding use level in at least one animal species for which the drug is approved or are regulated on a “no-residue” basis because of carcinogenic concern.

TYPES

FDA has further classified medicated feed products into one of three **TYPES**, (A, B, or C), based on the concentration of the drug in the feed product:

Type A Medicated Article

A Type A Medicated Article is a concentrated product containing one or more drugs which are intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed.

All Type A medicated articles are new animal drugs and the manufacturer of Type A articles are subject to an approved new animal drug application (NADA), if manufactured from drug components.

Manufacturers producing medicated feeds requiring an approved medicated feed mill license are subject to the full set of current Good Manufacturing Practices (CGMP's) in 21 CFR Sections 225.10 through 225.115. The CGMP's specify detailed practices, controls and record keeping requirements. For feeds requiring a medicated feed mill license, the CGMP's also require manufacturers to assay three samples of medicated feed containing each drug or drug combination used each year. Manufacturers holding an approved medicated feed mill license also are subject to inspection by the FDA every two years. A detailed explanation of the CGMP's can be found in the FDA Compliance Program Guidance Manual (CPGM) 7371.004 in addition to the Feed Additive Compendium.

Type B Medicated Article

A Type B medicated feed is intended solely for manufacture of another Type B or Type C medicated feed and is less concentrated than Type A articles.

Type B Medicated Feed is produced by diluting a Type A Medicated Article or another Type B Medicated Feed, or is produced from a non-standardized drug component (bulk or "drum-run"), which is a dried crude fermentation product. Often they will contain a substantial quantity of nutrients including vitamins and/or minerals and/or nutritional ingredients in the amount not less than 25 percent of the weight.

For the Category I drugs, the maximum concentration allowed for a Type B feed is 200 times the maximum approved continuous use level. For Category II drugs, the maximum concentration allowed for a Type B feed is 100 times the maximum approved continuous use level. Drug concentrations above these maximum levels are prohibited in Type B feeds and are only found in Type A articles.

Type C Medicated Article

A Type C medicated feed contains drugs at a level that may be offered in a complete feed for animals or may be fed top dressed or offered free choices in conjunction with other animal feed.

They are not intended for mixing.

It is normally produced from a Type A medicated article or a Type B medicated feed.

Medicated feed manufacturers do not need a medicated feed mill license or to register with FDA if they produce: 1) medicated liquid and free-choice feeds only using Category I drugs and a published formula and/or specifications; and 2) other medicated feeds only using Category I, Type A, B, or C and/or Category II Type B and C medicated products.

These manufacturers are subject to the less stringent set of current Good Manufacturing Practices (CGMP's) found in 21 CFR Sections 225.120 through 225.202.

REGULATORY SCHEME FOR MEDICATED FEED PRODUCTS

Regulatory Scheme		
	Category I Drugs	Category II Drugs
Mfg. of Type A Medicated Article	Premixes containing drugs at levels greater than permitted in Type B feed FDA-356 Approval Required	Premixes containing drugs at levels greater than permitted in Type B feed FDA-356 Approval Required
Use of Type A Medicated Article	License and registration required, and full CGMPs apply if manufacturing medicated liquid feeds or medicated free-choice feeds with a proprietary formula and/or specifications; otherwise: <ul style="list-style-type: none"> • No license • No establishment registration • 21 CFR 225.120-202 CGMP's apply • No required drug assays 	<ul style="list-style-type: none"> • License required • Establishment registration • Subject to FDA inspection every two years • Full CGMPs apply • For feeds requiring a license, assay three samples containing each drug or drug combination used each year

<p>Use of Type B or Type C Medicated Feed</p>	<p>License and registration requirements, and full CGMPs apply if manufacturing medicated liquid feeds or medicated free-choice feeds with a proprietary formula and/or specifications; otherwise:</p> <ul style="list-style-type: none"> • No license • No establishment registration • No mandatory FDA inspections • Relaxed CGMPs apply • No required drug assays 	<p>License and registration requirements, and full CGMPs apply if manufacturing medicated liquid feeds or medicated free-choice feeds; otherwise:</p> <ul style="list-style-type: none"> • No license • No establishment registration • No mandatory FDA inspections • Relaxed CGMPs apply • No required drug assays
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* Feed Additive Compendium, 201

Preventative Controls for Animal Food (PCAF) Rule CGMP & PC Inspections for FSMA

Before you conduct any federal CGMP, you must have the legal authority to do so e.g., current contract with the FDA for the particular CGMP you are performing or you state has adopted the federal language in to your state law.

The Food and Drug Administration (FDA) is adding regulations (21 CFR part 507) for the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals. These regulations will, for the first time, establish requirements for the current good manufacturing practice (CGMP) for food for animals. In addition, FDA is adding requirements for certain domestic and foreign animal food facilities to establish and implement hazard analysis and risk-based preventive controls for food for animals. FDA is taking this action to provide greater assurance that animal food is safe and will not cause illness or injury to humans and animals and to implement new statutory provisions in the FDA Food Safety Modernization Act (FSMA). The rule is intended to build an animal food safety system for the future that makes modern science- and risk-based preventive controls the norm across all sectors of the animal food system. The FDA Food Safety Modernization Act (FSMA) signed into law by President Obama on January 4, 2011, is intended to allow FDA, and their state partners, to better protect public (human and animal) health by helping to ensure the safety and security of the food supply. FSMA enables us to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. The law also provides new enforcement authorities to help achieve higher rates of compliance with risk-based, prevention-oriented safety standards and to better respond to and contain problems when they do occur. In addition, the law contains important new tools to better ensure the safety of imported foods and encourages partnerships with State, local, tribal, and territorial authorities.

This rule is part of FDA’s implementation of FSMA, which intends to better protect public (human and animal) health by, among other things, adopting a modern, preventive, and risk-based approach to food safety regulation. This rule establishes new requirements for the production of animal food by registered food facilities in two ways. First, this rule creates new CGMP regulations that specifically address the manufacturing, processing, packing, and holding of food for animals. These requirements apply to establishments that are required to register with FDA as a food “facility.” Second, this rule creates new requirements for certain domestic and foreign facilities to establish and implement hazard analysis and risk-based preventive controls for food for animals. As with the CGMPs, these requirements apply to establishments that are required to register with FDA as a food facility. This portion of the rule requires registered animal food facilities to maintain a food safety plan, perform a hazard analysis, and institute preventive controls for the mitigation of those hazards, unless an exemption applies. Facilities must also monitor their controls, conduct verification activities to ensure the controls are effective, take appropriate corrective actions, and maintain records documenting these actions. These CGMPs establish baseline standards for producing safe animal food that take into consideration the unique aspects of the animal food industry and provide flexibility for the wide diversity in types of animal food facilities.

The Preventive Controls for Animal Food (PCAF) rule establishes CGMP provisions to ensure the safety and suitability of animal food. Specifically, the rule establishes requirements in the following areas:

- Personnel;
- Plant and grounds;
- Sanitation;
- Water supply and plumbing;
- Equipment and utensils;
- Plant operations;
- Holding and distribution; and
- Holding and distribution of human food by-products for use as animal food.

The PCAF rule implements the requirements of FSMA for covered facilities to establish and implement a food safety system that includes a hazard analysis and risk-based preventive controls. Specifically, the rule establishes requirements for:

- A written food safety plan;
- Hazard analysis;
- Preventive controls;
- Monitoring;
- Corrective actions and corrections
- Verification;
- Supply-chain program;

- Recall plan; and
- Associated records.

Although there are similarities between these requirements of FSMA and the requirements of food safety systems known as Hazard Analysis and Critical Control Point (HACCP) systems, not every provision in FSMA is identical to the provisions of HACCP systems, and we have revised much of our terminology to distinguish FSMA's requirements for hazard analysis and risk-based preventive controls from HACCP requirements.

State partners and other regulatory partners will receive extensive training from FDA prior to conducting these inspections. The training will be specific to animal food and will include information on developing a food safety plan tailored to each facility's unique hazards.

This rule will require ALL animal food facilities that manufacture, process, pack or hold animal food and are required to register under section 415 of the Food, Drug & Cosmetic Act (FD&C Act) to be inspected. This may include facilities that have never been inspected for compliance before. There will also be facilities that are subject to both CGMP requirements of 21 CFR part 225 and 21 CFR part 507. Facilities that are manufacturing, processing, packing, or holding animal food and are producing medicated feed must comply with the CGMP requirements for licensed or non-licensed mills found in 21 CFR part 225. For example, a feed mill, manufactures both non-medicated feed and medicated feed, its production of non-medicated feed is subject to 21 CFR part 507, subpart B, and its production of medicated feed is subject to 21 CFR part 225 and part 507, subpart B.

PRE-INSPECTION PREPARATION

Preparation may be the best time spent in conducting the inspection. Review previous inspection(s) reports, if available. Review the Summary of Findings of the prior inspections to become familiar with all aspects of the firm or operation.

Note names of responsible individuals for each phase (these may change from inspection to inspection). Is the firm registered as required under 415 of the FD & C Act, if the firm is a licensed medicated feed mill, is their drug establishment registration current?

Note the type of operation from previous inspections, (commercial feed mill, mixer/feeder operation, customer formula mixer, warehouse, ingredient manufacturer, pet food manufacturer). Note previous violations. This allows the inspector to specifically note changes and gives some insight into management's feeling toward CGMP's (pays little or no attention to the previously noted discrepancies, attempted corrections with little results, made all corrections immediately, etc.)

Make sure all needed equipment and reference materials are available during the inspection.

- For FDA required forms please reference the FDA's website for the most up to date version of all forms. Formal training for administering and completing the FDA cGMP checklist is conducted by the FDA.
- Typical forms required for an FDA Medicated Feed Mill Inspection include 482 (Notice of Inspection), 2481 (Medicated Feeds Inspection Report), and 483 (Inspectional Observations) 3719 (BSE Checklist). <http://www.fda.gov/aboutfda/reportsmanualsforms/forms/default.htm>
- Compliance Program Guidance Manual 7371.004
- Feed Additive Compendium (with Conversion Tables). This publication is very useful in determining approved levels. However, it can be out of date or incorrect. The ultimate source is 21 CFR (Code of Federal Regulations). Copies may be obtained through the federal government.
- Note Paper, scratch pads, etc.

CGMP Entrance to the Firm - Introductory Steps

Determine the most responsible person on the premises (President, General Manager, etc.). Introduce yourself and present your credentials stating the purpose of your visit. Since you make many visits to these same firms as an inspector for the purposes of sampling, auditing, etc., the purpose of each visit must be clearly stated to the firm.

CHAPTER 7 FEED INGREDIENTS

INGREDIENT SAFETY

In recent years, consumers, manufacturers and regulators have become increasingly focused on food safety. Food safety begins with ingredients.

The Food Safety Modernization Act of 2010 mandates that the FDA develop regulations where most food and feed manufacturers and importers will be required to assess and document the risks inherent in their ingredients, processes and products and develop programs to prevent safety issues from arising. Some examples of international and U.S. programs to assist suppliers and feed manufactures in ensuring their products are safe are:

- Safe Feed/Safe Food (American Feed Industry Association (AFIA))
- International Safe Feed/Safe Food (AFIA/European Union (EU) Association of Specialty Feed Ingredients and their Mixtures (FEFANA)
- FAMI-QS Certification (FEFANA)
- HACCP Certification (various certifiers)
- NGFA Feed Quality Assurance Program (National Grain & Feed Association)
- AAFCO Good Manufacturing Practices Guidelines

It is impractical for manufacturers and distributors to test each and every ingredient and final product for every possible contaminant or unsafe levels of ingredients. Though not complete, the following narrative provides some basic descriptions of practices that promote product safety.

Characteristics

Physical characteristics of an ingredient should be monitored, upon receipt. It should be visually examined to make sure it looks and smells as expected. For example, fishmeal should smell like fishmeal.

The weight of a load should be consistent with past loads. For example, if a truck's capacity changes from 23 tons of a product to 21 tons, the variance should be investigated and explained.

In determining physical characteristics of an ingredient, the label and Safety Data Sheet (SDS) should be read. Some ingredient labels and SDS' carry warnings requiring protective equipment to be used when handling. Follow all label and SDS cautions and warnings prior to handling any product.

Labeling

Adequate and accurate labeling for each ingredient received at a facility is imperative. If one is not provided, it should be demanded of the supplier. If meat and bone meal was ordered, the label should state meat and bone meal, not meat meal.

Labels should include required information on how to safely and effectively use the ingredient. For some ingredients, such as soybean meal, labeling may only display protein, fat, and fiber guarantees. However, drug labels should include directions for use, warnings, cautions, and handling instructions. Under the U.S. Bioterrorism Act, products must be traceable one step back and one step forward. Normally, information pertinent to traceability would be on the product label, and on shipping papers for bulk products.

Assays

While many tests may be costly, with a little planning and forethought, assays can be very beneficial and an economically sound management practice.

Complete records of all incoming ingredients and outbound products must be maintained for at least two years. Samples do not necessarily have to be analyzed, but should be saved for a length of time appropriate for the feed or feed ingredient. Feed products being investigated occasionally will have been consumed, with none remaining for sampling.

Integrity

Bins and containers must be properly labeled so there is no question to what ingredient is in what location. If the identity or integrity of an ingredient is lost, it is virtually useless.

Bulk bins need to be cleaned prior to receiving an ingredient to prevent carryover and/or contamination. Augers, pits, and handling equipment need to be cleaned, as well.

Open bags should have the tops rolled down to prevent dust or other contaminants from getting inside. This is extremely important where medications are concerned.

Management

Inventory needs to be managed on a first-in, first-out basis and in quantities to avoid decomposition and loss of potency.

Spills, broken bags, and floor sweepings should be cleaned up and disposed of regularly to minimize pest infestation.

Contaminants

- **Molds**
Grains and other feed ingredients may be susceptible to molds, which can destroy the quality of grains and other ingredients and produce mycotoxins that are dangerous to animals.
- **Insects**
Insect infestation can destroy grains in storage. Grains should be monitored for insect infestation and professionally treated. Infestation can be discovered within a few days of sampling a grain.
- **Oxidation**
Some ingredients, such as Vitamin A deteriorate when exposed to air.
- **Humidity or Water**
High humidity or water damage may cause ingredients to dissolve, clump, cake, or set up, making it difficult to mix uniformly into feeds. Ingredients should be stored off concrete floors and roof leaks repaired.
- **Pests**
Rats, cats, and birds can carry and transmit diseases. Steps should be taken to minimize their existence in a facility.

Ingredient Composition

Ingredients supply various nutrients to the feed. Protein may come from one or two sources, calcium from three or four, while other nutrients may come from a single source.

Some ingredients going into feed may be produced chemically or have a known nutrient value. Other ingredients, such as corn or grains, may vary widely in their nutrient compositions. A variety of factors, including growing conditions and harvesting techniques, play an important role in determining the final energy and protein level in a crop. Manufacturers should be urged to obtain as much information as possible as to what grain levels will be running from year to year, especially in their locale.

- The most comprehensive list of acceptable feed ingredients, with correct nomenclature, may be found in the Association of American Feed Officials Official Publication.
- The Miller Publishing Company publishes an annual Reference Issue & Buyers Guide listing nutrient values for various common feed ingredients. It is available by subscription and may be found at <http://fdsmagissues.feedstuffs.com/fds/ReferenceIssue2012.html>
- The Miller Publishing Company/Feedstuffs also offers the Feed Additive Compendium, by subscription. It is a guide to the use of medicated ingredients and may be found at <http://www.feedcompendium.com>

Other ingredient references include:

- Title 21 of the Code of Federal Regulations (21 CFR, Subchapter E) <http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR>
- FDA website at <http://www.fda.gov/AnimalVeterinary/default.htm>

CHAPTER 8 VFD

WHAT IS A VFD?

The Food and Drug Administration's Center for Veterinary Medicine (CVM) on Dec. 8, 2000, published final regulations implementing the Veterinary Feed Directive (VFD) provisions of the Animal Drug Availability Act of 1996. The VFD Rule was amended and final changes published on June 3, 2015.

VFD drugs are animal drugs intended for use in or on animal feed, and are limited to those drugs approved for use under the professional supervision of an appropriately licensed veterinarian in the course of the vet's professional practice, where a valid veterinarian-client-patient relationship exists. The VFD is a written statement issued by a veterinarian authorizing a client (animal producer) to obtain and use a VFD drug to treat their animals.

During its development, CVM supported the VFD concept as a means to reduce unnecessary use of certain antimicrobial drugs in animals and to slow or prevent the potential increase of bacterial resistance to antimicrobial drugs. CVM also endorsed the VFD provisions because the regulations allow animal producers to continue to obtain needed drugs in a timely and effective manner. In contrast, the process of administering such drugs by prescription would be cumbersome, and would result in state board of pharmacies becoming involved with the regulations and dispensing practices associated with distributing medicated feeds.

THE VFD PROCESS

Under the VFD process, an appropriately licensed veterinarian, operating within the confines of a valid veterinarian-client-patient relationship, examines and diagnoses animal conditions and determines whether a condition warrants use of a VFD drug. If it does, the veterinarian will issue a signed VFD containing information specified by regulation. Extra-label use of a VFD drug is not permitted by anyone, including the veterinarian. The VFD form has at least 3 copies.

The veterinarian keeps a copy of the original VFD order in its original form (electronic or hardcopy). The veterinarian is required to send a signed copy to the distributor and the animal producer. The veterinarian, animal producer, and distributor must keep a copy for two years. The VFD authorizes the VFD feed to be shipped to the producer's animal feeding operation.

Anyone intending to distribute VFD feeds must notify CVM prior to beginning distribution. The term "distributor" includes the VFD feed manufacturer, feed retailer, veterinarian, or anyone in the distribution chain who ultimately supplies VFD feed to an animal producer. This could include the veterinarian if they are the source of VFD feed. A VFD feed may not be distributed to an animal producer without a signed VFD. However, VFD feed may be sent down the distribution chain if the consignee provides the distributor with a signed acknowledgment letter affirming that it will only ship the VFD feed to a VFD holder or to another distributor who supplies a similar acknowledgment letter.

WHAT HAS TO BE SPECIFIED ON THE VFD FORM?

- Veterinarian's name, address and telephone and number.
- Client's (animal producer) name, business or home address and telephone number.
- Premises where the animals specified in the VFD are located.
- Date VFD was issued.
- Expiration Date of the VFD.
- Name of the VFD drug(s).
- Species and production class of animals to be fed the VFD feed.
- Approximate number of animals to be fed the VFD feed by the expiration date of the VFD.
- Indication for which the VFD is issued;
- Level of VFD drug in the feed, and the duration of use;
- Withdrawal time, special instructions, and cautionary statements.
- Number of reorders (refills) if permitted by the approval.
- The statement: "Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extra label use), is not permitted."
- Affirmation of intent for combination VFD drugs.
- Veterinarian's electronic or written signature.

Optional Information:

- More specific description of the location of treated animals (e.g., site, pen, barn, stall, tank, or another descriptor the veterinarian deems appropriate);
- Approximate age and weight range of the animals
- Any other information the veterinarian deems appropriate to identify the animals.

COMMON QUESTIONS AND ANSWERS

What does the term “appropriately licensed” veterinarian mean?

The term “appropriately licensed” veterinarian means that the veterinarian has a valid license to practice veterinary medicine in the State in which the animals being treated are located. It is the veterinarian’s responsibility to be familiar with the licensing and practice requirements in each State in which they practice medicine.

What is a valid veterinarian-client-patient relationship?

FDA is requiring that any veterinarian issuing a VFD be licensed to practice veterinary medicine and operate in compliance with appropriate State defined veterinarian-client-patient relationship (VCPR) requirements or Federally defined VCPR requirements where no applicable and appropriate State VCPR requirements exist. Some States’ licensing and practice requirements specify that a VCPR as defined by that State’s law must exist before a VFD can be issued. In those States with VCPR requirements that include the key elements of a VCPR as described in the Federal definition (§ 530.3(i)), FDA intends to defer to the State VCPR requirement.

Title 21 Section 530.3(i) (1) of the Code of Federal Regulations (CFR) states that a valid veterinarian-client-patient relationship is one in which:

- A veterinarian has assumed the responsibility for making medical judgments regarding the health of (an) animal(s) and the need for medical treatment, and the client (the owner of the animal or animals or other caretaker) has agreed to follow the instructions of the veterinarian; and
- There is sufficient knowledge of the animal(s) by the veterinarian to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s); and
- The practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy. Such a relationship can exist only when the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of examination of the animal(s), and/or by medically appropriate and timely visits to the premises where the animal(s) are kept.

What is the Distributor Notification Process?

All distributors are to submit a one-time notification letter to FDA of their intent to distribute medicated feed containing a VFD drug prior to beginning their first distribution. The term “distributor” means any person who distributes a medicated feed containing a VFD drug to another distributor or to the client-recipient of the VFD. A distributor notification is to include the name and address of each business site from which distribution will occur.

What is an Acknowledgment Letter?

An acknowledgement letter is a letter that a distributor obtains from a consignee-distributor when the distributor ships an animal feed containing a VFD drug in the absence of a valid VFD. The term “acknowledgement letter” means a written communication provided to a distributor by a consignee who is not the ultimate user of medicated feed containing a VFD drug. It affirms that the consignee will not ship such medicated animal feed to an animal production facility that does not have a VFD, and will not ship such feed to another distributor without receiving a similar acknowledgment letter. The acknowledgement letter also is to contain a statement from the consignee-distributor that it has sent a notification letter to CVM informing the agency that it will be distributing VFD-containing feeds.

Can a VFD medicated feed be produced without a VFD order?

Yes. VFD medicated feeds may be produced and distributed so long as the parties involved provide the required notification letters to FDA and obtain/provide the acknowledgement letters required by the regulation. However, a valid VFD order is required before a distributor provides the VFD medicated feed to an animal producer.

What are the methods by which a VFD order can be transmitted to the feed distributor?

VFD orders may be transmitted by paper copy or by facsimile or other electronic means.

When the order is both generated and transmitted electronically to the distributor using technologies that are in compliance with 21 CFR, Part 11 – Electronic Records, Electronic Signatures, such an order is referred to as an eVFD or eVFD order.

Can a VFD order be transmitted by telephone?

No. Telephone orders are not allowed.

Can a VFD order be transmitted via the Internet?

Yes. A VFD order can be transmitted by facsimile or other electronic means. The phrase “other electronic means” includes the Internet. For example, transmitting the VFD by “other electronic means” includes using the Internet to transmit the image of a paper VFD order (e.g., e-mailing a scanned VFD document), or using the Internet to transmit an eVFD order generated in a system that is shown to be in compliance with 21 CFR, Part 11.

What constitutes the “original signed VFD” order?

For purposes of a paper VFD order, the term “original signed VFD” means the original paper VFD order hand signed by the issuing veterinarian. When an electronic VFD order is used, the term means the eVFD order electronically signed by the issuing veterinarian with the veterinarian’s authorized electronic signature.

How long are VFD and eVFD orders and records to be retained?

All parties are required to keep VFD orders for a period of two years from the date of issuance. Feed distributors are to keep records of receipt and distribution of all medicated animal feed containing a VFD drug for 2 years from date of receipt and distribution.

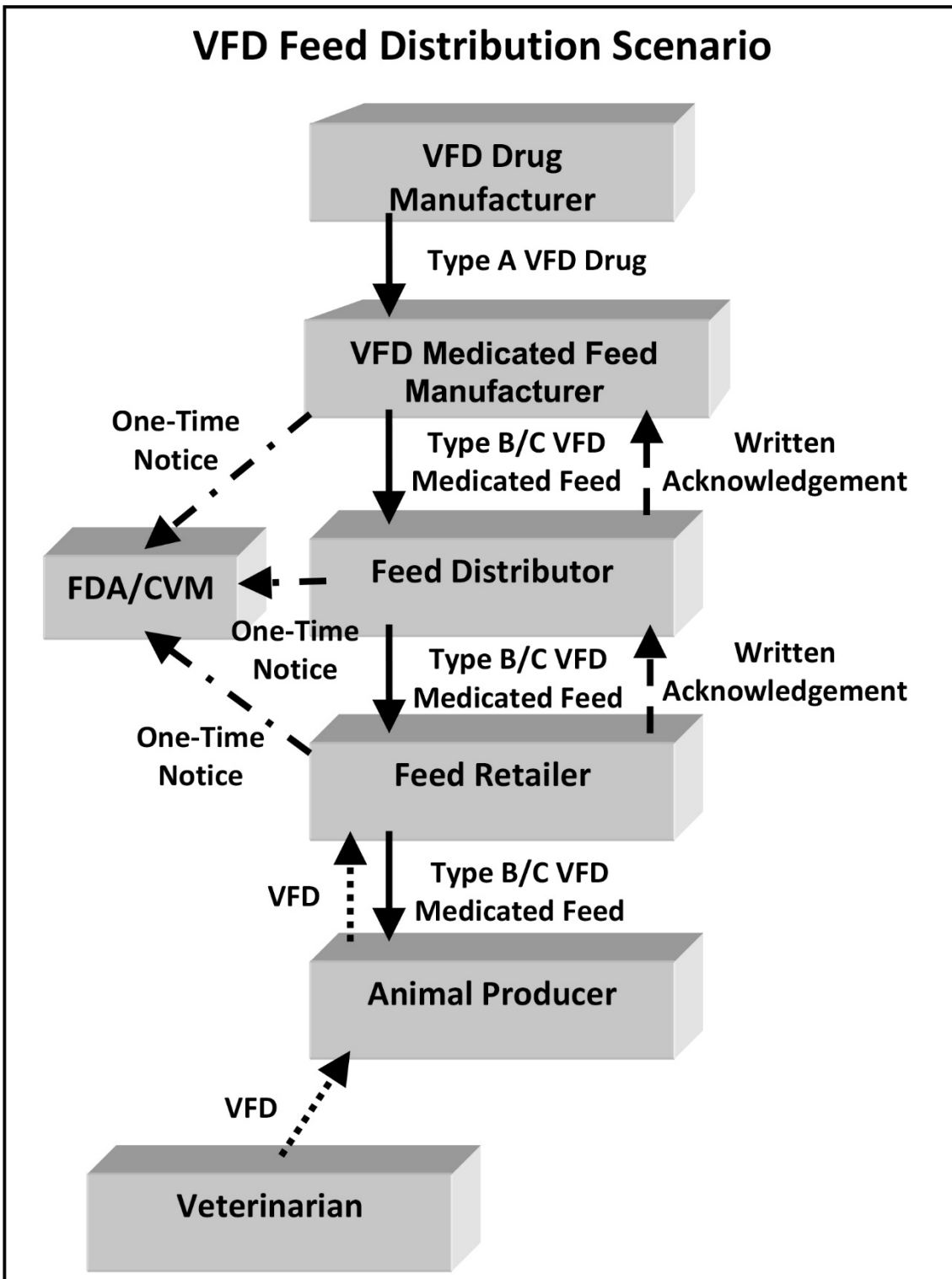
Can a veterinarian, distribute, or sell feeds containing VFD drugs?

Yes. The veterinarian would be required to comply with the VFD distributor requirements.

Where are the rules concerning VFDs published?

CVM’s final rule is published on pages 31708–31735 of the June 3, 2015, *Federal Register* (Volume 80, Number 106). The following Code of Federal Regulation (CFR) sections contain information pertaining to the rule’s provisions:

- 21 CFR 510.300 (a) (4): Records and reports concerning experience with new animal drugs.
- 21 CFR 514 New Animal Drug Applications
- 21 CFR 558 New Animal Drugs For Use In Animal Feeds
- 21 CFR 558.3 Definitions Section
- 21 CFR 558.6 (a) General Requirements related to VFD Drugs
- 21 CFR 558.6 (b) Responsibilities of the Veterinarian Issuing the VFD
- 21 CFR 558.6 (c) Responsibilities of Any Person Who Distributes an Animal Feed Containing a VFD Drug or Combination VFD Drug



CHAPTER 9

BSE

WHAT IS BOVINE SPONGIFORM ENCEPHALOPATHY?

Bovine Spongiform Encephalopathy is a progressive and fatal neurological disorder affecting the central nervous system of cattle. The disease was first diagnosed in 1986 in Great Britain and at its peak in January 1993 roughly one thousand new cases per week were being reported. Over the succeeding years, BSE has had a significant impact on livestock industries throughout the world. Besides Great Britain, the disease has been confirmed in a number of other countries including most of the countries of the European Union, Israel, Japan, Canada, the United States and others. Import restrictions and feed controls implemented by many countries in response to the BSE crisis have been highly effective in reducing the number of new cases of BSE. In addition to the regulatory controls suggested above, research has also been occurring, and we now recognize two different types of BSE, the “classical” and “atypical.” We will discuss this difference in a little more detail below, but it is important to note that only two cases of classical BSE were reported worldwide in 2016.

