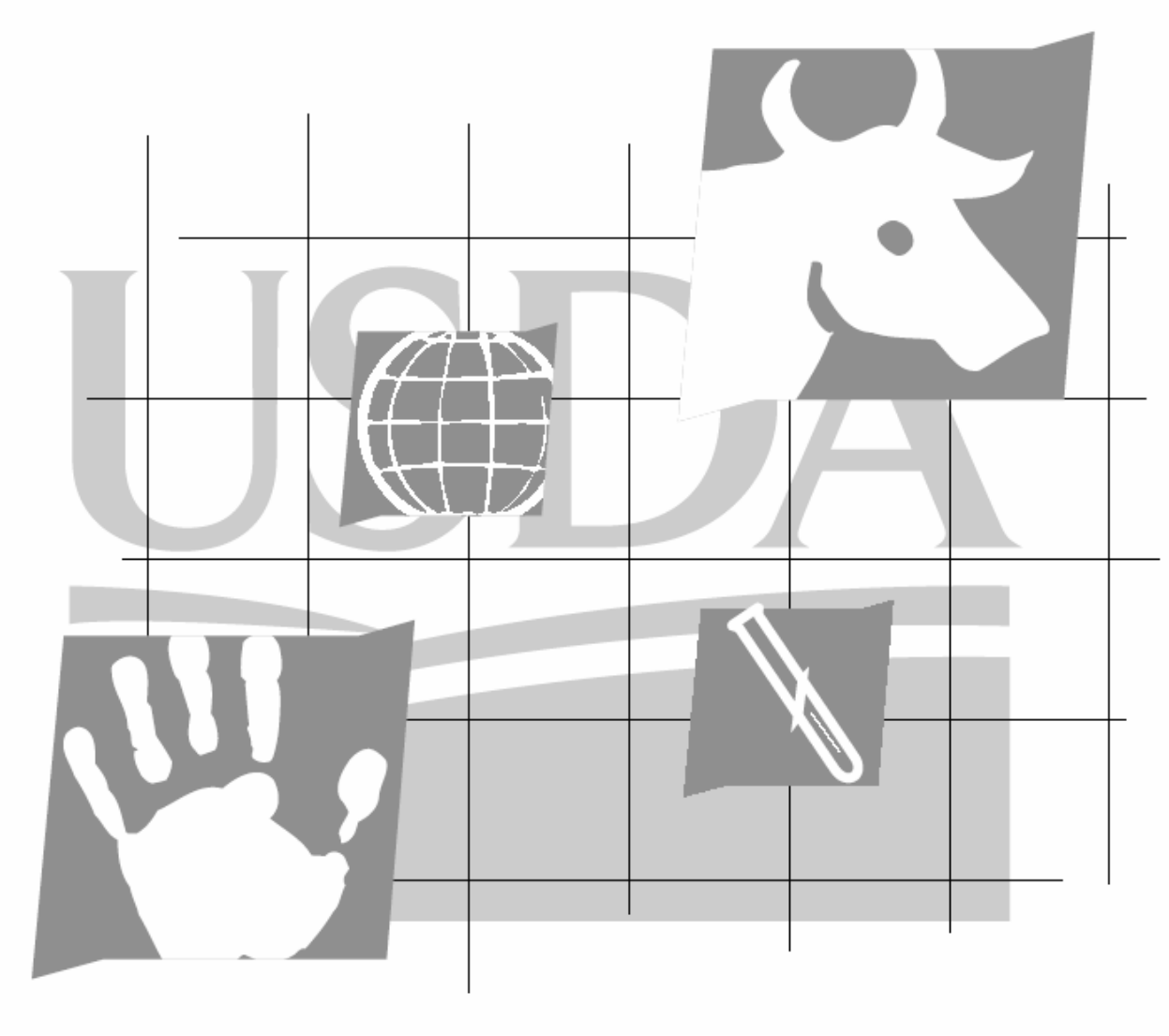
U.S. Department of Agriculture's Assessment of the Canadian Feed Ban



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Abbreviations

APHIS	Animal and Plant Health Inspection Service
BSE	Bovine Spongiform Encephalopathy
CFIA	Canadian Food Inspection Agency
FDA	Food and Drug Administration
HACCP	Hazard Analysis Critical Control Point
MCAP	Multi-Commodity Activity Program
NAI	No Action Indicated
OAI	Official Action Indicated
SRM	Specified Risk Material
UK	United Kingdom
USDA	U.S. Department of Agriculture
VAI	Voluntary Action Indicated

Definitions

Flushing: To follow a batch of feed through mixers or other equipment with a sufficient volume of a non-prohibited ingredient, usually bulk grain or oilseed products, to flush residual material out of the system.

Prohibited Material: Protein, or any material that contains such protein, that originated from a mammal, other than pure porcine or equine. This does not include milk, blood, gelatin, rendered animal fat or their products.

Sequencing: To predetermine the order of manufacturing different feed products so that any residual prohibited material is flushed into a feed product intended for non-ruminant species.

Specified Risk Material (SRM): Tissues that, in BSE-infected cattle, contain the agent that may transmit the disease. In diseased animals, the infective agent is concentrated in certain tissues. SRM are defined as the skull, brain, trigeminal ganglia (nerves attached to the brain), eyes, tonsils, spinal cord, and dorsal root ganglia (nerves attached to the spinal cord) of cattle aged 30 months or older (scientific research has shown that these tissues, in cattle younger than 30 months, do not contain the infective agent); and the distal ileum (portion of the small intestine) of cattle of all ages.

1 Executive Summary

On January 24, 2005, the U.S. Department of Agriculture sent a team to Canada to assess Canada's current feed ban and their feed inspection program to determine if the control measures put in place by the Government of Canada are achieving compliance with these regulations. Based on their review of inspection records and on-site observations, the inspection team found that Canada has a robust inspection program, that overall compliance with the feed ban is good, and that the feed ban is reducing the risk of transmission of bovine spongiform encephalopathy (BSE) in the Canadian cattle population.

The Canadian feed ban is not substantially different than the U.S. feed ban. Both feed bans prohibit the use of mammalian protein in ruminant feeds, with exceptions for milk products, blood products, gelatin, and protein derived solely from porcine or equine sources. Two minor differences between U.S. and Canadian feed regulations are that the United States allows plate waste and poultry litter to be used in ruminant feed, whereas Canadian feed regulations make no such allowances.

The Canadian feed ban has been implemented in stages since it was first proposed in 1996. Leading up to Canada's feed ban implementation in 1997, the Canadian Food Inspection Agency (CFIA) began educating the feed industry, livestock producers, and their own inspectors with regard to the impending regulations. All feed mills received an initial inspection between August 1997 and March 1998. At that time, none of the feed mills were found to be formulating ruminant feeds that contained prohibited material. From 1997 to 2000, the CFIA continued to educate, but also continued to conduct inspections to bring the feed industry into compliance with the feed ban. Rendering facilities were required to pass an annual inspection before renewing their permit to operate from 1998 onward. In 2000 and 2001, the CFIA modified its compliance programs by increasing the frequency of inspections of commercial feed mills from once every three years to every year, and they continued the annual inspection and permitting of all rendering facilities. Since 2002, the CFIA has been conducting annual inspections of all rendering and commercial feed mill facilities, as well as conducting inspections of some ruminant feeders and retail feed distributors. Verification activities for Canada's feed ban continue to be focused primarily on inspecting commercial feed mills and rendering facilities.

In conducting feed mill inspections, CFIA's inspectors evaluate each firm on its compliance with 86 tasks, of which, 13 are directly related to the feed ban. An unsatisfactory rating is given for each task in which the firm is not meeting the standard. Managers of a facility with an unsatisfactory rating must provide a plan to the inspection staff within 30 days that identifies corrective actions to be carried out to remedy the situation. The inspectors then re-inspect the facility within 30 days of the reported correction to verify that the corrective action has been taken.

Based on the U.S. evaluation of CFIA's data, the percentage of commercial feed mills in Canada that had unsatisfactory ratings on individual tasks has declined from 24.9 percent to 14.8 percent between 2002 and 2004, and that most of the non-compliant tasks were related to documentation and record-keeping. The team's review also indicated that the overall percentage of tasks rated as unsatisfactory for rendering facilities (excluding instances where the task was not applicable) across the 3 years of data, declined from 9.7 percent to 2.7 percent. The review of both types of firms identified that most of the unsatisfactory tasks were related to needed improvements for record-keeping and documentation of procedures.

There has been a movement toward dedicated processing lines in the rendering facilities or fully dedicated facilities. Also, since the feed ban's inception in 1997, the industry has moved toward dedicated feed manufacturing facilities, such that fewer commercial feed mills handle prohibited material and manufacture feeds for ruminants.

Moreover, approximately one-third of the commercial feed mills (producing at least 60 percent of the feed produced in commercial mills) have voluntarily become Hazard Analysis Critical Control Point (HACCP) -certified. The HACCP program provides a framework wherein feed mills can incorporate training of employees, developing standard operating procedures, and maintaining appropriate records relevant to the feed ban. This proactive measure is further evidence that the feed industry is increasing their efforts to comply with the feed ban.

The CFIA continues to revise and update their procedures to further enhance the effectiveness of the feed ban. The CFIA intends to revise some of the inspection forms to increase the objectivity of the standards, and to carry out additional training for the inspectors to improve standardization in the inspection and rating process. Moreover, the CFIA has proposed the complete removal of specified risk material (SRM) from animal feeds as an added safeguard to enhance the effectiveness of the feed ban.

The Canadian government, feed industry, and livestock producers have substantially increased their efforts to implement and comply with the Canadian feed ban. Based on the U.S. team's review of the inspection records for the past three years and on-site inspections of a sampling of commercial feed mills and rendering facilities, it is evident that considerable effort is being dedicated in all sectors to carry out the intent of the Canadian feed ban. It is the U.S. Inspection Team's determination that these efforts have reduced the risk of transmission of the BSE agent in feed to ruminant animals.

Canadian Feed Ban Risk Analysis

The information in this report was considered in light of the assumptions and conclusions of the original risk analysis conducted to support the minimal risk rule. That risk analysis documented the regulatory basis for the Canadian feed ban and summarized compliance efforts as reported by the CFIA. The risk analysis assumed that compliance with the feed ban was good, and that the

feed ban was effectively enforced. The risk analysis also considered other epidemiological information as evidence of the effectiveness of the feed ban.

It should be noted that the risk analysis did not assume 100 percent compliance with the feed ban, as that is not realistic in any situation. However, it also noted that effects on disease control can be expected, even with an imperfect feed ban. Specifically, a feed ban exerts significant downward pressure on the prevalence of BSE, even with incomplete compliance.

The information provided by the U.S. team verifies the information cited in the risk analysis, and supports the conclusion in the risk analysis that the feed ban is effective. The risk analysis included references that the CFIA reported a high level of compliance as noted in inspections. This report supports the same conclusion, noting that overall greater than 90 percent of individual tasks evaluated in inspections over the last 3 years were rated as satisfactory or not applicable. It also notes that the majority of the unsatisfactory ratings related to minor record-keeping infractions, such as not including full name and address information on invoices. Another common reason a facility might receive an unsatisfactory rating is because written standard operating procedures need additional detail. The report also confirms what is known from experience in the United States regarding feed ban enforcement – that compliance can not be immediately perfect upon implementation, and that compliance continues to increase as the program evolves.

2 Background

2.1 Overview of BSE in Canada

The sequence of events that led to the introduction of BSE into Canadian born and reared cattle may never be known. However, the most likely sequence is that infected cattle were imported from the United Kingdom (UK) in the 1980s, their carcass(es) were subsequently rendered into meat and bone meal (MBM), and the MBM was fed to young cattle. Some of the important events related to the BSE situation in Canada, beginning with the importation of UK cattle, are as follows:

- Cattle from the UK were imported into Canada from 1979 until 1990.
- BSE was first documented in the UK in 1986.
- Canada prohibited the import of cattle from the UK in 1990.
- In 1993, a case of BSE was detected in Canada in a cow imported from the UK.
- In 1994, all remaining UK cattle imports were depopulated and tested with negative results for BSE.
- The United States and Canada implemented a mammalian-to-ruminant feed ban (with some exemptions) as a precaution in 1997.
- During this same time, Canada also implemented an inspection program for renderers and feed mills to verify compliance with the feed ban.
- In May of 2003, Canada detected the first case of BSE in a cow born and reared in Canada.
- In December of 2003, BSE was diagnosed in a cow from Canada on a Washington State dairy farm.
- In December 2004, Canada proposed to strengthen their BSE firewalls by implementing a complete removal of SRM from animal feed.
- In January of 2005, two additional cases of BSE were diagnosed in Alberta, Canada.

2.2 Animal Industry and Feeding Practices

Until BSE was detected in May 2003, the Canadian cattle population was relatively stable at an estimated 15 million head. In 2001, there were 2.2 million dairy cows and 12.4 million beef cows in Canada. About 81 percent of Canada's dairy farms are located in Ontario and Quebec, 14 percent in the Western Provinces, and 5 percent in the Atlantic Provinces. Alberta and Saskatchewan host 70 percent of Canada’s beef cattle.

Most Canadian cattle are raised on either dairy farms or beef cattle operations, with a relatively small percentage raised on mixed species farms (Table 1). Approximately 3.7 percent of cattle operations also have swine on the premises, and approximately 6.5 percent have poultry on the

premises. As a proportion of the total cattle population, 2.7 percent of cattle are raised on mixed cattle and swine operations, while 4.1 percent are raised on mixed cattle and poultry operations.

Table 1. Cattle Operation Demographics

	Operations with Cattle and Calves		Operations with Cattle and Swine		Operations with Cattle and Poultry	
Province/Area	**Number of Operations**	**Number of Cattle**	**Number of Operations**	**Number of Cattle**	**Number of Operations**	**Number of Cattle**
Quebec/Atlantic	20,469	1,656,639	948	78,023	1,026	65,944
Ontario	28209	2,140,731	1384	107,219	2,591	158,485
Manitoba	11,333	1,424,427	500	44,129	698	62,376
Saskatchewan	22,555	2,899,502	556	48,822	1,129	102,587
Alberta	31,774	6,615,201	869	132,961	1,523	193,616
BC	7,726	814,949	254	7,994	936	49,013
Total	122,066	15,551,449	4,511	419,148	7,903	632,021

Source: 2001 Census of Agriculture, Statistics Canada (prepared by Agriculture and Agri-Food Canada)

Prior to 1997, Canadian feed regulations allowed the use of mammalian protein such as bovine MBM in ruminant feeds; as a result, some feeds would have contained these ingredients. Nutritional needs of dairy cattle differ from those of beef cattle, and the nutritional needs of both vary by age and stage of production. Animal source proteins are commonly used not only to boost protein levels, but also to balance specific nutrients (lysine and other amino acids, calcium, and phosphorus).

Animal proteins are not as commonly used in rations for beef animals as they are in dairy rations. Before the feed ban, the decision to use MBM in beef feed formulations depended largely on the nutritional philosophy of the feed manufacturer and the price and availability of protein sources such as peas, lupins, lentils, canola, or soybean meal. However, even before the feed ban, the use of ruminant proteins in feeds for beef cattle was reported to be rare. As with dairy rations, any ingredients used in beef rations after August 1997 are required to come from non-prohibited sources.

2.3 Feed Industry

- Total sales for Canada's feed industry represent over CDN$3.5 billion (global shipments of livestock and poultry feed products, excluding pet food.)
- Approximately 9,000 people are employed by feed industry manufacturing units.
- It takes an estimated 25 to 27 million metric tons of animal feed to feed all the livestock and poultry in Canada.
- The estimated total commercial production of complete feeds, supplements, and premixes in Canada is 15 million metric tons.
- Approximately 50 percent of the overall complete feed equivalent volume required to feed all livestock and poultry in Canada is manufactured by non-commercial, on-farm mixing establishments.
- Swine, dairy, and poultry feeds account for approximately 85 percent of all feeds manufactured and sold by Canadian commercial feed manufacturers.
- The feed industry relies on imports from the United States, Europe, and Asia for the majority of the high-value micro-ingredients, i.e. vitamins, trace minerals, amino acids, medicated feed additives, and other micro-feed additives used in most feed products. This is a result of the lack of production in Canada of vitamins, pharmaceuticals and other fine chemicals.
- Exports to the United States include cross-border movement of complete feeds that originate primarily from Ontario and Quebec in Eastern Canada and Manitoba, Saskatchewan, and Alberta in Western Canada. Exports of value-added specialty products such as milk replacers, mink and fox feeds, horse feeds, and some specialty micro-premixes are expanding in Mexico, Latin America, South America, Europe, and Asia.
- The Canadian feed industry is comprised of establishments that vary in size and manufacturing capacity, from relatively small mills to large, sophisticated, and vertically integrated operations. Annual sales of operations range from CDN$1 million to over CDN$150 million.

There are four major links in the feed chain that relate specifically to the use of ruminant derived proteins in animal feeds. (1) Renderers collect inedible products from slaughter and/or dead stock and transport these materials to the rendering plant. (2) The rendering plant processes this inedible material into products, primarily MBM, which is then transported to feed mills. (3) Feed mills mix the MBM with grains and other ingredients into numerous types of feed for a variety of animals, with the highest volume being used in feed for poultry. (4) These feeds or feed ingredients are distributed to farms where they may be used with or without further mixing. On a relative scale, in Canada there are approximately 20 feed mills per renderer and 400 livestock producers per feed mill (Table 2).

Table 2. Demographics of Rendering Plants, Feed Mills, and Farms		
Facility Type	**Number of Firms**	**Firms Handling Prohibited Material**
Rendering Plants	29	7
Commercial Feed Mills	550	94
On-farm Feed Mills	25,000	N/A
Total Farms	246,000	N/A

N/A Data not available

Over time, the feed industry has moved toward fully dedicated facilities or dedicated processing lines. In 2002/2003, there were 120 commercial feed mills that used prohibited material to manufacture feeds for non-ruminants and which also manufactured ruminant feed. However, in 2003/2004, there were 94 such mills. A similar trend is also evident for Canada's rendering industry (Table 3).

Table 3. Demographics of the Rendering Industry			
Year	**Dedicated Facilities**	**Facilities Using Dedicated Lines**	**Facilities Using Non-Dedicated Lines**
2002	18	4	7
2003	19	4	6
2004	23	4	2

Approximately 176 of the estimated 550 commercial feed mills in Canada are HACCP-certified through a program offered by the Animal Nutrition Association of Canada. The certification audit is consistent with HACCP requirements of the U.N. Codex Alimentarius Commission and also incorporates key elements of the CFIA's Food Safety Enhancement Program, the U.S. Food and Drug Administration (FDA) program, and the European Union's HACCP protocol. Renewal of certificates is based on results of full audits conducted every three years, and partial audits conducted annually. These HACCP-certified mills are estimated to produce 60 percent or more of the feed produced in commercial mills. The HACCP process can be readily adapted to accommodate the elements of the feed ban.

2.4 Canadian Feed Ban

The CFIA began public discussion of adopting a "feed ban" regulation in April 1996, and the proposed regulation was published in *Canada Gazette I* on March 29, 1997. This would be similar to publishing a proposed rule in the *Federal Register* in the United States. The regulation was finalized in the *Canada Gazette II* on June 8, 1997, by adding PART XIV *Food For Ruminants, Livestock And Poultry* (referred to in this report as the feed ban) to the Health of

Animals Regulations. Most of the regulation came into effect on August 4, 1997, although the part of the regulation that requires non-ruminant feed containing prohibited material to be labeled with a warning statement did not go into effect until October 3, 1997.

The CFIA, the agency within the Canadian Government with primary responsibility for carrying out these regulations, uses the Feeds Act and Regulations and the Health of Animals Act and Regulations as the basis of their authority to regulate animal feeds. The feed ban regulation was promulgated under the Health of Animals Act and is incorporated into the Health of Animals Regulations. The CFIA is empowered to inspect rendering facilities, feed mills, feed distributors, as well as farms where feeds are manufactured, distributed, and/or used. Additionally, feed mills are required to be registered with the CFIA and rendering firms are required to have an annual permit issued by the CFIA to operate.

Canada's feed ban regulation was implemented on August 4, 1997 – the same day the United States implemented a similar set of rules. In both countries, the feed ban was put in place as a precautionary measure in the absence of evidence that the domestic cattle herd in either country harbored BSE.

Canada's feed ban prohibits the feeding of mammalian derived proteins to ruminant animals with the exception of those that are derived solely from porcine or equine sources, blood and blood products from any source, milk products, and gelatin. In addition, the rule requires the labeling of all products that contain prohibited material with the caution statement, "Do not feed to cattle, sheep, deer, or other ruminants." Canadian feed regulations do not allow the feeding of poultry litter, plate waste, or salvaged pet food to ruminants. The U.S. feed regulations do not prohibit plate waste and poultry litter from being used as a ruminant feed and do not prohibit salvage/distressed pet food from being used if it does not contain prohibited material. Other than these minor differences, however, the Canadian and U.S. feed bans are very similar.