Unlike other diseases, BSE is not caused by a virus, bacterium, or parasite. BSE is classified as a transmissible spongiform encephalopathy (TSE). TSE diseases are thought to be caused by a misfolded form of a normal cell protein, known as a prion protein. The disease-causing version somehow changes native prion proteins into the harmful version, which damages the central nervous system leading to fatality.

During the incubation period, which could range between two and eight years, cattle infected with BSE show no clinical signs of the disease. Once symptoms occur, the affected animals change their behavior and display changes in temperament, such as nervousness or aggression, abnormal posture, difficulty in rising, decreased milk production, and loss of body weight despite continued normal appetite. Due to the clinical manifestations of these changes, BSE has been called “Mad Cow” disease.

Other species of animals are also susceptible to TSEs. Examples include scrapie in sheep and goats, and chronic wasting disease in deer and elk. During the early years of the BSE epidemic in the UK, cases of feline spongiform encephalopathy were identified in cats that had consumed beef products that were derived from cattle suffering from BSE. In humans, sporadic Creutzfeldt-Jakob disease (sCJD) is a TSE that occurs worldwide at a relatively stable rate of about 1-2 cases per million population per year. Variant Creutzfeldt-Jakob disease (vCJD) in humans is a new TSE disease caused by exposure to the BSE agent through the consumption of beef products derived from BSE infected cattle. According to the Centers for Disease Control (CDC), as of October 2014, approximately 220 cases of vCJD had been reported worldwide, 177 of these cases in the UK and 27 cases in France. Four cases of vCJD have been diagnosed in the US, although all four of these people were born outside of the US, had spent considerable time outside of the country during their lifetimes, and are thought to have been infected outside of the US [EFSA Panel on Biological Hazards (BIOHAZ); EFSA Journal 2011; 9(1):1945].

MODE OF TRANSMISSION OF BSE

During the UK outbreak in the 1980s, BSE transmission was clearly shown to be linked to the use of meat and bone meal (MBM) as a supplement in cattle feed. Infectivity was recycled when MBM derived from infected cattle was fed to other cattle.

HAS BSE BEEN DETECTED IN ANY U.S. CATTLE HERDS?

Five cases of BSE have been detected in the United States. The first BSE case was detected in 2003 in a Holstein cow imported from Canada into the State of Washington. The second case occurred in 2005 in a 12 year old Brahman cross beef cow in Texas. The third case was a 10 year old red crossbred beef cow detected in 2006 in Alabama. The fourth case was a 10 year old Holstein cow in California in 2012 and the fifth case, an 11 year old beef cow in Alabama in 2017. Of these cases, only the first case was considered a case of “typical” BSE – the form of the disease responsible for most of the cases in Europe, and which is spread via contaminated feed. The other four cases were considered “atypical.” Atypical cases are almost always found in older animals, are thought to be spontaneous in origin, and are not believed to be linked to the consumption of contaminated meat and bone meal.

PROTECTING US CATTLE HERDS FROM BSE

Unlike diseases caused by more conventional infectious agents, and unlike scrapie and CWD, BSE is not spread from one animal to another by direct or indirect contact. As the disease progresses in cattle, the BSE agent accumulates in the central nervous system, mainly in the brain and spinal cord. Other cattle are not exposed to infectious levels of the BSE agent unless infected cattle or cattle byproducts are rendered into MBM and used in cattle feed. One of the unusual characteristics of TSE agents is that they are much more resistant to inactivation, including inactivation during the rendering process, than more conventional pathogens.

On August 4, 1997 the regulation published by FDA under 21 CFR 589.2000 became effective. This regulation, often referred to as the 1997 BSE feed rule, or feed ban, prohibits the feeding of most mammalian proteins to ruminant animals. These products are often referred to as “prohibited materials”. The regulation exempts blood and blood products, gelatin, inspected meat products which have been cooked

and offered for human consumption and then further heat processed for feed (plate waste, used cellulosic food casings), milk products, and any product whose only mammalian protein consists entirely of porcine or equine protein.

On April 25, 2008, FDA published regulation 21 CFR 589.2001 further strengthening the 1997 mammalian protein ban. This regulation prohibits the use in all animal feed those tissues that are considered to be the highest risk for carrying the BSE agent, referred to in the regulation as cattle material prohibited in animal feed, or CMPAF. CMPAF includes the brain and spinal cord from cattle that are thirty months of age or older (the entire carcass if the brain and spinal cord are not removed), material from BSE-positive cattle, and mechanically separated beef derived from the above products. With the new regulation, 21 CFR 589.2000 was also amended to prohibit tallow (tallow is defined as the rendered fat of cattle) that contains more than 0.15% insoluble impurities from being used in ruminant feed. Tallow that contains more than 0.15% insoluble impurities and is derived from material containing CMPAF is prohibited in all animal feed. 21 CFR 589.2001 became effective April 27, 2009, with a compliance date of October 26, 2009.

Products allowed to be used in ruminant feeds

The following products are considered exempt under the regulation:

- Products not of mammalian origin
 - Marine (fish)
 - Poultry
 - Vegetable
- Products that are not considered to be protein, or which are highly processed proteins
 - Grease/Fat
 - Tallow (the fat of cattle, containing no more than 0.15% insoluble impurities)
 - Oils
 - Gelatin
 - Amino Acids
- Exempt Mammalian Protein:
 - Porcine Protein or Equine Protein
 - Blood and Blood Products
 - Milk Products
 - Plate Waste

In order for this regulation to be enforced, steps must be taken by all parties from the renderer down to the cattleman.

Who is affected by the ban?

- Renderers
- Protein Blenders
- Feed Manufacturers
- Distributors (Including Haulers)
- Persons responsible for feeding ruminant animals

Compliance Policy Guides, Guidance For Industry, and Other Materials

The FDA has compiled a large number of helpful documents on its BSE web page (link below), including a number of “Guidance for Industry (GFI)” and “Question and Answer” documents intended to assist the industry in complying with the regulations, as well as the “Compliance Program Guidance Manual 7371.009 – BSE/Ruminant Feed Ban Inspections” to assist the federal and state inspection force. Both types of documents, as well as a variety of other information related to BSE and FDA’s regulatory program, may be found on CVM’s website: <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/ComplianceEnforcement/BovineSpongiformEncephalopathy/default.htm>

Further, the FDA has also released a video entitled “Preventing the Spread of BSE”. This video contains information for truckers and other entities on methods to help protect our cattle herds from being infected with BSE. You can view the video on CVM’s website, at the same link above. The BSE Inspection Report Form (“BSE Checklist”) can be found at: <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM052412.pdf>

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CHAPTER 10 ENFORCEMENT

EDUCATION AND VOLUNTARY COMPLIANCE

The goal of all regulatory feed programs is to gain compliance with established laws, regulations, and policies. The two best means to gain compliance is through educational efforts and voluntary compliance.

I know you have heard the old phrase, “Ignorance of the law is no excuse!” While this is true, ignorance may be an obstacle that has to be overcome before any headway can be made. In this day and age of many regulatory agencies impacting upon agricultural businesses, the company may not be aware of all new laws or regulations they need to comply with.

Also, laws and regulations may be written in “legalese” and difficult for some to interpret as to what they mean in the everyday workings of their business. Education is time well spent. Once people understand what the law requires, they most likely will want to be in compliance.

Once people know the law, the battle will still not be won for a few cases. Many people, by their very nature, will see government influence as telling them how they should run their business and they resist this intrusion. Therefore, it is imperative that they not only understand the laws and regulations, but the intent behind them.

Voluntary compliance can often be gained by relating the benefits of complying with the law. Many rules and regulations are designed to make sure customers receive the proper products and know how to use them.

A good example involves making sure a customer formula label accompanies the feed with a bulk delivery. The law says a label has to accompany the feed to the farm. Many dealers will tell you that when they get to the farm, there is no place to leave the label. They say that they just blow away or the farmer doesn’t want it left there, he wants the company to mail it to him.

The law has that provision in it for two reasons. Ask the company what happens if the driver has an accident or spills the load? Does the driver know what is on the truck? Feeds may contain additives that would need to be known if an environmental cleanup was necessary. Also, which feeds go into which bulk bins? The driver may think he remembers the first compartment goes in bin 1 and the second into bin 2 but he may not be sure. If he has a label with him, he can verify that information for sure.

Also, what if a label is not left and the farmer misuses the feed? What if the feed contains Carbadox and the farmer really doesn’t understand what Carbadox is or how it is to be fed or used. Several cases have ended up in court because the farmer misused a medication or did not observe proper withdrawal times. All of which may have been avoided if a label had been left with the feed.

The farmer may have still misused the product, but the company would have avoided the liability of not having left the label. One firm decided to add rural mailboxes to each of their farms they delivered bulk feeds. The label was then placed in the mailbox. While you can’t make the consumer or farmer read the label, the mill had a policy in force that all their clients were aware of and may have headed off a liability lawsuit.

ENFORCEMENT: WHEN EDUCATION AND VOLUNTARY COMPLIANCE DON’T WORK.

The rest of this chapter is dedicated to the work performed by the AAFCO Enforcement Guidelines Task Force.

The history of AAFCO can be traced back to 1909 when control officials first convened and certain objectives were established: respond to industry questions with carefully considered composite opinions; prepare a uniform feed bill; formulate fair and equitable definitions, regulations and resolutions; consider acceptance of new ingredient definitions, and establish proper labeling requirements. Early in AAFCO’s evolution one of its most important purposes became promotion of uniformity in laws, regulations and enforcement policies. While AAFCO has long developed, maintained and revised model documents for feed laws, and regulations to support implementation of the laws, AAFCO has not, until now, specifically addressed provision of uniform guidance for enforcement.

The primary purposes of laws regulating animal feeds are the protection of animal health, the safety of the food supply, consumer protection and provision of a fair and just environment for conducting business in animal feeding stuffs. As found in the “AAFCO Philosophy”: “Feed regulations by themselves serve no useful purpose unless accompanied by a means of enforcement. Enforcement provisions must allow for the authority to verify compliance with regulations. Punitive actions for noncompliance must be provided for in regulations and need to be severe enough to act as a deterrent and yet not be crippling when imposed.” The AAFCO Philosophy further states, “Enforcement of regulations must be conducted by an independent and neutral group. Regulatory agencies must not have a vested interest in the outcome of enforcement and must not be accused of overzealous or complacent regulating.”

From the AAFCO Philosophy it is clear that AAFCO sees enforcement as an essential, but non-crippling deterrent, to be used impartially and without vested interest, only to the degree needed to obtain compliance, no more and no less. In today’s business environment with its

many perplexing problems, created in part by a dynamically changing feed industry and the internationalization of trade, it is a challenge to provide enforcement guidelines uniformly acceptable to all feed control officials, manufacturers, distributors and feeders. Only through intelligent planning and application, cooperative efforts and good judgment by all can enforcement guidelines be effective in promoting uniformity of action in obtaining compliance.

Outlook on Enforcement

These enforcement guidelines are provided with the intention of encouraging uniformity of enforcement by feed control officials; however, it is most important for all to recognize these are indeed guidelines, not a specific recipe to be blindly followed. It is clear that application of guidelines may vary somewhat in different environments, while guideline interpretations may be influenced or colored by local political realities.

With the size, diversity and complexity of the feed industry it would be difficult, if not impossible, to maintain a reasonable level of compliance without the acceptance and cooperation of the individual firms in the regulated community. Indeed, much of the success of feed regulatory programs is due to the cooperation received from industry in relation to their desire to ensure the safety, integrity and quality of the products they manufacturer and distribute.

Therefore, seeking voluntary compliance with the law should be given strong emphasis. The success of an enforcement program may be best measured by the level of industry compliance, rather than the number of citations issued. Correction of violative conditions or practices observed by an inspector and reported on the spot or described in the inspection report is highly encouraged. Such should go to the credit of the inspected firm and be recorded as part of a firm's compliance history.

It is particularly difficult to comply with laws and regulations when the requirements are not well known or understood. Industry participation in the development of regulations and policy is important in this regard. Providing educational programs for industry by control officials, especially for changes in old or initiation of new programs makes for smoother changes and less compliance conflict. Likewise, control official participation in industries' educational programs promotes understanding and a greater knowledge base for discussions and positive interaction on problem issues. In any situation, some form of education may be appropriate and actual training programs for employees of regulated firms may constitute compliance assistance.

To be reasonable, a regulatory official's inspection, sampling and analytical programs need to be representative and comprehensive. These must be done keeping in mind a potential need to blend proportional sampling with the attention and emphasis necessary to cover current problems, issues and bad actors. Inspection, sampling and investigation programs should be based on an annual review of past results which should also direct efforts to identified likely, future problem areas.

No guideline can be developed that is going to be current forever, and this is most certainly true today for feed regulatory enforcement guidelines. Thus, the guidelines being provided here represent today's environment with a view toward the future. As emphasis grows for process control based regulation, it will be necessary to be attuned to the potential need for guideline revision.

Selection of Enforcement Tools

If voluntary education and compliance are unsuccessful, then what should a feed control official do to achieve compliance? The answer to this question, unfortunately, is, "That depends." No two cases or sets of circumstances are quite identical. There are almost always several factors to consider before selection of an enforcement tool or tools and application of same for the purpose of achieving compliance. Some violations are only minor while others may be serious or very serious. Violation can be largely administrative or technical in nature. The following list of factors is provided as a guide for putting a violation into perspective.

- What is the nature or gravity of the violation? To what risks or potential risk has a violation exposed humans, animals or the environment? What level or potential level of harm/damage is associated with the violation?
- What is the violator's culpability? Is the violation an accident, mistake or omission or the result of intent, negligence, defiance, indifference, fraud, etc.?
- Has the violator shown good faith efforts to comply, be cooperative, correct errors or deficiencies?
- What is the history of prior violations including willingness and efforts to achieve compliance?
- If an economic penalty is available, what is appropriate for the current violation and business and would it provide the right economic deterrent to future violations?
- Can the state and the violator afford the resources to achieve compliance and are the resources in proportion to the violation and benefits of compliance?

Most of the enforcement tools provided here are found in the AAFCO Model Bill. Three tools are noted for their absence: mediation, referrals and civil penalties. Referrals are generally of two kinds: referral to a different regulatory agency with primary regulatory authority and referral to a regulatory agency with similar authority having better ability or more useful tools for dealing with the case in question.

Mediation may be a useful alternative means of compliance enforcement. It is a new concept that should be worked into your enforcement tool chest if it appears useful.

Civil penalties are sometimes seen as valuable tools by control officials while industry may sometimes find them objectionable for a host of reasons. Looking back at the “AAFCO Philosophy” one might ask when use of a civil penalty becomes a vested interest. When the penalty is automatic or used to finance a regulatory program, it may approach a conflict of interest situation. Since civil penalties can be reasonably applied and since several control officials have them in their current regulations, they are included here as an enforcement tool. Civil penalties are included here as an enforcement tool since they can be reasonably applied and several control officials have them in their current regulations.

ENFORCEMENT OPTIONS

Generally, it is good to leave room for progressive enforcement, so selection of an appropriate enforcement tool should normally allow opportunity for a more stringent action for a repeat violation or more grave violation of the same nature. Thus the following tools are generally arranged in progressive order.

Advisory or Informational Letter

This can be a form of both compliance assistance and education and would usually apply to non-repetitive violations of no risk to health, safety or the environment. Administrative violations involving licensing, product registration and payment of fees are examples.

Warning Letters with or without a Required Response

This tool would usually clearly outline the violation and require corrective action(s). The letter might or might not request a written response upon correction. This tool would be appropriate for violations that have or could present risk to health, safety or the environment. Further, it could be appropriate for repetitive administrative violations.

Withdrawal from Distribution Orders

This tool is appropriate when health, safety or the environment would be put at risk from distribution of a feed. It might also be used when other tools have failed to achieve compliance for serious administrative violations or gross labeling violations.

Informal Hearings/Meetings

This tool is appropriate for providing an opportunity to bringing together parties to discuss and understand the nature of a violation. It may lead to an agreed order or consent decree. Use of this tool would be appropriate for many violations including those that may be chronic; threats to health, safety or the environment; civil penalties and license denials/revocation or other serious administrative actions. This tool may be used in conjunction with others to facilitate compliance.

Mediation

A meeting of all parties which produces a consent decree or compliance agreement.

Civil Penalty

A civil penalty is a monetary penalty assessed for a violation. Civil penalty fines are based on a numeric point matrix determined by the severity of the violation and the repeat nature of the offense. A notice shall be given and an opportunity for an administrative (formal) hearing must be provided. This tool should be used in addition to other tools to prevent chronic violations or to address illegal acts when other tools are not available. Where appropriate, an informational letter, warning letter, informal hearing/meeting and/or administrative hearing should precede the use of civil penalties.

Cancellation, Probation or Conditional Status

These actions are usually taken against a license, permit or registration due to repeat violations, including reporting of distributions and payment of fees or chronic analytical deficiencies.

Administrative Hearing

An opportunity for an administrative (formal) hearing is provided to the regulated establishment prior to the issuance of a civil penalty, license denial or license revocation. An administrative hearing may result in a consent decree with the regulated establishment. This tool should be used in chronic violations or when threats to health or safety exist.

Condemnation and Confiscation

This tool may be applied to a lot of non-compliant feed and may involve a court in the local area. A feed found violative by the court may be subject to condemnation and disposition after first allowing the claimant/manufacture opportunity to seek release of the feed or request opportunity to reprocess or relabel the feed for compliance. This tool would be appropriate for use when a practice or product presents a risk to health, safety or the environment. It may also be applicable in other cases such as chronic violations.

Injunction

This tool may be used to restrain a firm from any or all violations. The tool would be used in case of a serious threat of immediate or irreparable harm. Use may also be appropriate to restrain a firm from operation in wanton violation of a chronic nature involving administrative aspects of the law.

Criminal prosecution

Prosecution in a court may be pursued against a firm or person that impedes, obstructs, hinders, or otherwise prevents or attempts to prevent enforcement of commercial feed regulation. This tool can be used for any violation, but other tools may be appropriate.

Many of these enforcement tools can be used together or in conjunction with one another, especially letters and stop sales. Use of tools in combination depends on the violation, response, compliance history and corrective actions required.

AAFCO ENFORCEMENT GUIDELINES FACTOR APPLICATION

Below is a listing and description of six (6) factors to consider when selecting an appropriate enforcement tool to deal with the finding of a violation in a product or product labeling, or in the manufacturing, holding/storage, and/or distribution process. Each factor description includes a numerical weight assigned to a relative condition of each factor. To use this guideline, select the most appropriate relative condition for each factor and note the numerical value. The total numerical value combined for all of the factors could then be used to help select the appropriate enforcement tool from the Violation Chart.

A sample Violation Chart follows this discussion of Factors. The chart suggests five (5) major categories of violations but could be modified to include additional violation categories or to break the larger category into more than one. The sample chart includes four (4) ranges of factor values but the chart could be modified to include more or less numbers of value ranges, or the values within a range could be modified. The modifications are suggested to meet the needs of any particular state.

Factor 1 – History of the Firm

The history of regulatory contact with a firm or individual can be indicative of their commitment to assuring they are operating in compliance. History can include inspections, sample analysis, label reviews, and previous enforcement actions. It should include consideration of whether corrections were promised and completed, whether corrections were made promptly, and whether the same or similar problems occur repeatedly. The following relative weights can be used in assessing the history of the firm:

- (0) Firm has extensive history and is always found in compliance
- (1) No history on file for this firm
- (2) Firm's history shows only minor violations, always corrected
- (3) Firm's history shows instances of significant violations and/or repeated minor violations
- (4) Firm's history shows instances of significant violations and promised corrections are rarely made

How far back do we go in considering history? What if history shows poor compliance 5 years ago, but the last couple of years they have had good compliance?

Factor 2 – Attitude

The attitude of the firm or individual can also be used to help assess their commitment to assuring they are operating in compliance, and the level of enforcement action needed to encourage commitment. Does the firm promise correction and follow through? Are they aware of laws/regulations/ requirements for their operation? Do they have Quality Assurance and/or training programs? Do they accept responsibility for problems that are uncovered? Are corrections made promptly? Do they make corrections while you are there but do not maintain the correction? When appropriate, do they examine similar systems/products to make overall correction? The following relative weights can be used in assessing the attitude of the firm:

- (0) Accept responsibility for assuring compliance; aware of the requirements and/or have Quality Assurance/training programs; corrections are promised and made promptly; when appropriate, extend corrections to similar products/systems
- (1) Accept responsibility for assuring compliance; aware of the requirements; corrections promised but not made in a timely manner or corrections are not sustained
- (2) Do not accept responsibility for assuring compliance; not aware of the requirements; no promise of correction; no correction

Factor 3 - Scope

Scope of the firm's business as well as the scope of the violation can be an important factor in choosing an appropriate enforcement action. Consider the distribution of the violative products - is it limited to local distribution; multi-county; statewide; multiple state; nationwide; worldwide? What is the quantity of violative product involved? How many animals are affected? Are the violative products intended for a limited or unique population, or are they for a broader population? Is the violation involving a single product and/or is it single lot specific, or is it multi-product or a process violation? Is this an industry practice? The following relative weights can be used in assessing the scope of the violation:

- (1) Very limited distribution, quantity, or limited purchaser; violation is limited to a single lot
- (2) Distribution is limited to statewide and/or bordering states; violation is limited to one or two products, quantity of product distributed is relatively small and/or the number of animals effected affected is relatively small; non-critical process violation

- (3) Distribution is unlimited and may involve large quantities of product and/or effect affect a large number of animals; violation involves critical processes and/or multiple products

Factor 4 – Nature of the Violation

The nature of the violation has an impact on the type of enforcement action and may influence whether the action focuses on the product/process or on individuals. Consider whether the violations are minor or significant; whether they are sporadic or continuous; whether they involve only record keeping/control issues or they include product defects or contaminations; whether they are the result of human error; whether they were the result of lack of knowledge and understanding of the firm/individual’s responsibility or the legal requirements; whether the violations were done knowingly or deliberately. When determining whether the violation is significant or not as significant, or whether it would be a major or minor violation, available and current science and policy should be considered. The following relative weights can be used in assessing the nature of the violation:

- (1) Minor labeling violations and/or minor, sporadic record keeping violations
- (2) Violations are not minor but they are isolated incidents, the result of human error, or the result of lack of knowledge about requirements
- (4) Significant GMP (asterisked items on FDA Form 2481) and/or labeling violations; contaminations; fraud
- (8) Deliberate, knowing violations that result in hazard to public health

Factor 5 – Impact of the Violation

Selecting the most appropriate enforcement tool is strongly tied to the impact the violation has on the user of the product (economic impact, fraud), the safety of the animal, and human health safety. You should consider whether the violations effect affect food-producing or non food-producing animals. Are they violations that are economic or fraudulent in nature? Do they compromise animal safety? Do they pose a risk to human health safety? Is there a particular population at risk (children, immune system compromised, elderly)? The following relative weights can be used in assessing the impact of the violation:

- (1) Minor economic or fraud violations
- (4) Animal safety concerns
- (8) Human health safety concern but limited population
- (10) Human health safety concern with a risk to all populations

Factor 6 - Resources

Consider what resources your agency has to devote to the violative findings. Has your agency established overall compliance goals and objectives? Has your agency prioritized their enforcement efforts? Are they devoted in part to special initiatives? Have you established communication networks to determine if the violations have been encountered elsewhere? If so, are they pursuing enforcement? Are there other agencies that may be able to pursue action consistent with your compliance goals?

- (1) No resources are available
- (2) Limited resources are available
- (3) Ample resources are available

EXAMPLE VIOLATION CHART

Factor Value Range				
	4 to 8	9 to 12	13 to 19	20 to 29
Violation Category				
Labeling	-No Action -Information Letter	-Warning Letter -Stop Sale -Informal -Hearing/Meeting	-Condemnation/ Seizure -Informal Hearing/Meeting -Injunction -Refer to Other Agency -Civil Money Penalty	-Prosecution -Formal Hearing -Injunction -Refer to Other Agency -Civil Money Penalty
GMP’s				
Sample Results				
Contaminations				
Administrative				

CHAPTER 11 DRUG CARRYOVER CONTROL AND PREVENTION

INTRODUCTION

As feed regulators, a major factor while conducting inspections at feed manufacturers is ensuring the prevention of contamination of animal feed with undesired drugs or other contaminants. Contamination can happen many different ways including carryover of feed containing drugs (drug carryover). For this section, the focus will be on feed contamination due to carryover or due to a mixer error with one type of feed inadvertently being mixed into a feed for another species (e.g., a cattle feed containing high levels of copper mixed into a sheep or goat feed).

Drug carryover or drug residue is a form of contamination in that the substance in question has been transferred (carried) from an acceptable location to an unacceptable or undesired location, such as another animal feed. Furthermore, unsafe contamination by animal drugs in medicated or non-medicated animal feeds is defined as that level of drug contamination in the animal feed which would result in an above tolerance residue in the edible products of the consuming animal or which is injurious to animals when the feed is fed as directed. The level of drugs in animal feeds which will constitute unsafe contamination may vary among species and ages of consuming animals (FDA Document Sec. 680.600 Sequencing as a Means to Prevent Unsafe Drug Contamination in the Production, Storage, and Distribution of Feeds (CPG 7126.35). Meaning, carryover may lead to serious consequences depending on the drug and the size and distribution of the batches that were contaminated. The impact from drug carryover may not only be harmful or lethal to the animal(s) that may be fed the adulterated feed, but also may result in food contamination such as elevated drug levels in meat, dairy products and eggs.

The difference between residue and carryover is relative to the amount of medicated feed from one batch of feed ending up in the wrong batch of another, whether intentional or not. Residue would be a small amount or trace, whereas carryover would be a large amount of medicated feed ending up in the wrong feed. These two terms will be used interchangeably in this section. Hopefully, this section will explain how drug carryover can happen and how it can be avoided.

DRUG CARRYOVER - HOW IT OCCURS

Manufacturers of feed, whether commercial manufacturers or on-farm mixers, want to prevent drug carryover or residue if at all possible. As mentioned, the impact of drug carryover could be severe to devastating. For example, carryover from a batch of cattle feed containing Monensin may be lethal to a horse or herd of horses that the cattle feed inadvertently got diverted to. A swine feed containing Tilmicosin may have harmful effects if a portion of the feed ended up in a dairy feed, eventually contaminating milk. The issue of drug carryover could occur within the production system as a result of design, improper maintenance, and failure for personnel to follow cleanout procedures or other reasons. Carryover occurs when substantial amounts of the drug(s) or medicated feed (or both) may remain in the production system and become intermingled with the next feed being manufactured. It may occur in one piece of equipment or it may result from a combination of residues throughout the entire system. To discover the source, all equipment from the point of addition of the drug(s) to the point of loading must be considered.

The following table demonstrates how carryover may occur:

Table 1. Sources of Carryover

Equipment	Mode Of Carryover
Dust system	-delayed return of dust to production line -excessive pickup of drug and carrier -hang-up (electrostatic or moisture)
Mixer	-residual feed remaining in mixer -buildup of material on ribbons and walls -electrostatic hang-up on walls and top -leaking mixer gate (not fully closed)
Surge bin	-incomplete clean-out -electrostatic or moisture hang-up
Conveyors	-same as surge bin
Elevators	-residual feed remaining in buckets and boot -electrostatic or moisture hang-up
Bins	-bridging -residual feed from incomplete cleanout
Bulk truck	-error in bin chart records -incomplete clean-out -bridging and hang-up

* Source: Joseph P. Harner III, et al., *Avoiding Drug Carryover During Feed Processing and Delivery*, Kansas State University, March 1996.

Once carryover occurs, other than having detrimental effects to humans and animals that may be fed this contaminated feed would be considered a violation of the Food and Drug Administration's (FDA) CGMPs for medicated feeds regulations.

PREVENTION

The role of the inspector is to ensure firms have control measures to prevent carryover from occurring. According to the Good Manufacturing Practices (GMPs), adequate procedures shall be established and used for all equipment used in the production and distribution of medicated feeds to avoid unsafe contamination of medicated and non-medicated feed. Ultimately, it is the responsibility of the firms to make sure they evaluate their own manufacturing equipment to come up with measures to prevent carryover. Inspectors need to verify that firms manufacturing medicated feeds do the following: flushing, sequencing, and equipment clean out.