Canada's feed ban was implemented with provisions for a phase-in period so that existing stocks of feed material could be depleted. Feed mills were allowed a 30-day period to use and distribute existing stocks, while farms were allowed 60 days to use existing stocks. No recall was ordered for products that were already in the production or distribution chain, including those that were present on farms. A 60-day implementation period was also allowed for the addition of the mandatory cautionary statement on the labels of those feeds which contained prohibited materials.

The inspection program corresponding to the Canadian feed ban has evolved since the feed ban became law. Since 1997, rendering facilities have been required to have an annual, renewable permit in order to operate. Moreover, a facility inspection has been required in order for the plant to operate. In addition, with the adoption of the feed ban, commercial feed mills were expected to be inspected at three-year intervals to ensure compliance. Inspections began immediately after initial implementation of the feed ban, and all commercial feed mills received an initial inspection

between August 1997 and March 1998. At that time, none of the commercial feed mills were found to be formulating ruminant feeds with prohibited material. All commercial feed mills have been inspected annually since 2002.

The CFIA also inspects retail feed outlets to assess compliance with the feed ban - principally, the labeling requirements. Approximately 100 of the estimated 1,300 retail outlets are inspected annually. As with the United States, farms and ruminant feeders are not inspected for compliance with the feed ban on a regular schedule, but an inspection is often done when the CFIA visits a livestock producer for some other purpose, such as a tissue residue traceback. In the period between April 2002 and March 2003, 175 farm inspections were conducted. Over a similar period for 2003/2004, there were 347 farm inspections. From April 2004 to January 15, 2005, there were 179 farm inspections. Verification activities for Canada's feed ban are focused primarily on rendering facilities and commercial feed mills.

In order to help evaluate feed ban compliance, the CFIA has conducted audits of the Feed Inspection Program. The primary objective of these audits was to determine whether the delivery of the National Feed Inspection Program, in each specific area, conformed to established guidelines. Methods for improving the design of the National Feed Inspection Program were also identified. Final audit reports dating from March 1999 to March 2002 were reviewed. The reviews were conducted nationwide by senior members of the National Feed Team. Auditors reviewed all feed inspection activities for both rendering plants and feed mills. Cases of nonconformance were identified and Corrective Action Reports were issued and followed up by the review team. These included both corrective actions for the feed mills and rendering plants and the responsible CFIA authority.

2.4.1 Comparison to the U.S. System

The FDA has the legal authority in the United States, through the Food, Drug & Cosmetic Act, to regulate nearly every segment of the feed and feeding industries. In the past, however, most issues related to facility permits, licenses, and registrations have been handled by State agencies under their own laws. Rendering plants and protein blending facilities historically have not been subject to a Federal permit, license, or registration, at least not for the purposes of feed regulation. Medicated feed manufacturers are required to obtain a license from the FDA if they wish to use category II type A medicated articles, and these firms have been subject to regular inspections. Feed mills not wishing to use category II type A medicated articles to manufacture medicated feeds, pet food manufacturers, and most feed ingredient manufacturers have not been subject to Federal licensing or registration, but most States do license or register these firms. Subsequent to the Bioterrorism Act of 2002, though, all of these firms have been required to register with the FDA as a feed or food manufacturing facility.

A significant difference in the approach to feed regulation between Canada and the United States is the role of the State agencies in the United States. Feed regulation in Canada is a function of

the Federal government, via the CFIA, and occurs in most cases without significant assistance from the Provincial governments. In this way, the program design, training, and implementation are standardized. In contrast, in the United States, the States have a long history of regulating animal feeds, and the majority of States have active programs to license/register facilities that manufacture feeds and feed ingredients in their States, inspect these facilities, and monitor the retail distribution of feeds within each State. The FDA works cooperatively with the States to maintain an accurate inventory of firms that are subject to the feed ban, and to ensure that all facilities subject to the feed ban regulations (21 CFR 589.2000) are inspected regularly. Firms that manufacture feeds containing prohibited material are inspected annually. All data from these inspections are compiled by the FDA and entered into a national database.

3 Addressing the Effectiveness of Feed Bans

There are many challenges to ensuring that a feed ban is effective. Some of the actions to overcome them are discussed below. Achieving full compliance with a feed ban inevitably takes time, due to the complexities of the regulations and the industries involved. The potential for cross-contamination during feed manufacture and transport is a key area to address. Finally, feed ban regulations cannot reliably prevent deliberate or unintentional mis-feeding on the farm. These challenges exist in any country that implements a feed ban, and each country must address them in a manner commensurate with the estimated risk and in a way that takes into account existing infrastructures.

During the rulemaking phase leading up to the 1997 feed ban, it was difficult to convince regulators, the animal feed industry, and livestock producers of the need for new BSE-related feed regulations. The feed bans in Canada and the United States were considered by many to be a proactive measure and by some as totally unnecessary, as BSE had not been detected in North American cattle. Because the risk in North America was considered low relative to the risk in Europe, both countries chose not to impose certain restrictions that eventually became necessary in Europe. Specifically, Canada and the United States decided not to prohibit the use of bovine-origin protein in all animal feed, not to require removal of SRM from animal feeds, and not to prohibit ruminant feed from being processed with equipment or in facilities that were used to process feed containing prohibited material (dedicated equipment/facilities). Instead, the regulations require that cross-contamination be prevented during feed manufacture and transport, and require that feed containing prohibited material be labeled to alert farmers and ranchers that it should not be fed to ruminants. While both countries intend to amend their feed regulations to require that the highest risk tissues be removed from all animal feed, much of the effort to enforce the current regulations continues to be directed at preventing cross-contamination during feed manufacture and transport, and preventing mis-feeding on the farm.

Controlling cross-contamination has been an issue in all countries that have implemented feed bans. The most stringent solution to cross-contamination is to completely prohibit the use of animal proteins in feed production. However, this approach creates another set of problems regarding disposal of carcasses and offal. Current regulations in Canada and the United States address cross-contamination through requirements for physical cleaning of equipment, flushing, or sequencing of feed production as control measures. Facilities may also choose to dedicate either their entire facility or specific lines within a facility to production of feed containing only non-prohibited material. The Canadian feed industry has been moving in the direction of dedicated facilities over the past several years. If not dedicated, however, facilities must use one of the control measures previously described. Flushing and sequencing strategies have been previously established and used for the control of cross-contamination when mixing medicated feeds. These same principles are applied in the feed manufacturing processes to comply with the feed ban. In addition, vacuuming, sweeping, and washing are commonly used methods of

physical cleanout. Firms are required by the CFIA to have written procedures describing how cross-contamination is to be controlled at their facility. The existence of these written documents, as well as compliance with the feed ban is verified during inspections by CFIA personnel.

Efforts to prevent the introduction of prohibited material into ruminant feed at the rendering and commercial feed mill level can be undone if care is not taken at the farm level. In countries such as Canada and the United States, where prohibited material is allowed to be used in feed for non-ruminant species, cattle can still be exposed to prohibited material if livestock producers accidentally or deliberately feed their cattle a feed product intended for other species; if cattle on mixed-species farms gain access to feed intended for other species, such as swine or poultry; or if producers do not fulfill their obligation to prevent cross-contamination during on-farm mixing or transport. According to the background material the CFIA provided, there are an estimated 122,000 farms and ranches with cattle or calves in Canada (Table 1). Of these, an estimated 3.7 percent also have swine on the premises and 6.5 percent have poultry on the premises. (Note: these categories are not mutually exclusive.) The proportion of these mixed operations that actually use prohibited material in animal diets is unknown, as is the number and identity of operations with on-farm feed mixing capability. The proportion of the total cattle population on these types of operations is relatively small, 2.7 percent and 4.1 percent respectively. Resources are not available to inspect all farms and ranches for compliance with the feed ban. The CFIA works to ensure compliance at the farm level by using educational programs conducted by their own personnel, the extension service, trade associations, and producer groups. As part of the education campaign, livestock producers are informed of their requirement to maintain records of their receipt and use of prohibited material. Further, the requirement that firms label products containing prohibited material with the caution statement, “Do not feed to cattle, sheep, deer, or other ruminants” is intended, in part, to deter farmers and ranchers from accidentally or intentionally using products containing prohibited material in ruminant feed.

The feed trace-out investigation conducted in May 2003 provides evidence that these efforts to ensure on-farm compliance are effective. Before positive test results were obtained in May 2003, the carcass of Canada’s first BSE case had already been rendered and entered into animal feed channels. The CFIA subsequently traced a large volume of rendered product through feed distribution channels. The MBM was traced to commercial feed mills and feeds manufactured over a 39-day period. From among the farms that received feeds containing MBM manufactured during the target dates, a biased sample of 204 farms that were likely to have ruminant animals was selected for inspection. Of these farms, 170 had ruminants present. On 150 farms (88.2 percent), no exposure of ruminants to the suspect feed could be identified. On 13 farms (7.7 percent), potential opportunities for cattle exposure to the suspect feed were identified. Exposure was considered possible if appropriate cleanout procedures for cross-utilized feed manufacturing equipment had not been performed, or if the farm failed to document that clean-out procedures had been performed. In addition, there could have been exposure of ruminants to poultry or hog manure that may have contained some of the spilled suspect feed. On 7 farms (4.1 percent), there

was likely systematic or routine exposure to the suspect feed. This exposure was determined based on statements from the producer that the ruminants had access to spilled or stored feed containing the MBM on a routine basis. Three of the farms were quarantined and 63 cattle that may have eaten poultry feed were destroyed. Taking into account the very small probability of exposure of ruminants on the remaining farms, and impending enhancements to BSE risk management, the CFIA decided not to impose specific risk management measures on other farms. This decision was consistent with the recommendations of the international scientific experts who reviewed the CFIA's investigation.

3.1 Non-traditional Feeds

Historically, the livestock feeding industry has simultaneously evolved with the food manufacturing and agricultural processing industries, resulting in by-products being used as feed ingredients. Therefore, when referring to the "feed industry", other types of firms beyond feed mills and renderers need to be included. Other associated industries that supply materials into the feed supply include meat processing, food manufacturing, pet food manufacturing, as well as certain types of industrial operations. Further, a salvage industry has evolved to collect and find a reasonable use for items such as food and pet food products that are unable to be sold for their intended use. Under the CFIA's feed regulations, salvaged/distressed pet food is not considered an approved feed ingredient, and therefore may not be used in livestock feed. The CFIA's feed regulations allow a variety of food manufacturing by-products to be incorporated into livestock feed; however, a specific clearance process is followed for each ingredient before those ingredients are permitted. Plate waste is not allowed to be fed to livestock in Canada. As is the case in any manufacturing system, occasionally a feed product is mis-manufactured while it is in-process. The CFIA regulations allow a feed manufacturer to reprocess mis-manufactured feeds, as long as the manufacturer and product complies with any and all applicable regulations.

4 U.S. Audit of the Canadian Feed Ban

4.1 Scope and Methodology

On January 24, 2005, the U.S. Department of Agriculture sent a team to Canada to assess Canada's current feed ban and their feed inspection program to determine if the control measures put in place by the Government of Canada are achieving compliance with these regulations. On January 25, 2005, the CFIA provided an overview of processes and procedures related to the feed ban including: (1) the CFIA structure and authorities, (2) feed ban implementation in Canada, (3) inspection and compliance activities, (4) proposed future activities, and (5) the CFIA's plans for their own audit of the current feed ban.

The U.S. team utilized published materials from the CFIA website, including the risk assessment conducted in 2001, a description of the past cases of BSE in Canada, published notices, educational materials, and the report of the International Review Team from June of 2003. The team also reviewed historical documentation for the inspection and compliance procedures related to the implementation of the 1997 feed ban, including the CFIA directives, various forms used to carry out and record inspection activities, results of past audits of the inspection activities, and summaries of historical levels of compliance with the feed ban.

Additionally, the U.S. team reviewed historical inspection and compliance data related to the feed ban for the past three years. When an unsatisfactory rating is given by an inspector, the facility is given a period of time in which to resolve the problems that resulted in the rating. The inspector then verifies that the problem has been resolved and enters a resolution date into the Multi-Commodities Activities Program (MCAP) database. The U.S. team calculated the times until resolution for all unsatisfactory tasks and the number of unsatisfactory tasks that were never fully resolved. In addition to tabulating the number of tasks rated as unsatisfactory and time to resolution for the inspected facilities, the U.S. team attempted to categorize the reasons for the unsatisfactory rating according to criteria used in the United States by the FDA to determine if there is a need for official action (OAI) or voluntary action (VAI), to try to make a more direct comparison of compliance with the U.S. inspection program.

As part of the planned Canadian audit of their feed ban, the CFIA stratified commercial feed mills and rendering facilities with regard to potential risk for contamination of feeds, and then selected establishments to inspect. From the 94 commercial feed mills that used prohibited material and also manufactured ruminant feeds, they randomly selected 27 to be inspected. From the remaining feed mills (approximately 450) that either did not handle prohibited material or did not manufacture ruminant feeds, they selected 4 to inspect. From the total population of renderers (n=29) only 7 produced both prohibited and non-prohibited material. All 7 of these rendering facilities were selected for inspection. The CFIA inspector for the facility, accompanied by a

CFIA area manager and a member of the CFIA headquarters staff, conducted the Canadian feed ban audit and inspections of these facilities.

The U.S. team was provided hardcopies of the previous inspections for the selected facilities in addition to having access to inspection data that had been entered into the CFIA MCAP database. The U.S. team compared the hardcopy inspection records with the electronic database to determine if there were significant discrepancies.

The U.S. team accompanied the CFIA inspection staff on inspections of 7 of the 31 commercial feed mills selected randomly for inclusion in the Canadian audit as well as 3 of the 8 rendering facilities to be inspected. These 10 facilities were chosen by the U.S. team based on location (geographically distributed in three Canadian provinces). The U.S. team visited two commercial feed mills and a rendering plant located in each of Alberta and Saskatchewan, and three commercial feed mills and a rendering plant located in Ontario. While accompanying the CFIA inspectors, the U.S. team observed the application of the inspection standards, including review of records and labels, viewed the facilities and observed manufacturing practices, and discussed processes with facility personnel involved in various steps of feed manufacturing.

The U.S. team also visited the Canadian feed testing laboratory in Ottawa to discuss procedures and processes related to the feed ban, including the historical use of feed microscopy and other feed evaluation techniques and future plans for feed testing related to the feed ban.

4.2 Results

4.2.1 U.S. Review of the CFIA Verification Program and Processes

A review of the verification program procedures and processes was conducted. This included a review of all documents currently stored at the CFIA office in Ottawa, Ontario that specifically address verification activities pertaining to the feed ban. These documents included training documents, inspector checklists, program plans and projections, and Feed Inspection Review reports. Verification activities for Canada's feed ban continue to be focused primarily on inspecting commercial feed mills and rendering facilities. The U.S. team also focused their review on these areas.

Timeline of Activities for Implementation, Review and Improvement of the Canadian Feed Ban								
CFIA Feed Mill Activities								
1. Mammalian to Ruminant (BSE) Compliance Guide	2. Begin audits of Commercial Feed Mills for Feed Ban once every 3 years	3. Program Review Conducted by CFIA Feed Inspection Team	4. New Feed Mill Inspection Form 5. Conduct audits of Feed Mills every year	6. Program Review conducted by CFIA Feed Inspection Team	7. Feed Mill Training Modules 8. Feed Ban Traceability Forum 9. Program Review by CFIA Inspection Team		10. Audits conducted yearly.	11. Review of Feed Ban by CFIA Headquarters
1997	***1998***	***1999***	***2000***	***2001***	***2002***	***2003***	***2004***	***2005***
1. Animal Health Act Rendering Plant Audit 8/97 2. Rendering Plant Audit Protocol	3. New Rendering Plant Audit Protocol – Includes Regulations and guidance	4. Begin to conduct audits of all Rendering Plants	5. Conduct audits of all rendering plants each year	6.New Audit Tool – Feed Inspection 1A- Rendering Plants		7. Update to Feed Inspection 1A- Rendering Plants	8. Update to Feed Inspection 1A- Rendering Plants 9. Audits conducted yearly	10. Review of Feed Ban by CFIA Headquarters
CFIA Rendering Plant Activities								

Chart A - Timeline of Activities.

4.2.1.1 CFIA Verification Activities at Rendering Facilities

Prior to the feed ban, the need for regulatory oversight of the rendering industry in Canada was minimal. In 1997, the CFIA began requiring that rendering plants obtain an annual permit to operate. Starting in 1998, a rendering plant had to pass an on-site inspection each year before its operating permit would be renewed. To assist CFIA inspectors in conducting the annual inspections, the CFIA issued the *Rendering Plant Audit Protocol* in 1997. According to the audit protocol, the objective of audits at rendering plants was to confirm that the plants operated in accordance with the requirements of the Health of Animals Regulations. The protocol document was "score based", and was chiefly used as an educational tool to help rendering plants become knowledgeable and compliant with the regulation. The document has undergone the following revisions:

- January 1998 – revised to include guidance for the inspector regarding the number of records and type of activities that should be observed. This edition also included a section giving instructions to inspectors on what actions to take if noncompliance is found. These potential compliance actions ranged from requiring additional documented procedures to ordering a recall of contaminated product
- February 2001 - This update of the audit protocol was the *Feed Program 1A- Compliance Guide for Rendering Plants* (dated February 2001). This edition added an introduction,

definitions, and instructions for the CFIA inspector, and incorporated inspection results into the CFIA MCAP database system.

- January 2003 and January 2004 - These editions included changes that pertained to labeling requirements of the Health of Animals Regulations along with further clarification of other tasks. The January 2004 version is the most current edition.

4.2.1.2 Verification Activities at Commercial Feed Mills and on Farms

Prior to the August 1997 implementation of the feed ban, the CFIA conducted inspections at feed mills according to the Feeds Act and regulations. The resulting Inspection Report was a numeric rating device used to rate the level of compliance to the existing feed regulations. With the feed ban, the CFIA implemented some changes in their inspection process to help ensure compliance with the new regulations. This initial implementation process included the release of the first edition of the *Mammalian to Ruminant (BSE) Compliance Guide* dated 1997. In addition, a National Feed and Fertilizer Inspection Workshop was conducted in November 1997. A Memorandum of Information entitled "Anticipated Responsibilities of Inspection Staff: Plant Products, Animal Health and Meat Hygiene Programs", was sent to all inspection personnel. This memo included background information and definitions, and explained the CFIA's responsibilities relative to renderers, feed manufacturers, imported rendered materials and feeds, and livestock producers under the new regulations.

The *Mammalian to Ruminant (BSE) Compliance Guide* was used during the initial inspections as a stand alone inspection tool to determine compliance with the regulation. This guide contained 17 tasks to be addressed during the audit. This edition provided inspectors with an explanation of corrective actions to take in the event that they found products being improperly labeled or mishandled, including holding or recalling contaminated products.

In March 2000, the *Feed Mill Inspection Form* was updated to incorporate inspection results into the CFIA MCAP database. The form included tasks to assess compliance with both the Feed Regulations and Health of Animals Regulations. A total of 46 tasks were to be evaluated by the inspector. Minor editing changes were made to the inspection document in December 2001. Then, in October 2002, an updated Commercial Feed Mill Inspection Report form was released. Although this document has undergone several revisions it continues to be used to assess a firm's compliance with requirements from both the Feeds Regulations and Health of Animals Regulations. The number of tasks that must be conducted by the CFIA Inspector has increased from 46 to 86. Of those 86 tasks, approximately 13 specifically address the feed ban.

<u>Training for Inspectors</u>

In September 2002, the first of three modules of a proposed Feed Inspector Certification Program was released to the inspection staff. The module was entitled, "Training Modules – Feed Mill/On-Farm Inspection" and "Rendering Inspection."

In December 2002, a Feed Ban Traceability Workshop was conducted in Winnipeg, Manitoba. The Agenda included the following topics: A Transmissible Spongiform Encephalopathy Overview; Review of the Feed Ban Regulations; Preparing for On-site; and Preparation of Reports/Presentations from On-site Tracing. This workshop was held for Senior Feed Inspectors with the intention of initiating a "Train the Trainer" process - Trained Senior Feed Inspectors were tasked with providing training to other field inspectors.

4.2.2 Program Reviews by the CFIA Feed Inspection Group

In order to ensure program compliance, the CFIA began conducting audits of the Feed Inspection Program (in 1999). The primary objective of these audits was to determine whether the delivery of the National Feed Inspection Program in the specified areas conformed to the established guidelines. Observations for improvements in the design of the National Feed Inspection Program were also identified. Final audit reports dating from March 1999 to March 2002 were reviewed by senior members of the National Feed Team to determine the level of compliance with program guidelines. In addition, different areas of Canada were reviewed, including the Western Area, Atlantic Area, Ontario Area, and Quebec Area.

The reviews were inclusive of all the feed inspection activities for both rendering plants and feed mills. The National Feed Team identified facilities that were noncompliant based on on-site reviews, issued Corrective Action Reports, and followed up on these facilities. The findings from these reviews are summarized here:

1. Mainland-and Interior/Costal Regions, British Columbia – Western Area, March 8-12, 1999. There were no significant issues identified in the report.
2. Final Report Feed Inspection Program, Atlantic Area, October 4-8, 1999
    a. Feed mills were not being inspected according to Program 37, one mill had not been inspected for over 4 years.
    b. Some smaller mills had never been inspected.
    c. The Mammalian to Ruminant Guide was not always completed during the feed mill inspections.
3. Final Audit Report, Feed Inspection Program, Ontario Area, February 14-18, 2000
    a. The Mammalian to Ruminant inspections had not been conducted in at least 15 commercial feed mills.
    b. Part 41, on-farm feed mill inspection had not been delivered at levels identified in the National Work Plan.
4. Draft Audit Report, National Rendering Plant Compliance Program, Atlantic Area February 18-22, 2002
    a. No formalized staff training program.
    b. No process for the formal assessment of the inspector's knowledge, skills, and abilities.
    c. Indicated that not all feed mills still had been inspected.

   d. No on-farm feed mill inspections for this district where at least 19 farms are known to have on-farm feed mill operations.
5. Audit Report National Rendering Plant Compliance Program, Ontario Area, March 4-8, 2002
   a. No on-farm inspections had been conducted.
6. Final Audit Report, National Rendering Plant Compliance Program, Western Area, March 4-8, 2002. There were no significant issues identified in the report.

4.2.3 Validation of Database Records

The results of inspections performed at rendering plants, feed mills, and on-farm feed mills have been entered into the CFIA MCAP database since 2002. The U.S. team reviewed the paper documents of 38 establishments and compared them to the electronic data in order to verify the authenticity of information and accuracy of data entry. The information included the tasks that directly addressed the feed ban for feed mills and rendering plants. The review of these records indicated that the electronic data accurately reflected what was present on the hardcopy forms and could be used to perform program verification.

4.2.4 Summary of Electronic Inspection Reports

The review included records transferred from the MCAP database to excel files that covered the time period from April 2002 to January 14, 2005 (approximately three years). Tasks specifically identified with the feed ban were reviewed and included the following:

Rendering Plants – 18 tasks with a total of 62 standards
Feed Mills – 13 tasks with a total of 83 standards
On-Farm Mills – 8 tasks with 62 standards

Each task includes a series of performance standards. In order for a task to be identified as "Satisfactory" all standards in that task must be met.

Data for the following number of inspections conducted were indicated by the data contained in the database:

Commercial Feed Mills
April 2002 – March 2003 – 504*
April 2003 – March 2004 – 550
April 2004 – January 2005 – 311

* 162 feed mills were inspected using an older version of the inspection form and 342 mills were inspected using the current version of the inspection form.

Rendering Plants
April 2002 – March 2003 – 30
April 2003 – March 2004 – 31
April 2004 – January 2005 – 8

On-Farm Feed Mills
A total of 701 on-farm feed mill inspections were conducted during the past 3 years, 175 in 2003, 347 in 2004, and 179 in 2005. There were a total of 140 "Unsatisfactory" tasks identified, with the overwhelming majority pertaining to absence of documented procedures.

4.2.4.1 Commercial Feed Mills

Overall, there was a low frequency of unsatisfactory ratings for all of the tasks, especially in the more recent years. The percentage of inspected facilities that had one or more unsatisfactory tasks was 24.9 percent (85/342) in 2002-2003, 19.6 percent (108/550) in 2003-2004, and 14.8 percent (46/311) in 2004-2005. *(In 2002-2003 162 commercial feed mills used an earlier edition of the commercial feed mill inspection form. In that inspection form the tasks evaluated were not necessarily specific for the feed ban as in some cases they also included evaluations regarding feed medications and good manufacturing processes in addition to evaluations for feed ban related issues. For this reason, even though all feed mills were inspected in each year the 2002-2003 data show only 342 commercial feed mills rather than approximately 550 commercial feed mills. The data are summarized separately below in Chart B and are not included in the subsequent charts due to differences in the way the information was supplied.)*

Charts throughout this report show ratings of commercial feed mills based on task numbers. The focus of each of the tasks is shown in Table 4.

Table 4. Inspection Tasks

Task #	Task Description
7	Assess adequacy of feed and feed ingredient labels (prohibited material)
8	Assess adequacy of feed invoices
13	Assess the adequacy of written procedures and documentation for the disposition of returned* and recalled feeds - "prohibited materials" (*feeds returned by customers, retailers etc.)
15	Assess the adequacy of written procedures and documentation for the disposition of flush or recovered* materials - "prohibited materials" (*materials recovered from spillage, dust collectors etc.)
66	Assess the written procedures and records regarding the reuse of used packaging (prohibited material)
1) Assess the adequacy of written clean-out procedures and production records 2) verify that employees are following procedures in the following areas:	
20	Receiving equipment
24	Ingredient storage and handling equipment
28	Ingredient processing equipment
36	Mixing equipment

45	Pelleting/extruding equipment (including pellet mill/extruder, cooler and sifter/shaker
56	Packaging equipment
76	Bulk finished feed storage and handling equipment
81	Loading/unloading of bulk delivery vehicles

Since there was a change in the inspection form that occurred during the 2002-2003 inspection year, the results from the older version of the form used in 162 commercial feed mills are summarized separately (Chart B). Again, these tasks being evaluated are not strictly limited to criteria related to the feed ban.

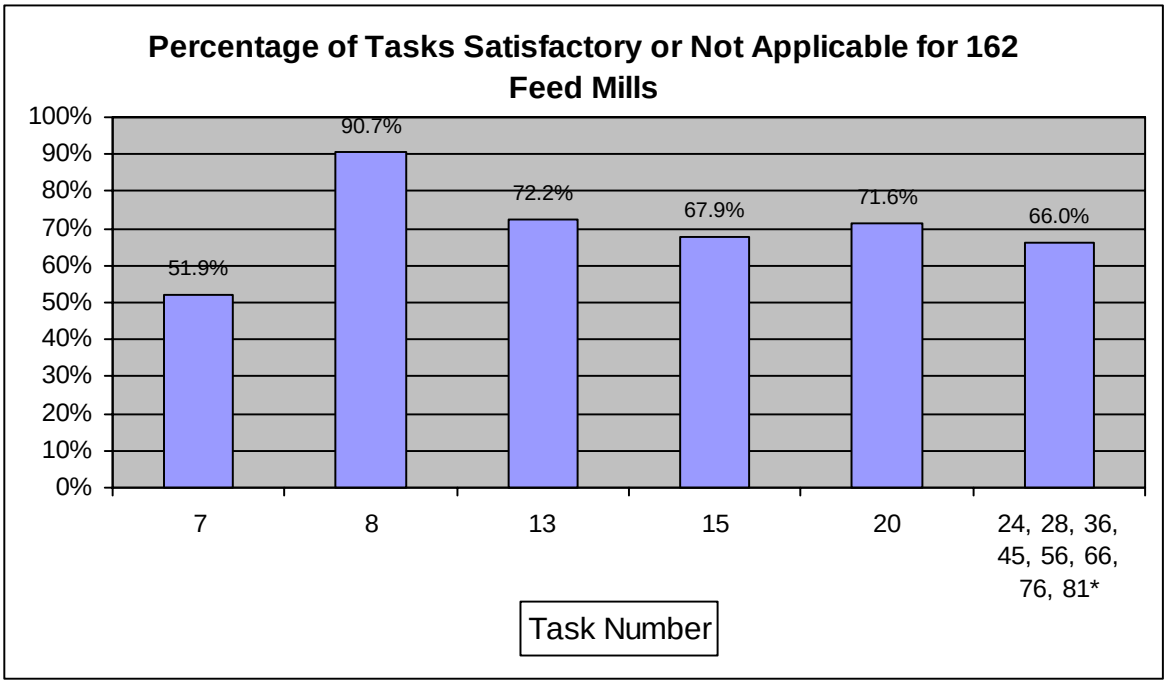

Chart B – The percentage of individual satisfactory or not applicable tasks for 162 commercial feed mills.
*** In the older version of the inspection form these tasks were evaluated in aggregate.**

Subsequent analyses report on data gathered using the revised inspection forms over a three year period.

Less than 3 percent of the majority of inspections resulted in an unsatisfactory rating for each of the tasks in the current year (Chart C). Task number 8 was most commonly given an unsatisfactory rating.[1]

[1] This task deals with feed invoices, including the need to have the name and address of the person to whom the feed is distributed or sold; a description of the feed, including the name and quantity; the name or other information used to identify the lot of feed; information as to whether or not the feed contains any prohibited material and where the

Overall, more than 90 percent of the tasks evaluated in each of the past three years were rated as either satisfactory or they did not apply to the feed mill. A not applicable rating may be given for a specific task if the firm does not have the piece of equipment referenced in the task or if they do not handle prohibited materials. The percentage of inspections resulting in a satisfactory or not applicable rating has increased across the three years for almost all tasks.

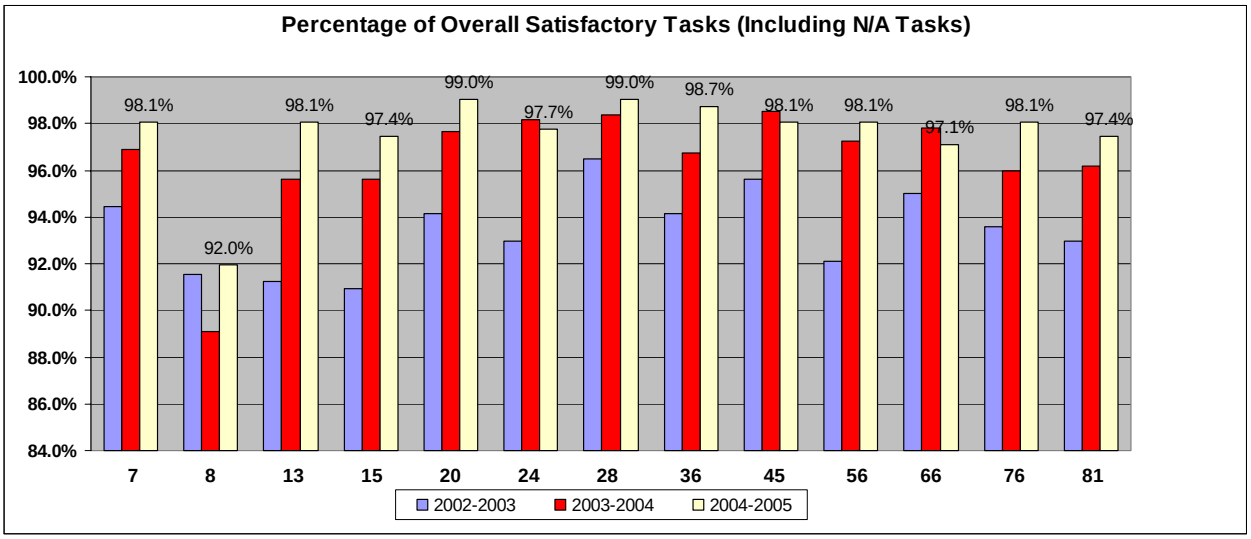

Chart C – The percentage of individual tasks for the period from 2002 to present that were rated as either satisfactory or not applicable for the facility. The data for 2002-2003 reflect the findings for the 342 commercial feed mills inspected with the current version of the inspection form.

In addition, unsatisfactory tasks are being resolved more quickly over the past three years, with the average resolution time decreasing from 100 (median = 70 days) to 70.1 (median = 54) days (Chart D). (Since inspections were on-going at the time of the U.S. team's visit, the resolution time could not be calculated for the current year.)

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feed contains prohibited material, the required statement, "Do not feed to cattle, sheep, deer or other ruminants." Copies of invoices must be kept for a period of at least two years from the last date of manufacture of that feed.

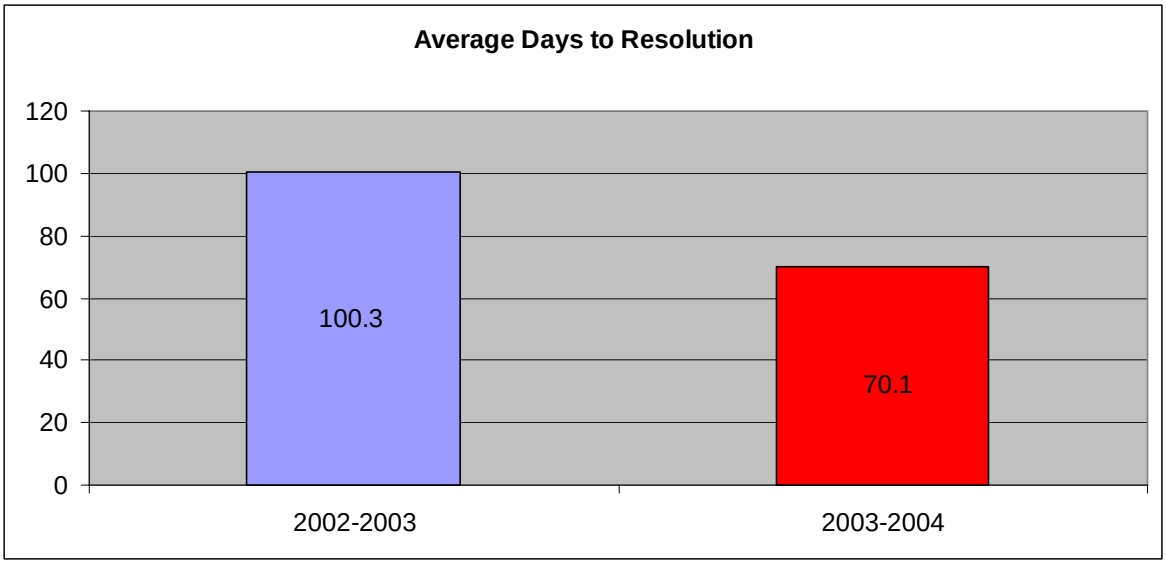

Chart D – The average number of days from the time an unsatisfactory rating was delivered for a task to the time it was verified as corrected.

The percentage of tasks with a rating (not applicable tasks removed) that were considered unsatisfactory has declined (Chart E).

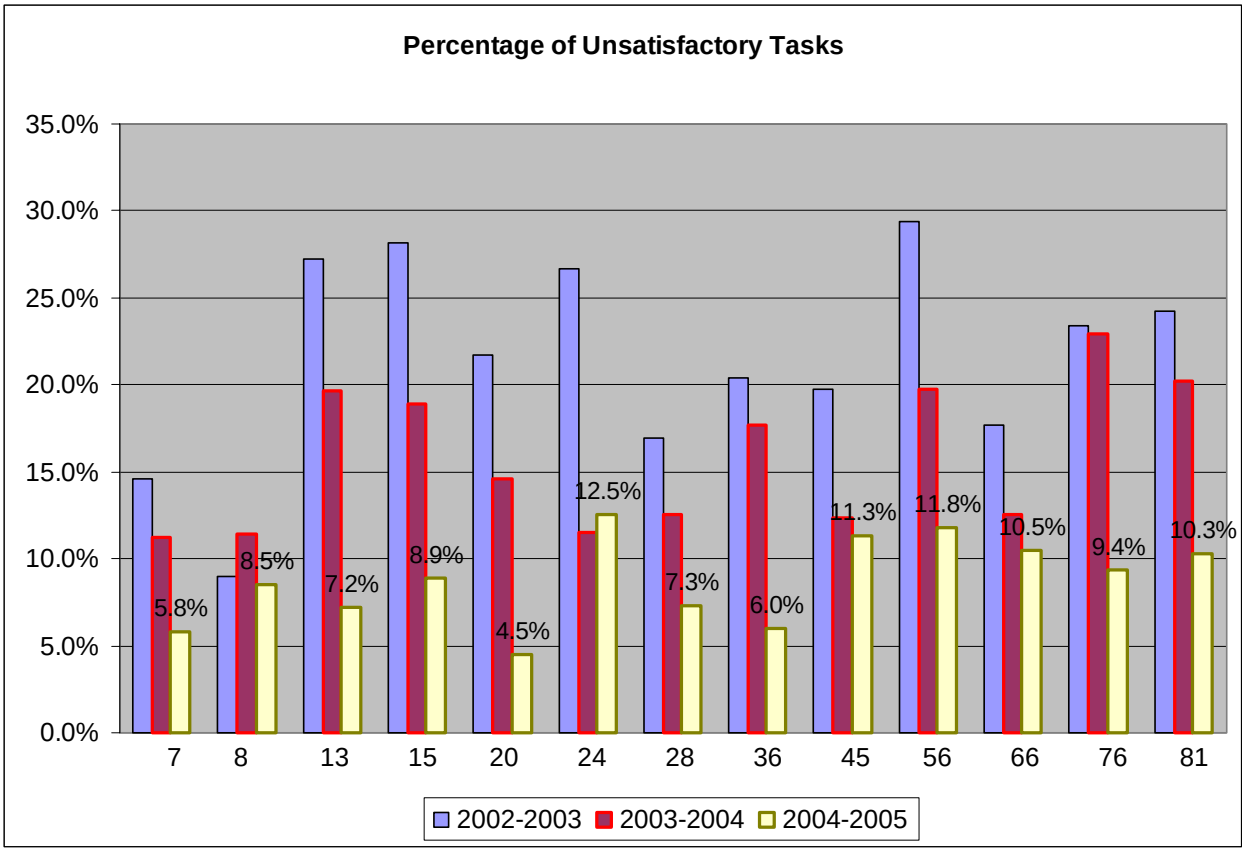

Chart E – The percentage of individual task rated as unsatisfactory from 2003 to present. Inspections where the task was considered not applicable were removed. The data for 2002-2003 reflect the findings for the 342 commercial feed mills inspected with the current version of the inspection form.

The proportion of commercial feed mills with at least one unsatisfactory task has declined over the 3 year period to the current level of 14.8 percent (Chart F). During the years of 2003-2004 and 2004-2005 approximately one-third of these feed mills received unsatisfactory ratings because they omitted part or all of the buyer information (name and address), or the name of the feed on some of the sales invoices, or because they were putting the cautionary statement, "Do not feed to cattle, sheep, deer or other ruminants" on feeds that did not contain prohibited material. Many of the unsatisfactory ratings for the remaining feed mills with unsatisfactory ratings were related to needed improvements for record-keeping and documentation of procedures. In some cases, the feed mill management may have viewed these procedures as general policy for the mill and therefore, found it unnecessary to document. For example, a feed mill may have a policy to not reuse packaging materials. If there is not a written procedure documenting how used packaging materials are handled, the feed mill would have received an unsatisfactory rating for that task. Since commercial feed mills that handle prohibited materials and manufacture ruminant feeds are evaluated on many more tasks (fewer tasks are not applicable) there are more opportunities for these feed mills to have an unsatisfactory task. These

feed mills were approximately twice as likely to have an unsatisfactory task as all commercial feed mills.

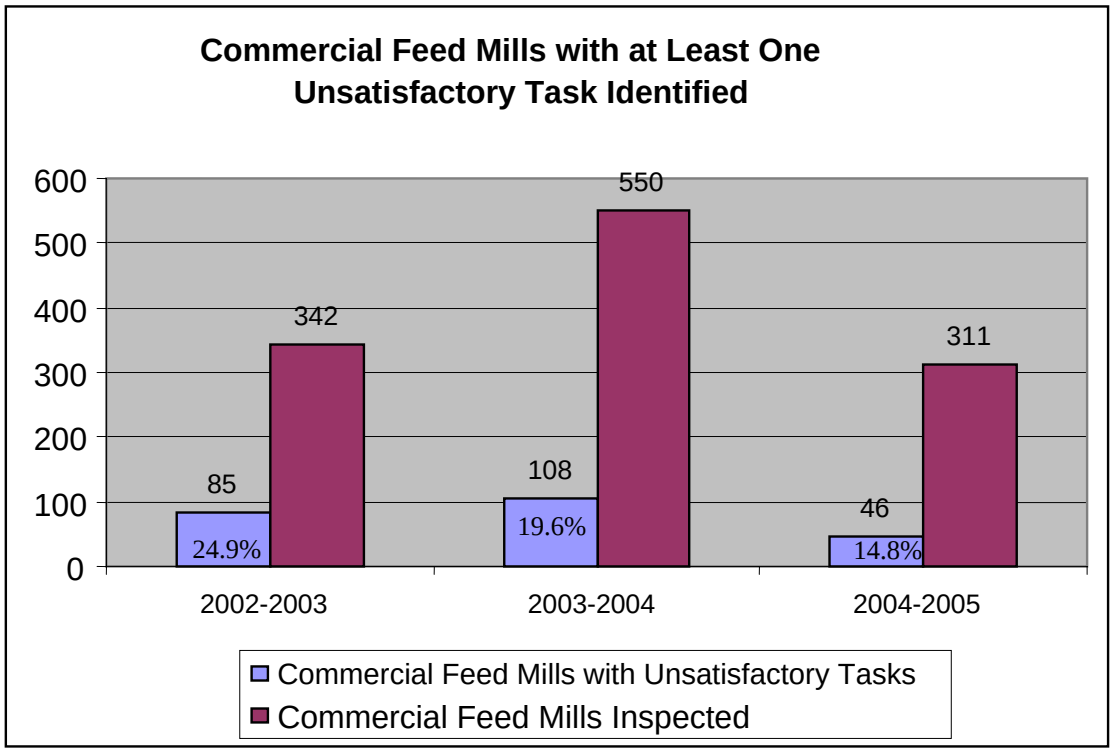

Chart F – The number and percentage of commercial feed mills where at least one unsatisfactory task was identified compared to the number of total number of commercial feed mills inspected. Data for 2002-2003 include feed mills inspected using both versions of the form. Inspections for 2004-2005 have not yet been completed.