Flushing

Flushing a feed manufacturing system means to take a known amount of flush material and add it to the production system following the manufacturing of a medicated feed. The flush material is then allowed to pass through the entire production system in order to collect any hung up material from the previous feed. The firm should determine what type of flush material it will be using. Flush material usually consists of a known amount of a single ingredient, such as corn (ground, shelled), soybean meal, calcium product, etc. The firm then should add the flush material at the point in manufacturing where the drug is added or in a preceding step. The amount of flush material depends on the type of equipment that is used, particularly the mixer. In general, the amount of flush material added to the system should equate to 5-10 percent of the mixers capacity. Also, firms should check with the manufacturers of the mixer to determine what they recommend.

After the flush material is added to the mixer, some literature suggests that the mixer should be allowed to run for at least a minute before the flush material is removed. After the mixer is flushed, the flush material should then pass through the entire production system in the same route the medicated feed traveled. The flush material from that point can be bagged and properly labeled to be used in production of

another batch of feed containing the same drug. For bulk deliveries, some firms use the same flush material to flush their bulk truck out after deliveries are made to the farm. Some firms also elect to simply discard the material to avoid mix-ups at a later time.

Inspectors should verify that feed manufacturer's procedures are adequate. Suggest that the manufacturers document their flushing procedures such as how they flush, when they flush, how much and what material is being used to flush, and disposition of the flush material. Inspectors need to check that feed manufacturers are following their own procedures. Suggest that the firm documents when they "flush" in their production records. During the inspection, if possible, inspectors should observe the firm flushing their system. Make sure the entire system is flushed including, the mixer, surge bins (if needed), conveyors, legs and bins. Examine the flush material once it passes through the system and look for any extraneous material that's not consistent with the flush material. Also, make sure the same amount of the flush material that went into the system is captured in the end. Make sure the disposition of the flush material is adequate including labeling, storing, properly discarded if doing so (note: land applying may not be acceptable and may result in environmental issues or wildlife feeding on the material), etc. Inspectors should also verify that bulk trucks delivering medicated feeds are properly flushed as well before loading another batch of feed into the bins on the truck. Firms should be able to explain how bulk trucks are flushed before another batch of feed is loaded into the bin on their bulk truck.

Sequencing

Sequencing is a method most manufacturers use to "clean" their production system. Sequencing is the method of production scheduling where a non-medicated batch of feed follows a medicated feed of a similar species (cattle feed that contains Monensin is followed with a non-medicated cattle or other species (i.e. chicken) that can accept that drug. (Never follow with a horse feed.) Firms should consider age, class type, and drug purpose when sequencing feeds. For example, a feed containing the drug oxytetracycline for broiler chickens should not be followed or sequenced with a non-medicated chicken feed intended for laying hens. Furthermore, inspectors would want to verify if that a medicated feed for swine that contained Carbadox, wasn't followed with a non-medicated swine feed intended for sow's that maybe pregnant.

The sequencing procedure may also be used to clean out bins on bulk trucks but the same principles need to be followed. Drivers or employees loading the trucks should try to unload a batch of feed that is medicated first followed by a non-medicated feed that is acceptable. Depending on the type of system on the bulk truck, the firm and operators of the bulk trucks must carefully schedule how the trucks are loaded and the order the bins are unloaded on the truck if the truck has multiple bins. The firm should be able to describe and possibly show documentation of when and how they sequence the bins on their bulk trucks. They should also be able to demonstrate that the bins are adequately cleaned prior to another batch of feed being added to the bins on the truck.

Physical Cleanout

Physical cleanout is the process to which employees can enter areas of a production system and physically clean the system by sweeping, washing, disinfecting, scraping, etc... equipment that is safely accessible (Note: Inspectors should not physically enter any of these areas unless approved and properly trained). This is probably the most effective way of cleaning out portions of a production system to ensure carryover doesn't happen. Furthermore, the GMPs stipulate that all equipment shall be designed, constructed, installed, and maintained to facilitate inspection and use of clean-out procedures. Some firms do this on a routine basis such as monthly, semi-annually, etc. Some firms do it as needed; such as when they're mixing feeds using liquid ingredients (fat or molasses) that usually create a greater frequency of "hang-ups" within the system. Some manufacturers also install vibrators, hammers, inspection windows or other devices to prevent carryover.

Inspectors should understand the firm's routine of conducting cleanouts and how they do it. Issues may also arise when employees are performing cleanouts such as: making sure all waste and debris is removed prior to manufacturing feed, use safe and approved cleaners, using safe and clean tools, personnel hygiene of employees performing the task including clothing, washing may spread microbiological or other contaminants, etc.

Inspectors should safely inspect these areas when and where accessible (such as mixers, bins, surge bins, conveyors, etc.) to make sure they are clean and to avoid carryover. Again, never enter a mixer or bin but a visual inspection inside the inspection should be performed. This includes bulk trucks.

INSPECTORS ROLE

As inspector's, it is our role to ensure that facilities are set up in a way that minimizes the potential for drug carryover. While conducting inspections, inspectors should understand the firm's method(s) for preventing carryover. Meanwhile, inspectors should understand that each manufacturer may have prevention measures different than other manufacturers. It is the inspector's responsibility to make sure each firm is practicing something, whether it is flushing, sequencing, cleanout or all the above. This is done by interviewing management and employees, reviewing documents such as production records and physically inspecting mixers, bins and bulk trucks, etc. Inspectors may also consider taking a sample of the non-medicated feed or flush material and have it assayed for the drug that was in the previous batch of feed. Test results may provide a great insight on how effective the firm's prevention measures are working. Inspectors should make sure they provide adequate time during the inspection to go over each of these areas thoroughly. Inspectors should carefully document any findings and go over them with the management of the firm.

Carryover and eventually cross contamination of the feed supply is what needs to be prevented. Inspectors should always assess the risk involved if or when carryover occurs and explain it to the firms they inspect. Carryover of drugs or other contaminants can lead to contamination of the food supply and have damaging impact to an animal or a herd, and eventually on humans who consume the meat, milk or eggs.

CHAPTER 12 FEED MANUFACTURING TECHNIQUES

HOW DO YOU MANUFACTURE A FEED?

There are four year Bachelor of Science degree programs in feed manufacturing technology. Therefore, this brief introduction is not designed to make you an expert on feed manufacturing; it is designed to give you a brief insight into how feeds are manufactured and some of the common pieces of equipment used.

PURPOSE

The purpose of all feed mixers is basically the same - to achieve a uniform distribution of nutrients in the final product. Most companies want to accomplish this task in the shortest time possible and still maintain an adequately mixed feed. During an inspection for compliance with 21 CFR part 507, a review of the firm's food safety plan may be necessary (unless an exemption applies). One known or reasonably foreseeable hazard requiring a preventive control is an improper mixing of ingredients of an animal food.

EQUIPMENT TYPES

As an inspector, you will probably encounter several types of feed mixers. These may either be horizontal mixers, vertical mixers or rotating drum mixers.

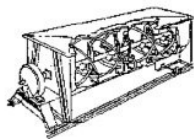
The manufacturer of the mixer has determined the proper amount of time needed for adequate mixing when the equipment is new.

HORIZONTAL MIXERS

The two most common types in use are the horizontal ribbon mixer and the horizontal paddle mixer.

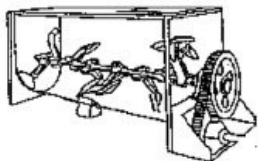
Horizontal Ribbon Mixer

May have one or more ribbons distributed throughout the mixer.



Horizontal Paddle Mixer

Has a series of paddles that lift and mix the feed.



Rotating Drum Mixer

The drum has mixing veins inside. As the drum is rotated, the feed is carried up and falls back down (like a front loading clothes dryer).



Advantages of Horizontal Mixers

- Shorter mixing times
- Clean out may be more complete
- More liquids can be added to the mix, especially with a paddle mixer
- More uniform mixing of feeds made from varying particle size ingredients
- Horizontal paddle mixer is the best option for fibrous ingredients

Disadvantages of Horizontal Mixers

- Higher initial cost and installation cost
- More floor space required
- Under filling and over filling inhibit mixing action.
- Higher horse power requirements for a horizontal ribbon mixer

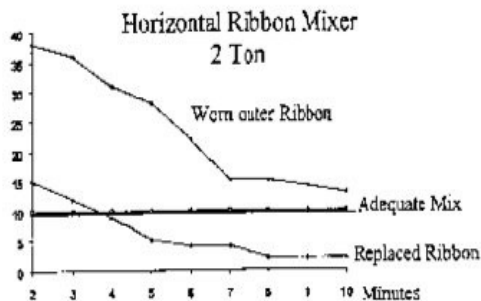


Observations Concerning Horizontal Mixers

Every mixer will have a zone of no mixing or very little mixing. From the way horizontal mixers are constructed, this appears to be a very small zone in the center of the mixer.

Ribbons and paddles should emerge at least 2 to 3 inches above the top of the feed material surface for optimum mixing performance.

Low revolutions per minute may not provide sufficient lateral movement of feed materials unless mixing time is extended. Most double ribbon mixers rotate about 30 to 40 revolutions per minute (RPM)



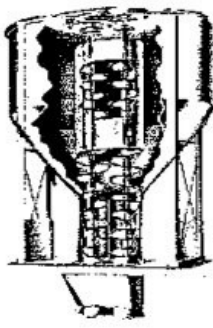
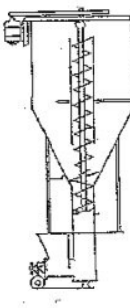
Note that as ribbons wear with usage and age of equipment, performance is reduced. It will take longer, as the ribbon deteriorates over time, to achieve an acceptable mix. In this diagram the “x” axis represents minutes to mix and the “y” axis is the % coefficient variable.

Equipment needs to be maintained and replaced.

Mixers are designed at a rated capacity. Mixing results may vary significantly if the mixer is over filled or under filled.

VERTICAL MIXERS

The vertical mixer also comes in various types. The two most common types are single screw mixers and double screw mixers.

<p>Vertical Twin Screw Mixer This diagram shows the twin screws of the vertical mixer.</p>		<p>Vertical Single Screw Mixer This diagram shows the single auger vertical mixer.</p>	
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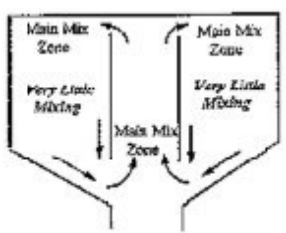
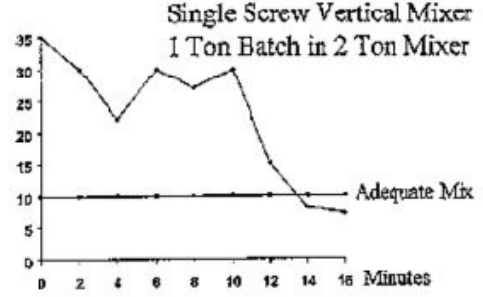
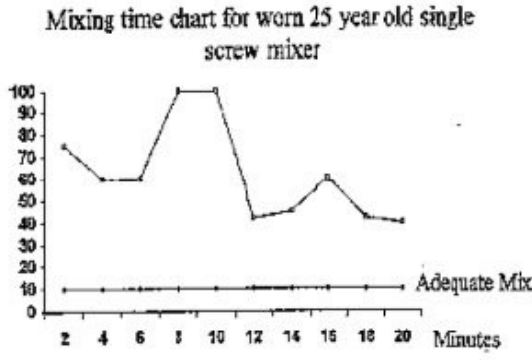
Advantages of Vertical Mixers

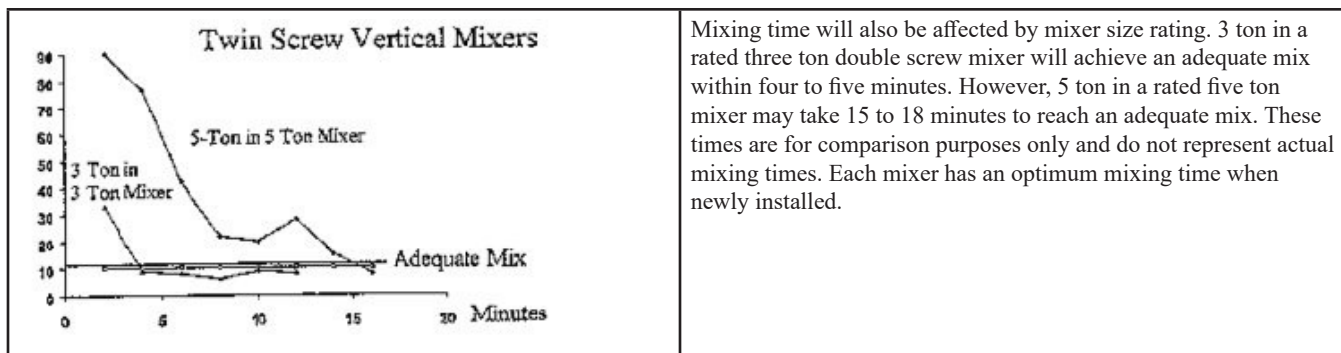
- Less floor space required over horizontal mixers
- Less initial cost and lower maintenance cost
- Mixing time for twin screw mixers comparable to horizontal mixers

Disadvantages of Vertical Mixers

- Single screw mixers have longer mix time requirements
- Complete clean out is difficult to obtain
- Liquids cannot be added at as high of a level as in horizontal mixers
- Not as efficient at mixing textured feeds

Observations Concerning Vertical Mixers

<p>The vertical single screw auger has been compared to a bulk bin with an auger in it. While this may not exactly be the case, the no mixing zone or dead mixing zone is quite large in a single screw mixer. While the mix zone in a double screw mixer is larger, there is still a fairly large dead mix area, depending on the capacity rating of the mixer.</p>	
<p>Single Screw Vertical Mixer 1 Ton Batch in 2 Ton Mixer</p> 	<p>Overfilling can seriously limit the mixing action that should take place at the top of the mixer. The head space between the top of the mixer screw and the top of the mixer shell should be a minimum of 8 - 12 inches. Once again "x" equals mixing time and "y" equals % coefficient variable.</p>
<p>Mixers need to be maintained and parts replaced. As in the horizontal mixers, parts do wear out. Metal fragments from mixers can come loose and become part of the feed. Screws need to be cleaned to assure buildup is removed from the screws. When screws become worn, no matter how long the mixer is run, an adequate mix will never be achieved. Wear on the mixer can markedly reduce the mixing action — ½ inch wear can increase mixing time five fold.</p> <p>Much higher revolutions per minute (RPMs) are required for vertical mixers. Generally, 200 to 300 RPMS as compared to 30 to 40 RPMs for horizontal mixers.</p>	<p>Mixing time chart for worn 25 year old single screw mixer</p> 



Mixing time will also be affected by mixer size rating. 3 ton in a rated three ton double screw mixer will achieve an adequate mix within four to five minutes. However, 5 ton in a rated five ton mixer may take 15 to 18 minutes to reach an adequate mix. These times are for comparison purposes only and do not represent actual mixing times. Each mixer has an optimum mixing time when newly installed.

SUMMARY

Mill personnel need to know and understand the equipment they have in use. They need to understand that different types of equipment have both advantages and disadvantages.

Equipment wears out! The mixer put into place twenty years ago, may or may not be working at optimum performance. Maintenance needs to be done to keep paddles, ribbons, and screws clean. After a period of time, the internal workings may need to be replaced.

Even if a mixer is old, it can still produce an adequately mixed feed.

For concerns about mixer wear, age and mixing efficiency, the firm can contact the equipment manufacturer.

To determine uniformity of a feed and efficiency of the mixer the firm can contact their major concentrate or ingredient supplier. They could assist in doing an official mixer study.

An inexpensive mixer on the market can make an adequately mixed feed if proper manufacturing techniques are followed.

ADDING INGREDIENTS TO THE MIXER

Is it important how a mixer is loaded? From all the data reviewed, the ideal loading of a mixer would be to:

- Add a portion of the grain or protein source (Major macro ingredient)
- All small hand adds (i.e. minerals, vitamins, medications)
- The balance of the grain or protein (And other macro ingredients)
- Any liquids that are required.

Micro ingredients, such as drugs, should not be added first or last to the mixer. If they are, a greater amount is placed in the non mix zone of the mixer. This is especially true in vertical mixers.

Minimum Recommended Inclusion Rates and Mixing Times		
Mixer Type	Minimum inclusion Rate per ton	Minimum Mixing Time (Minutes)
Vertical Single Screw	40#	15 to 30
Vertical Twin Screw	20#	4 to 6
Horizontal Double Ribbon	10#	3 to 5

The above mixing times are after the addition of the last ingredient. These mixing times and rates are safe recommendations and the firm can feel relatively comfortable they are obtaining a uniform mix. Anything below these recommendations should be supported by mixing studies and appropriate documentation. The chart also displays the differences between the various mixers in correlation to times and rates.

Mixer efficiency will be improved if low inclusion products are premixed prior to adding them to the mixer. For example, instead of adding 2 pounds of ingredient “x”, 3 pounds of “y” and 10 pounds of “z”, combined these 3 ingredients together prior to adding them to the mixer.

Can a feed manufacturer add 1/2 pound of a highly concentrated ingredient to a ton mix and end up with an adequate distribution throughout the feed? The answer may be yes or no. Some mills have performed studies to see what the lowest possible inclusion rate may be for their equipment. They may have performed tests showing they may be able to adequately mix such a product. However, ingredients

will vary in their particle size, particle shape, adherence capabilities, static charge, and other factors. A less concentrated product may produce a more uniform blend.

EQUIPMENT CLEAN OUT

When any feed is manufactured, some of that feed will remain in the manufacturing and distribution system. While one ingredient may be beneficial to a particular specie of animal, it may be toxic to others at relatively low concentrations. Therefore, the equipment must not contain any ingredients that would be harmful in the successive feeds. This may be accomplished in several ways.

Physical Clean out

Actually sweeping, vacuuming, or washing out the equipment

Sequential Production

Production runs are scheduled so that feeds are manufactured in a certain order. For instance, a feed containing a drug would not be followed by a feed destined for layers or lactating dairy. A feed with the drug would be manufactured and then another feed going to starter or grower animals of the same species would be manufactured.

Flushing

The system is “flushed” with an inert material (i.e. corn, soybean meal, non medicated feed, etc.) This material in essence flushes the previous material out of the system and anything remaining in the system is diluted or eliminated. This material can then be packaged and labeled and used in future batches of similar type feed.

The age old question is “How much flush material is enough?” The recommended amount of flush material to be used will depend on the equipment in use and the equipment manufacturer’s recommendation. Also, the feed manufacturer may have performed tests to determine what is an adequate flush for their equipment.

In general, five percent of the mixer capacity, but not less than 200 pounds, is recommended.

Clean out needs to include the whole manufacturing and distribution system. That means:

- Mixers
- Conveying Equipment
- Pellet Mills
- Holding Bins
- Bulk Trucks

CHAPTER 13 TOXINS

CONSIDER THE FOLLOWING “HYPOTHETICAL” SITUATION

An experienced horse breeder in your state recently began purchasing bags of feed from a new locally based company to supplement his clover-grass pasture. Over the course of the grazing season, the owner’s expensive champion quarter horses began to develop a variety of symptoms and eventually all of them died. Early cooperative efforts between the horseman, the feed company, the veterinarians, and the insurance companies broke down and lawsuits began to be filed. The feed company, the horse breeder, and the veterinarians were all financially devastated.

- What happened and who is to blame?
- Did the feed company sell feed that contained naturally occurring mycotoxins produced by molds on the feed?
- Did the feed contain weed seeds that have a detrimental effect on horses?
- Was the feed formulated with an excess of an added nutrient or other feed ingredient?
- Did the feed carry a contaminant left in the manufacturing and delivery system from the previous batch of feed manufactured?
- Did the feed contain a known problem ingredient that was not adequately detoxified?
- Did the veterinarians make matters worse by employing inappropriate therapy or surgeries?
- Did the horse breeder have poisonous plants in the pasture?
- Did the horse breeder under feed the horses so that unpalatable toxic plants were consumed by the horses?
- Was it a misdiagnosed disease by the veterinarian and not anything consumed by the animals?

Sooner or later, this scenario will happen to all inspectors. You will be called to perform an inspection where a toxin is suspected to be involved from the feed. By becoming aware of some of the major causes of animal poisons, you may be able to recognize some of the symptoms and aid in the investigation. This short section is not designed to make you an expert!!! It is simply designed to give you a starting place to become familiar with some possible toxins.

“All substances are poisons: There is none which is not a poison. The right dose differentiates a poison and a remedy.”
Paracelsus (1493-1541)

As Paracelsus discovered, it may be a fine line between nutrient, remedy, or poison. Nutrients and feed additives are designed to be included into feeds at certain levels. Specific nutrients may become highly toxic if over formulated in the ration. Some nutrients may be necessary at high levels in some species and poisonous at those levels in other species. A good example may be copper. Swine seem to show an increased growth potential at certain levels of copper in the diet, while that level in sheep would be toxic.

POISONOUS PLANTS AND NATURAL TOXINS

Many publications have been written on poisonous plants and their effect on various species. Many of these species of plants will be indigenous to certain areas and climates. To list them all, would be almost an impossible task.

If this is an area you wish to explore, some resources that might aid include:

- Cornell Poisonous Plant Page:
<http://www.ansci.cornell.edu>
- Colorado State Veterinary medicine and Biomedical Sciences
http://www.vth.colostate.edu/poisonous_plants/
- FDA Natural Toxins Page:
<http://www.fda.gov/Food/default.htm>
- University of Illinois Poisonous Plant Page:
<http://www.web.extension.illinois.edu/countrysidecenter/agnr2018.html>
- Texas AgriLife Extension Service Toxic Plants of Texas
<http://essmextension.tamu.edu/plants/toxics/>

SOME KNOWN TOXIC PLANTS

COMMON TOXIC PLANTS OF SOUTHWESTERN & WESTERN UNITED STATES			
NAME	DISTRIBUTION	TOXIC PRINCIPLE	LIVESTOCK AFFECTED
<i>Apocynum cannabinum</i> Indian Hemp	Throughout U.S.	Cardiac glycosides	All, especially sheep
<i>Asclepias</i> spp. Milkvetch	Throughout U.S.	Cardenolides	All

COMMON TOXIC PLANTS OF SOUTHWESTERN & WESTERN UNITED STATES			
NAME	DISTRIBUTION	TOXIC PRINCIPLE	LIVESTOCK AFFECTED
<i>Astragalus</i> spp. <i>Oxytopis</i> spp. Locoweeds	Western U.S.	Miserotoxin or Swainsonine	All
<i>Baileya multiradiata</i> Desert Baileya	Southwestern U.S. and Mexico	Unknown	Sheep and goats
<i>Cicuta</i> spp. Waterhemlock	Wet Habitats	Cicutoxin	All and humans
<i>Conium maculatum</i> Poison-Hemlock	Introduced; throughout U.S.	Piperidine alkaloids	All and humans
<i>Cymopterus watsonii</i> Spring parsley	Intermountain States	Furocoumarins	Sheep and cattle
<i>Delphinium</i> spp. Larkspur	Throughout U.S.	Diterpenoid alkaloids	All, but mostly cattle
<i>Drymaria</i> spp. Inkweed	Southwestern U.S. and Mexico	Alkaloids	All, especially cattle
<i>Gutierrezia sorathrae</i> Snakeweed	Western U.S.	Saponins	Sheep and cattle
<i>Halogeton glomeratus</i> Halogeton	Introduced; Intermountain States	Oxalates	All, but mostly sheep
<i>Helenium hoopesii</i> Orange sneezeweed	Western U.S.	Sesquiterpene lactones	Mostly sheep, cattle less
<i>Hymenoxys odorata</i> Bitterweed	Southwestern U.S.	Hymenoxon	Sheep
<i>Hymenoxys richardsonii</i> Pinque	Western U.S. and Canada	Sesquiterpenes	All, especially sheep
<i>Hypericum perforatum</i> St Johnswort	Introduced; throughout U.S.	Hypercin	All, but goats least
<i>Isocoma wrightii</i> Jimmyweed	Southwestern U.S. and Mexico	Termetol	All
<i>Lupinus</i> spp. Lupine	Throughout U.S. and Canada	Quinolizidine alkaloids	All, also deer
<i>Oxytenia acerosa</i> Copperweed	Southwestern U.S.	Alkaloids	All, especially cattle
<i>Prunus virginiana</i> Chokecherry	Western U.S.	Cyanogenic glycosides	All, especially sheep
<i>Psilostrophe</i> spp. Paperflowers	Southwestern U.S. and Mexico	Unknown	Sheep primarily, cattle suspected
<i>Pteridium aquilinum</i> Bracken-fern	Throughout U.S.	Thiaminase – horse Unknown - cattle	All, especially cattle and horses
<i>Quercus havardii</i> <i>Quercus gambelii</i> Shinnery and scrub oak	Southwestern and central Western U.S.	Tannins	All, especially cattle
<i>Sarcobatus vermiculatus</i> Greasewood	Western U.S. and Mexico	Oxalates	All, but mostly sheep
<i>Senecio longilobus</i> Threaded groundsel	Southwestern U.S. and Mexico	Pyrrolizidine alkaloids	All, cattle and horses most
<i>Solanum</i> spp. Nightshade	Throughout U.S.	Steroidal	All
<i>Tetradymia canescens</i> <i>Tetradymia glabrata</i> Horsebrush	Western U.S.	Furanoeremophilanes	Sheep

COMMON TOXIC PLANTS OF SOUTHWESTERN & WESTERN UNITED STATES			
NAME	DISTRIBUTION	TOXIC PRINCIPLE	LIVESTOCK AFFECTED
<i>Triglochin maritime</i> <i>Triglochin glabrata</i> Arrowgrass	Western U.S., Canada, and Mexico	Hydrocyanic acid	All
<i>Veratum californicum</i> Veratum	Pacific Coast, Northern Rocky Mountain States	Steroidal alkaloids	All
<i>Zigadenus</i> spp. Deathcamas	Western U.S.	Steroidal alkaloids	All, especially sheep

VARIOUS MODES OF ACTION OF POISONOUS PLANTS

ORGANS, SYSTEMS, & BODY FUNCTIONS AFFECTED BY POISONOUS PLANTS			
Organ/System/Syndrome		Scientific Name	Common Name
Abortion		<i>Astragalus</i> spp.	Locoweed
		<i>Gutierrezia</i> spp.	Perennial broomweed
		<i>Xanthocephalum</i> spp.	
		<i>Iva angustifolia</i>	Sumpweed
		<i>Pinus ponderosa</i>	Ponderosa pine
Birth Defects		<i>Astragalus</i> spp.	Locoweed
		<i>Conium maculatum</i>	Poison hemlock
		<i>Lathyrus odoratus</i>	Sweet pea
		<i>Lupinus sericeus</i>	Lupine, Bluebonnet
		<i>Nicotiana</i> spp.	Tobacco
		<i>Veratrum</i> spp.	False hellebore, Skunk cabbage
Blood	Anti-clotting	<i>Melilotus</i> spp.	Sweet clover
	Bone Marrow Dysfunction	<i>Pteridium aquilinum</i>	Bracken-fern
	Hemolysis	<i>Allium</i> spp.	Onion
Gastrointestinal Tract		<i>Centaurium</i> spp.	Mountain pink
		<i>Euphorbia</i> spp.	Spurges
		<i>Flourensia cernua</i>	Blackbrush, Tarbush
		<i>Jatropha</i> spp.	Nettlespurge
		<i>Melia zaedarach</i>	Chinaberry
		<i>Phytolacca americana</i>	Pokeweed
		<i>Quercus</i> spp.	Oaks
		<i>Ricinus</i> spp.	Castorbean
		<i>Sesbania</i> spp.	Sesbane, Rattlebox
	<i>Xanthium</i> spp.	Cocklebur	
Heart		<i>Asclepias</i> spp.	Milkweed
		<i>Bileya multiradiata</i>	Desert baileya
		<i>Datura</i> spp.	Jimson weed
		<i>Dymaria</i> spp.	Drymary, Alfombrilla
		<i>Kalanchoe</i> spp.	Kalanchoe
		<i>Nerium oleander</i>	Oleander
		<i>Taxus cuspidate</i>	Yew
	<i>Veratrum</i> spp.	False hellebore, Skunk cabbage	