When an unsatisfactory rating was given on any task the feed mills were given a period of time to develop a corrective action plan. In some cases the corrective action was made immediately. In other cases the corrective action took some time to implement. In any case, once the corrective action was reported to be complete by the feed mill the inspector re-inspected the facility to confirm the actions resolved the issue. The data show a small number of instances where the unsatisfactory rating was not resolved (Chart G). Given that inspections are on-going for 2005, it is expected that there will be unresolved unsatisfactory ratings as sufficient time may not have elapsed to perform the corrective action or to verify their completion. It is unclear from the database if the unresolved tasks from the 2002-2003 and 2003-2004 years really represent issues that remained unresolved or if they represent inattention to record-keeping and the closure of the identified issues. The CFIA plans to address this issue in their audit of the feed ban.

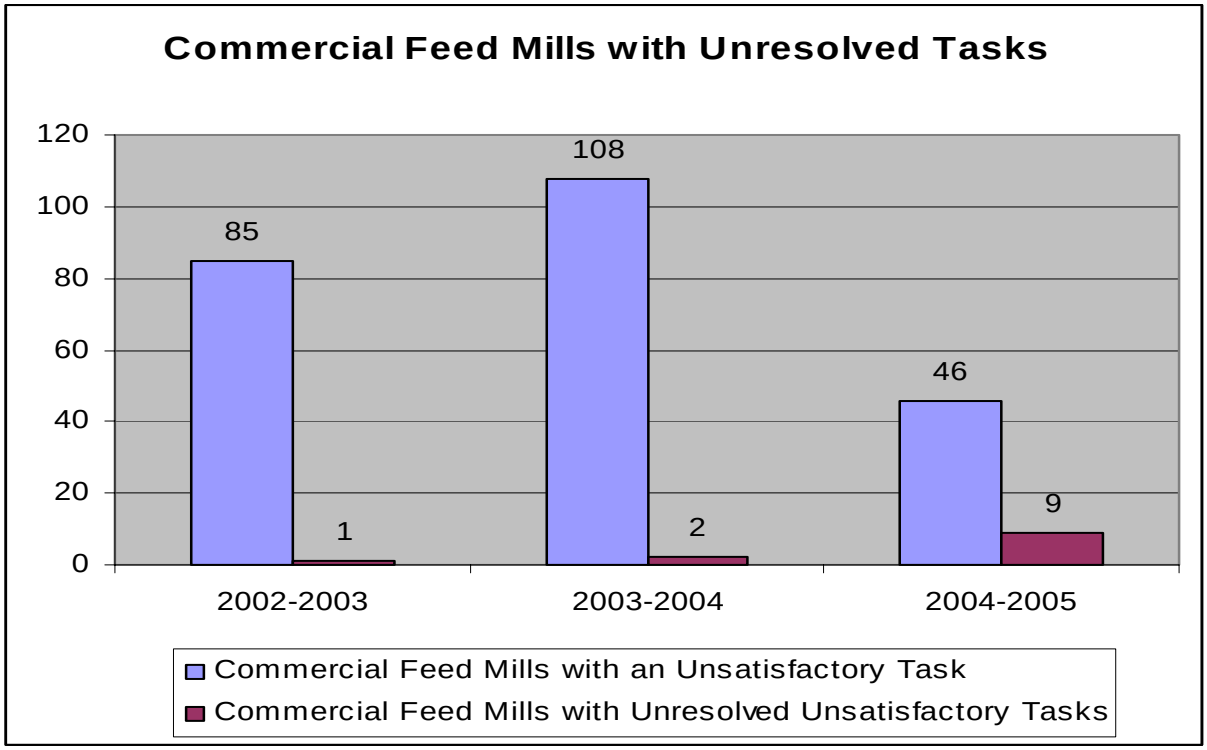

Chart G – The number of commercial feed mills audited with tasks that did not have a resolution date. Data from 2002-2003 include feed mills inspected using both versions of the form.

System used in the U.S. to evaluate feed ban compliance

U.S. inspections are conducted by FDA or State investigators and are classified to reflect the compliance status at the time of the inspection, based upon the objectionable conditions documented. These inspection conclusions are reported as OAI, VAI, or NAI.

An OAI inspection classification occurs when significant objectionable conditions or practices are identified and regulatory sanctions are warranted in order to address the establishment's lack of compliance with the regulation. An example of an OAI inspection classification would be findings of manufacturing procedures insufficient to ensure that ruminant feed is not contaminated with prohibited material. Inspections classified with OAI violations will be promptly re-inspected following the regulatory sanctions to determine whether adequate corrective actions have been implemented.

A VAI inspection classification occurs when objectionable conditions or practices identified do not meet the threshold of regulatory significance, but do warrant advisory actions to inform the establishment of findings that should be voluntarily corrected. Inspections classified with VAI violations are more technical violations of the Ruminant Feed Ban. These include provisions such as minor record-keeping lapses and conditions involving non-ruminant feeds.

A NAI inspection classification occurs when no objectionable conditions or practices are identified during the inspection or the significance of the documented objectionable conditions identified do not justify further actions.

Results as scored using the U.S. system

Given the differences between the CFIA's inspection program and the FDA's inspection program, it is difficult to make a direct comparison between deviations from the Canadian regulations found in Canadian facilities, and deviations from the U.S. regulations found in facilities in the United States. Nevertheless, the team felt it would be informative to try to evaluate the CFIA's inspection findings using the same scoring system that the FDA uses.

We attempted to score each unsatisfactory task in the MCAP database using criteria for classifying inspection findings as found in the FDA Compliance Program Guidance Manual (CPGM) 7371.009 "BSE/Ruminant Feed Ban Inspections" for guidance in classifying these tasks. The CPGM contains some specific guidance on classifying inspectional findings that deviate from the U.S. regulations. Differences in the way inspections are conducted and documented in the United States and Canada, as well as the small amount of information the database contained about some of the unsatisfactory tasks made scoring the Canadian findings difficult in some cases. The team was not able to have some of the inspection results from Quebec translated from French to English quickly enough to be included in this report. Additionally, some tasks that had been scored as unsatisfactory were found to be unrelated to the feed ban. The lines of data recorded in French, as well as the lines which contained comments unrelated to the feed ban, are contained in the "undetermined" column below (Table 5).

Finally, the FDA classifies the firm based on the outcome of the entire inspection, not on the individual elements or tasks that make up the inspection. We did not have the entire inspection report from each firm to use for our evaluation, so we scored each unsatisfactory task individually, then evaluated composite results for each firm. Feed mills with one or more unsatisfactory task that was scored OAI was then classified as an OAI facility. In the absence of any OAI unsatisfactory task, if a facility had one or more VAI unsatisfactory task then the facility was designated as a VAI facility.

Based on this method of evaluating the data, and considering the caveats, the percent of all feed milling facilities found in OAI status at the time of the inspection was 5.8 percent, 1.0 percent, and 3.8 percent for the recent three years of inspections (Table 5).

Table 5. Commercial Feed Mill Inspection Results								
Year	**Feed Mills Inspected**	**Tasks Evaluated**	**Tasks Applicable**	**Feed Mills with Unsatis-factory Tasks**	**Unsatis-factory Tasks**	**Feed Mills with at least one FDA OAI**	**Feed Mills with at least one FDA VAI**	***Undeter mined tasks****
2002-2003**	342	4446	1482	85	291	20 / 5.8%	51 / 14.9%	*45*
2003-2004	550	7150	1714	108	253	6 / 1.0%	73 /1.2%	*58*
2004-2005	311	4043	1135	46	99	12 / 3.8%	22 / 7.0%	*39*

* Unsatisfactory tasks that FDA was unable to classify.
** Using data from the current version of the inspection form.

4.2.4.2 Rendering Plants

Overall, the percentage of tasks rated as satisfactory or not applicable increased substantially over 2002-2003 levels (Chart H).

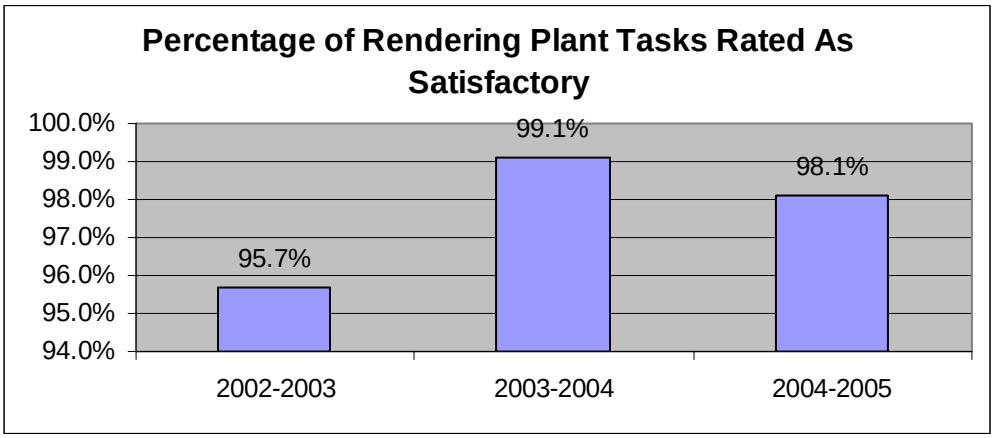

Chart H – The percentage of feed ban related tasks rated as satisfactory.

The percentage of rendering plants had one or more unsatisfactory task ratings has declined from 23 percentage in 2002-2003 to 12.5 percentage in 2004-2005 (Chart I). Most of the unsatisfactory tasks related to a need to improve record–keeping and written procedures.

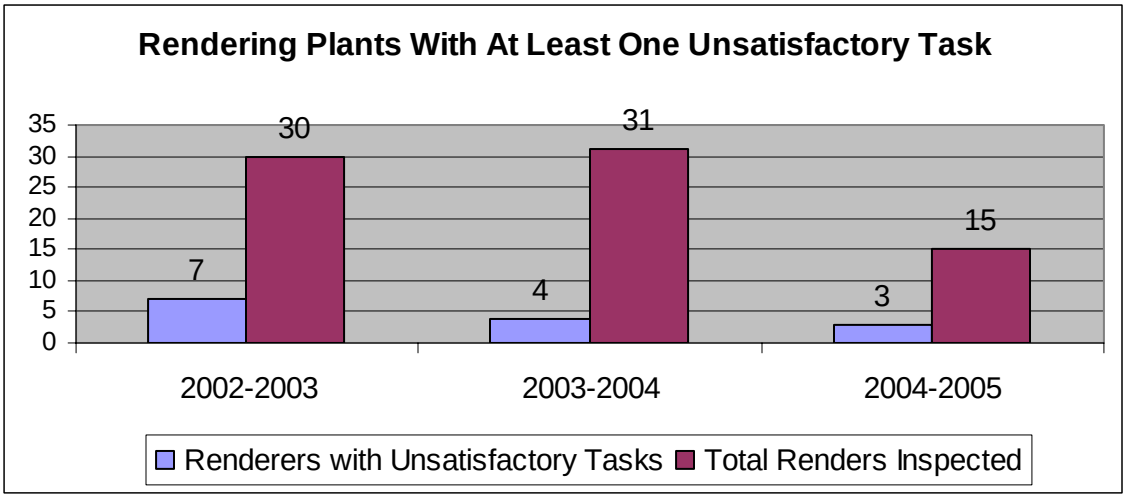

Chart I – The number of rendering plants where at least one task related to the feed ban that was identified as unsatisfactory.

As with the feed mill inspections, when a task is rated as unsatisfactory, the rendering facilities are given a period of time to correct the problem, and are then re-inspected to confirm the resolution. When the issue has been resolved, a resolution date is assigned. Over the three years of inspections in some cases the renderers have had unsatisfactory tasks that are shown in the database as unresolved (Chart J). Unresolved tasks are expected for the 2004-2005 year as there has not been sufficient time for the facilities to address all of the issues. Again, it is unclear if the unresolved unsatisfactory tasks represent issues that were truly unresolved or if they represent lack of follow through to update the MCAP database.

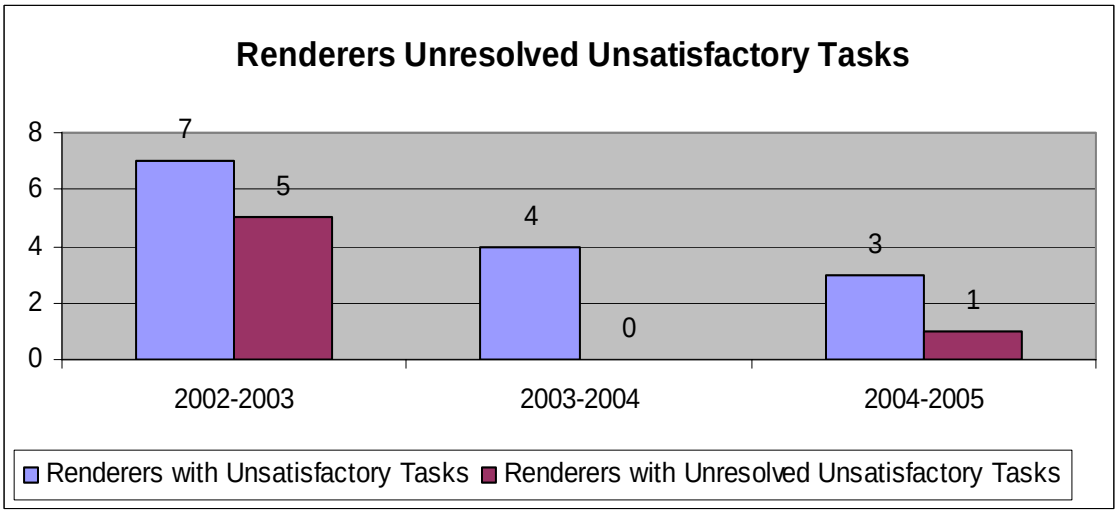

Chart J – The number of renderers with unresolved unsatisfactory tasks.

Rendering plant results as scored using the U.S. system

As was done with the feed mills, the U.S. audit team thought it would be informative to score the rendering plant inspection results according to the system used by the FDA. Again, given the differences between the CFIA's inspection program and the FDA's inspection program, it is difficult to make a direct comparison between inspection results from the two countries.

In order to handle the rendering plant inspection data in a manner consistent with the feed mill data, we attempted to score each unsatisfactory task in the MCAP database using FDA CPGM 7371.009 for guidance. There were far fewer rendering plant inspection records in the database than there were records for commercial feed mill inspections. A number of the explanatory comments were in French and could not be translated in time for this analysis. In looking at the results of 60 inspections over three years that could be used, there were only two inspections, both conducted in 2002-2003, that would be classified as OAI by the FDA criteria.

4.2.4.3 On-Farm Feed Mills

A review of the on-farm inspection data indicated that the majority of the tasks pertaining to the feed ban were considered to be not applicable. Of the total number of tasks reviewed during the audits (n=5610), the majority (n=5091) did not apply; only 519 tasks specifically addressed the feed ban issues. In all years, a high percentage of the tasks (approximately 97 percent) were rated as satisfactory or were not applicable. The overwhelming majority of unsatisfactory tasks pertained to a lack of documented standard operating procedures.

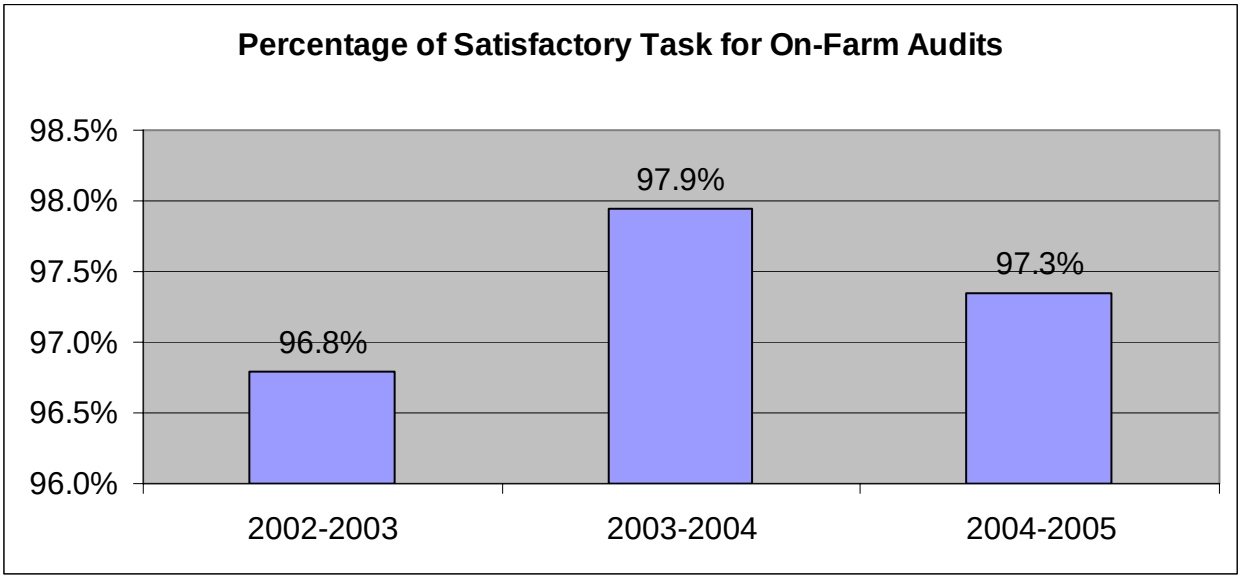

Chart K – The percentage of individual tasks rated as either satisfactory or not applicable.

5 Summary of the On-Site Inspection Review

The U.S. team accompanied the CFIA inspectors to seven commercial feed mills and three rendering facilities. These particular firms were selected for the site visits because they process and distribute feed or feed ingredients containing prohibited material, and because these firms are distributed over a wide geographic area across three Canadian provinces. The objectives of the U.S. team's on-site visits were to observe the CFIA's inspection process, assess CFIA's enforcement of the feed ban regulations, and evaluate industry compliance with Canada's feed ban.

Prior to the visits, the CFIA contacted the facilities to arrange a time for the inspection, to assure that the personnel that needed to represent the firm on-site would be present at the inspection, and to minimize the time required to retrieve historical records. The facilities were asked to collect records for two specified dates in 2003 and two specified dates in 2004. While at the facilities, the team requested records from two additional dates for review. Production records and standard operating procedures were reviewed, and a tour of each facility was conducted to evaluate if the procedures were being followed. Employees in several areas of each facility were interviewed to determine their familiarity with the operating procedures relative to the feed ban.

Inspection forms provided by the CFIA were used to rate each facility on each of the described tasks (Appendices 2-4). In most cases the tasks required a verbal response by the facility manager or an employee, as well as a review of records or written documentation of operating procedures. Rarely did the field inspector have their rating for a task changed by the CFIA headquarters representative. The inspectors demonstrated a strong knowledge of the feed industry, feed manufacturing processes, and requirements of the Animal Health Regulations and Feeds Regulations as they pertain to feed ban. The inspectors were well prepared with the latest edition of the task checklist, and a copy of the findings from the previous inspection, in order to compare changes in activity and identify and evaluate compliance with Canada's feed ban.

5.1 Commercial Feed Mills

Overall, for the seven commercial feed mills 90 percent of the tasks received a satisfactory rating. However, six of the feed mills received one or more unsatisfactory task ratings. Three of the feed mills had a single unsatisfactory task and one feed mill had two unsatisfactory tasks. The other feed mills had three and five unsatisfactory tasks. Most of the tasks rated "unsatisfactory" related to record-keeping issues (duration of records retention, completeness of invoice information) or deficiencies in written standard operating procedures (lack of complete documentation for current practices). Specific examples include one feed mill in which invoices for cash sales lacked buyer information (the only unsatisfactory task for this feed mill), another mill did not have production records available for the full two year history as required (resulting in four of the five unsatisfactory tasks for this feed mill), and another feed mill listed "meat meal" on their master

formulas and batch sheets instead of "prohibited meat meal" as required (resulting in two unsatisfactory tasks for this feed mill). However, inspection findings in two mills were considered more serious. One finding was for a historical issue that was corrected in 2003. A review of historical production records at one mill showed that after a batch of poultry feed containing prohibited material was processed on January 31, 2003, no flush or other cleanout procedures were used before processing a batch of soybean meal. The feed mill should have used cleanout procedures or else labeled the soybean meal with the required cautionary statement (Do not feed to cattle, sheep, deer or other ruminants), even though the soybean meal was destined for a hog farm to be used in swine feed. This deficiency had been previously identified during a January 15, 2003 CFIA inspection, but had not been corrected until February 24, 2003. Production records from March 27, 2003 showed that revised standard operating procedures requiring a flush between batches were being correctly followed. No further incidents were noted in subsequent records reviewed.