ORGANS, SYSTEMS, & BODY FUNCTIONS AFFECTED BY POISONOUS PLANTS		
Organ/System/Syndrome	Scientific Name	Common Name
Kidneys	<i>Amaranthus</i> spp.	Pigweed, Carelessweed
	<i>Beta vulgaris</i>	Beets
	<i>Halogeton glomeratus</i>	Halogeton
	<i>Kochia scoparia</i>	Summer cypress
	<i>Lantana camara</i>	Lantana
	<i>Quercus</i> spp.	Oaks
	<i>Sarcobatus vermiculatus</i>	Greasewood
Liver	<i>Agave lecheguilla</i>	Lechequilla
	<i>Amsinckia intermedia</i>	Fiddleneck
	<i>Crotalaria</i> spp.	Crotalaria
	<i>Cycas</i> spp.	Cycads
	<i>Eichium plantagineum</i>	Viper's bugloss
	<i>Eupatorium rugosum</i>	White snakeroot
	<i>Heliotropium eurpaeum</i>	Heliotrope
	<i>Lantana camara</i>	Lantana
	<i>Phyllanthus abnormis</i>	Abornal leafflower
	<i>Sartwellia flaveriae</i>	Sartwellia
	<i>Senecio</i> spp.	Groundsel
	<i>Xanthium</i> spp.	Cockleburr
Lungs	<i>Astragalus emoryanus</i>	Red-stemmed peavine
	<i>Astragalus miser</i>	Milkvetch
	<i>Brassica napus</i>	Rape
	<i>Panicum antidotale</i>	Blue panic grass
	<i>Perilla frutescens</i>	Beef steak plant
	<i>Salvia</i> spp.	Sage
Malnutrition Syndrome	<i>Alliums</i> spp.	Onions
	<i>Alloisia lycoides</i>	Whitebrush
	<i>Prosopis</i> spp.	Mesquite
Musculoskeletal	<i>Cassia</i> spp.	Senna
	<i>Cestrum diurnum</i>	Night blooming Jessamine
	<i>Lathyrus odorata</i>	Sweet pea
	<i>Solanum malacoxylon</i>	

ORGANS, SYSTEMS, & BODY FUNCTIONS AFFECTED BY POISONOUS PLANTS		
Organ/System/Syndrome	Scientific Name	Common Name
Nervous	<i>Acacia berlandieri</i>	Guajillo
	<i>Aconitum</i> spp.	Monkshood
	<i>Aesculus</i> spp.	Buckeye
	<i>Astragalus</i> spp.	Locoweed
	<i>Asclepias</i> spp.	Milkweeds
	<i>Centaurea</i> spp.	Yellow star thistle, Russian knapweed
	<i>Cicuta</i> spp.	Waterhemlock
	<i>Claviceps</i> spp.	Ergot
	<i>Conium</i> spp.	Poison-hemlock
	<i>Cycas</i> spp.	Cycads
	<i>Cynodon dactylon</i>	Bermudagrass
	<i>Datura</i> spp.	Jimson weed
	<i>Delphinium</i> spp.	Larkspur
	<i>Eupatorium rugosum</i>	White snakeroot
	<i>Helenium</i> spp.	Sneezeweeds
	<i>Hymenoxys</i> spp.	Bitterweed
	<i>Isocoma wrightii</i>	Rayless goldenrod
	<i>Kallstroemia</i> spp.	Caltrops
	<i>Lathyrus</i> spp.	Singletary pea
	<i>Lobelia</i> spp.	Indian Tobacco
	<i>Lupinus</i> spp.	Lupines, Bluebonnet
	<i>Nicotiana</i> spp.	Tobacco
	<i>Nothalaena sinuate</i> Var. <i>cochisensis</i>	Jimmy fern
	<i>Oxytropis</i> spp.	Locoweed
	<i>Peganum harmala</i>	African rue
	<i>Phalaris</i> spp.	Harding grass
	<i>Psilostrophe</i> spp.	Paperflower
	<i>Pteridium aquilinum</i>	Brackenfern
	<i>Solanum dimidiatum</i>	Threadsalve, Potatoweed
	<i>Sophora</i> spp.	Mescalbean, Mountain laurel
<i>Strychnos nuxvomica</i>	Strychnine	
<i>Trifolium repens</i>	White clover	
<i>Vicia villosa</i>	Hairy vetch	
<i>Zigadenus</i> spp.	Deathcamas	

ORGANS, SYSTEMS, & BODY FUNCTIONS AFFECTED BY POISONOUS PLANTS			
Organ/System/Syndrome		Scientific Name	Common Name
Photosensitization	Hepatogenous	<i>Agave lecheguilla</i>	Lecheguilla
		<i>Avena sativa</i>	Oats
		<i>Eupatorium rugosum</i>	White snakeroot
		<i>Cynodon dactylon</i>	Bermudagrass
		<i>Lantana</i> spp.	Lantana
		<i>Medicago</i> spp.	Alfalfa
		<i>Nolina</i> spp.	Sacahuista
		<i>Panicum cloratum</i>	Kleingrass
		<i>Tetradymia</i> spp.	Horsebrush
		<i>Tribulus terrestris</i>	Goat head, Puncture vine
	Primary	<i>Amni majus</i>	Bishop's weed
		<i>Cooperia pedunculata</i>	Rain lily
		<i>Cymopterus watsonii</i>	Desert parsley
		<i>Hypericum perforatum</i>	St. Johnswort
		<i>Polygonium fagopyrum</i>	Buckwheat
		<i>Thamnosma texana</i>	Dutchman's breeches
	Selenosis	<i>Astragalus</i> spp.	Locoweeds
		<i>Atriplex</i> spp.	Saltbrush
		<i>Conopsis</i> spp.	Goldenweed
		<i>Stanleya pinnata</i>	Prince's plume
<i>Xylorrhiza</i> spp.		Woody aster	

Reference Publications

- Cheeke, P.R. (Editor), 1989 Toxicants of Plant Origin, volumes 1-4, CRC Press, Boca Raton FL.
- Frohne, D. and Pfander, H.J., 1984. A Color Atlas of Poisonous Plants, Wolfe Publishing Ltd., London.
- Turner, N. J. and Szczawinski, A. F., 1991. Common Poisonous Plants and Mushrooms of North America, Timber Press, Portland,

MYCOTOXINS

Definitions

Mycotoxins are chemical compounds produced by fungi while growing on organic substances such as corn and peanuts. Many have been strongly implicated as chemical precursors of toxicity in humans and animals. These compounds have been labeled as carcinogens, which means cancer producing. Consequently, there is a growing awareness of the potential hazards of these substances as contaminants of food and feed. Interest in mycotoxins continues as new mycotoxins are discovered and as the information is developed on their possible involvement in animal and human disease. Mycotoxin contamination of food and feed supplies could increase the economic and health risks to humans and animals.

Mycotoxin was apparently derived from mycotoxicosis, described as diseases of Animals caused by fungal toxins. Subsequently, mycotoxin was defined as a toxin produced by a fungus. Ingestion of foods and feeds containing mycotoxins is the usual route of exposure. However, dermal or inhalation exposure may occur as well.

The direct effects of mycotoxins on humans and other animals may include:

- Growth retardation and reduced resistance to infection,
- Acute toxicity and death following exposure to high levels of a mycotoxin,
- Reduced milk and egg production, or
- Chronic disease including tumor formation after prolonged exposure to small quantities of toxin.

Although more difficult to define, the latter is of greater concern in developed countries where the food and feed supplies are of high quality and, therefore, probably contain lesser amounts of toxin(s). Wide diversity in susceptibility to a particular mycotoxin occurs among animal species, and this is influenced by age, sex, strain and nutritional status.

Indirect exposure of humans to mycotoxins may occur when toxic residues of mycotoxins or their metabolites are in milk, eggs, and animal tissues, and these products are consumed. Effects of such exposure to mycotoxins may include:

- Impaired immunity and resistance to disease,
- Lowered growth rates, and
- Reduced reproductive efficiency.

Occurrence of Mycotoxin producing Fungal Genera

Many of the fungi capable of producing mycotoxins are also frequent contaminants of food and agricultural commodities. These include members of the genera *Aspergillus*, *Penicillium*, *Fusarium*, *Alternaria*, *Claviceps*, *Stachybotrys*, *Pithomyces*, *Phoma*, *Diplodia*, *Trichothecium*, *Phomopsis*, *Cladosporium*, *Byssoschlamys*, *Chaetomium*, *Rhizopus*, and *Sclerotinia*. These organisms may grow on a variety of substrates and under diverse conditions of moisture, pH, and temperature. Thus, most foods and feeds are susceptible to invasion by fungi during some stage of production, processing, transport, or storage. Mycotoxins may be produced when fungal growth occurs. However, the presence of these fungi in or on a food product does not automatically mean the presence of mycotoxins but, rather, that a potential for mycotoxin contamination exists. On the other hand, the absence of these fungi does not guarantee that the commodity is free of mycotoxins, because the toxins may persist long after the fungi have lost viability. Mycotoxins often occur in crops in the field prior to harvest. Postharvest contamination can occur if crop drying is delayed and during storage of the crop, if water activity is allowed to exceed critical values for mold growth. Mycotoxin-producing fungi have been sporadically found in diverse foods and commodities.

Factors Involved in Fungal Growth and Mycotoxin Development

Mycotoxin problems vary from year to year depending on conditions favorable for the development of the organisms that produce them and unfavorable for the crops in which they develop. Many types of organisms produce mycotoxins and conditions favorable for their development vary depending on requirements of the pathogen and the host.

Many of the toxigenic fungi overwinter as mycelium or resting spore stages on plant debris or in the soil. Sporulation in or on this overwintered material results in an inoculum that is often spread by air currents, splashing rain, or insects.

Stress and subsequent reduced vigor often predispose crop plants to infestation, colonization, and contamination by toxigenic fungi. Water stress, high temperature stress, and insect damage of the host plant are major determining factors in mold infestation and toxin production. Similarly, specific crop growth stages, poor fertility, high crop densities, and weed competition have been associated with increased mold growth and toxin production (Diener et al., 1987; Lacey, 1986; Tuite, 1979). Toxin formation is also affected by associated growth of other molds. (Trucksess et al., 1988; Mislivec et al., 1988).

Pre-harvest mold growth and production of peanuts and corn adulterated with aflatoxin are favored by warm ambient temperatures and prolonged drought conditions typical of many parts of the world, including the southern United States (Diener et al., 1979). Post-harvest production of aflatoxins on corn and peanuts is favored by warm temperatures and high humidity, which also is typical in the southern United States. The greatest problems with contamination by aflatoxins have occurred in corn and peanuts in the southeastern area and in cottonseed in the southwestern area of the United States. Grains produced in the Midwestern area of the United States generally have been found to be relatively free of aflatoxins, with the exception of growing seasons characterized by drought stress, such as 1983 and 1988.

Major Classes of Mycotoxins

A wide diversity of toxic metabolites have been obtained from fungal laboratory cultures. Most of these compounds are not known as causes of human or animal disease. The mycotoxins currently considered to pose the greatest potential risk to human and animal health, as food and feed contaminants, are listed in the tables below, along with their effects in animals and the commodities in which the mycotoxins have been found.

There are four major aflatoxins, B1, B2, G1, and G2, plus two additional metabolic products, M1, and M2, that are of significance as direct contaminants of foods and feeds. The aflatoxin M toxins were first isolated from the milk of lactating animals fed aflatoxin preparations; hence, the M designation.

The effects of feeding moldy grain have been known for years, but not until 1961 was the cause properly identified as aflatoxin. In 1960, 100,000 turkey poults in the British Isles died from eating aflatoxin contaminated peanut meal.

The mycotoxin sterigmatocystin chemically resembles the aflatoxins and is a precursor in the biosynthesis of aflatoxin (Hsieh et al., 1973). Sterigmatocystin has been detected at low concentrations in green coffee, moldy wheat, and in the rind (normally discarded) of hard Dutch cheese (Bullerman, 1981; Scott, 1985; Vesonder and Horn, 1985).

The trichothecenes are a family of over 148 structurally related compounds (Grove, 1988). There are several naturally-occurring trichothecene mycotoxins produced in foods and feeds by *Fusarium* species, including deoxynivalenol, T-2 mycotoxin, nivalenol, and diacetoxyscirpenol. Deoxynivalenol contamination of corn and wheat has been significant in some crop years. Natural contamination of foods and feeds by T-2 mycotoxin in the United States has been reported in only one incident involving heavily molded corn. The T-2 mycotoxin is the trichothecene studied most extensively.

In 1980 and 1981 in Canada and 1982 in the United States, deoxynivalenol was found in wheat as the result of severe infestations with the wheat scab fungus, *F. graminearum*. In both Canada and the United States, the soft winter wheats were the most severely affected.

In Canada, dried corn was found to contain levels of deoxynivalenol that were slightly higher than those found in the wheat (Trenholm et al., 1985). In some parts of the United States, zearalenone was found to occur with deoxynivalenol in scabby wheat; in most cases of Gibberella ear rot of corn, zearalenone and deoxynivalenol are found together.

- **Zearalenone**

An estrogenic mycotoxin, causes vulvovaginitis and estrogenic responses in swine. Zearalenone is produced primarily by *F. graminearum*, occurring naturally in high moisture corn, and zearalenone has been found also in moldy hay and pelleted feeds. Physiological responses in swine occur when the zearalenone level in corn used for feeds exceeds about 1 ppm (Kurtz and Mirocha, 1978). Zearalenone can be transmitted to piglets in sows' milk and cause estrogenism in the young pigs. The natural occurrence of zearalenone is favored by high humidity and low temperatures. These conditions often occur in the Midwest during autumn harvest (Christensen et al., 1977; Diener et al., 1979).

- **Ochratoxins**

Are a group of structurally related metabolites. The major mycotoxin in this group is ochratoxin A. Ochratoxin has been suggested to be a factor in the etiology of a human disease known as Balkan endemic nephropathy (Krogh, 1977; Smith and Moss, 1985).

- **Citrinin**

Is a yellow-colored mycotoxin. Like ochratoxin A, citrinin causes kidney damage in laboratory animals similar to swine nephropathy, and may interact synergistically with ochratoxin A in cases of swine nephropathy as found in Denmark (Krogh, 1977).

- **Citreoviridin**

Was originally isolated from cultures of molds obtained from rice associated with a disease called cardiac beriberi that had occurred for three centuries in Japan (Ueno and Ueno, 1972). The natural occurrence of this mycotoxin in corn and other foods and feedstuffs has been observed (Wicklow et al., 1988). Interestingly, citreoviridin and aflatoxin were found to occur simultaneously in corn, and this allows for possible interaction of these two mycotoxins in producing animal disease (Wicklow et al., 1988). Citreoviridin causes paralysis, dyspnea, cardiovascular disturbances, and loss of eyesight in experimental animals (Ueno, 1974).

- **Cyclopiazonic acid (CPA)**

The potential significance of **Cyclopiazonic acid (CPA)** as a natural contaminant of foods and feeds became apparent with reports that it was produced by several molds found commonly on agricultural commodities or by molds used in fermented food production. This mycotoxin has been shown to occur naturally in corn (Gallagher et al., 1978), cheese (LeBars, 1979), and peanuts (Lansden and Davis, 1983), and occurred in Kodo millet (Rao and Husain, 1985) that was implicated in a natural human intoxication in India. Cole (1986) retrospectively presented evidence that CPA may have been involved, along with the aflatoxins, in the "Turkey V syndrome in England in 1960.

- **Fumonisin**

Are mycotoxins, isolated from *F. moniliforme* (Gelderblom et al., 1988). This organism is involved in producing equine leukoencephalomalacia, and the fumonisins (131) are described as being capable of reproducing the disease in horses (Marasas et al., 1988). Also, one of the fumonisins (BI) was shown to have cancer-promoting activity in rats (Gelderblom et al., 1988). Leukoencephalomalacia commonly occurs in horses in the United States, and the organism, *F. moniliforme*, is a frequent (almost universal) inhabitant of corn (Haliburton and Buck, 1986).

- **Tremorgenic mycotoxins**

The disease caused by Tremorgenic mycotoxins in cattle is called staggers. Clinical signs include muscle tremor, uncoordinated movements, and general weakness in the hind legs, with stiff stilted movements of the forelegs. Severely affected animals may not be able to stand. Other intoxications involving fungal tremorgens have been reported from moldy cheese, a hamburger bun, and walnuts consumed by dogs.

Penicillium roqueforti and *P. caseicolum* (*P. camemberti*), used to produce mold-ripened cheeses, have been shown to produce several toxic compounds, including **penicillic acid, roquefortine, isofumigaclavines A and B, PR toxin, mycophenolic acid, and cyclopiazonic acid** (Scott, 1981). The significance of the various toxins produced by *P. roqueforti* and *P. caseicolum* to public health is not clear because of the lack of scientific research on compound stability, production in agricultural commodities, and toxicity.

Mycotoxicoses and Animal Health

Fungal toxins produce a wide range of injurious effects in animals, in addition to serving as food-borne hazards to humans. The economic impact of reduced productivity, increased disease incidence because of immune suppression, subtle but chronic damage to vital organs and tissues, and interferences with reproductive capacity is many times greater than that of acute livestock death.

The aflatoxins, cause liver damage, decreased milk and egg production, and suppression of immunity in animals consuming low dietary concentrations. While the young of a species are most susceptible, all ages are affected, and clinical signs include gastrointestinal dysfunction, reduced reproductivity, decreased feed utilization and efficiency, anemia, and jaundice. Nursing animals may be affected by exposure to aflatoxin metabolites secreted in the milk.

The trichothecene mycotoxins are a large group of mycotoxins that cause necrosis and hemorrhage throughout the digestive tract, depress blood regenerative processes in the bone marrow and spleen, and cause changes in reproductive organs. Affected animals show signs of weight loss, poor feed utilization, apparent inappetence, vomiting, bloody diarrhea, abortion, and death. Suppression of immunity is a significant feature of certain trichothecene intoxications.

Ochratoxin A damages the kidneys of a wide variety of domestic and wild animals that consume contaminated feed. High concentrations of dietary ochratoxin A also can cause liver damage as well as intestinal necrosis and hemorrhage. Ochratoxin A has been shown to suppress immunity and to be carcinogenic.

Zearalenone mimics the effects of the female hormone estrogen and induces feminization at dietary concentrations of less than 1 ppm, while higher concentrations will interfere with conception, ovulation, implantation, fetal development, and the viability of newborn animals.

A variety of other effects has been attributed to mycotoxins, and these are briefly described in the following paragraphs.

Embryonic death, inhibition of fetal development, and abortions have been associated with ergot, aflatoxin, rubratoxin, and zearalenone in the rations of pregnant animals.

Teratogenicity (causing fetal malformations) has been documented in at least one mammalian species for aflatoxin, ochratoxin, rubratoxin, T-2 mycotoxin, zearalenone, and sterigmatocystin.

Nervous system functions are adversely altered by at least nine mycotoxins, inducing such clinical signs as tremors, uncoordinated movements, weakness of one or more limbs, staggering, and sudden muscular collapse from the consumption of contaminated forage, silage, cereal grains, or dietary supplements. In some instances, the neurological effects are complicated by seizures, diarrhea, and hemorrhage of the digestive tract, profuse salivation, feed refusal, and gangrene of the limbs, ears, or tail.

At least three mycotoxins (aflatoxins, ochratoxins, and sterigmatocystin) are known to induce tumors in one or more species of animal. The cancers have developed in liver, kidney, urinary system, digestive tract, and lung. The effects of some mycotoxins in producing skin irritations on contact and causing direct death of nervous tissue in the brain highlight the sensitivity of selected organs in certain species to these unique poisons.

The impact of fungal toxins upon animals extends beyond their obvious effect in producing death in the wide variety of animals that are likely to consume mycotoxin contaminated grain or feeds. The economic impact of lowered productivity, reduced weight gain, reduced feed efficiency, less meat and egg production, greater disease incidence because of immune system suppression, subtle damage to vital body organs, and interferences with reproduction is many times greater than that of immediate morbidity and lethality. Potential threats of cancer induced by mycotoxins in feeds and human foods, along with the unknown subtle effects of these mycotoxins, are coupled to the universal concerns about health risks.

Effects of Mycotoxins			
Mycotoxin	Commodities Found Contaminated	Affected Species	Pathological Effects
Aflatoxins (B1, B2, G1, G2, M1, M2)	Peanuts, corn, wheat, rice, cottonseed, copra, nuts, various foods, milk, eggs, cheese	Birds Duckling, turkey, poult, pheasant chick, mature chicken, quail Mammals Young pigs, pregnant sows, dog, calf, mature cattle, sheep, cat, monkey, human Fish Laboratory Animals	Hepatotoxicity (liver damage) Bile duct hyperplasia Hemorrhage Intestinal tract Kidneys Carcinogenesis (liver tumors)
Citrinin	Cereal grains (wheat, barley, corn, rice)	Swine Dog Laboratory Animals	Nephrotoxicity (tubular necrosis of kidney) Porcine nephropathy
Cyclopiazonic Acid	Corn, peanuts, cheese, kodo millet	Chicken, turkey, swine, rat, guinea pig, human?	Muscle necrosis Intestinal hemorrhage & edema Oral lesions
Ochratoxin A	Cereal grains (wheat barley, oats, corn), dry beans, moldy peanuts, cheese, tissues of swine	Swine, dog, duckling, chicken, rat, human	Nephrotoxicity (tubular necrosis of kidney) Porcine nephropathy Mild liver damage Enteritis Teratogenesis Carcinogenesis (kidney tumors)

Effects of Mycotoxins			
Mycotoxin	Commodities Found Contaminated	Affected Species	Pathological Effects
Patulin	Moldy feed, rotted apples, apple juice, wheat straw residue	Birds Chicken, chicken embryo, quail Mammals Cat, cattle, mouse, rabbit, rat Others Brine shrimp, guppies, zebra fish larvae	Edema Brain Lungs Hemorrhage Lungs Capillary damage Liver Spleen Kidney Paralysis of motor nerves Convulsions Carcinogenesis Antibiotic
Penicillic acid	Stored corn, cereal grains, dried beans, moldy tobacco	Mouse, rat, chicken embryo, quail, brine shrimp	Liver damage (fatty liver, cell necrosis) Kidney damage Digitalis-like action on heart Dilates blood vessels Antidiuretic Edema in rabbit skin Carcinogenesis Antibiotic
Penitrem	Moldy cream cheese, English walnuts, hamburger buns, beer	Dog, mouse, human	Tremors, death, incoordination, bloody diarrhea
Sterigmatocystin	Green coffee, moldy wheat, Dutch cheeses	Mouse, rat	Carcinogenesis Hepatotoxin
Trichothecenes (T-2 toxin, diacetoxyscirpenol, neosolaniol, nivalenol, diacetylnivalenol, deoxynivalenol, HT-2 toxin, fusarenon X)	Corn, wheat, commercial cattle feed, mixed feed	Swine, cattle, chicken, turkey, horse, rat, dog, mouse, cat, human	Digestive disorders (emesis, diarrhea, refusal to eat) Hemorrhage (stomach, heart, intestines, lungs, bladder, kidney) Edema Oral lesions Dermatitis Blood disorders (leucopenia)
Zearalenone	Corn, moldy hay, pelleted commercial feed	Swine, dairy cattle, chicken, turkey, lamb, rat, mouse, guinea pig	Estrogenic effects (edema of vulva, prolapsed of vagina, enlargement of uterus) Atrophy of testicles Atrophy of ovaries Enlargement of mammary glands Abortion

Occurrence of Mycotoxins in Foods and Feeds

Many foods and feeds can be contaminated with mycotoxins before harvest, during the time between harvesting and drying, and in storage. A few mycotoxins, such as those associated with ergotism, are produced exclusively in the field. Many other mycotoxins can contaminate crops before harvest and, under certain circumstances, progress from that point. Aflatoxins can be found in the field before harvest, and contamination can increase during post-harvest activities, such as crop drying, or in storage. However, the aflatoxins can contaminate stored products in the absence of field contamination. Many other fungi that produce mycotoxins contaminate crops in much the same way.

With the exception of the aflatoxins, the frequency of contamination of feeds and foods by other mycotoxins is not known. Corn, peanuts, and cottonseed are the most frequently analyzed domestic crops. Milk, eggs, and meat products are sometimes contaminated because the animal has consumed mycotoxin-contaminated feed.

Besides the aflatoxins, several other mycotoxins may contaminate foods and feeds. The ochratoxins and the Fusarium mycotoxins have been given the greatest attention. These mycotoxins tend to occur in the more temperate regions of the United States. Zearalenone; and deoxynivalenol are more of an economic concern to animal producers in the United States than ochratoxin. Many other mycotoxins

produced by various *Aspergillus*, *Penicillium*, *Fusarium* and *Alternaria* species can contaminate products, and the incidence and relative importance to animal and human health of these many different mycotoxins has not been established.

Because mycotoxin contamination of foods occurs in a random manner, it is impractical to think that a truly mycotoxin-free food supply can be guaranteed. The ability to identify and remove all naturally occurring mycotoxin contamination or even all of a specific mycotoxin from foods and feeds is limited. Thus, it is important to establish realistic goals for mycotoxin management.

Natural Occurrence in Raw Agriculture Products

Mycotoxins can contaminate raw agricultural products before harvest and/or after harvest. Some mycotoxins, such as the aflatoxins, can occur in the field as well as increase after harvest, if conditions are conducive to mold growth. Other mycotoxins, such as ergot toxins, are produced only prior to harvest. Many mycotoxins may be produced in stored products if conditions are favorable.

Ergotism is the oldest known mycotoxicosis of humans and animals. The ergot mycotoxins are present in the sclerotia (ergot) of the fungus, which replaces the grain seed. Van Rensburg (1977) stated that as little as 0.2% (by weight) ergot in grain could cause mild symptoms or signs of ergotism in humans, and death from gangrene could follow consumption of about 100 g of ergot over a few days. Canadian scientists have suggested a maximum level of 0.05% of ergot particles by count in flour may be acceptable (Peace and Harwig, 1982).

Aflatoxins have been found to contaminate many crops, sometimes at very high concentrations. The commodities with a high risk of aflatoxin contamination include corn, peanuts, and cottonseed.

Commodities with a lower risk of aflatoxin contamination include soybeans, beans, grain sorghum, millet, wheat, oats, barley, and rice are resistant or only moderately susceptible to aflatoxin contamination in the field. However, aflatoxins can occur when any of these commodities are stored under high moisture and temperature conditions. Insect or rodent infestations can create microclimates that facilitate mold invasion of some stored commodities.

Deoxynivalenol may be found in corn at levels > 1,000 ppb. Deoxynivalenol is frequently found in U. S. and Canadian wheat, especially associated with cool, wet growing and harvest seasons that favor the formation of scab, the result of grain invasion by *F. graminearum*. Lower amounts of deoxynivalenol have been found in barley, rice, and rye. The T-2 mycotoxin and diacetoxyscirpenol have been reported to occur in raw products less frequently, which may be related to inadequate analytical methodology.

Zearalenone is produced by several *Fusarium* species and is a frequent contaminant of corn, wheat, barley, and grain sorghum in the United States. Generally, zearalenone concentrations are well below 1 ppm (the level in feed that can cause oestrus in swine) in processed cereal foods, but higher amounts can be encountered in some feeds.

(Morehouse, 1985). Other toxic metabolites produced by *Fusarium* species that have been detected in corn or wheat include moniliformin and butenolide (Jelinek, 1987). The toxic metabolites of *F. moniliforme* are not well defined, nor have analytical methods for them been developed. Because of this, the incidence of mycotoxins derived from this fungus is poorly documented, although *F. moniliforme* is the most common *Fusarium* species found on corn. Mycotoxins from *F. moniliforme* were characterized in 1988 by South African investigators and given the trivial name of fumonisins. The fumonisins have been implicated in equine leukoencephalomalacia and have been shown to be precancerous in rats (Gelderblom et al., 1988). Many *Fusarium* toxins have been found in commodities susceptible to contamination with aflatoxins, ochratoxins, or other mycotoxins, but significant co-occurrence of mycotoxins from different mold species have not been found.

Pre-harvest aflatoxin contamination of corn and peanuts is associated with high temperatures, high insect activity, and severe and prolonged drought stress, whereas contamination by the *Fusarium* mycotoxins and ochratoxins are associated with cool temperatures and high moisture conditions at harvest. Ochratoxin has been reported as naturally occurring in corn, wheat, sorghum, oats, rice, and green coffee. Ochratoxin contamination of coffee, corn, and wheat is generally < 500 ppb, while barley and oats grown in Denmark and other Scandinavian countries are particularly susceptible to high levels of ochratoxin contamination (Krogh et al. 1973, 1974). Animal feeds in Canada, Europe, and Australia may be highly contaminated with ochratoxin (> 5000 ppb). (Jelinek, 1987; Tsubouchi et al., 1988). The highest reported incidence and levels have been in barley, oats, wheat, and corn produced in northern European (United Kingdom, Denmark, and Sweden) or Balkan (Yugoslavia) countries and in India. The reports indicate that levels approaching the parts per million range, at an incidence of over 20%, can be expected to occur in random samples of these grains in the affected areas. Surveys of barley, corn, oats, sorghum, and wheat in the United States over a number of years found some ochratoxin in all but sorghum, but at a low incidence (corn 0.5%, wheat 1%, oats 2%, barley 14%) and low level (all samples < 200 ppb) of contamination.

Citrinin can occur alone or with ochratoxin. However, there is no suitable quantitative method for citrinin analysis, so that current data is an estimation of the actual amount. Citrinin has been reported in peanuts, corn, barley, and other cereal grains (Jelinek, 1987). The importance of citrinin in human and animal health is difficult to determine without reliable estimates of the actual contamination frequency or levels.

Alternaria species can produce several mycotoxins including tenuazonic acid, alternariol, and alternariol methyl ether. *Alternaria* species frequently invade grains in the field and *Alternaria* metabolites could easily contaminate grains such as wheat, oats, barley, and grain

sorghum. Again, we lack survey data from the United States to make an accurate appraisal of the occurrence of these mycotoxins in food and feeds.

Other mycotoxins such as cyclopiiazonic acid, sterigmatocystin, sporidesmins, rubratoxin B, cytochalasins, penitremes, and slaframine have been reported in the literature as natural contaminants of agricultural commodities. Some of the above mycotoxins are of limited occurrence. More surveys designed to determine the incidence and levels of mycotoxins in foods and feeds are sorely needed, but surveys depend on the availability of suitable analytical methods. Patulin and penicillic acid are often considered in mycotoxin reports, but will not be considered here because of their inability to cause disease when given to animals by a natural route.

Control and Management of Mycotoxins

In the United States, the aflatoxins are the only mycotoxins that are formally and specifically regulated. Aflatoxins are considered unavoidable contaminants of food and feed where Good Manufacturing Practices (GMP's) have been followed and, as such, are regulated under the Food, Drug, and Cosmetic Act [Section 402 (a) (1)]. The FDA has established specific guidelines on acceptable levels of aflatoxins in human food and animal feed by establishing action levels that allow for the removal of violative lots from interstate commerce. The action levels for human food are 20 ppb total aflatoxins, with the exception of milk, that has an action level of 0.5 ppb for aflatoxin M₁ (a metabolite of aflatoxin B₁).

For feeds, the action level for aflatoxins is also 20 ppb, with the exception of up to 300 ppb of total aflatoxins in cottonseed meal intended for beef cattle, swine or poultry (regardless of age or breeding status), up to 300 ppb for corn and peanut products intended for finishing (feedlot) beef cattle, up to 200 ppb for corn and peanut products intended for finishing swine of 100 pounds or greater, and up to 100 ppb aflatoxin intended for breeding cattle, breeding swine, and mature poultry.

To effectively monitor food and feed for a particular mycotoxin, it is important to be able to accurately estimate its concentration. However, this is very difficult to accomplish in a large quantity of material, because of the variability associated with established testing procedures. The total variability of these procedures is equal to the sum of errors associated with each step (i.e., sampling, comminuting/sub-sampling, and analysis of aflatoxins). Because of these errors, the true aflatoxin concentration in a lot cannot be determined with 100 % certainty. The only way to achieve a better estimate of the lot concentration is to reduce the total variance associated with test results. The sampling variance can be reduced by increasing the sample size. The sub-sampling variance can be reduced by increasing the size of the sub-sample or by increasing the degree of comminution (number of particles per unit mass in the sub-sample). The analytical variance can be reduced by increasing the number of analyses.

Presently, a high degree of technical expertise and laboratory sophistication [e.g., thin-layer chromatography (TLC), gas and high performance liquid chromatography (GLC and HPLC), and GLC/mass spectrometry, etc.] are widely utilized for the detection and confirmation of identity of various mycotoxins.

The development of rapid and field-practical screening tests for mycotoxins (e.g., minicolumns, and immunoassays) has greatly facilitated control through effective monitoring programs that allow for the detection and diversion of contaminated crops and animal feeds. A variety of structure-selective techniques have emerged in chemistry and immunology. Early technology included selective adsorption of multi-mycotoxins (SAM) and more recent technology includes immunoassays. The immunoassays utilize mycotoxin specific antibodies that can discriminate between minor differences in chemical structure. A number of commercial kits (including minicolumns and immunoassays) are currently available for the field-practical analysis of mycotoxins.

Although rigorous guidelines have been long established for the preventive management of aflatoxins in crops (i.e., recommended practices for growing/production, harvesting, handling, storage, processing/manufacturing, and sampling and analysis), significant contamination can still occur. It is important to understand that good crop management techniques and practical methods of aflatoxin detection (although significant tools) do not provide a complete solution, because aflatoxin contamination is unavoidable, and sampling problems may easily bias aflatoxin analysis. Consequently, we must also develop and utilize safe and effective procedures for the decontamination/detoxification of aflatoxin containing food and feed.

Numerous strategies for the detoxification of aflatoxins, have been proposed. These generally include methods of physical separation, thermal inactivation, irradiation, microbial degradation, and treatment with a variety of chemicals. The detoxification strategy that has received the most attention is the treatment of aflatoxin-contaminated feed with ammonia (i.e., ammoniation). The ammoniation procedure is currently being utilized in Arizona and California to reduce the parent aflatoxin levels in cottonseed products and in France, Senegal, and Brazil for the treatment of aflatoxin-contaminated peanut meal. Although ammoniation was apparently safe and effective in earlier studies, it has not been sanctioned by the U.S. Food and Drug Administration, due to the potential toxicity and carcinogenicity of reaction products. Another approach to the detoxification of aflatoxins is the addition of inorganic adsorptive compounds such as hydrated sodium calcium aluminosilicate (HSCAS) in the diet that possess the ability to tightly bind and neutralize aflatoxins in the gastrointestinal tract of animals. The use of HSCAS for binding of dietary aflatoxins has not been sanctioned by the U.S. Food and Drug Administration.

REGULATORY CONTROL

A broad spectrum of mycotoxins have been identified in the environment associated with human food and animal feeds, and new ones will undoubtedly be discovered in the future, because improved scientific methods for analysis and safety evaluation are constantly being developed. Presently in the United States, only aflatoxins are formally and specifically regulated. For the other known mycotoxins, the observed level, incidence, estimated consumption, and toxicological profiles have not warranted regulation by the FDA beyond the general requirements for safe and wholesome food and feeds. As new information is generated, additional controls may be justified.

In the United States, aflatoxin is considered an unavoidable contaminant in food and feed where Good Manufacturing Practices (GMP's) have been followed. The FDA has regulated aflatoxins under the Food, Drug, and Cosmetic Act, Section 402 (a) (14), which states, "A food shall be deemed to be adulterated ... if it bears or contains any poisonous or deleterious substance which may render it injurious to health..." The FDA established specific guidance on acceptable levels of aflatoxins in animal feed by establishing action levels allowing for removal of a violative lot from interstate commerce.

Currently, the action levels for total aflatoxins in human food are 20 ppb, except for milk, which has an action level of 0.5 ppb of aflatoxin M₁. For feeds, the action level for aflatoxins is also 20 ppb, with the exception of up to 300 ppb of total aflatoxins in cottonseed meal intended for beef cattle, swine or poultry (regardless of age or breeding status), up to 300 ppb for corn and peanut products intended for finishing (feedlot) beef cattle, up to 200 ppb for corn and peanut products intended for finishing swine of 100 pounds or greater, and up to 100 ppb aflatoxin intended for breeding cattle, breeding swine, and mature poultry.

Table 1. U.S. Food and Drug Administration guidelines for acceptable levels of aflatoxins in animal feed

Commodity	Action Level (ppb)	Reference
Animal Feeds		
Corn and peanut products intended for finishing (i.e., feedlot) beef cattle	300	CPG 683.100
Cottonseed meal intended for beef, cattle, swine, or poultry (regardless of age or breeding status)	300	CPG 683.100
Corn and peanut products intended for finishing swine of 100 pounds or greater	200	PG 683.100
Corn and peanut products intended for breeding beef cattle, breeding swine, or mature poultry	100	CPG 683.100
Corn, peanut products, and other animal feeds and feed ingredients but excluding cottonseed meal, intended for immature animals	20	CPG 683.100
Corn, peanut products, cottonseed meal, and other animal feed ingredients intended for dairy animals, for animal species or uses not specified above, or when the intended use is not known	20	CPG 683.100

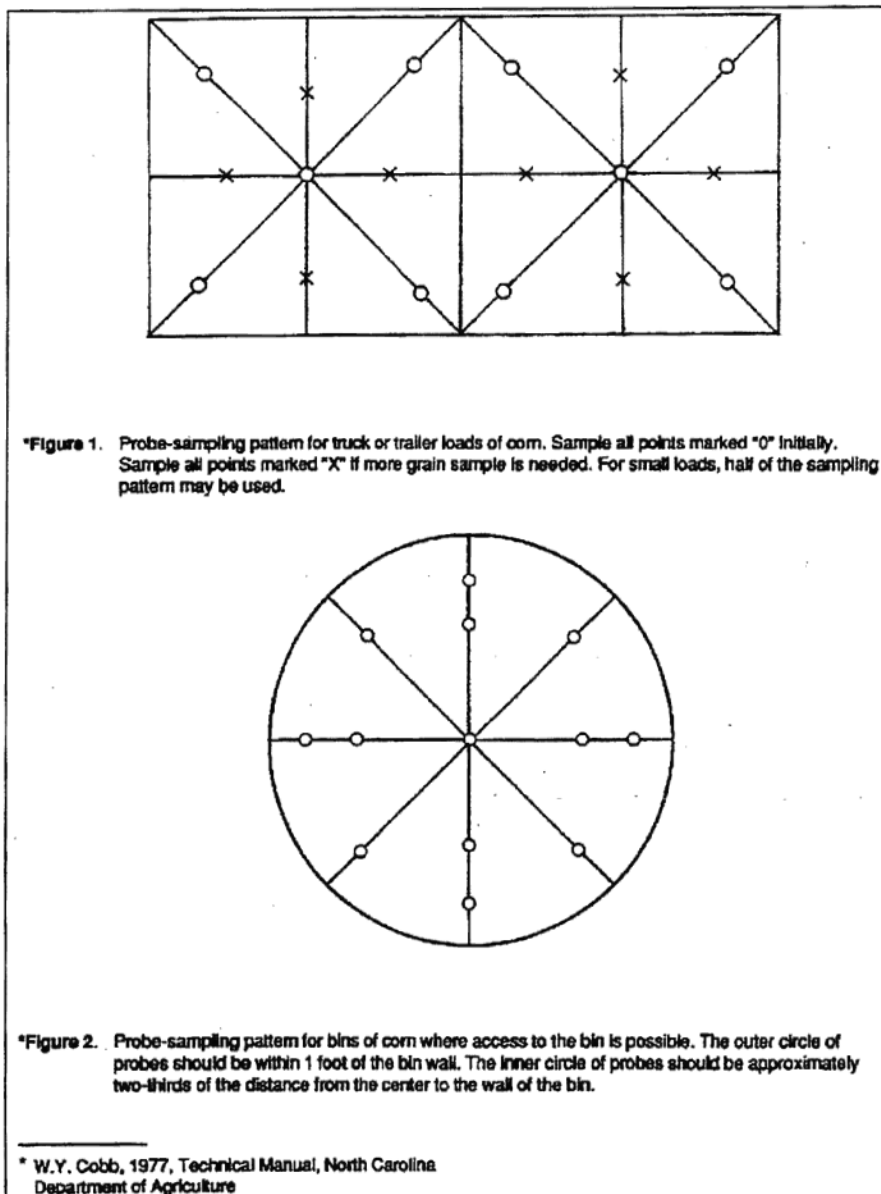
Sampling, Sample Preparation, and Analytical Variability

Proper sampling is essential for obtaining reliable test results. Failure to obtain a proper sample can result in unnecessary economic loss by causing loads of grain to be improperly condemned or by inadvertently feeding unsafe lots of grain to livestock. Kernels of corn containing aflatoxin are seldom distributed uniformly in a lot. For this reason it is best to use stream or multiple probe sampling.

Sampling loads of grain for aflatoxin presents technical problems that seem insurmountable at times. Results obtained may be incapable of duplication and inequitable to either or both parties. This presentation attempts to explain why this situation exists but will fall short of offering a total solution to the problem.

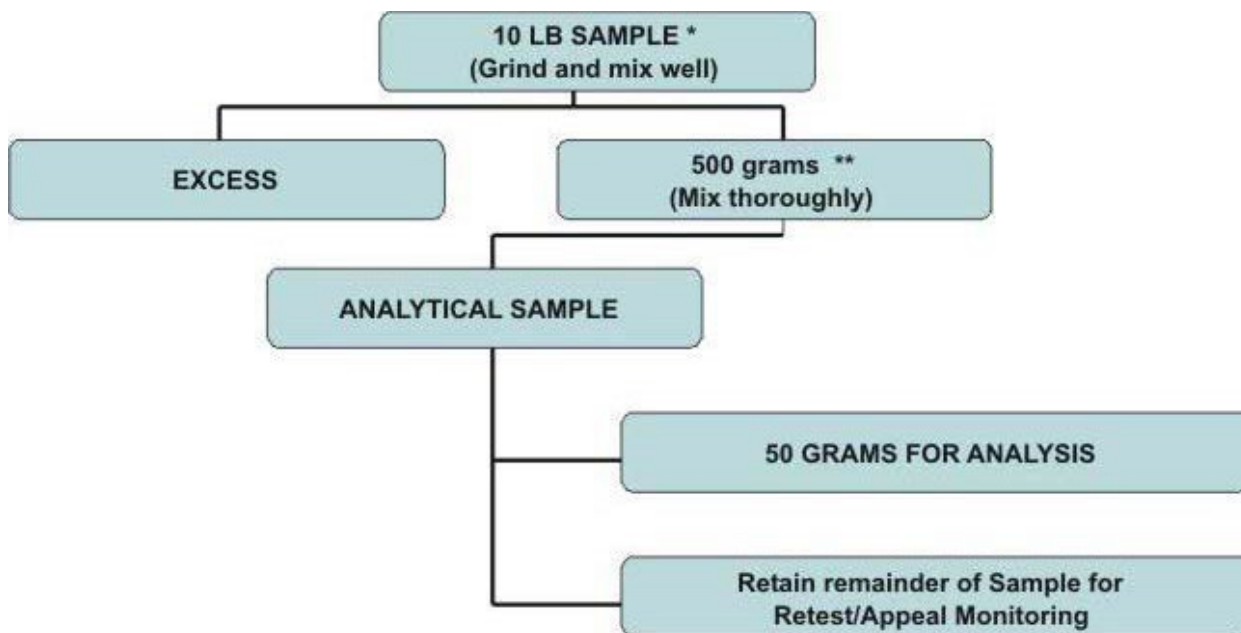
Probe sampling is commonly used for lots of corn that have been recently mixed. Use a double shelled, compartmented probe of sufficient length to reach the bottom of the container to obtain a representative sample. Make probes in at least five locations to ensure the taking of a representative sample. Note the drawings in **Figures 1 and 2** showing suggested locations.

Stream sampling is one of the most effective ways of obtaining a representative sample. When automatic samplers are not available, a person can be assigned to pass a cup under the stream at periodic intervals. This process should continue throughout the time that the lot is being moved.



A sufficient quantity of grain (a minimum of ten pounds) should be drawn to adequately sample the lot or load. Store or transport in cotton, burlap, or paper bags. Do not place samples in closed glass containers or plastic bags. Keep samples as cool and dry as possible.

Grind and thoroughly mix the entire 10 pound sample and follow the diagram during sample reduction to preserve its representative property. The final sample should be ground finely enough that 70% will pass through a 20 mesh sieve.



Variability in sampling grain for aflatoxin analysis occurs because of (1) individual contaminated kernels do not contain equal amounts of aflatoxin, (2) not all kernels contain aflatoxin, (3) contaminated kernels are not uniformly distributed in the lot and (4) the ratio of contaminated and clean kernels is not uniform.

Improvement in accuracy can be achieved by selecting, grinding, and mixing larger samples and by taking more samples and using an average. However, both of these suggestions increase the time and expense of the testing operation.

The inequitable distribution problem is essentially solved when testing liquids such as raw milk in tanker trucks. Due to mixing, a drawn sample is representative of the entire load. This is not easily achieved with grain, however, unless the entire load is ground and blended.

Individual testing points normally develop probe patterns that they consider adequate for their operation. The object is to select samples that are truly representative of the load or lot being evaluated.

CHAPTER 14 FIELD GLOSSARY

NOTE: The definitions of AAFCO Official Feed Terms, as published in the 1994 Official Publication, are shown in italics.

A.O.M.:

Active Oxygen Method, a laboratory test for determining the rancidity point for fat.

Abortion:

Premature expulsion from the uterus of the products of conception, i.e., embryo or nonliving fetus. Includes miscarriage as well as forced abortion.

Absorption:

Taking up of fluids or other substances by the skin, mucous surfaces or absorbent vessels.

Acid:

Any compound that dissociates in water to form hydrogen ions. It reacts with alkalis (bases) to form salts. For example, hydrochloric acid reacts with the base sodium hydroxide to form the salt sodium chloride (table salt).

Acidic:

Having a pH less than 7.0. Any compound that reacts with a base to form a salt.

Acidosis:

Decreased pH or increased acidity of the blood.

Acidulant:

Product used to provide acid taste.

Acquired:

Immunity developed by exposing an animal to the antigen associated with a given disease. It consists of two types: Active and Passive Immunity (see below).

Actinomycete:

A class of microscopic fungi. Certain antibiotics are derived from actinomycetes, e.g., oxytetracycline (Terramycin) is obtained from the actinomycete, *Streptomyces rimosus*.

Acute Disease:

Characterized by swift onset and short course.

Additive:

An ingredient or combination of ingredients added to the basic feed mix or pails thereof to fulfill a specific need. Usually used in micro quantities and requires careful handling and mixing.

Adjuvant:

Substance which enhances the immune response to a biological product by controlling the rate at which antigen is released in the body, e.g., a bacterin may be alum precipitated or aluminum hydroxide adsorbed; alum and aluminum hydroxide are adjuvants.

Adrenal Glands:

Flattened body situated anterior to each of the two kidneys. It consists of an internal medulla and external cortex. The adrenal cortex secretes adrenal cortical hormones which include glucocorticoids and mineralocorticoids.

Adsorption:

Ability of a substance to hold gases, liquids and other dissolved substances onto its surface.

Adulterant:

Any undeclared poisonous, deleterious or non-nutritive substance.

Aerial Pails:

(Part) The above ground parts of plants.

Aerobe:

In the presence of air. The term usually applied to microorganisms that require oxygen to live and reproduce.

Air Ashed:

(Process) Reduced by combustion in air to a mineral residue.

Air Sac:

End portion of the air passage of a lung in poultry.

Airsacculitis:

Inflammation of the air sacs.

Air Sac Disease:

Disease complex that occurs when *Mycoplasma gallisepticum* (PPLO) infection is complicated by secondary infections, e.g., coliforms and *Salmonellae*. This complex is often called Complicated Chronic Respiratory Disease (CRD).

Alcohols:

Derivatives of hydrocarbons containing the hydroxyl group - OH. The two most common alcohols in flavor applications are ethyl alcohol and propylene glycol, used as solvents for flavor ingredients.

Aldehydes:

Members of a class of organic compounds containing the aldehydic group.

Aliphatic:

The term applied to the "open chain" or fatty series of hydrocarbons.

Alkali:

Class of compounds that react with acids in aqueous solutions to form neutral salts; also called BASES.

Alkaline:

Having a pH greater than 7.0. Any base that is soluble in water and gives off ions in solution. Any mineral salt that can neutralize acids.

Alkalosis:

Increased pH or alkalinity of the blood.

Alkyl:

The radical which results when an aliphatic hydrocarbon loses one hydrogen atom.

Allergen:

Antigen capable of inducing an allergic reaction.

Ameba (Amoeba):

One-celled protozoan animal microorganism which is constantly changing its protoplasmic shape by extending pseudopodia from its circumference. This nucleated mass absorbs nourishment through its cell membrane. Amebae may produce amoebiasis, an intestinal inflammation in animals.

Amino Acids:

Organic acids containing nitrogen, in addition to carbon, hydrogen, and oxygen, forming the chief structure of proteins. They are essential in nutrition. Some can be synthesized by the animal, while others must be provided by the diet and are referred to as essential amino acids.

Ammoniated, Ammoniating:

(Process) Combined with or impregnated with ammonia or an ammonium compound.

Amylase:

An enzyme that hydrolyzes starch.

Anaerobe:

A microorganism that normally does not require air or free oxygen to live and reproduce.

Analytical Variations:

Guidelines derived from the AAFCO Check Sample Program for helping control officials make routine decisions on acceptability of products.

Androgen:

Male sex hormone.

Anemia:

Condition due to deficiency of quantity or size of red corpuscles or hemoglobin in the blood.

Animal Protein:

Animal by-products used as protein sources. Examples are meat, milk, fish, meal and dried whey.

Animal Rights:

The belief that animals have the same rights as humans, and that animals have human like emotions.

Animal Waste:

Means a material composed of excreta, with or without bedding materials, and collected from poultry, ruminants, or other animals except humans.

Animal Welfare:

The belief in humane treatment of animals, as contrasted to animal rights. Farmers are strong supporters of "animal welfare," as opposed to animal rights.

Antagonism:

The killing, injury, or inhibition of growth of one species of microorganism by another.

Anthelmintic:

An agent which is destructive to worms (helminths).

Antibiotics:

A class of drug. They are usually synthesized by a living microorganism and in proper concentration inhibit the growth of other microorganisms.

Antibody:

Substance produced by the body in response to invasion by a specific antigen and capable of reacting with it.

Anticaking Agent:

Moisture absorbing agent used to prevent caking.

Antigen:

Any foreign protein capable of stimulating the production of a specific antibody and reacting with it.

Antigen-Antibody Reaction:

Reaction between an antigen and an antibody specific to it.

Antimicrobial:

Inhibiting microorganisms by biological or chemical agents.

Antioxidant:

Compound which inhibits the oxidation of a chemical product; often used to preserve vitamins and fats.

Antiseptic:

Compound which inhibits the growth of microorganisms without necessarily killing them.

Antiserum:

Blood serum containing antibodies associated with a specific disease. Inoculation of anti-serum gives short-term immunity to the disease.

A.O.A.C. International:

An association that conducts collaborative studies of analytical methods. An Official Methods Book is periodically updated.

Aquaculture:

The rearing of aquatic organisms under controlled or semi-controlled conditions.

Aromatic:

Product used primarily because of its aroma.

Arsenical:

Any drug containing arsenic. Used in animals as a growth promotant as well as in disease and parasite control.

Artificially Dried:

(Process) Moisture having been removed by other than natural means.

Artificial Flavor:

Any flavoring which is not derived from the sources which yield natural flavorings.

Ascorbic Acid:

Chemical name for vitamin C.

Ash:

The incombustible residue remaining after exposure to heat.

Aspergillus Niger:

Filamentous fungi used for the production of enzymes and other fermentation products. The fruiting bodies are dark to black.

Aspergillus Oryzae:

Filamentous fungi used in the production of citric acid and enzymes. Mycelia are whitish color with pale yellow to green fruiting bodies.

Aspirated, aspirating:

Having removed chaff, dust, or other light materials by use of air.

Assimilation:

Conversion of digested nutrients into an integral and homogeneous part of the solids or fluids of the organism.

Ataxia:

Failure of muscular coordination; irregularity of muscular action.

Bacilli:

Rod-shaped bacteria.

Bacteria:

One-celled microscopic organism of the order Eubacteriales.

Bactericidal:

Capable of destroying bacteria.

Bacterin:

Suspensions of killed or attenuated bacteria which stimulate active immunity to the same type of bacteria.

Bacteriocidin:

An agent or substance which causes disintegration of bacteria.

Bacteriolysin:

Antibacterial antibody which kills bacteria by dissolving them.

Bacteriostatic:

Inhibiting the growth of multiplication of bacteria.

Bagasse:

(Part) Pulp from sugarcane. (See pulp.)

Balanced:

A term that may be applied to a diet, ration, or feed having all known required nutrients in proper amount and proportion based upon recommendations of recognized authorities in the field of animal nutrition, such as the National Research Council, for a given set of physiological animal requirements. The species for which it is intended and the function such as maintenance or maintenance plus production (growth, fetus, fat, milk, eggs, wool, feathers, or work) shall be specified.

Balanced Ration:

Is one that supplies all the dietary essentials in the proper amounts to the animal in every mouth-full so as to support the physiological needs (maintenance) of the animal plus what is necessary to perform his specific physiological function such as meat production, milk production, fetal growth or maximum reproduction.

Barrow:

Male pig castrated at an early age.

Barn Cured:

(Process) Forage material dried with forced ventilation in an enclosure.

Basal Ration:

Ration giving the basic required nutrition but lacking in the substance to be tested.

Bentonite:

A montmorillonite clay used in the feed industry as a pelleting aid, an anticaking agent, and a filler.

Beans:

Seed of leguminous plants especially of the genera Phaseolus, Dali Chos, and Vigna.

Bile:

A fluid produced by the liver, stored in the gall bladder and secreted into the intestine at regular intervals by the way of the bile duct. Essential for emulsification and absorption of fats.

Binder:

An adhesive used to stick feed particles together; mineral or vegetable oils which can be added to premix carriers to increase their carrying capacity for fine powders.

Bio-Availability:

Portion of a nutrient that is actually utilized by the animal.

Biological Availability:

(Biological Value) A measure of the ability of an element to support some physiological process. Sources of nutrients to vary, and the differences can be measured and compared to a standard. For a nutrient to have nutritional value, it must be in a form that can be digested, absorbed and transported to that part of the body where it is utilized for its essential function.

Biscuits:

(Physical form) Shaped and baked dough.

Blending:

(Process) To mingle or combine two or more ingredients of feed. It does not imply a uniformity of dispersion.

Blocked, blocking:

(Process) Having agglomerated individual ingredients or mixtures into a large mass.

Blocks:

(Physical form) Agglomerated feed compressed into a solid mass cohesive enough to hold its form and weighing over two pounds, and generally weighing 30-50 pounds.

Blood:

(Part) Vascular fluid of animals.

Blood Albumin:

(Part) One of the blood proteins.

Blowings:

(Part) See mill dust.

Boar:

Mature male swine.

Bolls:

(Part) The pods or capsules of certain plants, especially flax or cotton. Bolted, bolting: (Process) Separated by means of a bolting cloth as bran from flour.

Bolus:

Large pill usually administered with a balling gun.

Bone:

(Part) Skeletal parts of vertebrates.

Botanical:

Flavoring substances obtained from plant materials by physical means such as extraction or distillation.

Bovine:

Cattle species.

Bran:

(Part) Pericarp of grain.

Branded Feed:

A specific feed manufactured for sale or distribution.

Brand Name:

Any word, name, symbol, or device, or any combination thereof, identifying the commercial feed of a distributor and distinguishing it from that of others.

Bred Animal:

Female animal that has been serviced and considered pregnant.

Bricks:

(Physical form) Agglomerated feed, other than pellets, compressed into a solid mass cohesive enough to hold its form and weighing less than two pounds. (See blocks.)

Broad-Spectrum Antibiotics:

Active against both gram-positive and gram-negative bacteria. It may also show activity against other disease agents, such as spirochetes, rickettsiae, and certain large viruses. The tetracycline, e.g., oxytetracycline (Terramycin), chlortetracycline (Aureomycin), and tetracycline (Tetracycln) are broad- spectrum antibiotics.

Broiler:

Chicken approximately 8-10 weeks old, of either sex, weighing approximately 3-3 1/2 pounds and sufficiently soft-meated to be broiled.

Bronchitis:

Inflammation of the bronchial tubes (bronchi).

Brood Sow:

Mature female swine.

Browse:

(Part) Small stems, leaves and/or flowers and fruits of shrubs, trees and woody vines.