While reviewing production records at another feed mill, the inspector identified one instance where a flush was not recorded between a batch of poultry feed containing prohibited material and a batch of cattle feed. The flush is normally executed automatically by the computerized batch mixing system. The plant management's tentative assessment was that in this particular case, the operator may have changed to manual mode in order to deal with an equipment problem. The CFIA requested that the plant investigate the incident further and report its findings to CFIA. In addition, CFIA inspectors returned to the feed mill two days later to check production records for other instances where the feed mill failed to perform a required flush. The plant's investigation concluded that the batch mixing system had in fact been switched to manual mode in order to deal with an equipment problem. A manual flush was not performed when the equipment was brought back on-line. The CFIA has required the feed mill to develop a corrective action plan to preclude future similar occurrences. CFIA is also considering additional enforcement action in this case.

Other than these situations, most of the issues identified required only minor modifications to existing written procedures and forms, or involved improvement in record maintenance or record retention time.

The U.S. team also noted that at several of the feed mills, haulers delivering feed ingredients to the mill were required to sign an affidavit that the previous load of material they had hauled did not contain prohibited material. In addition, when trucks were being loaded with finished feeds at the feed mills, most of those mills visited routinely inspected the interior of the trucks to assure there was not residual feed that could contaminate the feed products being loaded.

5.2 Rendering Plants

Among the three rendering facilities visited, two plants had one or more tasks rated as unsatisfactory. One unsatisfactory rating was for failure to keep a log of errors that had occurred in processing. The other unsatisfactory rating was due to the need for a standard operating

procedure to be written that would require an external truck operator to sign-off that the truck had been cleaned if it had previously hauled prohibited material and was not going to haul non-prohibited material. All three rendering firms were aware of the requirements to comply with the feed ban and used a combination of dedicated facilities, flushing, and other procedures to decrease the risk of cross-contamination. When there is cross-utilization of equipment in the rendering facilities, it appears that the amount of equipment used for both prohibited and non-prohibited material is minimized. For example, in one facility only the cooker was cross-utilized, while in another facility only the load-out equipment was used for both types of products. For the cooker that was cross-utilized, a flush of one hour production (approximately 6250 kg) of non-prohibited material is currently being diverted into the bin with the prohibited material to prevent carryover contamination of non-prohibited material. All three rendering plants had good standard operating procedures to meet feed ban requirements, and good documentation of these procedures. In each inspection, minor corrections were needed, mostly concerning clarifications to the firm's standard operating procedures, or reformatting existing record forms to provide additional information. The inspectors discussed these issues with firm management and firm management committed to making changes. In many cases, these changes were above and beyond what is required by the regulations. As was the case with the feed mill inspections, the CFIA inspectors were thorough, and possessed the skills necessary to help ensure compliance with the Canadian feed ban. Inspectors demonstrated good working knowledge of the inspection process and good familiarity with the feed and rendering industries.

5.3 Feed Testing Laboratory

The U.S. team visited the CFIA's Ottawa Laboratory of the Bioanalysis Unit, Feed and Fertilizer Section, to determine the extent to which feed testing is used to enforce Canada's feed ban. Part of the reason for the U.S. visit was because the CFIA's pilot program, to evaluate the usefulness of feed microscopy as a feed ban enforcement tool, was the subject of recent news reports. These reports featured two consumer groups who claimed that test results on feed samples collected between January and March 2004, obtained through the Access to Information Act, raised doubt regarding the effectiveness of Canada's feed ban.

During their visit, the U.S. team found that the Ottawa Laboratory is well equipped for feed microscopy, and has experienced analysts. For over ten years the lab has routinely used feed microscopy on complaint samples to test for contaminants, extraneous and/or injurious material, unlabeled ingredients, and noxious weed seeds. Feed microscopy also evaluates the presence of insects, mold, dust, and heat damage. The laboratory maintains an extensive computer reference library of photomicrographs of hair, muscle, and bone from a large number of animal species. The laboratory also maintains a reference collection of these tissues mounted on microscope slides, as well as a reference collection of vials of feed and feed ingredients of interest.

During the U.S. team's visit to Canada, the CFIA completed a report on the analytical results of the 110 feed samples that had been mentioned in media reports. The report also provided results

of follow-up investigations at establishments where feeds that tested positive for animal proteins had been processed. The CFIA has posted a copy of the report to their website.

According to their report, the CFIA concluded that limitations of the feed microscopy method outweigh its utility as a feed ban enforcement tool. In the United States, the FDA acknowledges that this analytical method has some limitations. Feed microscopy can reliably detect the presence of bone, hair, and muscle, but cannot reliably determine the animal species of origin. Therefore, feed microscopy alone is usually not sufficient to determine if feed contains prohibited material. The FDA uses feed microscopy on a limited basis to test domestic feed. Follow-up investigations at feed manufacturers and distributors are needed before a determination can be made that positive samples contain prohibited material. Both the United States and Canada are evaluating polymerase chain reaction analysis, commercially available test kits using enzyme-linked immunoassay technology, and combinations of these methods in an effort to find a test protocol that can reliably detect prohibited material in feed.

6 Conclusions

The Canadian feed ban is not substantially different than the U.S. feed ban. Both feed bans prohibit the use of mammalian protein in ruminant feeds, with exceptions for milk products, blood products, gelatin, and protein derived solely from porcine or equine sources. Two minor differences between U.S. and Canadian feed regulations are that the United States allows plate waste and poultry litter to be used in ruminant feed, whereas Canadian feed regulations make no such allowances. The inspection program in Canada is administered by the CFIA without significant involvement by the Provincial governments, in contrast to the United States where the FDA and States work cooperatively.

Shortly after the feed ban was first proposed in 1996, the CFIA began educating the feed industry, livestock producers, and their own inspection force about the impending regulations. Although the Canadian feed ban became effective on August 4, 1997, full implementation was a stepwise process. The feed ban allowed a short phase-in period for the feed industry to deplete their existing product supplies and begin to conform to labeling and record-keeping requirements. As in the United States, there was no systematic recall of feeds already in marketing channels or on farms that may have been affected by the regulation. From 1997 to 2000, the CFIA continued to educate, but also continued to conduct inspections to bring the feed industry into compliance with the feed ban. Rendering facilities were required to pass an annual inspection before renewing their permit to operate from 1998 onward. In 2000 and 2001, the CFIA modified its compliance programs by increasing the frequency of inspections of commercial feed mills from once every three years to every year, and continuing the annual inspection and permitting of all rendering facilities. Since 2002, the CFIA has been conducting annual inspections of all rendering and commercial feed mill facilities and some ruminant feeders and retail feed distributors. Similar to the approach used in the United States, the CFIA made the most efficient use of resources by focusing their efforts to implement the feed ban at the feed manufacturing level, rather than at the farm level. The feed industry has also taken aggressive steps to comply with the feed ban. For example, approximately one-third of the commercial feed mills (producing at least 60 percent of the feed produced in commercial mills) have become HACCP-certified through a program of the Animal Nutrition Association of Canada. Under this program feed mills have incorporated elements of the feed ban into their HACCP plan, including training employees, developing standard operating procedures, and maintaining appropriate records.

The U.S. team's review of electronic records for the inspection and compliance program showed that some feed mills and rendering plants were not fully compliant with the requirements of the feed ban. Thirteen inspection tasks out of the 86 tasks that make up a full commercial feed mill inspection are related to feed ban requirements. Plants are scored as satisfactory on a task only if they meet every subtask requirement. In the event of an unsatisfactory rating on any of the tasks, the facility management is required to provide the inspection staff, within a specified period of time, with a corrective action plan. The inspectors then must verify that the corrective action has

been taken. In the records reviewed, most unsatisfactory ratings on individual tasks were for documentation problems. Most of these unsatisfactory ratings were related to record-keeping issues such as not retaining the purchaser name and address, or for incomplete written documentation of operating procedures. The percentage of commercial feed mills in Canada that had unsatisfactory ratings on individual tasks has declined from 24.9 percent (85/342) in 2002-2003 to 14.8 percent (46/311) in 2004-2005.

Based on scoring of the facilities in a manner similar to that used by the FDA to score U.S. facilities 5.8 percent, 1.0 percent, and 3.8 percent would have been classified as having an OAI respectively for the years of 2002-2003, 2003-2004, and 2004-2005.

During the site visits, the U.S. team found a higher proportion of facilities that had unsatisfactory ratings for individual tasks than was seen in the overall historical records. Most of these cases were the result of record-keeping deficiencies or the lack of fully documented standard operating procedures.

The Canadian feed ban provides protection against the spread of BSE in the Canadian cattle population. Although appropriate safeguards are in place and are effectively enforced, the potential for cross-contamination at facilities that handle prohibited material and also process ingredients for ruminant feed is always a concern. There has been a movement toward dedicated processing lines in the rendering facilities or fully dedicated facilities. Also, since the feed ban's inception in 1997, the industry has moved toward dedicated feed manufacturing facilities, such that fewer commercial feed mills handle prohibited material and manufacture feeds for ruminants. In addition, the CFIA has proposed to remove SRM from all animal feed, which will significantly reduce the risks associated with cross-contamination, and also address risk associated with on-farm mis-feeding.

The CFIA has not been able to dedicate extensive resources to evaluating on-farm feed manufacturing or feeding practices to determine the level of compliance with the feed ban. Instead, an educational approach has been used to encourage the appropriate handling of feeds that contain prohibited material. These efforts, along with those aimed at preventing cross-contamination and providing adequate labeling of feeds containing prohibited material, are meant to decrease the likelihood of inadvertent exposure of ruminants to prohibited material.

The CFIA continues to revise and update their procedures and processes to further enhance the effectiveness of the feed ban. Based on the results of the current Canadian audit, the CFIA intends to revise some of the inspection forms to increase the objectivity of the standards, and carry out additional training for the inspectors to improve standardization in the inspection rating process. The CFIA will also make adjustments to the program to continue to improve compliance with the feed ban. Moreover, inspectors performing reviews for the program are full-time agency personnel. These employees are provided the most current information and tools, ongoing individual training, and direct supervision by CFIA management personnel. In addition,

the CFIA has proposed the complete removal of SRM from animal feeds. Recognizing that there are opportunities for cross-contamination to occur along the feed manufacturing chain, on December 10, 2004, Canada proposed new regulations to further enhance the effectiveness of the feed ban.

The Canadian government, feed industry, and livestock producers have substantially increased their efforts to implement and comply with the Canadian feed ban. Based on the U.S. team's review of the inspection records for the past three years and on-site inspections of a sampling of commercial feed mills and rendering facilities, it is evident that considerable effort is being dedicated in all sectors to carry out the intent of the Canadian feed ban. It is the U.S. team's determination that these efforts have reduced the risk of transmission of the BSE agent in feed to ruminant animals.

Appendix 1 — Feed Ban Rule

PART XIV
FOOD FOR RUMINANTS, LIVESTOCK AND POULTRY

Prohibited Material

162. (1) In this Part, "prohibited material" means anything that is, or that contains any, protein that originated from a mammal, other than a porcine or an equine. It does not include milk, blood, gelatin, rendered animal fat or their products.

(2) Prohibited material that has been treated in a manner approved by the Minister to inactivate the agents that cause transmissible spongiform encephalopathies is no longer prohibited material. SOR/97-362, s. 4.

163. (1) A person who identifies prohibited material by means of adding to it a marker or tracer substance that has been approved by the Minister in the manner specified in that approval, is not required to keep the records referred to in subsections 165(2) and 166(2) and section 171.

(2) Every person who identifies prohibited material in accordance with subsection (1) shall maintain a record of the manner in which the marker or tracer substance was added to the prohibited material. SOR/97-362, s. 4.

Feeding Prohibited Material to a Ruminant.

164. No person shall feed prohibited material to a ruminant. SOR/97-362, s. 4.

Rendering Plants

165. (1) No person shall operate a rendering plant unless the person does so under and in accordance with a permit issued pursuant to section 160.

(2) Every person who operates a rendering plant shall keep a record of

(*a*) the date of production of all products of the rendering plant;

(*b*) whether or not any product of the rendering plant is, or contains any, prohibited material;

(*c*) the name, and quantity of, and any other information that is sufficient to identify, the products of the rendering plant; and

(*d*) the name and address of any person to whom any product of the rendering plant is distributed or sold and the information referred to in paragraph (*c*) with respect to that product.

(3) No person who operates a rendering plant shall distribute or sell any product of a rendering plant that contains prohibited material unless the documentation required by these Regulations relating to the product and any label on any packaging or container containing the product is marked conspicuously, legibly and indelibly with a statement approved by the Minister that indicates that the product shall not be fed to ruminants. SOR/97-362, s. 4.

Importation of Products of Rendering Plants

166. (1) No person shall import any product of a rendering plant unless the person does so under and in accordance with a permit issued pursuant to section 160.

(2) Every person who imports or has the possession, care or control of any product of a rendering plant shall keep a record of

(*a*) the name and address of the rendering plant and the date of production of the product;

(*b*) the name and address of the exporter;

(*c*) the name and quantity of, and any other information that is sufficient to identify, the product;

(*d*) the name and address of any person to whom any product is distributed or sold and the information referred to in paragraph (*c*) with respect to that product; and

(*e*) whether or not the product is, or contains any, prohibited material. SOR/97-362, s. 4.

Importation or Sale of Products of Rendering Plants

167. No person who imports or has the possession, care or control of a product of a rendering plant shall sell or distribute the product unless the documentation required by these Regulations relating to the product and any label on any packaging or container containing the product is marked conspicuously, legibly and indelibly with the statement referred to in subsection 165(3). SOR/97-362, s. 4.

Food and Food Ingredients

168. No person shall import, manufacture, package, label, store, distribute, sell or advertise for sale any animal food for ruminants that contains prohibited material. SOR/97-362, s. 4.

169. No person shall import, manufacture, package, store, distribute, sell or advertise for sale any animal food for equines, porcines, chickens, turkeys, ducks, geese, ratites or game birds that contains prohibited material unless the documentation required by these Regulations relating to the animal food and any label on any packaging or container containing the animal food is marked conspicuously, legibly and indelibly with a statement approved by the Minister that indicates that the animal food shall not be fed to ruminants. SOR/97-362, s. 4.

170. (1) No person shall have any prohibited material or anything, including an animal food for equines, porcines, chickens, turkeys, ducks, geese, ratites or game birds, that contains prohibited material on the same premises or in the same conveyance as a product of a rendering plant that does not contain prohibited material or any animal food for ruminants, without having procedures to prevent the mixing or contamination of the rendering plant product or animal food for ruminants, with prohibited material.

(2) In a case referred to in subsection (1), the person shall

(*a*) ensure that the procedures are followed from the time the product or animal food is received until it leaves their possession, care or control; and

(*b*) keep records to establish that the procedures were followed.

(3) If a person fails to follow the procedures required by subsection (1),

(*a*) the person shall change the records to show that all of the product or animal food is prohibited material and any label on any packaging or container containing the product or animal food shall be marked conspicuously, legibly and indelibly with a statement approved by the Minister that indicates that the product or animal food shall not be fed to ruminants; and

(*b*) all of the product or animal food shall be considered to be prohibited material for the purposes of section 164. SOR/97-362, s. 4.

Records

171. (1) Every person who manufactures animal food for ruminants, equines, porcines, chickens, turkeys, ducks, geese, ratites or game birds shall keep records that contain

(*a*) the formula for the animal food, including the name and weight of each ingredient used for each lot of the animal food;

(*b*) a mixing sheet that shows that each lot of the animal food has been produced in accordance with the formula referred to in paragraph (*a*);

(*c*) information as to whether or not the animal food contains any prohibited material;

(*d*) the date of preparation of the animal food;

(*e*) any information used to identify each lot of animal food; and

(*f*) the name and address of any person to whom any animal food is distributed or sold and a description of the food, including the name and quantity.

(2) Every person who imports, packages, stores, distributes, sells or advertises for sale animal food for ruminants, equines, porcines, chickens, turkeys, ducks, geese, ratites or game birds shall keep records that contain

(*a*) the name or other information used to identify the animal food;

(*b*) the name and address of any person to whom the animal food is distributed or sold and a description of the animal food, including the name and quantity; and

(*c*) information as to whether or not the animal food contains any prohibited material.

(3) Every person who owns or has the possession, care or custody of a ruminant shall keep copies of all invoices for animal food that contains prohibited material. SOR/97-362, s. 4.

Appendix 2 — Inspection Form for Commercial Feed Mills (tasks related to feed ban)

Information may be accessible or protected as required under the provisions of the Access to Information Act.

Copy to: ***Feed Review Team***
Area Operations Contact
Feed Program Specialist

PART I - OPENING MEETING

At the outset of the inspection, inspectors will conduct an opening meeting with management to explain the purpose of this review activity and answer any questions (see Attachment I for additional information). At the same time, the inspector should, with the help of management collect the tombstone information on the facility.

GENERAL INFORMATION	
Type of Facility	[ ] Single Species Commercial Feed Mill [ ] Multi-species Commercial Feed Mill
Date of Inspection:	Date of Last Inspection:
MCAP Client Code (if available):	Inspector:
Name, Address, Phone/Fax Number of Feed Mill (should be identical to information in MCAP system):	
Manager's Name:	Nutritionist(s) Name(s):
After Hours Contact (Name/Phone #):	

PRODUCTION INFORMATION	
Total Feed Produced/Year (tonnes):	
Bulk Feed Produced/Year (tonnes):	Bagged Feed Produced/Year (tonnes):
Medicated feed produced/year (tonnes):	Non-medicated feed produced/year (tonnes):
Animal Feeds Produced (check all that apply):	
[ ] Beef [ ] Dairy [ ] Ducks [ ] Geese [ ] Goats [ ] Horses [ ] Laying Hens [ ] Meat Chickens [ ] Rabbits [ ] Sheep [ ] Swine [ ] Turkeys	[ ] Buffalo [ ] Deer [ ] Elk [ ] Game Birds [ ] Ratites (e.g., ostrich, emu) [ ] Other (please specify)
USE OF PROHIBITED MATERIALS	
Does this facility receive feeds that contain “prohibited materials”? [ ] Yes [ ] No	
Does this facility manufacture feeds that contain “prohibited materials”? [ ] Yes [ ] No	

Is this facility in compliance with all requirements of the Health of Animal Regulations respecting the ban on the feeding of mammalian tissues to ruminant animals? If No, please list all related tasks which were non-compliant at the time of the initial inspection: **Note: All non-compliant tasks must be addressed by feed mill management in a timely manner to fully achieve compliance.**

FEED INGREDIENTS		
Indicate each of the following feed ingredients that is used in the manufacture of feeds in this facility **Note: Salvaged pet food is not approved for use as a livestock feed ingredient.**		
Salvaged Pet Food **(unapproved ingredient)**		**Porcine Meat and Bone Meal** **(Part I - no registration requirement)**

FEED MANUFACTURING EQUIPMENT
Feed Processing Equipment [ ] Rollermill [ ] Hammermill [ ] Flaking [ ] Other (describe)
Feed Type [ ] Dry [ ] Moist [ ] Liquid [ ] TMR [ ] Modified TMR
Feed Mixing Equipment (Please provide details on each piece of equipment)
[ ] Proportioner Mill/Volumetric Mixer
[ ] Batch Mixer Type [ ] Horizontal [ ] Vertical [ ] Tumble Capacity_____ tonnes
[ ] TMR Mixer Type [ ] Horizontal [ ] Vertical [ ] Truck Capacity_____ tonnes
[ ] Continuous Mixer (molasses blender, screw auger, cut and fold mixer)
Further Processing Equipment [ ] Pelleter(s) [ ] Extruder(s) [ ] Expander(s)
[ ] Fat Coater [ ] Molasses Blender [ ] Bagging/Packaging Equipment

Inspector's Signature/Date

_____

Signature of Feed Mill Management/Date

_____

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Please note:

I The following tasks do not apply to manufacturers who do not use “prohibited material” or who do not manufacture feeds for any of following species: ruminants, equines, porcines, chickens, turkeys, ducks, geese, ratites or game birds.

Tasks 7, 13, 15, 20, 24, 28, 36, 45, 56, 66, 76, & 81.

II For the tasks where records are required to be reviewed (e.g., Tasks 1, 2, 7 and 8 inclusive and all tasks where historical production records are reviewed, the tonnage of feed manufactured in the facility should be used to determine the minimum number of records to be reviewed as follows:

0 - 100 tonnes = 2 records
101 - 1000 tonnes = 3 records
1001 - 70,000 tonnes = 5 records
> 70,000 tonnes = 8 records

At least one of the records of each type reviewed should be for the same feed, e.g., follow one feed from the master formula through to the label and invoice to get a better overall picture of compliance. If there are compliance issues identified with the first set of records reviewed, additional records should be reviewed.