Bull:

Mature male cattle.

Buttermilk:

(Part) All residue from churning cream.

By-Product:

(Part) Secondary products produced in addition to the principal product.

Cake:

(Physical form) The mass resulting from pressing of seeds, meat or fish in order to remove oil, fats, and other liquids.

Calciferol:

Chemical name for vitamin D2.

Calcined, calcining:

(Process) Treated at high temperature in presence of air.

Canned:

(Process) A term applied to a feed which has been processed, packaged, sealed, and sterilized for preservation in cans or similar containers.

Cannery Residue:

(Part) Residue suitable for feeding obtained in preparing a product for canning.

Capon:

Male chicken castrated through surgical or chemical means.

Capillary:

Any one of the minute vessels which connect the arterioles and the venules, forming a network in nearly all of the body.

Caprine:

Goat species.

Carbohydrates:

Organic compounds containing carbon, hydrogen and oxygen, e.g., glucose and corn, and comprising sugar and starch. In the body, carbohydrates are oxidized to yield heat and energy, stored in the liver, and converted into fat.

Carcass Grade:

Rankings for carcass quality assigned by U.S. Government meat graders.

Carcass Meat Trimmings:

(Part) Clean flesh obtained from slaughtered animals. It is limited to striate, skeletal, and cardiac muscles, but may include the accompanying and overlying fat and the portion of skin, sinew, nerve, and blood vessels which normally accompany the flesh.

Carcass Residue, Mammals:

(Part) Residues from animal tissues including bones and exclusive of hair, hoofs, horns, and contents of the digestive tract.

Carotene:

Yellow plant pigment converted into vitamin A in the animal body.

Carrier:

An edible material to which ingredients are added to facilitate uniform incorporation of the latter into feeds. The active particles are absorbed, impregnated or coated into or onto the edible material in such a way as to physically carry the active ingredient.

CC (Cubic Centimeter):

Metric unit of volume. Once used for measuring dosage recommendations of injectable products--is being replaced by mL (milliliter).

Cellulose Gum:

Carboxymethyl cellulose. Cellulose chemically modified to make it water soluble. It acts as a thickener and stabilizer in emulsions, also used as a pelleting aid.

Centipoise:

Unit of measure for viscosity.

Chaff:

(Part) Glumes, husks, or other seed covering and other plant parts separated from seed in threshing or processing.

Charcoal:

Dark-colored porous form of carbon made from the organic parts of vegetable or animal substances by their incomplete combustion.

Chemo-Therapeutic Agent:

Any chemical substance that demonstrates therapeutic activity against a disease.

Chipped, Chipping:

(Process) Cut or broken into fragments; also meaning prepared into small thin slices.

Choline:

Water soluble B-complex vitamin essential for fat metabolism, growth, and feed utilization.

Chopped, Chopping:

(Process) Reduced in particle size by cutting with knives or other edged instruments.

Chromatogram:

Profile resulting from chromatographic analysis.

Chronic Disease:

Disease which is slow in its progress and of long duration.

Chronic Respiratory Disease (CRD):

Respiratory disease produced by *Mycoplasma gallisepticum*. (PPLO) in chickens and generally involving other organisms such as coliforms and *Salmonellae*.

Classes of Nutrients:

Refers to the six categories of water, proteins, carbohydrates, fats/oils, minerals and vitamins.

Cleaned, Cleaning:

(Process) Removal of material by such methods as scalping, aspirating, magnetic separation, or by any other method.

Cleanings:

(Part) Chaff, weed seeds, dust, and other foreign matter removed from cereal grains.

Cobalt:

Essential mineral involved in synthesis and metabolism of vitamin B12. Necessary for respiration, growth and production of red blood cells.

Cobs With Grain:

(Part) The ears of maize without the husks, but consisting of the entire cobs and adhering grain.

Cobs With Husks:

(Part) Kernel-free fibrous inner portion of the ear of maize with enveloping leaves.

Cocci:

Round or oval shaped bacteria.

Coccidia:

One celled parasites.

Cockerel:

Mature male chicken.

Code of Federal Regulations:

Compilation of all final rules published by regulatory agencies in the Federal Register. Part 558 contains regulations for animal drug approvals for use in animal feeds. This is the official reference for animal drug approval requirements, permitted users, use levels and labeling information.

Coefficient of Variation:

The Standard Deviation divided by the mean and multiplied by 100.

Colitis:

Inflammation of the colon.

Collagen:

Main supportive protein of the skin, tendon, bone, cartilage, and connective tissue.

Collective Terms:

Terms used to recognize a general classification of ingredient origin, which perform a similar function, but do not imply equivalent nutritional values.

Colony:

A discreet group of microorganisms as a collection of bacteria in a culture.

Colostrum:

Milk substance, usually containing a high antibody concentration, secreted by the mammary glands a few days before or after birth.

Commercial Feed:

As defined in the Model State Feed Bill, means all materials except whole seeds unmixed or physically altered entire unmixed seeds, when not adulterated within the meaning of Section 7(a), which are distributed for use as feed or for mixing in feed. Refer to Regulation I for list of exempt commodities.

Commercial Premix:

Uniform mixture of micro-ingredients and carriers offered at standard potencies to be used for addition to complete feeds.

Complete Feed:

A nutritionally adequate feed for animals other than man; by specific formula is compounded to be fed as the sole ration and is capable of maintaining life and/or promoting production without any additional substance being consumed except water.

Compound:

A substance containing two or more elements chemically combined in fixed proportions: distinguished from a mixture in that the constituents of a compound lose their individual characteristics and the compound has its own, unique characteristics (e.g., water, calcium carbonate, proteins, carbohydrates, vitamins).

Concentrate:

A feed used with another to improve the nutritive balance of the total and intended to be further diluted and mixed to produce a supplement or a complete feed.

Condensed, Condensing:

(Process) Reduced to denser form by removal of moisture.

Conditioned, Conditioning:

(Process) Having achieved pre-determined moisture characteristics and/or temperature of ingredients or a mixture of ingredients prior to other processing.

Cooked, Cooking:

(Process) Heated in the presence of moisture to alter chemical and/or physical characteristics or to sterilize.

Cooled:

Temperature reduced by air movement, usually accompanied by a simultaneous drying action.

Copper:

Essential mineral which aids in formation of hemoglobin. Anemia and weight loss result from its deficiency.

Cow:

Mature female cattle after delivery of first calf.

Cracked, Cracking:

(Process) Particle size reduced by a combined breaking and crushing action.

Cracklings:

Residue after removal of fat from tissue or skin of animals by dry heat.

Creep Feeding:

Providing feed in an enclosure so that younger animals have free access to it without competition by adult animals.

Crimped, Crimping:

(Process) Rolled by use of corrugated rollers. It may entail tempering or conditioning and cooling.

Crude Protein:

The total in a feed is determined from the nitrogen (N) assay. ($N \times 6.25 = \% \text{ Crude Protein}$)

Crumbled, Crumbling:

(Process) Pellets reduced to granular form.

Crumbles:

(Physical form) Pelleted feed reduced to granular form.

Crushed, Crushing:

(Process) See rolled, rolling.

Cubes:

(Physical form) See pellets.

Cubes, range:

(Physical form) See pellets and range cubes.

Cull:

Material rejected as inferior in the process of grading or separating.

Culture:

Nutrient medium inoculated with specific microorganisms which may be in a live or dormant condition.

Cultured, culturing:

(Process) Biological material multiplied or produced in a nutrient media.

Cure, curing, cured:

(Process) To prepare for keeping for use, or to use, or to preserve. The process may be by drying, use of chemical preservatives, smoking, salting, or by use of other processes and/or materials for preserving.

Custom-Mix:

A feed that is formulated to the specifications of the purchaser.

Custom Premix:

Mixture of micro-ingredients and carriers formulated to the customer's specifications.

Customer Formula Feed:

Consists of a mixture of commercial feeds and/or feed ingredients each batch of which is manufactured according to the specific instruction of the final purchaser.

Cut, Cutting:

(Process) See chopped, chopping.

Cyano-Cobalamine:

Chemical name for vitamin B12.

D-Activated, D-Activating:

Plant or animal sterol fractions which have been vitamin D activated by ultra-violet light or by other means.

Deficiency:

Refers to a shortage of one or more basic nutrients. A deficient level of a given nutrient is generally considered to be the level at which animal performance or health starts to decline.

Defluorinate, Defluorinating:

(Process) Having had fluorine removed.

Defoaming Agent:

Surface active agent.

Degermed:

(Process) Having had the embryo of seeds wholly or partially separated from the starch endosperm.

Dehulled, dehulling:

(Process) Having removed the outer covering from grains or other seeds.

Dehydrating, Dehydrated:

(Process) Having been freed of moisture by thermal means.

Deliquescent:

Attracts and absorbs moisture from the air.

Densifiers:

Compounds such as calcium carbonate which can be added to a premix to adjust the bulk density.

Dextrose Equivalent (D.E.):

(Physical form) The reducing power calculated as dextrose, expressed as a percentage of the dry substance. It is used in conjunction with sugars and starch hydrolyzates.

Diet:

Feed ingredient or mixture of ingredients including water, which is consumed by animals.

Dietary Essential:

Refers to a specific nutrient that must be present in the diet in order to allow the animal to perform its physiological function.

Digest:

To convert food into materials fit to be absorbed.

Digested, digesting:

(Process) Subjected to prolonged heat and moisture, or to chemicals or enzymes with a resultant change or decomposition of the physical or chemical nature.

Diluent:

(Physical Form) An edible substance used to mix with and reduce the concentration of nutrients and/or additives to make them more acceptable to animals, safer to use, and more capable of being mixed uniformly in a feed. (It may also be a carrier.)

Direct-Fed Microbials:

Feed additive which is a source of living (viable) naturally-occurring microorganisms.

Disinfectant:

Chemical that destroys or inactivates microorganisms, e.g. quaternary ammonium compounds and phenols.

Distillation Solubles:

(Part) Stillage filtrate.

Dressed:

Made uniform in texture by breaking or screening of lumps from feed and/or the application of liquid(s).

Dried:

Materials from which water or other liquid has been removed.

Drug:

(As defined by FDA as applied feed) - A substance (a) intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals or (b) a substance other than food intended to affect the structure or any function of the body of man or other animals.

Drug Establishment:

Regulatory classification of any facility which mixes any animal drug into animal feed, further mixes medicated animal feed or repackages a medicated feed. Such facilities must register as drug establishments before performing those tasks.

Drug Fast Bacteria:

Resistant to the action of a specific drug or to staining.

Drug Sponsor:

Firm that produces effectiveness, safety and related data to FDA in order to obtain the agency's approval to manufacture and market animal drugs for specific uses. The sponsor's initial approval limitations apply to individuals and firms that use the sponsor's product to make medicated premixes or feeds.

Dry Cow:

Cow not producing milk.

Dry-milled:

(Process) Tempered with a small amount of water or steam to facilitate the separation of the various component parts of the kernel in the absence of any significant amount of free water.

Dry-Rendered, Dry Rendering:

(Process) Residues of animal tissues cooked in open steam-jacketed vessels until the water has evaporated. Fat is removed by draining and pressing the solid residue.

Dry Lot Feeding:

Feeding cattle in a feedlot.

Dust:

(Part) Fine, dry pulverized particles of matter usually resulting from the cleaning or grinding of grain.

Dyspnea:

Difficult or labored breathing.

Ears:

(Part) Fruiting heads of Zea maize, including only the cob and grain.

Egg Albumin:

(Part) Whites of eggs of poultry.

Element:

Any one of the primary parts of constituents of a thing. One of the 103 known chemical substances that cannot be divided into simpler substances by chemical means. (e.g., calcium, phosphorus, oxygen, nitrogen, hydrogen, carbon). At this time, only 28 of the 103 are thought to be required for proper nutrition.

Emulsifier:

A material capable of causing fat or oils to remain in liquid suspension.

Encephalomalacia:

The condition in chicks resulting from a deficiency of vitamin E (also called "crazy chick disease"). It is characterized by uncoordinated gait, prostration and brain lesions. Softening of the brain.

Encephalomyelitis:

Inflammation of the brain and spinal cord.

Endocarditis:

Inflammation of the heart lining.

Endosperm:

(Part) Starchy portion of seed.

Energy (Of a Ration):

Components of feed which maintain body heat and mechanical activity, e.g., carbohydrates, fats, and some proteins.

Enhancer:

Product used to improve and enrich the characteristics of other products.

Ensiled:

(Process) Aerial parts of plants which have been preserved by ensiling. Normally the original material is finely cut and blown into an air tight chamber such as a silo, where it is pressed to exclude air and where it undergoes an acid fermentation that retards spoilage.

Enteritis:

Inflammation of the intestinal tract.

Enzyme:

Proteins produced by living cells which accelerate the rate of a reaction.

Epithelium:

Covering of the internal and external surfaces of the body including skin, eyes, and blood vessels.

Equine:

Horse species.

Erythrocyte:

Red blood cell.

Esophagus:

The tube which connects the mouth with the stomach.

Essential Oil:

Aromatic essence derived from a natural source.

Esters:

Compounds formed from the reaction between an alcohol and an acid.

Estrogen:

Female sex hormone.

Etiolated:

(Process) A material grown in the absence of sunlight, blanched, bleached, colorless or pale.

Evaporated, evaporating:

(Process) Reduced to a denser form, concentrated as by evaporation or distillation.

Eviscerated:

(Process) Having had all the organs in the great cavity of the body removed.

Ewe:

Mature female sheep.

Expanded, expanding:

(Process) Subjected to moisture, pressure and temperature to gelatinize the starch portion. When extruded, its volume is increased, due to abrupt reduction in pressure.

Extract:

Product derived from its source through the use of solvents. Remove fat or oil from materials by heat and mechanical pressure.

Extracted, Mechanical:

(Process) Having removed fat or oil from materials by heat and mechanical pressure. Similar terms: expeller extracted, hydraulic extracted, "old process."

Extracted, Solvent:

(Process) Having removed fat or oil from materials by organic solvents. Similar term: "new process."

Extruded:

(Process) A process by which feed has been pressed, pushed, or protruded through orifices under pressure.

Extrusion:

The process by which feeds are prepared by passing the ingredient through a die under high temperature and pressure, resulting in a floating pellet.

Fat:

(Part) A substance composed chiefly of triglycerides of fatty acids, and solid or plastic at room temperature.

Fatty Acids:

(Part) Aliphatic monobasic acids containing only the elements carbon, hydrogen, and oxygen.

Feathers:

(Part) The light, horny epidermal outgrowths that form the external covering of birds.

Fed Out:

Fattening of steers.

Federal Register:

Daily publication by the U.S. Government Printing Office which lists proposed and adopted changes in regulations by the U.S. government agencies, including the Food & Drug Administration.

Feed(s):

Edible material(s) which are consumed by animals and contribute energy and/or nutrients to the animal's diet. (Usually refers to animals rather than man.)

Feed Additive:

Ingredient or combination of ingredients added to the basic feed mix or its parts to fulfill a specific need. Usually used in micro-quantities and requires careful handling and mixing.

Feed Additive Compendium:

Unofficial guide to the use of drugs in animal feeds, based on regulations by the Food and Drug Administration as interpreted by drug manufacturers who sponsor the drugs for FDA approval. Published by The Miller Publishing Company in cooperation with the Animal Health Institute.

Feed Additive Concentrate:

(As defined by FDA) - An article intended to be further diluted to produce a complete feed or a feed additive supplement and is not suitable for offering as a supplement or for offering free choice without dilution. It contains, among other things, one or more additives in amounts in a suitable feed base such that from 100 to 1000 pounds of concentrate must be diluted to produce 1 ton of a complete feed. A "feed additive concentrate" is unsafe if fed free choice or as a supplement because of danger to the health of the animal or because of the production of residues in the edible products from food producing animals in excess of the safe levels established.

Free Additive Premix:

(As defined by FDA) - An article that must be diluted for safe use in a feed additive concentrate, a feed additive supplement or a complete feed. It contains, among other things, one or more additives in high concentration in a suitable feed base such that up to 100 pounds must be diluted to produce 1 ton of a complete feed. A feed additive premix contains additives at levels for which safety to the animals has not been demonstrated and/or which may result when fed undiluted in residues in the edible products from food producing animals in excess of the safe levels established.

Feed Conversion:

The amount of feed fed divided by weight gain.

Feed Efficiency:

Lbs. of feed Consumed per Lb. of weight Gain.

Feed Efficiency Index:

Feed efficiency of Experimental Group \times 100. Feed Efficiency of Control Group.

Feed Grade:

Suitable for animal consumption.

Feed Ingredient:

Each of the constituent materials making up a commercial feed.

Feed Mixture:

See formula feed.

Feed Ratios:

The variable relationships of the cost of feeding animals to market weight sales prices, expressed as ratios, such as the hog/corn ratio. These serve as indicators of the profit return or lack of it in feeding animals to market weight

Feeder Cattle:

Beef cattle being fattened in feedlot for market.

Feed Stuff:

See feed(s).

Fermentation:

Anaerobic oxidation of carbohydrates by enzyme action of microorganisms.

Fermentation Aid:

A substance added to assist in providing proper conditions which results in action by yeasts, molds or bacteria in a controlled aerobic or anaerobic process used for the manufacture of certain products.

Fermentation Product:

Product formed as a result of an enzymatic transformation or organic substrates.

Fermented, fermenting:

(Process) Acted on by yeasts, molds, or bacteria in a controlled aerobic or anaerobic process in the manufacture of such products as alcohols, acids, vitamins of the B-complex group, or antibiotics.

Fetus:

The unborn offspring of any pregnant animal.

Fiber:

Carbohydrate (mostly cellulose) which comprises plant cell walls and wood. It is utilized chiefly by ruminants and horses.

Fibrin:

Insoluble protein formed from fibrinogen by the action of thrombin (fibrin ferment), in the clotting of blood. Fibrin forms the essential portion of the blood clot.

Fibrinogen:

Soluble protein in the blood plasma, which by the action of thrombin (fibrin ferment) is converted into fibrin, thus producing clotting of the blood.

Fines:

(Physical form) Any materials which will pass through a screen whose openings are immediately smaller than the specified minimum crumble size or pellet diameter.

Finishing Stock:

Fattening steers, hogs, or lambs in the last stage.

Fish Meal, Dried:

Source of vitamins, unidentified growth factors, minerals and amino acids. Prepared from residues of canning or oil extraction operations.

Fish Solubles Condensed:

Made by evaporating to semi-solid conditioners, the water-oil liquid which results when fish wastes are processed by a hydraulic method. Source of B complex vitamins and unidentified growth factors.

Flaked, Flaking:

(Process) See rolled.

Flakes:

(Physical form) An ingredient rolled or cut into flat pieces with or without prior steam conditioning.

Flour:

(Part) Soft, finely ground and bolted meal obtained from the milling of cereal grains, other seeds, or products. It consists essentially of the starch and gluten of the endosperm.

Flavor:

Product providing taste and aroma.

Floating Feed:

Feed prepared by extrusion that remains on the water surface for extended periods.

Fodder:

(Part) The green or cured plant, containing all the ears or seed heads, if any, grown primarily for forage. (It has been applied more specifically to corn and sorghum).

Folic Acid:

Water soluble B-complex vitamin essential for growth and development of red blood cells.

Food(s):

When used in reference to animals, is synonymous with feed(s). See feed.

Form FDA 1900, Medicated Feed Application:

Form which must be approved by the Food and Drug Administration before a person or firm may legally manufacture a medicated animal feed bearing or containing a new animal drug. In addition to getting FDA approval for such feed manufacturing, the applicant also agrees to follow specific conditions to maintain his approval.

Formula Feed:

Two or more ingredients proportioned, mixed, and processed according to specifications.

Free Choice:

A feeding system by which animals are given unlimited access to the separate components or groups of components constituting the diet.

Fry:

Newly hatched fish that externally are replicates of the adult.

Fryer:

Chicken approximately 10-12 weeks old of either sex, weighing 3 1/2 - 4 1/2 lbs.

Full Feed:

Process of increasing feed intake of an animal until it reaches a maximum level for economical gain or production.

Fungi:

Certain plant organisms which vary in size from microscopic (e.g., molds and actinomycetes) to mushrooms and toadstools.

Fungicidal:

Capable of destroying fungi.

Fused, fusing:

(Process) Melted by heat.

Gangrene:

Massive death of tissue due to loss of blood supply and followed by bacterial invasion and putrefaction.

Gastritis:

Inflammation of stomach lining.

Gelatinize, Gelatizing:

(Process) Having had the starch granules completely ruptured by a combination of moisture, heat and pressure, and in some instances, by mechanical shear.

Germ:

(Part) The embryo found in seeds and frequently separated from the bran and starch endosperm during milling.

Gilt:

Young female swine.

Gluten:

(Part) The tough, viscid nitrogenous substance remaining when the flour or wheat or other grain is washed to remove the starch.

Glycerin:

An odorless, colorless, syrupy liquid prepared by the hydrolysis of fats and oils; it is used as a solvent, etc. and in the manufacture of explosives.

Glycogen:

A complex carbohydrate stored in the liver, glycogen is converted to simple sugars when the normal sugar reserves of the body are depleted. Referred to as “animal starch.”

Good Manufacturing Practices:

Regulations issued by FDA (separate sets for medicated feeds and for medicated premixes) which establish basic quality control procedures (in terms of such parameters as facilities and equipment, quality control, records, and reports) for manufacture of medicated feeds and premixes.

Gossypol:

(Part) A phenolic pigment in cottonseed that is toxic to some animals.

Grain:

(Part) Seed from cereal plants.

Gram:

A unit of weight in the metric system. 453.6 grams = 1 pound, 1000 milligrams = 1 gram 1,000,000 micrograms = 1 gram

Gram Positive and Gram Negative:

Means of classifying bacteria by first staining bacteria in a crystal violet dye solution and then attempting to decolorize this stain by exposure to alcohol or acetone. Bacteria which retain the crystal violet color are called gram-positive bacteria, and those which are decolorized are called gram-negative bacteria.

GRAS:

Abbreviation for the phrase “Generally Recognized as Safe.” A substance which is generally recognized as safe by experts qualified to evaluate the safety of the substance for its intended use.

Grease:

Animal fats with a titer below 40°C.

Grit:

Course ground, insoluble, non-nutritive material (e.g. granite rock) for the in vivo mechanical grinding of feed by avian species.

Grits:

(Part) Coarsely ground grain from which the bran and germ have been removed, usually screened to uniform particle size.

Groats:

(Part) Grain from which the hulls have been removed.

Ground, grinding:

(Process) Reduced in particle size by impact, shearing or attrition.

Hay:

(Part) The aerial portion of grass or herbage especially cut and cured for animal feeding.

Heads:

(Part) The seed or grain containing portions of a plant.

Heat-Processed Heat-processing:

(Process) Subjected to a method of preparation involving the use of elevated temperatures, with or without pressure.

Heat Rendered, Heat rendering:

(Process) Melted, extracted, or clarified through use of heat. Usually, water and fat are removed.

Heifer:

Young cow (15-24 months of age). A heifer calf is 2-10 months of age.

Hemoglobinuria:

Presence of blood in the urine.

Hemoglobin:

The oxygen carrying red pigment of the blood corpuscles. Contains iron.

High Efficiency Ration:

High energy, low fiber ration which enhances feed.

Hilum:

A scar left where the seed was attached to the placenta.

Homogenized, homogenizing:

(Process) Particles broken down into evenly distributed globules small enough to remain emulsified for long periods of time.

Hormones:

Chemical agents produced by ductless glands (e.g., adrenals, pituitary, thyroid), and which influence growth, metabolism, reproduction and other body processes

Hulls:

(Part) Outer covering of grain or other seed.

Humectant:

Product used to provide and preserve moisture.

Husks:

(Part) Leaves enveloping an ear of maize, or the outer coverings of kernels or seeds, especially when dry and membranous.

Hydrocarbons:

Organic compound which contains hydrogen and carbon only.

Hydrolyzed, hydrolyzing:

(Process) Complex molecules having been split to simpler units by chemical reaction with water, usually by catalysis.

Hydrophilic:

Having an affinity for water.

Hydrophobic:

Having a non-affinity for water.

Hygroscopic:

A substance that readily attracts or absorbs moisture from the air. In ingredients this causes caking and clumping and if enough moisture is absorbed, the analysis can be significantly altered.

Hyper Sensitivity:

A state in which the body reacts to a foreign agent more strongly than normal.

Impurities:

Undissolved substances in fats and oils obtained from processing animal or plant materials.

Indigenous:

Existing or growing naturally in a region.

Ingest:

To take food, medicines, etc., into the stomach. Not to be confused with “Digest” (see above).

Ingredient, Feed ingredient:

Means a component part or constituent of any combination or mixture making up a commercial feed.

Inoculation:

Introduction of microorganisms into the body or culture medium in an effort to product growth or aid in the production of antibodies and immunity.

Intra-Muscular (IM):

Injection deep into the muscle.

Intravenous (IV):

Injection into a vein.

Intrauterine:

Injection into the uterus.

Intravaginal:

Injection into the vagina.

In Vitro:

Test method of evaluating the action of a drug in the laboratory or test tube.

Iodinated:

(Process) Treated with iodine.

Iodine:

Element which is essential for proper function of the thyroid gland and basal metabolism.

Iodize, iodized:

(Process) To treat with iodine or an iodide.

Ionophores:

Class of chemical compounds which modify the gut microflora of ruminants to provide improved animal performance.

Iron:

Mineral essential in information of hemoglobin. Anemia and weight loss result from deficiency.

Irradiated, irradiating:

(Process) Treated, prepared, or altered by exposure to a specific radiation.

Juice:

(Part) The aqueous substance obtainable from biological tissue by pressing or filtering with or without addition of water.

Keratin:

The principal matter of hair, nails, horn, feathers, etc.

Keratitis:

Inflammation of the cornea (surface of the eye over the eyeball).

Kernel:

(Part) A whole grain. For other species, dehulled seed.

Ketones:

Organic compounds containing a carbonyl group which is linked to two other groups via carbon atoms.

Kibbled, kibbling:

(Process) Cracked or crushed baked dough, or extruded feed that has been cooked prior to or during the extrusion process.

Kilo:

1000 calories or grams.

Label:

A display of written, printed, or graphic matter upon or affixed to the container in which a commercial feed is distributed, or on the invoice or delivery slip with which a commercial feed is distributed.

Labeling:

All labels and other written, printed or graphic matter (1) upon a commercial feed or any of its containers or wrapper or (2) accompanying such commercial feed. Any instrument, such as tags, invoices, delivery tickets or printed tags, upon which the feed analysis guarantees and other required information are stated.

Laboratory Method:

A technique or procedure of conducting scientific experiment, test, investigation or observation according to a finite established logical or systematic plan.

Lard:

(Part) Rendered fat of swine.

Leached:

(Process) The condition of a product following subjection of the material to the action of percolating water or other liquid.

Least Cost:

A loosely used word to describe the most inexpensive formulation of a product, ration or diet by combining raw materials, ingredients, and nutrient requirements in some specified format.

Least Cost Formulation:

A final step in ration formulation (typically done by computer) where the ingredients are chosen based on their ability to provide available nutrients at the least cost.

Leaves:

(Pan) Lateral outgrowths of stems that constitute part of the foliage of a plant, typically a flattened green blade, and primarily functions in photosynthesis.

Lecithin:

(Part) A specific phospholipid. The principal constituent of crude phosphatides derived from oil bearing seeds.

Legume:

Fruit or seed of leguminous plants, e.g., peas and soybeans.

Leukocyte:

White blood cell.

Leukocytosis:

An increase in the number of white blood cells.

Ligno-Sulfonate:

The extract of spent sulfite liquor derived from the sulfite digestion of wood in the paper making process. Used in the feed industry as a pelleting aid, an energy source, and a surfactant.

Lipids:

Certain fats or fat-like substances which are insoluble in water, but soluble in organic solvents.

Lipophilic:

Having an affinity for oil.

Liver:

(Pan) The hepatic gland.

Lipophobic:

Having a non-affinity for oil.

Lot/Batch Serial Number:

LBS; for the purpose of the GIBC and HIBCC Standards, identification of a product that groups the product in a unique manner to identify those products manufactured during the same relative time or in the same facilities. Some products have both a serial number and a lot/batch number. In this case, the serial number appearing on higher levels of packaging.

Lubricant:

An additive which causes the pellet mill to run smoother, faster, and with less sticking of ingredients to the surface of the die.

Lymph:

Transport body fluid found in the lymphatic vessels.

Lymphadenitis:

Inflammation of lymph glands.

Lysine:

An amino acid; an essential amino acid for most species.

Macroscopic:

Large enough to be observed with the naked eye.

Magnesium:

Essential mineral, which promotes proper function of the neuromuscular system and sound skeletal development.

Malt:

(Part) Sprouted and steamed whole grain from which the radicle has been removed.

Malted, malting:

(Process) Converted into malt or treated with malt or malt extract.

Manganese:

Essential mineral, which ensures proper bone formation, growth, and reproduction.

Manufacturer's Identification Number:

In the UPC system, the four or five-digit number assigned to a manufacturer by the Uniform Code Council, Inc. This number appears as the left half of the UPC number. See item code.

Mash:

An ingredient which has been ground or otherwise reduced in particle size.

Mastitis:

Inflammation of the mammary glands.

Meal:

An ingredient which has been ground or otherwise reduced in particle size, i.e. corn meal.

Medicated Feed:

Any feed which contains drug ingredients intended or presented for the cure, mitigation, treatment, or prevention of diseases of animals other than man or which contains drug ingredients intended to affect the structure or any function of the body of animals other than man. Antibiotics included in a feed at growth promotion and/or efficiency levels are drug additives and feeds containing such antibiotics are included in the foregoing definition of "Medicated Feeds"

Meningitis:

Inflammation of the membranes surrounding the brain and spinal cords.

Metabolism:

The sum of all the physical and chemical processes by which living organized substance is produced and maintained.

Methionine:

An amino acid which contains sulfur; an essential amino acid for most species.

Microbe:

Same as microorganism.

Microflora:

Microbial life characteristic of a specific region.

Micro-ingredients:

Vitamins, minerals, antibiotics, drugs, and other materials normally required in small amounts and measured in milligrams, micrograms or parts per million (ppm).

Micro-organism:

Minute living organism of microscopic size, e.g., bacteria.

Middlings:

(Part) A by-product of the flour milling comprising several grades of granular particles containing different proportions of endosperm, bran, germ each of which contains different levels of crude fiber.

Milk:

Total lacteal secretion from the mammary gland.

Mill By-Product:

(Part) A secondary product obtained in addition to the principal product in milling practice.

Mill Dust:

(Part) Fine feed particles of undetermined origin resulting from handling and processing feed and feed ingredients.

Mill Run:

(Part) The state in which a material comes from the mill, ungraded and usually uninspected.

Mineral:

Inorganic elements, e.g., calcium, phosphorus, sodium, zinc, and copper.

Mineralize, mineralized:

(Process) To supply, impregnate, or add inorganic mineral compounds to a feed ingredient or mixture.

Mini-Pellet:

Small pellet 1/8 inch in diameter.

Miscible:

When a substance can be finely dispersed in a second substance.

Mixing:

(Process) To combine by agitation two or more materials to a specific degree of dispersion.

(Part) Combination of different drugs or ingredients. In chemistry, any combination of different compounds.

Molasses:

The thick, viscous by-product resulting from refined sugar production or the concentrated, partially dehydrated juices from fruits.

Molds (Fungi):

Fungi which are distinguished by the formation of mycelium (a network of filaments or threads), or by spore masses.

Molt:

To cast off or slough off feathers.

Monogastric:

Animal having a simple stomach such as poultry, swine or humans.

Mortality:

Frequency of deaths; proportion of deaths in a specified number of the population, the death rate.

Mucous Membranes:

Living membranes of those cavities of the body which communicate directly or indirectly with the exterior, e.g., mouth and anus.

Mycosis:

Caused by the active growth of fungi within the animal body.

Mycotoxicosis:

Caused by the introduction of a toxic substance into the animal body (feed, dust, litter, etc.).

NPN:

Nitrogen found in the feed which is not contained in feed protein. May be added as urea, ammonia, etc.

Narrow Spectrum Antibiotic:

Activity restricted to either gram-positive or gram-negative bacteria, penicillin and streptomycin, respectively.

Natural Flavor:

The essential oil, oleoresin, essence, extractive, protein hydrolysate, distillate, or any product of roasting, heating, or enzymolysis which contains the flavoring principles derived from a spice, fruit or its juice, vegetable or its juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products, or the fermentation product of any of the above.

Natural Immunity:

Immunity possessed by animal species as part of its normal biological make up.

Needs:

Any discrepancy between perceived expectations and present reality. Any variance from 100% satisfaction.

Nematode:

Roundworm parasite.

Niacin (Nicotinamide, Nicotine Acid, Niacinami):

Water soluble B-complex vitamin concerned with utilization of carbohydrates. Aids in cell growth and function.

Nitrofurans:

A class of synthetic organic nitrogen compounds which have the ability to inhibit the growth of or to destroy microorganisms.

Nutrient:

A feed constituent in a form and at a level that will help support the life of an animal. The chief classes of feed nutrients are proteins, fats, carbohydrates, minerals and vitamins.

Nutrition:

Involves various chemical and physiological activities which change food elements into body elements. This involves the acquisition, degradation, digestion, absorption, and metabolism of the food elements.

Offal:

(Part) Material left as a by-product from the preparation of some specific product, less valuable portions and the by-products of milling.

Oil:

(Part) A substance composed chiefly of triglycerides of fatty acids, and liquid at room temperature.

Ovine:

Sheep species.

Ovum:

Female reproductive (egg) cell which, after fertilization, develops into a new member of the same species.

Oxidation:

Chemical change resulting from exposure to oxygen. Chemical process involving addition of oxygen or removal of hydrogen and increase in the valency of an element. The substance causing the oxidation is the oxidizing agent.

Oxidize:

Combine with oxygen.

pH:

Measurement of acidity. A term used to express the relative acidity or alkalinity of a solution. A solution with a pH of 7 is neutral; less than 7 - acid; greater than 7 - alkaline.

Parasite:

A plant or animal which lives on or within another living organism at whose expense it obtains some advantage without compensation.

Parasitism:

A way of life in which one species, the parasite, living in or on another species, the host, gains its livelihood at the expense of the latter. By definition, parasites damage the host.

Parboiling:

A hydrothermal process in which the crystalline form of starch is changed into the amorphous form, due to the irreversible swelling and fusion of starch. This is accomplished by soaking, steaming, drying and milling to produce physical and chemical modifications.

Passive Immunity:

Immunity induced by injection of antibodies previously produced in another animal, e.g., gamma globulin and serums. Duration of passive immunity is usually short (few weeks).

Pathological:

Diseased or due to disease.

Pearled, pearling:

(Process) Dehulled grains reduced by machine brushing into smaller smooth particles.

Peel:

(Part) See skin.

Pellets:

(Physical form) Agglomerated feed formed by compacting and forcing through die openings by a mechanical process. Similar terms: pelleted feed, hard pellet.

Pellet Durability:

The ability of a pellet to withstand abrasion.

Pellet Hardness:

The ability of a pellet to withstand a crushing load.

Pellets, soft:

(Physical form) Similar term: High Molasses Pellets, Pellets containing sufficient liquid to require immediate dusting and cooling.

Pelleting Aid:

Any additive which helps the pelleting process, i.e. a binder, a lubricant, a wetting agent.

Pelleted, pelleting:

(Process) Having agglomerated feed by compaction and forced through die openings.

Peptides:

Combination of two or more Amino Acids.

Perception:

The process by which an individual maintains contact with the environment.

Pericarp:

The wall of the ripened ovary of a flower, constituting the germ of the fruit.

Physical Distribution:

The economics and operations required for procurement, storage and transportation of material to support production and sales.

Polished, polishing:

(Process) Having a smooth surface produced by mechanical process usually by friction.

Pomance:

(Part) Pulp from fruit. See pulp.

Porcine:

Swine species.

Potassium:

Mineral essential for normal growth and in control of passage of fluids through membranes.

Potency:

Powder of a drug to produce its desired effect.

Poult:

Young turkey.

PPM (Parts Per Million):

Unit of measure used for dosage recommendations of antibiotics and other drugs in drinking water and feed, e.g., 1 milligram per kilogram.

Precipitated, Precipitating:

(Process) Separated from suspension or a solution as a result of some chemical or physical change brought about by a chemical reaction, by cold, or any other means.

Premix:

A uniform mixture of one or more micro-ingredients with diluent and/or carrier. Premixes are used to facilitate uniform dispersion of the micro- ingredients in a larger mix.

Premixing:

(Process) The preliminary mixing of ingredients with diluents and/or carriers.

Preservative:

A substance added to protect, prevent or retard decay, discoloration or spoilage under conditions of use or storage.

Pressed, pressing:

Compacted or molded by pressure; also meaning having fat, oil or juices extracted under pressure.

Presswater:

The aqueous extract of fish or meat free from the fats and/or oils. Presswater is the result of hydraulic pressing of the fish or meat followed by separation of the oil either by centrifuging or other means.

Probiotic:

A live microbial feed supplement which beneficially affects the host animal by improving its intestinal microbial balance.

Product:

(Part) A substance produced from one or more other substances as a result of chemical or physical change.

Product Uniformity:

Consistent appearance from batch to batch.

Prophylaxis:

Prevention of disease.

Proteins:

(Part) Any of a large class of naturally-occurring complex combinations of amino acids.

Processed Animal Waste:

Animal waste that has been artificially dried, dry stacked, ensiled, oxidized, chemically treated, micro- biologically digested, chemically or physically fractionated or otherwise treated to render the material suitable for feeding.

Pullet:

Immature female chicken (non-laying stage).

Pulp:

(Part) The solid residue remaining after extraction of juices from fruits, roots, or stems. Similar terms: Bagasse and Pomace.

Pulverized, pulverizing:

(Process) See ground, grinding.

Pyogenic:

Puss-producing.

Qualitative Assay:

Quick, simple test to determine the proper identification of a substance.

Quality:

Most important characteristic of a feed or feed ingredient.

Quantitative Assay:

For animal drugs, usually a laboratory test conducted to measure the amount of a given drug present in a medicated feed or ingredient. Such tests are required periodically by the Good Manufacturing Practices that apply to products mixed under approved medicated feed applications.

Ram:

Mature male sheep.

Range Cake:

(Physical form) See cake.

Range Cubes:

(Physical form) Large pellets designed to be fed on the ground. Similar term: range wafer.

Ration:

The amount of the total feed which is provided to one animal over a 24-hour period.

Raw:

Food in its natural or crude state not having been subjected to heat in the course of preparation as food.

Recall:

Removal of a product from the market. Product may have been distributed beyond direct control of the maker, may be still in the firm's control or may not yet be fully processed. Recall may be prompted by a variety of factors ranging from emergency contamination to improper, but non-threatening, label errors.

Refuse:

(Part) Damaged, defective, or superfluous edible material produced during or left over from a manufacturing or industrial process.

Renal:

Pertaining to the kidneys.

Residue:

Part remaining after the removal of a portion of its original constituents.

Resin:

A solid or semi-solid, amorphous (shapeless), organic substance soluble in organic solvents but not in water.

Resistance:

Ability of microorganisms to survive contact with an antibiotic or other drug.

Resistance Bacterial:

Ability of organisms to survive on contact with an antibiotic or other drug.

Rhino-Pneumonitis:

Inflammation of the nasal and bronchial passages.

Rhinotracheitis:

Inflammation of the nasal passages and trachea windpipe.

Riboflavin:

Chemical name for vitamin B22.

Rickets:

Abnormal bone development in the young resulting from a deficiency of vitamin D and/or calcium and phosphorus.

Rickettsiae:

Small microorganisms varying in size between viruses and bacteria.

Rolled, Rolling:

(Process) Having changed the shape and/or size of particles by compressing between rollers. It may entail tempering or conditioning.

Roots:

(Part) Subterranean parts of plants.

Roughage:

Pasture, hay or silage.

Rumen:

Fore-stomach of a ruminant (see below). Also called Paunch.

Rumen contents:

Contents of the first two compartments of the stomach of a ruminant.

Ruminant:

Animals having a complex foregut (rumen) which allows for predigestion of fibrous feeds, such as cattle, sheep or goats.

Ruminant Animal:

Is one that has a multi-compartmented digestive system that can utilize more forage type feedstuffs due to active microbial fermentation.

Saccharomyces Cerevisiae:

A fungus that is a true yeast used in baking and brewing for the production of carbon dioxide and alcohol. Also produces enzymes, vitamins and other metabolites.

Sanitation:

Establishment of environmental conditions favorable to health.

Sanitizer:

Chemical that promotes sanitation.

Saponification:

Convert fats into soaps and glycerol by heating with alkali.

Sauce:

A multiple component fluid dressing or topping consisting of a combination of one or more ingredients imparting special characteristics or flavors. It may be formulated separately and added to another ingredient or combination of ingredients.

Scalped:

Having removed larger material by screening.

Scours:

Diarrhea.

Scratch:

(Physical form) Whole, cracked, or coarsely cut grain. Similar terms. Scratch grain, scratch feed.

Screened, screening:

(Process) Having removed larger material by screening.

Seed:

(Part) The fertilized and ripened ovule of a plant.

Secondary Invaders:

Infected agents which attack after a primary causative organism has established an infection.

Self-Fed:

A feeding system where animals have continuous free access to some or all component(s) of a ration, either individually or as mixtures.

Self-Feeding:

Animals obtain feed themselves from a trough or feeder, which is kept replenished.

Separating:

(Process) Classification of particles by size, shape, and/or density.

Separating, Magnetic:

(Process) Removing ferrous material by magnetic attraction.

Sequencing:

The procedure of scheduling one mix after another to minimize potential carry-over that could influence animal performance or health.

Sequestrant:

Agent that will inactivate trace metals.

Serum:

Clear portion of any animal liquid separated from its more solid elements, especially the clear liquid which separates in blood clotting from the clot and corpuscles.

Shells:

(Part) The hard, fibrous, or calcareous covering of a plant or animal, i.e., nut, egg, oyster.

Shoots:

(Part) The immature aerial parts of plants, stems with leaves and other appendages in contrast to the roots.

Shorts:

(Part) Fine particles of bran, germ, flour, or offal from the tail of the mill in commercial flour milling.

Shrink:

Usually the loss incurred due to the handling of the commodity; beginning physical inventory plus additions less subtractions less ending physical inventory equals shrink.

Shrinkage:

Difference between the weight of an animal when loaded and on arrival on the stockyard.

Shuttling:

The practice of changing growth promotant or therapeutic agents at intervals to maintain drug efficacy and animal performance.

Sifted:

(Process) Materials that have been passed through wire sieves to separate particles in different sizes. The separation of finer materials then would be done by screening.

Silage:

Corn or other field crops stored in a green instead of dry state.

Sizing:

(Process) See screening.

Skimmed:

(Process) Material from which floating solid material has been removed. It is also applied to milk from which fat has been removed by centrifuging.

Skin:

(Part) Outer coverings of fruits or seeds, as the rinds, husks, or peels. May also apply to dermal tissue of animals.

Sodium Chloride (Salt):

Mineral salt which maintains proper acid-base balance and promotes good digestion.

Soluble:

When a substance can be completely dissolved in another substance.

Solubles:

Liquid containing dissolved substances obtained from processing animal or plant materials. It may contain some fine suspended solids.

Solvent:

Substance into which other items can be dissolved.

Solvent Extracted:

(Process) A product from which oil has been removed by solvents.

Species:

Group of animals or plants which possess in common one or more distinctive characteristics, and may interbreed and reproduce these characteristics in their offspring.

Spectrum:

A profile of the amount of energy absorbed, or emitted, by a given chemical at different wave lengths.

Spent:

Exhausted of active or effective properties, i.e., absorbing activity.

Spirilla:

Thread-shaped or corkscrew-shaped bacteria.

Spirochetes:

A spiral shaped class of bacteria.

Spot Tests:

Identification of individual crystals by the use of appropriate chemical solutions.

Spray Dehydrated:

(Process) Material which has been dried by spraying on the surface of a heated drum. It is recovered by scraping from the drum.

Stability:

The ability of a substance to retain its original physical state, chemical structure, composition, and/or properties.

Stabilize:

To retard degradation of ingredients.

Stalk(s):

(Part) The main stem of an herbaceous plant often with its dependent parts, as leaves, twig, and fruit.

Standard Deviation:

A unit of measure used to describe the width or spread of distribution.

Starch:

A white, granular glucose polymer of plant origin. The principal part of seed endosperm.

Steamed, steaming:

(Process) Having treated ingredients with steam to alter physical and/or chemical properties. Similar terms: steam cooked, steam rendered, tanked.

Steep-extracted, steep-extracting:

(Process) Soaked in water or other liquid (as in the wet milling of corn) to remove soluble materials.

Steepwater:

Water containing soluble materials extracted by steep-extraction, i.e. by soaking in water or other liquid (as in the wet milling of corn).

Steer:

Castrated young male cattle.

Stem:

(Part) The coarse, aerial parts of plants which serve as supporting structures for leaves, buds, fruit, etc.

Steroid:

Class of chemical compounds which has numerous metabolic functions. Many sex hormones belong to this chemical class.

Sterols:

(Part) Solid cyclic alcohols which are the major constituents of the unsaponifiable portion of animal and vegetable fats and oils.

Stick:

See stickwater; presswater.

Stickwater, fish:

(Part) The aqueous extract of cooked fish free from the oil. Stickwater contains the aqueous cell solutions of the fish and any water used in processing.

Stickwater, meat:

(Part) The aqueous extract of meat free from the fat. Meat stickwater is the result of the wet rendering of meat products and contains the aqueous cell solution, the soluble glue proteins, and the water condensed from steam used in wet rendering.

Stillage:

(Part) The mash from fermentation of grains after removal of alcohol by distillation.

Stokes:

A compression device used to measure pellet hardness. Originally designed for testing pill hardness.

Stover:

(Part) The stalks and leaves of corn after the ears, or sorghum after the heads have been harvested.

Straw:

(Part) The plant residue remaining after separation of the seeds in threshing. It includes chaff.

Stress:

Environmental factors which tend to lower the ability of an animal to resist disease.

Subcutaneous Administration:

Injection into the loose connective tissue between the skin and muscles.

Sun-cured:

(Process) Material dried by exposure in open air to the direct rays of the sun.

Supplement:

A feed used with another to improve the nutritive balance or performance of the total and intended to be:

1. Fed undiluted as a supplement to other feeds; or
2. Offered free choice with other parts of the ration separately available, or
3. Further diluted and mixed to produce a complete feed.

Surface Tension:

Tension between a liquid surface and a gas.

Surfactant:

Surface active agent.

Sweeteners:

Substances that provide a sweet taste (sucrose, dextrose, saccharin, aspartame).

Synergistic:

Cooperative action of discrete agencies such that the total effect is greater than the sum of the effects of each used alone.

Synergism Antibiotic:

Refers to the ability of a combination of antibiotics to be more effective than the single antibiotics which make up the combination.

Syrup:

(Part) Concentrated juice of a fruit or plant.

Tallow:

(Part) Animal fats with titer above 400.

Tankage:

(Pail) See carcass residue.

Tempered, tempering:

(Process) See conditioned, conditioning.

Therapy:

Therapeutic treatment of disease.

Thiamine:

Chemical name for vitamin B1.

Thrombin:

Enzyme present in blood, which converts fibrinogen into fibrin, the essential protein portion of a blood clot.

Thyroid Gland:

Gland situated in the front of the trachea at the base of the neck, which is vital to body metabolism.

Thyroxin:

Hormone secreted by thyroid gland. Chemically, it is an organic iodine compound.

Tissue Culture Origin:

(See Modified Live Virus Vaccine).

Titer:

A property of fat determined by the solidification point of fatty acids liberated by hydrolysis.

Toasted:

(Process) Browned, dried, or parched by exposure to a fire, or to gas or electric heat.

Tom:

Male turkey.

Total Digestible Nutrients:

Difference between intake of feed nutrients and what is excreted in the feces.

Toxic:

Of a poisonous nature. Any nutrient, even those essential for growth are toxic if fed at high enough levels. According to the N.A.S. publication "Mineral Tolerance of Domestic Animals," the maximum tolerable level is defined as that dietary level that, when fed for a limited period, will not impair animal performance and should not produce unsafe residues in human food derived from the animal.

Toxin:

Any poisonous substance of microbic, vegetable or animal origin.

Trace Minerals:

Mineral nutrients required by animals in micro amounts only (measured in milligrams per pound or smaller units).

Tracheitis:

Inflammation of the trachea (windpipe).

Trematodes:

Fluke.

Tubers:

(Part) Short, thickened fleshy stems or terminal portions of stems or rhizomes that are usually formed underground, bear minute scaled leaves, each with a bud capable under suitable conditions of developing into a new plant, and constitutes the resting stage of various plants.

Twigs:

(Part) Small shoots or branches, usually without leaves, portions of stems of variable length or size.

Type A Medicated Article:

Is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. It consists of a new animal drug(s), with or without inactive ingredients. The manufacture of a Type A medicated article requires an application approved under 21 CFR § 514.105(a).

Type B Medicated Feed:

Is intended solely for the manufacture of other medicated feeds (Type B or Type C). It contains a substantial quantity of nutrients including vitamins and/or minerals and/or other nutritional ingredients in an amount not less than 25 percent of the weight of the Type A medicated article. It is manufactured by diluting a Type A medicated article or another Type B medicated feed. The maximum concentration of animal drug(s) in a Type B medicated feed is 200 times the highest continuous use level for Category II drugs. The term "highest continuous use level" means the highest dosage at which the drug is approved for continuous use (14 days or more), or, if the drug is not approved for continuous use, it means the highest level used for disease prevention or control. If the drug is approved for multiple species at different use levels, the highest approved level of use would govern under this definition. The manufacture of a Type B medicated feed from a Category H, Type A medicated article requires an application approved under 21 CFR § 514.105(b).

Type C Medicated Feed:

Is intended as the complete feed for the animal or may be fed "top dressed" (added on top of usual ration) or offered "free choice" (e.g., supplement) in conjunction with other animal feed. It contains a substantial quantity of nutrients, including vitamins, minerals, and/or other nutritional ingredients. It is manufactured by diluting a Type A medicated article or a Type B medicated feed. A Type C medicated feed may be further diluted to produce another Type C medicated feed. The manufacture of a Type C medicated feed from a Category H, Type A medicated article requires an application approved under 21 CFR § 514.105(b).

U. S. P. Grade:

Chemical whose purity specifications conform to those of the United States Pharmacopoeia.

Ulcer:

Disintegrated dead tissue.

Uncleaned:

(Physical form) Containing foreign matter.

Ungraded Protein:

Protein that escapes degradation in the rumen. Also known as by-pass protein.

Undulant:

Fluctuating.

Unidentified Growth Factors (U. G. F.):

One of a group of nutrients that have not been isolated and identified, and which promote growth on a diet containing ample quantities of all known nutrients.

Unit:

Standard of measurement for amount of penicillin and certain vitamins, e.g., International Unit (IU) and U.S.P. Units.

Unaponifiable, matter:

(Part) Ether-soluble material extractable after complete reaction with strong alkali.

Urease Activity:

The test that determines the degree of toasting that soybean meal has been exposed to.

Vaccination:

Injection of a vaccine (or bacterin) to induce immunity.

Vaginitis:

Inflammation of the vagina.

Veal Calf:

Young cattle, birth to 2 months of age.

Vegetable Protein:

Protein supplied by vegetable products such as soybean meal.

Vermiculite:

A mined silicate mineral used as a filler and a binder.

Viable:

Able to maintain a living independent existence.

Vines:

(Part) Any plant whose stems require support, or lie on the ground.

Virulence:

Disease-producing ability of a microorganism indicated by mortality rates and ability to invade the tissues of the host.

Virus:

Smallest form of life not visible under an ordinary optical microscope, and living parasitically upon plants and animals.

Viscera:

(Part) All the organs in the three great cavities of the body (abdominal, thoracic and pelvic).

Viscera, fish:

(Part) All organs in the great cavity of the body; it includes the gills, heart, liver, spleen, stomach, and intestines.

Viscera, mammals:

(Part) All organs in the great cavity of the body; it includes the esophagus, heart, liver, spleen, stomach, and intestines, but excludes the contents of the intestinal tract.

Viscera, poultry:

(Part) All organs in the great cavity of the body; it includes the esophagus, heart, liver, spleen, stomach, crop, gizzard, undeveloped eggs, and intestines.

Viscosity:

Measurement of flowability.

Vitaminize, vitaminized:

(Process) To provide or supplement with vitamins.

Vitamins:

Organic compounds that function as parts of enzyme systems essential for the transmission of energy and the regulation of metabolism of the body.

Vitamin A:

Fat soluble alcohol obtained from carotene, essential to growth, protection of epithelial tissue, and prevention of night blindness.

Vitamin B, (Thiamine):

Water soluble vitamin necessary for health of nervous and digestive systems, reproduction, lactation, and good appetite.

Vitamin B2 (Riboflavin):

Water soluble vitamin important for growth and energy.

Vitamin B6:

See pyridoxine.

Vitamin B12 (Cyano-Cobalamine):

Water soluble vitamin essential for formation of red blood cells.

Vitamin C (Ascorbic Acid):

Water soluble vitamin essential for growth.

Vitamin D:

Fat soluble vitamin required for proper assimilation of calcium and phosphorous and for prevention of rickets. Vitamins D2 and D3 are two forms of vitamin D; cattle, swine, sheep and other livestock can utilize both vitamins D2 and D3. However, D3 is more efficiently utilized, and poultry can utilize only vitamin D3.

Vitamin E (Tocopherol):

Fat soluble vitamin important in certain enzyme systems and often referred to as the anti-sterility vitamin.

Vitamin K:

Fat soluble vitamin maintains normal blood clotting

Volatilization:

Potency of a product being reduced by the emission of gases (vapors).

Wafered, Wafering:

(Process) Having agglomerated a feed of a fibrous nature by compressing into a form usually having a diameter of cross section measurement greater than its length.

Wafers:

(Physical form) A form of agglomerated feed based on fibrous ingredient, in which the finished form usually has a diameter or cross section measurement greater than its length.

Warning Statement:

Statement to be included on a medicated feed label to instruct the consumer of conditions (e.g., withdrawal time, species restrictions, use as the sole ration) which must be followed for proper use of the medicated feed. Any such warnings are required by FDA in initial marketing approval of a drug for the sponsor.

Waste:

(Part) See refuse.

Weathered:

(Process) A material which has been subjected to the action of the elements.

Wet:

(Physical form) Material containing liquid or which has been soaked or moistened with water or other liquid.

Wether:

Castrated male sheep.

Wet-milled:

(Process) Steeped in water with or without sulfur dioxide to soften the kernel in order to facilitate the separation of the various component parts.

Wet-Rendered, wet rendering:

(Process) Cooked with steam under pressure in closed tanks.

Wetting Agent:

Surfactant.

Whey:

(Part) The watery part of milk separated from the curd.

Whey Factor:

Unidentified growth factor present in whey and certain other feedstuffs.

Whey Solids:

(Part) The solids of whey (proteins, fats, lactose, ash, and lactic acid).

Whole:

(Physical form) Complete, entire.

Whole Broth Culture:

Liquid culture medium for cultivation of all strains of a given species of microorganisms.

Whole Pressed, whole pressing:

(Process) Having the entire seed to remove oil.

Wilted:

(Physical form) A product without turgor as a result of water loss.

Wort:

(Part) The liquid portion of malted grain. It is a solution of malt sugar and other water soluble extracts from malted mash.

Xantophyll:

Compound which structurally resembles carotene, but has no vitamin A activity.

Yearling:

Calf, 10-12 months of age.

Yeast:

Common name for *Saccharomyces* microorganism species. Yeasts are used for leavening bread, fermentation, and (to some extent) as remedial agents.

Zinc:

Essential mineral which influences the rate of absorption of carbohydrates and proteins from the gastrointestinal tract.