IV **Reminder:** All N/A ratings require a comment as to why the particular task does not apply. Only need to show for first one in a series of tasks when the reason is the same, e.g., pelleting area if the feed mill has no pellet mill

PART II - REVIEW OF WRITTEN PROCEDURES AND PRODUCTION RECORDS

Section 1. MANUFACTURING CONTROLS AND DOCUMENTATION

Task 1 Assess adequacy of on site master formulae

Rating Type Compliance *Health of Animals Regulations* Section 91(3)(a) & 171(1)(a)

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

Standard To receive a satisfactory rating, master formulae must:

[ ] include the name of the feed;
[ ] include the name and weight of each ingredient used in the manufacture of the feed;
[ ] include information as to whether the feed contains any “prohibited material”; and
[ ] be kept for a period of at least two years from the last date of manufacture of that feed.

Comments:

Task 2 Assess adequacy of on site mixing sheets

Rating Type Compliance *Health of Animals Regulations* Section 91(3)(a) & 171(1)(b)

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

Standard To receive a satisfactory rating, mixing sheets must:

[ ] include the name of the feed;
[ ] include the manufacturing date;
[ ] include the name and weight of each ingredient used in the manufacture of the feed;
[ ] include the information used to identify each lot of feed;
[ ] include information as to whether the feed contains any “prohibited material”; and
[ ] be kept for a period of at least two years from the last date of manufacture of that feed.

Comments

Task 7 **Assess adequacy of feed and feed ingredient labels* (prohibited material)**

Rating Type **Compliance** ***Health of Animals Regulations* - Section 169**

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

Standard To receive a satisfactory rating:

Labels of feeds for equines, porcines, chickens, turkeys, ducks, geese, ratites or game birds that contain “prohibited materials” must bear the required statement “Do not feed to cattle, sheep, deer or other ruminants”.

Labels for rendered products that contain “prohibited material” must bear the required statement “Do not feed to cattle, sheep, deer or other ruminants”.

Comments

* The regulatory definition of a “label” is a follows:

A label includes any legend, word, mark symbol or design applied or attached to, included in, belonging to or accompanying any feed or package.

Labels will typically be attached to bags, or attached to the invoice for bulk shipments. However,

an invoice for bulk shipments can be a label if all the information as required by regulations is on the invoice.

Task 8 **Assess adequacy of feed invoices**

Rating Type **Compliance** ***Health of Animals Regulations*** **Section 91(3)(a), 171(1) and 171(2) .**

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

This requirement applies to ALL commercial feeds intended for feeding to ruminants, equines, porcines, chickens, turkeys, ducks, geese, ratites or game birds.

Standard To receive a satisfactory rating, invoices must contain the following information:

[ ] the name and address of the person to whom the feed is distributed or sold;
[ ] a description of the feed, including the name and quantity;
[ ] the name or other information used to identify the lot of feed;
[ ] information as to whether or not the feed contains any “prohibited material” and where the feed contains “prohibited material”, the required statement, “Do not feed to cattle, sheep, deer or other ruminants” and,
[ ] copies of invoices must be kept for a period of at least two years from the last date of manufacture of that feed.

Comments

Task 13a **Assess the adequacy of written procedures and documentation for the disposition of returned* and recalled feeds - “prohibited materials”** (*feeds returned by customers, retailers etc.)

Rating Type **Compliance** ***Health of Animals Regulations*** **Sections 170(1)&(2)**

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

Standard To receive a satisfactory rating, the establishment must have written procedures which

require that returned and recalled feeds must be handled as follows:

[ ] disposal in accordance with local environmental regulations;
[ ] if the feed contains “prohibited materials” it may only be used as an ingredient in nonruminant feeds labelled as containing “prohibited material”;
[ ] when stored, the returned/recalled feed must be labelled with the required statement “Do not feed to cattle, sheep, deer or other ruminants” and any other pertinent information; and
[ ] the establishment must have evidence documenting these procedures.

Comments

Task 15a **Assess the adequacy of written procedures and documentation for the disposition of flush or recovered* materials - “prohibited materials”** (*materials recovered from spillage, dust collectors etc.)

Rating Type **Compliance** ***Health of Animals Regulations*** **Sections 170(1)&(2)**

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

Standard To receive a satisfactory rating, the establishment must have written procedures which require that flush and recovered material must be handled as follows:

[ ] disposal in accordance with local environmental regulations;
[ ] if the feed is or contains “prohibited materials” it may only be used as an ingredient in nonruminant feeds labelled as containing “prohibited material”;
[ ] when stored, the flush/recovered material must be labelled with the required statement “Do not feed to cattle, sheep, deer or other ruminants” and any other pertinent information; and
[ ] the establishment must have evidence documenting these procedures.

Comments

Sections 3 - 6 CLEAN-OUT PROCEDURES AND PRODUCTION RECORDS

Tasks **Assess the adequacy of written clean out procedures and production records for:**

- **(Task 20a) receiving equipment**
- **(Task 24a) ingredient storage and handling equipment**
- **(Task 28a) ingredient processing equipment**
- **(Task 36a) mixing equipment**
- **(Task 45a) pelleting/extruding equipment (including pellet mill/extruder, cooler and sifter/shaker)**
- **(Task 56a) packaging equipment**
- **(Task 76a) bulk finished feed storage and handling equipment**
- **(Task 81a) loading/unloading of bulk delivery vehicles (including contract vehicles)**

Rating Type **Compliance - *Health of Animals Regulations* Sections 91(3)(a), 170(1), 170(2) & 171(1)**

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

This task only applies to establishments who use common equipment to manufacture "prohibited materials"/feeds containing "prohibited materials" and who manufacture ruminant feeds.

Standard. To receive a satisfactory rating, the manufacturer must maintain written clean out procedures and production records for manufacturing equipment which contains the following information:

Production records

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

date of manufacture of that feed.

Equipment Cleanout Procedures

[ ] written equipment clean out procedures must indicate that feeds must be sequenced such that ruminant feeds never immediately follow feeds containing “prohibited materials”

unless the equipment is physically cleaned (swept/vacuumed) or flushed prior to manufacturing the ruminant feeds.

Comments

Task 66a **Assess the written procedures and records regarding the reuse of used packaging (prohibited material)**

Rating Type **Compliance** ***Health of Animals Regulations*** **Sections 170(1)&(2)**

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

Standard To receive a satisfactory rating, the establishment must have written procedures and records which require/demonstrate that used packaging is handled as follows:

[ ] not reuse packaging of unknown origin; and

[ ] not reuse packaging that contained non-ruminant feeds for ruminant feeds.

Comments

PART III - ON-SITE INTERVIEWS WITH MILL OPERATIONAL STAFF

After reviewing written procedures and historical production records, inspection staff should conduct interviews with production staff at the applicable steps in the manufacturing process to confirm that the staff are aware of, and, are following the written procedures. In addition, a minimum of one record of each type for the date of inspection should be reviewed.

Task 13b **Confirm through interviews with production staff that written procedures are being followed and production records completed properly for the disposition of returned* and recalled feeds - "prohibited materials"** (*feeds returned by customers, retailers etc.)

Rating Type **Compliance** ***Health of Animals Regulations*** **Sections 170(1)&(2)**

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

Standard To receive a satisfactory rating, the establishment must be following their written procedures which require that returned and recalled feeds be handled as follows, and, maintaining records that document these procedures:

[ ] disposal in accordance with local environmental regulations;
[ ] if the feed contains "prohibited materials" it may only be used as an ingredient in nonruminant feeds labelled as containing "prohibited material"; and
[ ] when stored, the returned/recalled feed must be labelled with the required statement "Do not feed to cattle, sheep, deer or other ruminants" and any other pertinent information.

Comments

Task 15b **Confirm through interviews with production staff that written procedures are being followed and production records completed properly for the disposition of flush or recovered* materials - "prohibited materials"** (*materials recovered from spillage, dust collectors etc.)

Rating Type **Compliance** ***Health of Animals Regulations*** **Sections 170(1)&(2)**

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

Standard To receive a satisfactory rating, the establishment must be following their written procedures which require that flush and recovered material be handled as follows, and, maintaining records that document these procedures:

[ ] disposal in accordance with local environmental regulations;
[ ] if the feed is or contains “prohibited materials” it may only be used as an ingredient in nonruminant feeds labelled as containing “prohibited material”; and
[ ] when stored, the flush/recovered material must be labelled with the required statement “Do not feed to cattle, sheep, deer or other ruminants” and any other pertinent information.

Comments

Sections 3 - 6 CLEAN-OUT PROCEDURES AND PRODUCTION RECORDS

Confirm through interviews with production staff that written clean out procedures are being followed and production records completed properly for:

- **(Task 20b) receiving equipment**
- **(Task 24b) ingredient storage and handling equipment**
- **(Task 28b) ingredient processing equipment**
- **(Task 36b) mixing equipment**
- **(Task 45b) pelleting/extruding equipment (including pellet mill/extruder, cooler and sifter/shaker)**
- **(Task 56b) packaging equipment**
- **(Task 76b) bulk finished feed storage and handling equipment**
- **(Task 81b) loading/unloading of bulk delivery vehicles (including contract vehicles)**

Rating Type **Compliance - *Health of Animals Regulations* Sections 91(3)(a), 170(1), 170(2) & 171(1)**

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

This task only applies to establishments who use common equipment to manufacture "prohibited materials"/feeds containing "prohibited materials" and who manufacture ruminant feeds.

Standard. To receive a satisfactory rating, the manufacturer must be following their written clean out procedures and have current production records for manufacturing equipment which contain the following information:

Production records

[ ] the name of the piece of equipment to which the production record refers;
[ ] the manufacturing date(s);
[ ] the name of the feeds in the order which they pass through the equipment;
[ ] the information used to identify each lot of feed;
[ ] the amount of each feed;
[ ] include information as to whether the feed contains any "prohibited material";
[ ] details of any feed safety precautions taken between batches of feed, e.g., equipment clean out procedures including the amount and type of flush material; and

[ ] copies of production records must be kept for a period of at least two years from the last date of manufacture of that feed.

Equipment Cleanout Procedures

[ ] written equipment clean out procedures must indicate that feeds must be sequenced such that ruminant feeds never immediately follow feeds containing “prohibited materials” unless the equipment is physically cleaned (swept/vacuumed) or flushed prior to manufacturing the ruminant feeds.

Comments

Task 66b **Confirm through interviews with production staff that written procedures are being followed and production records completed properly regarding the reuse of used packaging (prohibited material)**

Rating Type **Compliance** ***Health of Animals Regulations*** **Sections 170(1)&(2)**

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

Standard To receive a satisfactory rating, the establishment must be following their written procedures and have current records which require/demonstrate that used packaging is handled as follows:

[ ] not reuse packaging of unknown origin; and
[ ] not reuse packaging that contained non-ruminant feeds for ruminant feeds.

Comments

PART IV - CLOSING MEETING

When the inspection has been completed, inspectors will conduct a closing meeting with management to discuss any areas of non-compliance and establish timeframes for their corrective action plans to be developed and implemented. At the same time, the inspector should record any comments that the management might have on the inspection activity.

Task 85 **Additional Comments from Inspector**

Rating Type **N/A**

Standard Inspection staff should capture any additional comments on the facility in the comment field provided for future reference.

Comments

Task 86 **Feedback from Mill Management**

Rating Type **N/A**

Standard Inspection staff should capture any feedback received from establishment personnel in the comment field provided for future reference.

Comments

Appendix 3 -- Inspection Form for Rendering Facilities (tasks related to feed ban)

FEED INSPECTION PROGRAM 1A - RENDERING PLANTS

(Health of Animals Regulations Sections 162 - 171)

TABLE OF CONTENTS

1. Collect and record general information, raw material, processing / production and product from the Operator in Tables 1 -3.

2. **Upon COMPLETION OF THE INSPECTION, complete the Inspector's Recommendation page.**

3. Please forward completed copies of all of Section 1 which includes: general inspection information (Table 1), raw material survey (Table 2), processing/production survey (Table 3), and Inspector's Recommendation to:

Sergio Tolusso
Feed Program Coordinator
Feed Section, Animal Health & Production Division
Canadian Food Inspection Agency
59 Camelot Drive
Ottawa, Ontario
K1A 0Y9

Ph: (613) 225-2342
Fax: (613) 228-6614
E-mail: stolusso@inspection.gc.ca

4. The tonnage of the feed manufactured in the facility should be used to determine the minimum number of records to be reviewed as follows: * 1 record shall be day of inspection record *
0 - 100 tonnes = 2 records 101 - 1000 tonnes = 3 records

1001 - 70,000 tonnes = 5 records > 70,000 tonnes = 8 records

5. **All other ratings, comments, action plans etc. associated with each inspection task are to be entered into the CFIA Multi Commodity Activities Program (MCAP) system for Feed Inspection "Program 1A-2003 Rendering Plants".**

PART I OPENING MEETING GENERAL INFORMATION, SURVEYS & RECOMMENDATION

At the onset of the inspection, inspectors will conduct an opening meeting with management to explain the purpose of this review activity and answer any questions. At this time, the inspector should with the help of the management collect the tombstone information on the facility.

TABLE 1 - General Information *(Please forward completed copy of this Table to Feed Section)*	
Inspector's Name	**Date of Inspection**
Name and Address of Rendering Plant **Telephone:** **Fax:** **E-mail:**	**Operator's Name**
Date of Last Inspection	
Current Rendering Plant Permit Number	

<u>For the information of Operators</u>
Information collected in Tables 1-3 of this inspection report may be accessible or protected as required under the provisions of the *Access to Information Act*.

Feed Inspection Program 1A - Rendering Plants

TABLE 2 - Raw Material Survey
(Please forward completed copy of this Table to Feed Section)

Identify each raw material type and quantity processed by the rendering plant during the past year. [e.g., offal - (identify species), feathers, blood, dead stock, restaurant grease etc.]

Description of Raw Material	Quantity Processed (tonnes/year)	Particle Size[1] (cm)	Quantity Imported for Processing (tonnes/year)
Abattoir offal			
Cattle			
Other ruminant *(specify)*:			
Swine			
Poultry			
Other *(specify)*:			
Other *(specify)*:			

Feed Inspection Program 1A - Rendering Plants

TABLE 2 - Raw Material Survey
(Please forward completed copy of this Table to Feed Section)

Identify each raw material type and quantity processed by the rendering plant during the past year. [e.g., offal - (identify species), feathers, blood, dead stock, restaurant grease etc.]

Description of Raw Material	Quantity Processed (tonnes/year)	Particle Size[1] (cm)	Quantity Imported for Processing (tonnes/year)
Other *(specify)*:			
Dead stock & other inedible animal tissues			
Cattle			
Other ruminant *(specify)*:			
Swine			
Poultry			
Wildlife *specify*			

Feed Inspection Program 1A - Rendering Plants

TABLE 2 - Raw Material Survey
(Please forward completed copy of this Table to Feed Section)

Identify each raw material type and quantity processed by the rendering plant during the past year. [e.g., offal - (identify species), feathers, blood, dead stock, restaurant grease etc.]

Description of Raw Material	Quantity Processed (tonnes/year)	Particle Size[1] (cm)	Quantity Imported for Processing (tonnes/year)
Fur animal carcasses (e.g. mink, fox)			
Other *(specify)*:			
Other *(specify)*			
Other Raw Materials			
Blood			
Feathers			

TABLE 2 - Raw Material Survey
(Please forward completed copy of this Table to Feed Section)

Identify each raw material type and quantity processed by the rendering plant during the past year. [e.g., offal - (identify species), feathers, blood, dead stock, restaurant grease etc.]

Description of Raw Material	Quantity Processed (tonnes/year)	Particle Size[1] (cm)	Quantity Imported for Processing (tonnes/year)
Hair			
Chain bone & fat [2]			
Restaurant grease & other used fats			
Plate waste			
Wastewater treatment solids			
Other *(specify)*:			
Other *(specify)*:			

[1] **Size raw material(s) is reduced to by grinding, chopping, screening etc. prior to cooking.**
[2] **Meat trimmings from butcher shops, grocery stores etc.**

Feed Inspection Program 1A - Rendering Plants

TABLE 3 - Processing & Production Survey
(Please forward completed copy of this Table to Feed Section)

Finished Rendered Products	Production (tonnes/year)	Cooker Type (Batch or Continuous)	Processing Conditions			Imports (tonnes/ year)	Exports (tonnes/ year)
			Time (minutes)	Temperature (°C)	Cooker Pressure: Ambient (0 bars) Pressure (+ bars) Vacuum (- bars)		
Protein Meals							
Ruminant meat & bone meal							
Porcine meat & bone meal							
Poultry byproduct meal							
Mixed meat & bone meal							
Other meat & bone meal *(specify)*:							
Feather meal							
Blood meal							
Other protein meal *(specify)*:							
Other protein meal *(specify)*:							
Fats & Oils							
Tallow[1]							
Poultry fat[1]							
Yellow grease[2] (restaurant grease)							
Other fats or oils (*specify*):							

Feeds Regulations, Schedule IV, Part I
[1] **= 4.5.1** Animal fat (or Feeding fat)
[2] **= 4.5.2** Animal vegetable fat (or Animal vegetable feeding fat)

Feed Inspection Program 1A - Rendering Plants

Inspector's Recommendation

*(Please forward completed copy of this Recommendation to Feed Section **once all "Compliance"-rated Tasks are "Satisfactory"**)*

Pursuant to Section 162(1) of the *Health of Animals Regulations*:
" 'prohibited material' means anything that is or that contains any, protein that originated from a mammal, other than a porcine or an equine. It does not include milk, blood, gelatin, rendered animals fat or their products."

A Permit to Operate for this rendering plant may be issued for the manufacture of :	***Check one:***
ONLY Protein Meals defined as "Prohibited Material"	[ ]
ONLY Protein Meals NOT defined as "Prohibited Material"	[ ]
BOTH Protein Meals defined as "Prohibited Material" and those not defined as "Prohibited Material"	[ ]
Endorsement	**DATE**
Inspector's Signature:	
Operator's Signature:	

PART II REVIEW OF WRITTEN PROCEDURES AND PRODUCTION RECORDS

Task 2 Assess the adequacy of on-site production records.

Rating Type Compliance
Health of Animals Regulations Section 165(2)

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

Standard To receive a satisfactory rating, on-site production records must contain:

[ ] date of production of each rendered product;
[ ] information as to whether each product is or contains “prohibited material”;
[ ] the name, and quantity of, and any other information that is sufficient to identify the products of the rendering plant

Example records that may be inspected include raw material receiving records, cooking records, storage records, sequencing/flushing or other equipment clean out records.

If the records do not contain the information specified, have the Operator modify production records immediately and/or suspend the Permit to Operate until the Operator fully complies with regulatory requirements

[ ]Satisfactory
[ ]Unsatisfactory

Comment:

Task 3 Assess the adequacy of distribution records - prohibited material (product invoices, bills of lading etc. for bulk and bagged product deliveries)

Rating Type Compliance
Health of Animals Regulations Section 171(1) and 171(2)

All unsatisfactory ratings require a record of compliance action taken 0and/or a signed action plan for correction of non-compliance. Note details for all non-conforming invoices in the comments box, and describe reason for non-conformance.

Standard To receive a satisfactory rating, distribution records must contain the following information; (check at least one invoice for each animal protein product manufactured to a maximum of 10 invoices (no more than 3 for the same finished product)):

[ ] the name and address of the person to whom the product is distributed or sold;
[ ] a description of the finished product, including the name and quantity;
[ ] information used to identify the product lot;
[ ] information as to whether or not the product is, or contains “prohibited material”;
[ ] where the product either is, or contains “prohibited material”, the required statement, “Do not feed to cattle, sheep, deer or other ruminants”; and
[ ] be available for inspection for the previous two (2) years and .

Statement is required regardless of whether distributions are to domestic or export customers. ***Detain rendered products containing “prohibited material” if modification of invoices to include required statement is necessary.***

[ ]Satisfactory
[ ]Unsatisfactory

Comment:

Feed Inspection Program 1A - Rendering Plants

Task **4 Assess the adequacy of labelling - prohibited material (if labels used to accompany bulk deliveries or on bags)**

Rating Type Compliance
Health of Animals Regulations Section 171(1) and 171(2)

All unsatisfactory ratings require a record of compliance action taken and/or a signed action plan for correction of noncompliance. Note details for all non-conforming labels in the comments box, and describe reason for non-conformance.

Standard To receive a satisfactory rating, all products distributed by the rendering plant must be labelled in accordance with the Health of Animals Regulations

Check at least 1 label for each "prohibited material" product to a maximum of 10 labels (no more than 3 for the same finished product) to confirm that they:

[ ] contain the required statement: "Do not feed to cattle, sheep, deer or other ruminants" if the product is or contains "prohibited material";

Statement is required regardless of whether distributions are to domestic or export customers. Detain rendered products containing "prohibited material" if modification of labels to include required statement is necessary.

[ ]Not Applicable - Label not used to accompany invoices for bulk deliveries and finished products not distributed in packages
[ ]Not Applicable - rendering plant does not manufacture, sell or distribute "prohibited material"
[ ]Satisfactory
[ ]Unsatisfactory

Comment:

Task 6 **Assess the adequacy of written procedures and records for clean out of all processing lines and equipment used in the manufacture of finished products**.

Rating Type **Compliance Health of Animals Regulations Section 170(1) & (2)**

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

This task only applies to establishments who manufacture both "prohibited material" and "non-prohibited material" in the same production line.