**APPENDIX A
CONVERSION TABLES**

I. DRUG CONVERSION TABLES GRADUATED IN 0.005% INCREMENTS

Per Cent %	PPM*	Grams Per Ton	Lbs Per Ton	Ounces Per Ton		Per Cent %	PPM*	Grams Per Ton	Lbs Per Ton	Ounces Per Ton
0.0005	5.00	4.54	.01	.16		0.0130	130.00	118.04	.26	4.16
0.0010	10.00	9.08	.02	.32		0.0135	135.00	122.58	.27	4.32
0.0015	15.00	13.62	.03	.48		0.0140	140.00	127.12	.28	4.48
0.0020	20.00	18.16	.04	.64		0.0145	145.00	131.66	.29	4.64
0.0025	25.00	22.70	.05	.80		0.0150	150.00	136.20	.30	4.80
0.0030	30.00	27.24	.06	.96		0.0155	155.00	140.74	.31	4.96
0.0035	35.00	31.78	.07	1.12		0.160	160.00	145.28	.32	5.12
0.0040	40.00	36.32	.08	1.28		0.0165	165.00	149.82	.33	5.28
0.0045	45.00	40.86	.09	1.44		0.0170	170.00	154.36	.34	5.44
0.0050	50.00	45.40	.10	1.60		0.0175	175.00	158.90	.35	5.60
0.0055	55.00	49.94	.11	1.76		0.0180	180.00	163.44	.36	5.76
0.0060	60.00	54.48	.12	1.92		0.0185	185.00	167.98	.37	5.92
0.0065	65.00	59.02	.13	2.08		0.0190	190.00	172.52	.38	6.08
0.0070	70.00	63.56	.14	2.24		0.0195	195.00	177.06	.39	6.24
0.0075	75.00	68.10	.15	2.40		0.0200	200.00	181.60	.40	6.40
0.0080	80.00	72.64	.16	2.56		0.0205	205.00	186.14	.41	6.56
0.0085	85.00	77.18	.17	2.72		0.0210	210.00	190.68	.42	6.72
0.0090	90.00	81.72	.18	2.88		0.0215	215.00	195.22	.43	6.88
0.0095	95.00	86.26	.19	3.04		0.0220	220.00	199.76	.44	7.04
0.0100	100.00	90.80	.20	3.20		0.0225	225.00	204.30	.45	7.20
0.0105	105.00	95.34	.21	3.36		0.0230	230.00	208.84	.46	7.36
0.0110	110.00	99.88	.22	3.52		0.0235	235.00	213.38	.47	7.52
0.0115	115.00	104.42	.23	3.68		0.0240	240.00	217.92	.48	7.68
0.0120	120.00	108.96	.24	3.84		0.0245	245.00	222.46	.49	7.84
0.0125	125.00	113.50	.25	4.00		0.0250	250.00	227.00	.50	8.00

*Parts Per Million

I. DRUG CONVERSION TABLES (CONTINUED) GRADUATED IN 0.005% INCREMENTS

Per Cent %	PPM*	Grams Per Ton	Lbs Per Ton	Ounces Per Ton		Per Cent %	PPM*	Grams Per Ton	Lbs Per Ton	Ounces Per Ton
0.0255	255.00	231.54	.51	8.16		0.0380	280.00	345.04	.76	12.16
0.0260	260.00	236.08	.52	8.32		0.0385	385.00	349.58	.77	12.32
0.0265	265.00	240.62	.53	8.48		0.0390	390.00	354.12	.78	12.48
0.0270	270.00	245.16	.54	8.64		395.00	395.00	358.66	.79	12.64
0.0275	275.00	249.70	.55	8.80		0.0400	400.00	363.20	.80	12.80
0.0280	280.00	254.24	.56	8.96		0.0405	405.00	367.74	.81	12.96
0.0285	285.00	258.78	.57	9.12		0.0410	41.00	372.28	.82	13.12
0.0290	290.00	263.32	.58	9.28		0.0415	415.00	376.82	.83	13.28
0.0295	295.00	267.86	.59	9.44		0.0420	420.00	381.36	.84	13.44
0.0300	300.00	272.40	.60	9.60		0.0425	425.00	385.90	.85	13.60
0.0305	305.00	276.94	.61	9.76		0.0430	430.00	390.44	.86	13.76
0.0310	310.00	281.48	.62	9.92		0.0435	435.00	394.98	.87	13.92
0.0315	315.00	286.02	.63	10.08		0.0440	440.00	399.52	.88	14.08
0.0320	320.00	290.56	.64	10.24		0.0445	445.00	404.05	.89	14.24
0.0325	325.00	295.10	.65	10.40		0.0450	450.00	408.60	.90	14.40
0.0330	330.00	299.64	.66	10.56		0.0455	455.00	413.14	.91	14.56
0.0335	335.00	304.18	.67	10.72		0.0460	460.00	417.68	.92	14.72
0.0340	340.00	308.72	.68	10.88		0.0465	465.00	422.22	.93	14.88
0.0345	345.00	313.26	.69	11.04		0.0470	470.00	426.76	.94	15.04
0.0350	350.00	317.80	.70	11.20		0.0475	475.00	431.30	.95	15.20
0.0355	355.00	322.34	.71	11.36		0.0480	480.00	435.84	.96	15.36
0.0360	360.00	328.88	.72	11.52		0.0485	485.00	440.38	.97	15.52
0.0365	365.00	331.42	.73	11.68		0.0490	480.00	444.92	.98	15.58
0.0370	370.00	335.96	.74	11.84		0.0485	495.00	449.46	.99	15.84
0.0375	375.00	340.50	.75	12.00		0.0500	500.00	454.00	1.00	16.00

*Parts Per Million

I. DRUG CONVERSION TABLES (CONTINUED) GRADUATED IN 0.005% INCREMENTS

Per Cent %	PPM*	Grams Per Ton	Lbs Per Ton	Ounces Per Ton		Per Cent %	PPM*	Grams Per Ton	Lbs Per Ton	Ounces Per Ton
.05	500	454	1.00	16.00		1.30	13,000	11,804	26.00	416.00
.10	1,000	908	2.00	32.00		1.35	13,500	12,258	27.00	432.00
.15	1,500	1,362	3.00	48.00		1.40	14,000	12,712	28.00	448.00
.20	2,000	1,816	4.00	64.00		1.45	14,500	13,166	29.00	464.00
.25	2,500	2,270	5.00	80.00		1.50	15,000	13,620	30.00	480.00
.30	3,000	2,724	6.00	96.00		1.55	15,500	14,074	31.00	496.00
.35	3,500	3,178	7.00	112.00		1.60	16,000	14,528	32.00	512.00
.40	4,000	3,632	8.00	128.00		1.65	16,500	14,982	33.00	528.00
.45	4,500	4,086	9.00	144.00		1.70	17,000	15,436	34.00	544.00
.50	5,000	4,540	10.00	160.00		1.75	17,500	15,890	35.00	560.00
.55	5,500	4,994	11.00	176.00		1.80	18,000	16,344	36.00	576.00
.60	6,000	5,448	12.00	192.00		1.85	18,500	16,798	37.00	592.00
.65	6,500	5,902	13.00	208.00		1.90	19,000	17,252	38.00	608.00
.70	7,000	6,356	14.00	234.00		1.95	19,500	17,706	39.00	624.00
.75	7,500	6,810	15.00	240.00		2.00	20,000	18,160	40.00	640.00
.80	8,000	7,264	16.00	256.00		2.05	20,500	18,614	41.00	656.00
.85	8,500	7,718	17.00	272.00		2.10	21,000	19,068	42.00	672.00
.90	9,000	8,172	18.00	288.00		2.15	21,500	19,522	43.00	688.00
.95	9,500	8,626	19.00	304.00		2.20	22,000	19,976	44.00	704.00
1.00	10,000	9,080	20.00	320.00		2.25	22,500	20,430	45.00	720.00
1.05	10,500	9,534	21.00	336.00		2.30	23,000	20,884	46.00	736.00
1.10	11,000	9,988	22.00	352.00		2.35	23,500	21,338	47.00	752.00
1.15	11,500	10,442	23.00	368.00		2.40	24,000	21,792	48.00	768.00
1.20	12,000	10,896	24.00	384.00		2.45	24,500	22,246	49.00	784.00
1.25	12,500	11,350	25.00	400.00		2.50	25,000	22,700	50.00	800.00

*Parts Per Million

1 Pound (lb)	=	454 Grams (g)
1 Gram (g)	=	0.0022 Pounds (lb)
1 Gram (g)	=	1,000 Milligrams (mg)
1 Kilogram (kg)	=	1 Million Micrograms (µg)
1 Kilogram (kg)	=	1,000 Grams (g)
1 Kilogram (kg)	=	2,205 Pounds (lb)
1 Milligram (mg)	=	0.001 Grams (g)
1 Milligram (mg)	=	1,000 Micrograms (µg)
1 Microgram (µg)	=	0.001 Milligrams (mg)
1 Microgram Per Gram	=	1 Part Per Million (ppm)
1 Part Per Million (ppm)	=	0.454 Milligrams Per Pound
1 Part Per Million (ppm)	=	0.907 Grams Per Ton

APPLYING CONVERSIONS TO CONCENTRATIONS

The most critical application in the formulation of feeds the numerical calculations. The inability to solve equations can result in improper or illegal drug usage or critically low or toxic levels of specific nutrients. When solving concentration-type problems, the following general equation is of particular use:

$$C1 \times A1 = C2 \times A2$$

where:

- C1 = Concentration of the source
- A1 = Amount of the source
- C2 = Concentration of the finished feed
- A2 = Batch size of the finished feed

CONVERT	INTO	METHOD	EXAMPLE
Grams Per Ton	Per Cent	Multiply by 0.00011	$113 \text{ g/ton} \times 0.00011 = 0.01243\%$
Per Cent	Grams Per Ton	Divide by 0.00011	$0.1243\% \div 0.00011 = 113 \text{ g/ton}$
Grams Per Ton	Parts Per Million	Multiply by 1.1	$50 \text{ g/ton} \times 1.1 = 55 \text{ ppm}$
Parts Per Million	Grams Per Ton	Divide by 1.1	$55 \text{ ppm} \div 1.1 = 50 \text{ g/ton}$
Per Cent	Parts Per Million	Move decimal point 4 places to right	$0.01\% = 100 \text{ ppm}$
Parts Per Million	Per Cent	Move decimal point 4 places to left	$100 \text{ ppm} = 0.01\%$
Milligrams Per Kilogram	Milligrams Per Pound	Divide by 2.2	$45 \text{ mg/kg} \div 2.2 = 20.45 \text{ mg/lb}$
Milligrams Per Pound	Milligrams Per Kilogram	Multiply by 2.2	$20.45 \text{ mg/lb} \times 2.2 = 45 \text{ mg/kg}$
Micrograms Per Gram	Milligrams Per Pound	Divide by 2.2	$576.4 \text{ } \mu\text{g/g} \div 2.2 = 262 \text{ mg/lb}$
Milligrams Per Pound	Micrograms Per Gram	Multiply by 2.2	$262 \text{ mg/lb} \times 2.2 = 576.4 \text{ } \mu\text{g/g}$
Milligrams Per Pound	Milligrams Per Gram	Divide by 454	$557 \text{ mg/lb} \div 454 = 1.23 \text{ mg/g}$
Milligrams Per Gram	Milligrams Per Pound	Multiply by 454	$6 \text{ mg/g} \times 454 = 2,724 \text{ mg/lb}$
Milligrams Per Pound	Parts Per Million	Multiply by 2.2	$15 \text{ mg/lb} \times 2.2 = 33 \text{ ppm}$
Parts Per Million	Milligrams Per Pound	Divide by 2.2	$33 \text{ ppm} \div 2.2 = 15 \text{ mg/lb}$
Micrograms Per Kilogram	Micrograms Per Pound	Divide by 2.2	$88 \text{ } \mu\text{g/kg} \div 2.2 = 40 \text{ } \mu\text{g/lb}$
Micrograms Per Pound	Micrograms Per Kilogram	Multiply by 2.2	$40 \text{ } \mu\text{g/lb} \times 2.2 = 88 \text{ } \mu\text{g/kg}$
Grams	Kilograms	Move decimal point 3 places to left	$330 \text{ g} = 0.33 \text{ kg}$
Kilograms	Grams	Move decimal point 3 places to right	$0.33 \text{ kg} = 330 \text{ g}$
Grams	Milligrams	Move decimal point 3 places to right	$1.4 \text{ g} = 1400 \text{ mg}$
Milligrams	Grams	Move decimal point 3 places to left	$1400 \text{ mg} = 1.4 \text{ g}$
Grams	Pounds	Divide by 454	$1816 \text{ g} \div 454 = 4.0 \text{ lbs}$
Pounds	Grams	Multiply by 454	$4.0 \text{ lbs} \times 454 = 1816 \text{ g}$
Grams	Ounces	Divided by 28.4	$56.9 \text{ g} \div 28.4 = 2 \text{ oz}$
Ounces	Grams	Multiply by 28.4	$2 \text{ oz} \times 28.4 = 56.9 \text{ g}$
Ounces	Pounds	Divide by 16	$64 \text{ oz} \div 16 = 4.0 \text{ lbs}$
Pounds	Ounces	Multiply by 16	$4.0 \text{ lbs} \times 16 = 64 \text{ oz}$
Grams Per Ton	Milligrams Per Pound	Multiply by 0.5	$50 \text{ g/ton} \times 0.5 = 25 \text{ mg/lb}$
Milligrams Per Pound	Grams Per Ton	Divide by 0.5	$25 \text{ mg/lb} \div 0.5 = 50 \text{ g/ton}$
Grams Per Ton	Pounds Per Ton	Multiply by 0.0022	$240 \text{ g/ton} \times 0.0022 = 0.528 \text{ lbs/ton}$
Pounds Per Ton	Grams Per Ton	Divide by 0.0022	$0.528 \text{ lbs/ton} \div 0.0022 = 240 \text{ g/ton}$
Grams Per Ton	Grams Per Pound	Multiply by 0.0005	$1200 \text{ g/ton} \times 0.0005 = 0.6 \text{ g/lb}$
Grams Per Pound	Grams Per Ton	Divide by 0.0005	$0.6 \text{ g/lb} \div 0.0005 = 1200 \text{ g/ton}$
Grams Per Pound	Grams Per Ton	Multiply by 2,000	$0.2 \text{ g/lb} \times 2,000 = 400 \text{ g/ton}$
Grams Per Ton	Grams Per Pound	Divide by 2,000	$400 \text{ g/ton} \div 2,000 = 0.2 \text{ g/lb}$

EXAMPLE 1 - CALCULATING GRAMS/TON

An invoice shows that a swine starter containing 3.75 lbs of Tylosin 40 (40 grams per lb.) with a total batch weight of 3,000 lbs. The feed is to be fed for increase rate of weight gain and feed efficiency. Refer to the Feed Additive Compendium for approved levels and claims.

Step 1

3.75 lbs.	× 40 g/lb.	= 150 grams
Premix Added	Premix Level	Drug In Total Batch

Step 2

150 grams	÷ 3,000 lbs.	= .05 g/lb.
Drug In Total Batch	Total Batch Weight	Grams Per Lb. In Feed

Step 3

.05 g/lb.	× 2,000 lbs.	= 100 g/ton
Grams Per Lb. In Feed	Lbs. Per Ton	Grams Per Ton In Feed

EXAMPLE 2 - CALCULATING %/TON AND GRAMS/TON

An invoice shows that a swine grower containing 15 lbs. of CSP 250 (containing 10 grams/lb of Chlortetracycline, 2.2 % Sulfathiazole, and 5 gram/lb Penicillin with a total batch weight of 3,000 pounds. The feed is to be fed as a complete feed to swine for the reduction of the incidence of cervical abscesses. Refer to the Feed Additive Compendium for approved levels and claims.

Step 1 (Chlortetracycline)

15 lbs.	× 10 g/lb.	= 150 grams
Premix In Batch	Premix Level	Grams Per Batch

Step 2

150 grams	÷ 3,000 lbs.	= 0.05 g/lb.
Grams Per Batch	Total Batch Weight	Grams/Pound In Feed

Step 3

.05 g/lb.	× 2,000 lbs.	= 100 g/ton
Grams/Pound In Feed	Pounds Per Ton	Finished Feed Level

Step 4 (Sulfathiazole)

15 lbs.	× 2.2 %	= 33 lbs.
Premix In Batch	Premix Level	Batch Drug Level

Step 5

33 lbs.	÷ 3,000 lbs.	= 0.011%
Batch Drug Level	Batch Weight	Finished Feed Level

Step 6 (Penicillin)

15 lbs.	× 5 g/lb.	= 75 grams
Premix In Batch	Premix Level	Grams Per Batch

Step 7

75 grams	÷ 3,000 lbs.	= .025 g/lb.
Grams Per Batch	Batch Weight	Grams/Pound In Feed

Step 8

.025 g/lb.	× 2,000 lbs.	= 50 g/ton
Grams/Pound In Feed	Pounds Per Ton	Finished Feed Level

EXAMPLE 3 - CALCULATING MILLIGRAMS/LB BODY WEIGHT

An invoice shows that a calf feed containing 3 lbs. of Aureomycin 4G (4 grams per lb. of Chlortetracycline) with a total batch weight of 3,000 lbs. The feed is to be fed at 5 pounds per head per day to 200 pound calves for growth promotion and feed efficiency. Refer to the Feed Additive Compendium for approved levels and claims.

Step 1 (Chlortetracycline)

4 g/lb.	× 1,000	= 4,000 mg/lb.
Premix Level	Milligrams/Gram	Premix Level

Step 2

3 lbs.	× 4,000 mg/lb.	= 12,000 mg
Batch Drug Level	Premix Level	Milligrams In Batch

Step 3

12,000 mg	÷ 3,000 lbs.	= 4 mg/lb.
Milligrams In Batch	Batch Weight	Amount Per Pound

Step 4

4 mg/lb.	× 5 lb/day	= 20 mg
Amount Per Pound	Amount Fed	Amount Per Day

Step 5

20 mg	÷ 200 lbs.	=0.1 mg/lb.
Amount Per Day	Animal Weight	Finished Feed Level

EXAMPLE 4 - CALCULATING MILLIGRAMS/HEAD/DAY

An invoice shows that a cattle feed containing 4.2 lbs of CTC 10 (10 grams per lb. of Chlortetracycline) with a total batch weight of 3,000 lbs. The feed is to be fed at 5 pounds per head per day for growth promotion, feed efficiency and prevention of liver abscess. Refer to the Feed Additive Compendium for approved levels and claims.

Step 1 (Chlortetracycline)

10 grams/lb.	× 1,000	= 10,000 mg/lb.
Premix Level	Milligrams/Gram	Premix Level

Step 2

4.2 lbs.	× 10,000 mg/lb.	= 42,000 mg
Premix Added	Premix Level	Milligrams Total Batch

Step 3

42,000 mg	÷ 3,000 lbs.	= 14 mg
Milligrams Total Batch	Batch Weight	Amount Per Pound

Step 4

14 mg	× 5 lbs.	= 70 mg/hd/day
Amount Per Pound	Amount Fed	Finished Feed Level

Weight of Animal	0.1 mg/# body wt req/day	Pounds of Feed Required Per Day								
		10 g/ton	If 15 g/ton	If 20 g/ton	If 25 g/ton	If 30 g/ton	If 35 g/ton	If 40 g/ton	If 45 g/ton	If 50 g/ton
200	20.0	4.0	2.7	2.0	1.6	1.3	1.1	1.0	.9	.8
250	25.0	5.0	3.5	2.5	2.0	1.7	1.4	1.2	1.1	1.0
300	30.0	6.0	4.0	3.0	2.4	2.0	1.7	1.5	1.3	1.2
350	35.0	7.0	4.7	3.5	2.8	2.3	2.0	1.8	1.6	1.4
400	40.0	8.0	5.3	4.0	3.2	2.7	2.3	2.0	1.8	1.6
450	45.0	9.0	6.0	4.5	3.6	3.0	2.6	2.2	2.0	1.8
500	50.0	10.0	6.7	5.0	4.0	3.3	2.9	2.5	2.2	2.0
550	55.0	11.0	7.3	5.5	4.4	3.7	3.1	2.8	2.4	2.2
600	60.0	12.0	8.0	6.0	4.8	4.0	3.4	3.0	2.7	2.4
650	65.0	13.0	8.7	6.5	5.2	4.3	3.7	3.2	2.9	2.6
700	70.0	14.0	9.3	7.0	5.6	4.7	4.0	3.5	3.1	2.8
750	75.0	15.0	10.0	7.5	6.0	5.0	4.3	3.8	3.3	3.0
800	80.0	16.0	10.7	8.0	6.4	5.3	5.3	4.6	4.0	3.6
850	85.0	17.0	11.3	8.5	6.8	5.7	4.9	4.2	3.8	3.4
900	90.0	18.0	12.0	9.0	7.2	6.0	5.1	4.5	4.0	3.6
950	95.0	19.0	12.7	9.5	7.6	6.3	5.4	4.8	4.2	3.8
1000	100.0	220.0	13.3	10.0	8.0	6.7	5.7	5.0	4.4	4.0
1050	105.0	21.0	14.0	10.5	8.4	7.0	6.0	5.2	4.7	4.2
100	110.0	22.0	14.7	11.0	8.8	7.3	6.3	5.5	4.9	4.4
1150	115.0	23.0	15.3	11.5	9.2	7.7	6.6	5.8	5.1	4.6
1200	120.0	24.0	16.0	12.0	9.6	8.0	6.9	6.0	5.3	4.8
1250	125.0	25.0	16.7	12.5	10.0	8.3	7.1	6.2	5.6	5.0
1300	130.0	26.0	17.3	13.0	10.4	8.7	7.4	6.5	5.8	5.2

II. CALCULATING FEED FORMULAS

The following is a step-by-step example of how to calculate feed ingredients utilizing the data below of percent protein, fat, fiber, ash, NPN (non-protein nitrogen), calcium (Ca), phosphorus (P), salt (NaCl), and added minerals:

Source	Protein	Fat	Fiber	Ash	Calcium	Phos.	Weight
Ground Corn	.08	.035	.029	.027	.013		1,200
Rolled Barley	.10	.022	.06	.026			520
Urea	2.81						33
Dicalcium Phosphate				.78	.22	.185	54
Limestone				.958	.38		153
Salt				1.00			40
Total							2,000 lbs.

Protein

Source	Equation	Method	Units of Protein
Corn	$\frac{\text{Units Protein}}{\text{Pounds}}$	$1,200 \times .08$	96
Barley	$\frac{\text{Units Protein}}{\text{Pounds}}$	$520 \times .10$	52
Urea	$\frac{\text{Units Protein}}{\text{Pounds}}$	33×2.81	92.7
Total Units of Protein			240.7
Per Cent Complete	$\frac{\text{Total Units} \times 100}{\text{Ton}}$	$240.7 \times 100 \div 2,000$	12.035 or 12.0% (rounded off)
Per Cent NPN	$\frac{\text{Total Units} \times 100}{\text{Ton}}$	$92.7 \times 100 \div 2,000$	4.6%

Fat

Source	Equation	Method	Units of Fat
Corn	$\frac{\text{Units Fat}}{\text{Pounds}}$	$1,200 \times .035$	42
Barley	$\frac{\text{Units Fat}}{\text{Pounds}}$	$520 \times .022$	11.44
Total Units of Fat			53.44
Per Cent Complete	$\frac{\text{Total Units} \times 100}{\text{Ton}}$	$53.44 \times 100 \div 2,000$	2.67 or 2.7% (rounded off)

Fiber

Source	Equation	Method	Units of Fiber
Corn	$\frac{\text{Units Fiber}}{\text{Pounds}}$	$1,200 \times .029$	34.8
Barley	$\frac{\text{Units Fiber}}{\text{Pounds}}$	$520 \times .06$	31.2
Total Units of Fiber			66
Per Cent Complete	$\frac{\text{Total Units} \times 100}{\text{Ton}}$	$66 \times 100 \div 2,000$	3.3%

Ash

Source	Equation	Method	Units of Ash
Salt	$\frac{\text{Units Ash}}{\text{Pounds}}$	40×1.00	40.0
Corn	$\frac{\text{Units Ash}}{\text{Pounds}}$	$1,200 \times .013$	15.6
Barley	$\frac{\text{Units Ash}}{\text{Pounds}}$	$520 \times .026$	13.5
Dicalcium Phosphate	$\frac{\text{Units Ash}}{\text{Pounds}}$	$54 \times .78$	42.1
Limestone	$\frac{\text{Units Ash}}{\text{Pounds}}$	$153 \times .958$	146.6
Total Units of Ash			257.8
Per Cent Complete	$\frac{\text{Total Units} \times 100}{\text{Ton}}$	$257.8 \times 100 \div 2,000$	12.9%

Calcium

Source	Equation	Method	Units of Calcium
Dicalcium Phosphate	$\frac{\text{Units Calcium}}{\text{Pounds}}$	$54 \times .22$	11.9
Corn	$\frac{\text{Units Calcium}}{\text{Pounds}}$	$1,200 \times .013$	15.6
Limestone	$\frac{\text{Units Calcium}}{\text{Pounds}}$	$153 \times .38$	58.1
Total Units of Calcium			85.6
Per Cent Complete	$\frac{\text{Total Units} \times 100}{\text{Ton}}$	$85.6 \times 100 \div 2,000$	4.28 or 4.3%

Phosphorus

Source	Equation	Method	Units of Phosphorus
Dicalcium Phosphate	$\frac{\text{Units Phosphorus}}{\text{Pounds}}$	$54 \times .185$	10.0
Total Units of Phosphorus			10.0
Per Cent Complete	$\frac{\text{Total Units} \times 100}{\text{Ton}}$	$10.0 \times 100 \div 2,000$	0.5%

Salt

Salt	Equation	Method	Percent of Salt
Complete Feed	$\frac{\text{Total Units} \times 100}{\text{Ton}}$	$40 \times 100 \div 2,000$	2.0%

Added Minerals

Equation	Method	% Added Minerals
$\frac{\text{Total Weight of DCP \& Limestone} \times 100}{\text{Total Weight}}$	$54 + 153 \times 100 \div 2,000$	10.35%

Expected Feed Consumption by Horses (% Body Weight)			
Mature Horses			
	Forage	Concentrate	Total
Maintenance	1.5-2.0	0-0.5	1.5-2.0
Mares, late gestation	1.0-1.5	0.5-1.0	1.5-2.0
Mares, early lactation	1.0-2.0	1.0-2.0	2.0-3.0
Mares, late lactation	1.0-2.0	0.5-1.5	2.0-2.5
Working Horses			
Light Work	1.0-2.0	0.5-1.0	1.5-2.5
Moderate Work	1.0-2.0	0.75-1.5	1.75-2.5
Intense Work	0.75-1.5	1.0-2.0	2.0-3.0
Young Horses			
Nursing foal, 3 months	0	1.0-2.0	2.5-3.5
Weanling foal, 6 months	0.5-1.0	1.5-3.0	2.0-3.5
Yearling foal, 12 months	1.0-1.5	1.0-2.0	2.0-3.0
Long yearling, 18 months	1.0-1.5	1.0-1.5	2.0-2.5
Two year old (24 months)	1.0-1.5	1.0-1.5	1.75-2.5

Body Weights and Feed Consumption of Large-Type Turkeys during the Holding and Breeding Periods					
Age (weeks)	Females			Males	
	Weight (kg)	Egg production (%)	Feed per Turkey Daily (g)	Weight (kg)	Feed per Turkey Daily (g)
20	8.4	0	260	14.3	500
25	9.8	0	320	16.4	570
30	11.1	0	310	19.1	630
35	11.1	68	280	20.7	620
40	10.8	64	280	21.8	570
45	10.5	58	280	22.5	550
50	10.5	52	290	23.2	560
55	10.5	45	290	23.9	570
60	10.6	35	290	24.5	580

APPENDIX B LABORATORIES THAT ANALYZE FEED

The list of laboratories is being supplied only as a reference source. AAFCO does not endorse any of these laboratories or accredit any of their results. It is only being supplied in case questions arise as to where feed analysis can be done.

A & L Great Lakes Laboratories, Inc.

3505 Conestoga Drive
Fort Wayne, IN 46808-4413
Telephone: (260) 483-4759
Fax: (260) 483-5274
URL: <http://www.algreatlakes.com/main.asp>

Litchfield Analytical Services

535 Marshall St. P. O. Box 457
Litchfield, MI 49252
Telephone: (517) 542-2915
URL: <http://members.tripod.com/~litchlab/>

Spectrum Analytic, Inc.

1087 Jamison Road
P. O. Box 639
Washington Court House, OH 43160
Telephone: (800) 321-1562
Fax: (740) 335-1104
URL: <http://www.spectrumanalytic.com/>

Woodson-Tenent Laboratories, Inc.

3507 Delaware - Des Moines, IA 50313
P. O. Box 1292 - Des Moines, IA 50305
Telephone: (515) 265-1461
Fax: (515) 266-5453

Woodson-Tenent Laboratories, Inc.

17570 N Highway #902
Bear Creek, NC 27207
Telephone: (919) 837-2121