Standard To receive a satisfactory rating **where non-dedicated lines are used to manufacture both "prohibited material" and "non-prohibited material"** on the same premises, the operator must have written procedures and records to demonstrate:

[ ] physical cleaning (washing, sweeping, vacuuming etc.) and/or flushing of the processing equipment after processing batches or runs of "prohibited material" are employed. As a guideline, an acceptable minimum flush procedure must comprise the complete filling of the entire processing system with a "non-prohibited material" (e.g. porcine offal, poultry offal meal) serving as the flush material which is subsequently handled, and stored as "prohibited material" before the processing of any "non-prohibited material" begins. Any clean out procedure employed by the Operator that fails to meet this guideline must have been supported by acceptably validated alternative clean out procedures and the procedures have been sent, evaluated and approved by the Feed Section);

[ ] inspection and physical cleaning (washing, sweeping, vacuuming etc.) are employed for any equipment or vehicles used in common to store, convey and distribute "prohibited material" and "non-prohibited material";

Written procedures and records are must be inspected for any of the following points and equipment in the manufacturing process that are used in common to make "prohibited material" and "non-prohibited material":

[ ] raw material delivery vehicles/equipment **Requirements are described in Task 32**
[ ] raw material receiving **Requirements are described in Task 31**
[ ] raw material handling and storage **Requirements are described in Task 29**
[ ] cooking **Requirements are described in Task 27**
[ ] pressing and milling **Requirements are described in Task 25**
[ ] finished product packaging **Requirements are described in Task 22 & 23**
[ ] finished product handling and storage **Requirements are described in Task 20**
[ ] finished product bulk loading and shipping **Requirements are described in**

Task 18

[ ] finished product delivery vehicles/equipment operated by the rendering plant **Requirements are described in Task 15**
[ ] finished product delivery vehicles/equipment **not** operated by the rendering plant **Requirements are described in Task 16**

When appropriate controls are not in place to prevent the introduction of "prohibited material" with "non-prohibited material", all rendered products must be considered to contain "prohibited material" and be labelled with the required statement. The Permit to Operate must be amended to indicate that the facility may only distribute "prohibited material" until the Operator has developed and follows documented procedures.

Task 8 **Assess the adequacy of written procedures and records for identifying and handling flush material**

Rating Type **Compliance Health of Animals Regulations Section 170**

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

This task only applies to establishments who manufacture both "prohibited materials" and "non-prohibited materials."

Standard. If the rendering plant does not employ common production lines to manufacture "prohibited material" or "non-prohibited material", check "Not Applicable" in the Comment box below.

To receive a satisfactory rating, the Operator must have written procedures and records to demonstrate that all flush material:

[ ] if it contains "prohibited material", it is only used as an ingredient in another product that is or contains "prohibited material" **OR**
[ ] is disposed of in accordance with local environmental regulations;
[ ] is stored separately and identified or labelled as "prohibited material"; **OR**
[ ] is handled, stored and delivered as "prohibited material"

When appropriate controls are not in place to prevent the introduction of flush material into "non-prohibited material", all rendered products must be considered to contain "prohibited material" and be labelled with the required statement. The Permit to Operate must be amended to indicate that the facility may only distribute "prohibited material" until the Operator has developed and follows documented procedures.

Task 9 **Assess the adequacy of records of manufacturing errors and corrective actions taken**

Rating Type **Compliance Health of Animals Regulations, s. 170(3)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating, the operator must maintain a file or other records which include the following information:

[ ] the date of the manufacturing error;
[ ] the name or other information used to identify the product lot;

[ ] provides details of the manufacturing error;
[ ] provides details of the manufacturer's investigation of the error;
[ ] provides details of the corrective actions taken including disposition of the recovered/rework/returned/recalled material.

When appropriate controls are not in place to prevent the mixing or cross-contamination of "non-prohibited material" with "prohibited material", all rendered products must be considered to contain "prohibited material" and be labelled with the required statement. The Permit to Operate must be amended to indicate that the facility may only distribute "prohibited material" until the Operator has developed and follows documented procedures.

[ ]Not Applicable - facility is dedicated to the manufacture of "prohibited material" or non-"prohibited material" only
[ ] Satisfactory
[ ] Unsatisfactory

Comment:

Task 10 **Assess the adequacy of written procedures and records for the handling and end-use of recovered* materials within the rendering plant.- prohibited material (* materials recovered from spills, leaks, manufacturing errors [rework, returns, recalls], waste water treatment etc.)**

Rating Type **Compliance Health of Animals Regulations Sections 170(1)&(2)**

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

This task only applies to establishments who manufacture only "prohibited materials" and both "prohibited materials" and "non-prohibited materials."

Standard To receive a satisfactory rating, the Operator must have written procedures and records to demonstrate that recovered materials are handled as follows:

[ ] disposal in accordance with local environmental regulations;
[ ] if the material contains "prohibited material" and is re-processed in the rendering plant it must be used as an ingredient in the processing of other "prohibited material"
[ ] if the material is or contains "prohibited material" and is not re-processed, it may only be used as an ingredient in finished products identified as "prohibited material";
[ ] when stored, the recovered material must be labelled with identifying information and any pertinent information respecting composition, i.e., contains "prohibited material";

When appropriate controls are not in place to prevent the mixing or cross-contamination of "non-prohibited material" with "prohibited material", all rendered products must be considered to contain "prohibited material" and be labelled with the required statement. The Permit to Operate must be amended to indicate that the facility may only distribute "prohibited material" until the Operator has developed and follows documented procedures.

[ ] Satisfactory
[ ] Unsatisfactory

Comments:

PART III - ON-SITE INTERVIEWS WITH MILL OPERATIONAL STAFF

After reviewing written procedures and historical production records, inspection staff should conduct interviews with production staff at the applicable steps in the manufacturing process to confirm that the staff are aware of, and, are following the written procedures. In addition, a minimum of one record of each type for the date of inspection should be reviewed.

Task 10(a) **Confirm through interviews with production staff that written procedures are being followed and production records completed for the handling and end-use of recovered* materials within the rendering plant.- prohibited material (* materials recovered from spills, leaks, manufacturing errors [rework, returns, recalls], waste water treatment etc.)**

Rating Type **Compliance Health of Animals Regulations Sections 170(1)&(2)**

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

This task only applies to establishments who manufacture only "prohibited materials" and both "prohibited materials" and "non-prohibited materials."

Standard To receive a satisfactory rating, the Operator must have written procedures and records to demonstrate that recovered materials are handled as follows:

[ ] disposal in accordance with local environmental regulations;
[ ] if the material contains "prohibited material" and is re-processed in the rendering plant it must be used as an ingredient in the processing of other "prohibited material"
[ ] if the material is or contains "prohibited material" and is not re-processed, it may only be used as an ingredient in finished products identified as "prohibited material";
[ ] when stored, the recovered material must be labelled with identifying information and any pertinent information respecting composition, i.e., contains "prohibited material";

When appropriate controls are not in place to prevent the mixing or cross-contamination of "non-prohibited material" with "prohibited material", all rendered products must be considered to contain "prohibited material" and be labelled with the required statement. The Permit to Operate must be amended to indicate that the facility may only distribute "prohibited material" until the Operator has developed and follows documented procedures.

[ ] Satisfactory
[ ] Unsatisfactory

Comments:

Task 15 **Confirm through interviews with production staff (and visual inspection where possible) that written procedures are being followed and production records completed for the inspection & cleaning of finished product delivery vehicles operated by the rendering plant**

Rating Type **Compliance Health of Animals Regulations Section 170.**

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

Standard To receive a satisfactory rating, delivery vehicles operated by the rendering plant must:

[ ]be managed according to written procedures for finished product delivery vehicle
[ ]be inspected to ensure cleanliness (including separating walls and covering tarpaulins)

of delivery vehicles;

[ ] be dedicated to the delivery of “prohibited material” and “non-prohibited material” separately **OR**, if used to deliver both “prohibited material” and “non-prohibited material”, be inspected and cleaned according to clean out procedures (flushing, physical clean out) between loads of “prohibited material” and “non-prohibited material”;

[ ] if shipping multiple products in bulk, procedures are followed to prevent the overflow or other introductions of “prohibited material” and “non-prohibited material” between compartments during loading and delivery.

When appropriate controls are not in place, all loads of rendered products must be considered to contain prohibited materials and be labelled with the required statement. The Permit to Operate must be amended to indicate that the facility may only ship prohibited material until the Operator has developed and follows documented procedures.

[ ] Not Applicable - company does not operate any delivery vehicles
[ ] Not Applicable - vehicles dedicated to delivery of “prohibited material” or non- “prohibited material” only
[ ] Satisfactory
[ ] Unsatisfactory

Comments:

Task 16 **Confirm through interviews with production staff (and where possible visual inspection) that written procedures are being followed and production records completed for the inspection & cleaning of delivery vehicles not operated by the rendering plant**

Rating Type **Compliance Health of Animals Regulations Section 170.**

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

Standard To receive a satisfactory rating, the Operator requires delivery vehicles not operated by the rendering plant to:

[ ] be managed according to written procedures for non-company-operated vehicles;

[ ] be inspected to ensure cleanliness (including separating walls and covering tarpaulins) of delivery vehicles

[ ] be dedicated vehicles for the delivery of “prohibited material” or “non-prohibited material” only **OR**, if used to deliver both “prohibited material” and “non-prohibited material”, be inspected and cleaned according to clean out procedures (flushing, physical clean out) between loads of “prohibited material” and “non-prohibited material”;

[ ] if non-company delivery vehicles are not clean, notify the operator of the vehicle of the problem;

[ ] have operators of non-company delivery vehicles carry records regarding previous load(s) and clean out procedures used to prevent cross contamination.

When appropriate controls are not in place to prevent the contamination of “non-prohibited material” with “prohibited material”, all loads of rendered products must be considered to contain prohibited materials and be labelled with the required statement. The Permit to Operate must be amended to indicate that the facility may only ship prohibited material until the Operator has developed and follows documented procedures.

Feed Inspection Program 1A - Rendering Plants

[ ] Not Applicable - Rendering plant only uses delivery vehicles it operates
[ ] Not Applicable - vehicles dedicated to delivery of "prohibited material" or non- "prohibited material" only
[ ] Satisfactory
[ ] Unsatisfactory

Comments:

Task 18 **Confirm through interviews with production staff and visual inspection that written procedures are being followed and production records completed for of finished product loading equipment - prohibited material**

Rating Type **Compliance Health of Animals Regulations Section 170.**

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

This task only applies to establishments who manufacture both "prohibited materials" and "non-prohibited materials."

Standard To receive a satisfactory rating, the loading equipment must:

[ ] use dedicated loading equipment for "prohibited material" and "non-prohibited material", **or** follow written procedures for clean out/flushing of the loading equipment between batches of "prohibited material" and "non-prohibited material".

[ ] be managed to handle spills and leaks of finished products in accordance with written recovered material handling procedures to prevent cross-contamination of "non-prohibited material" with "prohibited material";

When appropriate controls are not in place to prevent the introduction of "prohibited material" with "non-prohibited material", all rendered products must be considered to contain "prohibited material" and be labelled with the required statement. The Permit to Operate must be amended to indicate that the facility may only distribute "prohibited material" until the Operator has developed and follows documented procedures.

Task 20 **Confirm through interviews with production staff and visual inspection that written procedures are being followed and production records completed for finished product handing & storage area(s) and equipment - prohibited material**

Rating Type Compliance Health of Animals Regulations Section 170

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

This task only applies to establishments who manufacture both "prohibited materials" and "non-prohibited materials."

Standard To receive a satisfactory rating, finished product storage (bins, tanks, silos etc.) and handling equipment (pipes, conveyors, drag lines, elevators, etc.) must:

[ ] use dedicated bins and handling equipment for "prohibited material" and "non-prohibited material", **or** follow written procedures for clean out/flush the storage bins and equipment between batches of "prohibited material" and "non-prohibited material".

[ ] be managed to handle spills and leaks of finished products in accordance with written recovered material handling procedures to prevent cross-contamination of "non-prohibited material" with "prohibited material";

When appropriate controls are not in place, all rendered products must be considered to contain prohibited materials and be labelled with the required statement. The Permit to Operate must be amended to indicate that the facility may only ship prohibited material until the Operator has developed and follows documented procedures.

Feed Inspection Program 1A - Rendering Plants

Task 22 **Confirm through interviews with production staff and visual inspection that written procedures are being followed and production records completed for finished product packaging equipment - prohibited material**

Rating Type **Compliance Health of Animals Regulations Section 170**

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

This task only applies to establishments who manufacture both "prohibited materials" and "non-prohibited materials."

Standard To receive a satisfactory rating, finished product packaging equipment must :

[ ] use dedicated equipment to package "prohibited material" and "non-prohibited material", **or** follow written procedures for clean out/flushing of the packaging equipment between batches of "prohibited material" and "non-prohibited material".
[ ] be managed to handle spills and leaks of finished products in accordance with written recovered material handling procedures to prevent cross-contamination of "non-prohibited material" with "prohibited material";

When appropriate controls are not in place, all rendered products must be considered to contain prohibited materials and be labelled with the required statement. The Permit to Operate must be amended to indicate that the facility may only ship prohibited material until the Operator has developed and follows documented procedures.

[ ]Not Applicable - facility dedicated to the manufacture of "prohibited material" or non-"prohibited material" only
[ ]Not Applicable - facility does not package any finished products
[ ]Satisfactory
[ ]Unsatisfactory

Comments:

Task 23 **Confirm through interviews with production staff that written procedures are being followed and production records completed for packaging materials**

Rating Type **Compliance Health of Animals Regulations Section 170**

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

Standard To receive a satisfactory rating the Operator must:

[ ] only use new packaging materials; or
[ ] dedicate bags to "prohibited material" and "non-prohibited material" only if bags are reused.

When appropriate controls are not in place, all packaged rendered products must be considered to contain prohibited materials and be labelled with the required statement. Detain rendered products containing "prohibited materials" if modification of labels to include required statement is necessary.

[ ] Not Applicable - facility does not package any finished products
[ ] Satisfactory
[ ] Unsatisfactory

Comments:

Task 25 **Confirm through interviews with production staff and visual inspection that written procedures are being followed and production records completed for the pressing and milling area(s) and equipment - prohibited material**

Rating Type **Compliance Health of Animals Regulations Section 170**

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

This task only applies to establishments who manufacture both "prohibited materials" and "non-prohibited materials."

Standard To receive a satisfactory rating, pressing and milling areas and equipment must :

[ ] use dedicated equipment to press and mill "prohibited material" and "non-prohibited material", **or** follow written procedures for clean out/flushing of the packaging equipment between batches of "prohibited material" and "non-prohibited material".
[ ] be managed to handle spills and leaks of finished products in accordance with written recovered material handling procedures to prevent cross-contamination of "non-prohibited material" with "prohibited material";

When appropriate controls are not in place, all rendered products must be considered to contain prohibited materials and be labelled with the required statement. The Permit to Operate must be amended to indicate that the facility may only ship prohibited material until the Operator has developed and follows documented procedures.

Task 27 **Confirm through interviews with production staff and visual inspection that written procedures are being followed and production records completed for the cooking area and equipment - prohibited material**

Rating Type **Compliance Health of Animals Regulations Section 170**

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

This task only applies to establishments who manufacture both "prohibited materials" and "non-prohibited materials."

Standard To receive a satisfactory rating, the cooking area and equipment must:

[ ] use dedicated equipment to cook "prohibited material" and "non-prohibited material", **or** follow written procedures for clean out/flushing of the cooking equipment between batches of "prohibited material" and "non-prohibited material".
[ ] be managed to handle spills and leaks of finished products in accordance with written recovered material handling procedures to prevent cross-contamination of "non-prohibited material" with "prohibited material";

When appropriate controls are not in place, all rendered products must be considered to contain prohibited materials and be labelled with the required statement. The Permit to Operate must be amended to indicate that the facility may only ship prohibited material until the Operator has developed and follows documented procedures.

[ ]Not Applicable - facility dedicated to the manufacture of "prohibited material" or non-"prohibited material" only
[ ]Satisfactory
[ ]Unsatisfactory

Comments:

Task 29 **Confirm through interviews with production staff and visual inspection that written procedures are being followed and production records completed for the raw material handling & storage area(s) and equipment - prohibited material**

Feed Inspection Program 1A - Rendering Plants

Rating Type **Compliance Health of Animals Regulations Section 170**

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

This task only applies to establishments who manufacture both "prohibited materials" and "non-prohibited materials."

Standard **To receive a satisfactory rating, the raw material handling and storage area(s) and equipment must:**

[ ] use dedicated equipment to receive "prohibited material" and "non-prohibited material", **OR** be managed according to written clean out/flush procedures if shared equipment is being used handle or store raw "prohibited material" and "non-prohibited material";
[ ] be managed to handle spills and leaks of raw products in accordance with written recovered material handling procedures to prevent cross-contamination of "non-prohibited material" with "prohibited material";

When appropriate controls are not in place to prevent the introduction of raw "prohibited material" into raw "non-prohibited material", all rendered products must be considered to contain prohibited materials and be labelled with the required statement. The Permit to Operate must be amended to indicate that the facility may only ship prohibited material until the Operator has developed and follows documented procedures.

Task 31 **Confirm through interviews with production staff and visual inspections that written procedures are being followed and production records completed for the raw materials receiving area(s) and equipment - "prohibited material".**

Rating Type **Compliance Health of Animals Regulations Section 170**

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

This task only applies to establishments who manufacture both "prohibited materials" and "non-prohibited materials."

Standard To receive a satisfactory rating, the raw material receiving area must:

[ ] be managed to prevent cross-contamination of raw "non-prohibited material" with "prohibited material"
[ ] be managed to handle spills and leaks of raw materials in accordance with written recovered material handling procedures to prevent cross-contamination of "non-prohibited material" with "prohibited material";

When appropriate controls are not in place, all rendered products must be considered to contain prohibited materials and be labelled with the required statement. The Permit to Operate must be amended to indicate that the facility may only ship prohibited material until the Operator has developed and follows documented procedures.

Task 32 **Confirm through interviews with production staff that written procedures are being followed and production records completed for the inspection & cleaning of vehicles used to deliver raw materials to the rendering plant**

Rating Type **Compliance Health of Animals Regulations Section 170.**

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

Standard To receive a satisfactory rating, raw material delivery vehicles must::

[ ] be inspected, cleaned and sanitized according to written procedures for raw material delivery vehicles
[ ] be managed to prevent cross-contamination of raw "non-prohibited material" with "prohibited material"

Feed Inspection Program 1A - Rendering Plants

When appropriate controls are not in place, all rendered products must be considered to contain prohibited materials and be labelled with the required statement. The Permit to Operate must be amended to indicate that the facility may only ship prohibited material until the Operator has developed and follows documented procedures.

[ ] Not Applicable - Rendering plant does not use delivery vehicles (e.g. abattoir)
[ ] Satisfactory
[ ] Unsatisfactory

Comments:

PART IV - CLOSING MEETING

When the inspection has been completed, inspectors will conduct a closing meeting with management to discuss any areas of non-compliance and establish timeframes for their corrective action plans to be developed and implemented. At the same time, the inspector should record any comments that the management might have on the inspection activity.

Task 33 **Additional Comments from Inspector**

Rating Type **Not Applicable**

Standard Inspection staff should capture any additional comments on the facility in the comment field provided for future reference.

Comments:

Task 34 **Additional Comments from Rendering Plant Management**

Rating Type **Not Applicable**

Standard Inspection staff should capture any additional feedback received from Rendering Plant personnel in the comment field provided for future reference.

Comments:

Appendix 4 — Inspection Form for On-Farms

ON-FARM FEED MILL INSPECTION MCAP 2002

CFIA·ACIA

Information may be accessible or protected as required under the provisions of the Access to Information Act.

Copy to: *Feed Section*
Area Feed Program Specialist
Area Operational Contact

GENERAL INFORMATION	
Type of Facility	☐ Single Species Farm Feed Mill ☐ Multi-species Farm Feed Mill
Date of Inspection:	Date of Last Inspection:
Inspector:	
Name, Address, Phone/Fax Number of Producer (should be identical to information in MCAP system):	
Farm Manager's Name:	Nutritionist's Name:

PRODUCTION INFORMATION

Total Feed Produced/Year (tonnes):

Animal Feeds Produced (check all that apply):

Feeds Regulations and Health of Animals Regulations	Feeds Regulations only	Health of Animals Regulations only
☐ Beef	☐ Aquaculture	☐ Buffalo
☐ Dairy	☐ Fox	☐ Deer
☐ Ducks	☐ Mink	☐ Elk
☐ Geese		☐ Game Birds
☐ Goats		☐ Ratites (e.g., ostrich, emu)
☐ Horses		☐ Other (please specify)
☐ Laying Hens		
☐ Meat Chickens		
☐ Rabbits		
☐ Sheep		
☐ Swine		
☐ Turkeys		

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ON-FARM FEED MILL INSPECTION MCAP 2002

USE OF PROHIBITED MATERIALS
Does this farm receive feeds that contain "prohibited materials"? □ Yes □ No
Does this farm manufacture feeds that contain "prohibited materials"? □ Yes □ No
Is the producer aware of the Regulations respecting a ban on the feeding of mammalian tissues to ruminant animals? □ Yes □ No
Is the facility in compliance with all requirements of the Health of Animals Regulations respecting the ban on the feeding of mammalian tissues to ruminant animals? □ Yes □ No If No, please list all related tasks which were non-compliant at the time of the initial inspection: **Note: All non-compliant tasks must be addressed by feed mill management in a timely manner to fully achieve compliance.**

MANUFACTURE OF MEDICATED FEEDS		
Does this facility manufacture medicated feeds?	□ Yes	□ No
Are medications/medicated feeds received in bulk ?	□ Yes	□ No
Are medications/medicated feeds received in bags/totes?	□ Yes	□ No

Is the producer knowledgeable in regard to feed and meat residues, possible causes and how to prevent them (e.g. the importance of measuring and mixing medications and ingredients properly, withdrawal times, etc.)?

□ Yes □ No

Source(s) of medication used (Check all that apply)	**Type(s) of medicated feeds manufactured:** (Check all that apply)
□ Drug Premix (DIN)	□ Dilute Drug Premix (DIN/Feed Registration#)
□ Dilute Drug Premix (DIN/Feed Registration#)	□ Medicated Feed MicroPremix
□ Medicated Feed MicroPremix	□ Medicated Feed MacroPremix
□ Medicated Feed MacroPremix	□ Medicated Mineral Feed
□ Medicated Mineral Feed	□ Medicated Feed Supplement
□ Medicated Feed Supplement	□ Medicated Complete Feed
□ Medicated Complete Feed	□ Medicated Total Mixed Ration (TMR)
	□ Medicated Modified TMR

Species/class of livestock for which <u>medicated</u> feeds are manufactured: (Check all that apply)

□ Swine	□ Sheep
□ Meat Chickens	□ Buffalo
□ Turkeys	□ Deer
□ Laying Hens	□ Elk
□ Aquaculture	□ Ratites
□ Horses	□ Mink
□ Beef	□ Fox
□ Dairy	□ Other (please specify)

Indicate which of the following medicating ingredients are used in the manufacture of feeds on this farm.

3-nitro-4-hydroxyphenylarsonic acid		Monensin sodium	
Amprolium		Morantel tartrate	
Arsanilic acid		Narasin	
Bambermycins		Narasin and Nicarbazin	
Carbadox		Nicarbazin	
Chlortetracycline hydrochloride		Novobiocin	
Chlortetracycline hydrochloride and Sulfamethazine		Oxytetracycline hydrochloride	
Chlortetracycline hydrochloride, Sulfamethazine and Procaine penicillin		Oxytetracycline hydrochloride and Neomycin sulphate	
Clopidol		Penicillin from Procaine penicillin	
Decoquinate		Piperazine	
Dichlorvos		Poloxalene	
Diclazuril		Pyrantel tartrate	
Dimetridazole		Pyrantel tartrate and Carbadox	
Erythromycin thiocyanate		Robenidine hydrochloride	
Fenbendazole		Salinomycin sodium	
Halofuginone hydrobromide		Semduramicin sodium	
Hygromycin B		Thyroactive iodinated casein	
Ivermectin		Tiamulin	
Lasalocid sodium		Tilmicosin	
Levamisole		Tylosin phosphate	
Lincomycin		Tylosin phosphate and Sulfamethazine	
Lincomycin and Spectinomycin		Virginiamycin	
Maduramicin ammonium		Zinc Bacitracin	
Melengestrol acetate		Zinc bacitracin and Procaine penicillin	
Methylene disalicylate Bacitracin		Zoalene	

Are there medications other than those listed in the CMIB used in the manufacture of feeds on this farm?

□ Yes □ No

If non-CMIB drugs are used, please list and indicate the authority for off-label use, i.e., veterinary prescription, emergency drugs release, research approval, other:

Other approved medication sources used

Water	□ Yes	□ No
Injectable	□ Yes	□ No
Bolus	□ Yes	□ No
Implants	□ Yes	□ No

ON-FARM FEED MILL INSPECTION MCAP 2002

FEED INGREDIENTS			
Indicate each of the following feed ingredients that is used in the manufacture of feeds in this facility(special attention should be paid to these ingredients when evaluating compliance for Task 19). **Note: All of the listed ingredients, with the exception of salvaged pet food, poultry litter and porcine meat and bone meal, are listed in Part II of Schedule IV of the *Feeds Regulations* and each source must have a valid registration number. Salvaged pet food and poultry litter are not approved for use as livestock feed ingredients.**			
Bifidobacteria Culture Dehydrated/Dried Bifidobacteria Culture		Lactococcus culture dehydrated/ Dried Lactococcus culture	
Chromium enriched yeast		Enterococcus culture dehydrated	
Haematococcus algae meal/ Dried Haematococcus algae meal		Pediococcus culture dehydrated	
Lactobacillus culture dehydrated		Phaffia rhodozyma yeast	
Dried Propionibacterium jensenii culture		Selenium enriched yeast/ Seleno yeast dehydrated	
Yeast active dehydrated		Food Waste/Edible Residual Material	
Salvaged Pet Food (unapproved ingredient)		**Porcine Meat and Bone Meal (Part I - no registration requirement)**	
Poultry Litter (unapproved ingredient)			

FEED MANUFACTURING EQUIPMENT

Feed Processing Equipment

□ Rollermill □ Hammermill □ Flaking □ Other (describe)

Feed Type

□ Dry □ Moist □ Liquid □ TMR □ Modified TMR

Feed Mixing Equipment (Please provide details on each mixer)

□ Proportioner Mill/Volumetric Mixer

□ Batch Mixer Type □ Horizontal □ Vertical □ Tumble

Capacity _____ tonnes

□ TMR Mixer Type □ Horizontal □ Vertical □ Truck

Capacity _____ tonnes

Inspector's Signature/Date

_____

Signature of Feed Mill Management/Date

_____

Summary of SCALE VERIFICATION Inspections		
Scale Area/Inspection Results	Mixing Area Tasks 35, 37, 38, 39	Medication Area Tasks 44, 46, 47, 48
Scale Description		
Suitable Capacity		
Suitable Sensitivity		
Suitable Graduation		
Written Scale Verification Procedures		
Complete Scale Verification Records		
Investigations for out of tolerance test results		

Summary of METERING DEVICE Verification Inspections		
Scale Area/Inspection Results	Mixing Area Tasks 36-39	Medication Area Tasks 45-48
Metering Device Description		
Suitable Sensitivity		
Suitable Graduation		
Written Metering Device Verification Procedures		
Complete Metering Device Verification Records		
Investigations for out of tolerance test results		

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Please note:

I The following tasks do not apply to manufacturers who do not mix medicated feeds (for livestock or other food producing animals);

Tasks 3, 4, 6, 7, 9, 16, 17, 18, 20, 21, 22, 24, 25, 28, 32, 33, 34, 40, 41, 42, 43, 44, 45, 46, 47, 48, 50, 51, 52, 55, 56, 57

II The following tasks do not apply to manufacturers who do not use "prohibited material" or who do not manufacture feeds for any of following species: ruminants, equines, porcines, chickens, turkeys, ducks, geese, ratites or game birds.

Tasks 10, 15, 19, 23, 31, 49, 54

For the tasks where records are required to be reviewed (e.g., Tasks 1 through 7 inclusive and all tasks where production records are reviewed including 19 and 83), the tonnage of feed manufactured on the farm should be used to determine the minimum number of records to be reviewed as follows:

0 - 100 tonnes = 2 records
101 - 1000 tonnes = 3 records
1001 - 70,000 tonnes = 5 records
> 70,000 tonnes = 8 records

At least one of the records of each type reviewed should be for the same feed, e.g., follow one feed from the master formula through to the label and invoice to get a better overall picture of compliance.

If there are compliance issues identified with the first set of records reviewed, additional records should be reviewed.

Reminder: All N/A ratings require a comment as to why the particular task does not apply

ON-FARM FEED MILL INSPECTION **MCAP 2002**

Section 1. MANUFACTURING CONTROLS AND DOCUMENTATION

Task 1 **Assess adequacy of on site master formulae**

Rating Type Compliance **Feeds Regulations Sections 14(a) and (b), 15(1)(a)**
Health of Animals Regulations Section 91(3)(a) & 171(1)(a)

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

Standard To receive a satisfactory rating, master formulae must:

- include the name of the feed;
- include the name and weight of each ingredient, including medications, used in the manufacture of the feed;
- list only ingredients, including medications, that are approved, authorized and/or registered as required;
- include all medicating ingredients at the level authorized by the CMIB, veterinary prescription or emergency drug release;
- include information as to whether the feed contains any "prohibited material"; and
- be kept for a period of at least two years from the last date of manufacture of that feed.

Comments

Task 2 **Assess adequacy of on site mixing sheets**

Rating Type Compliance **Feeds Regulations Sections 14(a) and (b), 15(1)(a)**
Health of Animals Regulations Section 91(3)(a) & 171(1)(a)

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

Standard To receive a satisfactory rating, mixing sheets must:

- include the name of the feed;
- include the manufacturing date of the feed;
- include the name and weight of each ingredient, including medications, used in the manufacture of the feed;
- list only ingredients, including medications, that are approved, authorized and/or registered as required;
- include all medicating ingredients at the level authorized by the CMIB, veterinary prescription or emergency drug release;
- include the information used to identify each lot of feed;
- include information as to whether the feed contains any "prohibited material"; and
- be kept for a period of at least two years from the last date of manufacture of that feed.

Comments

Task 3 **Assess adequacy of medicating ingredient inventory**

ON-FARM FEED MILL INSPECTION	MCAP 2002
Rating Type	**Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)** All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.
Standard	To receive a satisfactory rating, the establishment must maintain an inventory, for each medicating ingredient/medicated feed used in the preparation of medicated feeds on that day, which demonstrates that the correct medicating ingredients/medicated feeds, in the correct quantities were used.

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 4 **Assess adequacy of written orders for veterinary prescription feeds**

Rating Type **Compliance Feeds Regulations Sections 5(2)(g), 15(1)(b), and (15)(4)(b)**

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

Standard Pursuant to Section 2 of the Feeds Regulations, a "**veterinary prescription feed**" is a feed manufactured pursuant to a veterinary prescription.

To receive a satisfactory rating:

□ all veterinary prescription feeds must conform to Section 5(2)(g) of the Feeds Regulations as follows:
(i) the sale of such feed is authorized under section C.08.012 of the Food and Drug Regulations,
(ii) the amount of feed manufactured does not exceed the amount that would be normally consumed by the number of animals prescribed to receive the feed during the prescribed period of medication,
(iii) the veterinary prescription pursuant to which the feed is manufactured is signed by the veterinarian who issued it and the prescription contains the following information:
(a) the date on which the prescription is written,
(b) the name and address of the person for whom the feed is to be manufactured and by whom it is intended to be used,
(c) the name and level of inclusion in the feed of the medicating ingredient prescribed by the veterinarian,
(d) the type and amount of feed to be manufactured,
(e) the number, kind, class and age or weight of the livestock intended to be fed the feed,
(f) special manufacturing instructions including necessary mill clean-up warnings, if any,
(g) feeding instructions or directions for use of the feed including the period of medication during which the feed is to be fed to the livestock, and
(h) warning statements and caution statements, where applicable,
(iv) the veterinary prescription pursuant to which the feed is manufactured contains a statement, signed by the person for whom the prescription was issued, indicating that he has read and understands the feeding instructions or directions for use and the warning statements and caution statements set out on the prescription, except that no such statement is necessary in those cases where, for practical reasons, the veterinarian who issued the prescription issued it directly to the manufacturer of the feed and is satisfied that the person for whom the prescription was issued was adequately aware of the information set out on the prescription,
(v) a copy of the veterinary prescription is in the possession of the manufacturer of the feed prior to the delivery of the feed, and

□ copies of veterinary prescriptions and the formula for the manufacture of veterinary prescription feeds, together with a list of each date on which the feed was manufactured must be kept for a period of at least one year from the last date of manufacture of that feed.

Comments

ON-FARM FEED MILL INSPECTION **MCAP 2002**

Task 5 **Assess retention of feed invoices**

Rating Type **Compliance Health of Animals Regulations Section 91(3)(a) & 171(1)(a)**

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

Standard To receive a satisfactory rating, every person who owns or has the possession, care or custody of a ruminant shall keep copies of all invoices for feeds that contains "prohibited material" for a period of at least two years from the date of purchase of that feed.

Comments

Task 6 **Assess adequacy of the file on manufacturing errors and corrective actions taken**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating, the establishment must maintain a file on manufacturing errors and corrective actions taken which contains the following information:

- the date of the manufacturing error;
- the name or other information used to identify the lot of feed;
- details of the manufacturing error;
- details of the manufacturer's investigation of the error; and
- details of the corrective actions taken including disposition of the rework material in accordance with the following:
  - if the rework contains a medication, it may only be used as an ingredient in feeds containing the same medication; and
  - copies of dated mixing sheets for the feeds in which the rework material was used as an ingredient must be kept for a period of at least two years from the last date of use.

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 7 **Assess adequacy of investigations of out of tolerance sample results**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating, the manufacturer must:

- sample finished feed according to an appropriate sampling plan using an appropriate sampling method;
- submit a minimum of four samples of finished feed annually for drug guarantee verification and/or drug residue analysis or other equivalent analytical tests for verifying drug guarantee or residue levels which have been approved by the Feed Section of the CFIA; and
- conduct follow up investigations on all internal sample results related to drug guarantees or residues, which are out of tolerance, to determine the cause of the sample being out of tolerance. These follow up investigations must include a review of all critical control points in the manufacture of the lot of as outlined in the Canadian Food Inspection Agency's *"Guide on Conducting Follow Up Inspection of Out of Compliance Feed Samples."*

Comments

Task 8 **Assess adequacy of on site regulatory documents**

Rating Type **Good Manufacturing Practice**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating, the establishment must have:

- an up to date version of the most recent edition of the Compendium of Medicating Ingredients Brochures (CMIB), including any updates or at least the MIBs for the medications being used on this farm;
- a current version of the Feeds Act and Regulations, including any amendments; and
- SOR 97-362 Regulations amending the Health of Animals Regulations.

Internet access to pertinent documents is acceptable provided that the operator can demonstrate, at the time of inspection, that the documents can be retrieved in this manner. The Internet site for the Feed Section's main page is as follows: http://www.inspection.gc.ca/english/anima/feebet/feebete.shtml

Comments

ON-FARM FEED MILL INSPECTION **MCAP 2002**

Task 9 **Assess written procedures and documentation for disposition of flush or recovered* materials - medications** (*materials recovered from spillage, rework, dust collectors etc.)

Rating Type Compliance ***Feeds Regulations*** **Sections 14(b)**

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

Standard To receive a satisfactory rating, the establishment must have written procedures which require that flush and recovered material must be handled as follows:

- disposal in accordance with local environmental regulations;
- if the feed contains a medication, it may only be used as an ingredient in feeds containing the same medication;
- when stored, the flush/recovered material must be labelled the name of the medication and any other pertinent information; and
- the establishment must have evidence documenting these procedures.

Comments

Task 10 **Assess written procedures and documentation for disposition of flush or recovered* materials - "prohibited materials"** (*materials recovered from spillage, rework, dust collectors etc.)

Rating Type Compliance ***Health of Animals Regulations*** **Sections 170(1)&(2)**

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

Standard To receive a satisfactory rating, the establishment must have written procedures which require that flush and recovered material must be handled as follows:

- disposal in accordance with local environmental regulations;
- if the feed is or contains "prohibited materials" it may only be used as an ingredient in nonruminant feeds labelled as containing "prohibited material";
- when stored, the flush/recovered material must be labelled with the required statement "Do not feed to cattle, sheep, deer or other ruminants" and any other pertinent information; and
- the establishment must have evidence documenting these procedures.

Comments

ON-FARM FEED MILL INSPECTION **MCAP 2002**

Section 2. PEST CONTROL PRODUCTS STORAGE AREA

Area 2.1 Pest Control Products Storage Area

Task 11 Evaluate condition of pest control product storage area

Rating Type Compliance Pest Control Products Regulations, Section 43

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

Standard To receive a satisfactory rating:

- pesticides (rodenticides, insecticides or other pesticides) must be stored to prevent cross-contamination with feeds, i.e.,
  - separately from feeds and feed ingredients
  - in closed containers with the registered label attached; and
- MSDS sheets must be available on site for employees reference regardless of whether the pest control program is managed internally or contracted out.

Comments

Section 3. RECEIVING, STORAGE AND DISTRIBUTION OF INGREDIENTS

Area 3.1 Receiving of Bulk Ingredients

Task 12 Evaluate condition of receiving area(s)

Rating Type Good Manufacturing Practice (Related to Tasks 15, 16 and 17)

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating, receiving area(s) must be relatively free of accumulated material and oil or fuel spills.

Accumulated material in the receiving area is an visible indication of a potential problem. Accumulated material may: provide a breeding ground for rodents, birds and insects; allow for the production of naturally-occurring toxins; and become a microbiological hot spot for bacteria such as Salmonella.

Comments

ON-FARM FEED MILL INSPECTION **MCAP 2002**

Task 13 **Evaluate condition of receiving equipment**

Rating Type **Good Manufacturing Practice (Related to Tasks 15, 16 and 17)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating, receiving pits must be designed to prevent the cross-contamination of feed ingredients on receipt:

- covered; and/or
- elevated so precipitation/runoff does not accumulate around/in; and/or
- protected (e.g. with walls and a roof).

and must have augers, belts, drag lines, elevators, pumps, hoses etc. that are:

- in good repair;
- in good working order; and
- relatively free of accumulated material.

Receiving pits should be designed so that incoming ingredients are protected from the elements, e.g., rain, snow, etc. as moisture is required for growth of bacteria such as Salmonella. Further, the area should be designed so that it can be easily cleaned to ensure that there is not a build up of accumulated material. Receiving equipment must be functional to ensure that there is not a build up of accumulated material.

Comments

Task 14 **Verify compliance of ALL ingredients in stock**

Rating Type **Compliance Feeds Regulations Section 14(a) and (b)**

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

Standard To receive a satisfactory rating, all incoming ingredients, including medicating ingredients, must be:

- approved, authorized and/or registered as required (e.g., non-medicating ingredients are listed in Schedule IV or V of the *Feeds Regulations*);
- all medicating ingredients used in the manufacture of feeds, for domestic use, have an approved Drug Identification Number or are covered by an Emergency Drug Release and/or an authorization of Sale for Experimental Purposes issued by Health Canada and a copy of supporting documentation is on site;
- all ingredients, including medicating ingredients, used in the manufacture of feeds, must not have passed their expiry date; and
- all ingredients in the establishment must be labelled in accordance with the *Feeds Regulations*.*

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002
Task 15	**Assess the adequacy of written receiving procedures and production records for receiving equipment ("prohibited material")**
Rating Type	**Compliance - *Health of Animals Regulations* Sections 91(3)(a) 170(1), 170(2) & 171(1)** All unsatisfactory ratings require a record of compliance action taken and/or a signed action plan for correction of noncompliance. **This task only applies to establishments who receive "prohibited materials"/feeds containing "prohibited materials" and who manufacture ruminant feeds.**
Standard	To receive a satisfactory rating, the manufacturer must maintain written clean out procedures and production records for receiving equipment which contains the following information: **Production records** □ the name of the piece of equipment to which the production record refers; □ the manufacturing date(s); □ the name of the feeds in the order which they pass through the equipment; □ the information used to identify each lot of feed; □ the amount of each feed; □ include information as to whether the feed contains any "prohibited material"; □ details of any feed safety precautions taken between batches of feed, e.g., equipment clean out procedures including the amount and type of flush material; and □ copies of production records must be kept for a period of at least two years from the last date of manufacture of that feed. **Equipment Cleanout Procedures** □ written equipment clean out procedures must indicate that feeds must be sequenced such that ruminant feeds never immediately follow feeds containing "prohibited materials" unless the equipment is physically cleaned (swept/vacuumed) or flushed prior to manufacturing the ruminant feeds.

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 16 **Assess adequacy of production records for receiving equipment (medications)**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard **This task only applies to establishments using common equipment to receive medicated feeds containing different medications or medicated and non-medicated feeds.**

To receive a satisfactory rating, the establishment must maintain production records for receiving equipment which must contain the following information;

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

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 17 **Assess the adequacy of written clean out procedures for receiving equipment (medications)**

Rating Type Compliance *Feeds Regulations* **Sections 14(b)**

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

This task only applies to establishments using the same equipment to receive medicated feeds containing different medications or medicated and nonmedicated feeds.

Standard To receive a satisfactory rating, written receiving procedures must detail practices which prevent contamination of ingredients, including:

That feeds be sequenced such that:

- feeds intended for animals producing milk for human consumption, laying hens, finisher animals or other "market-ready" animals do not follow a feed containing a medication that has a withdrawal established for any use level **unless additional cleaning procedures are used** (e.g., flushing, physical clean out) **or unless otherwise authorized**; (e.g., use in "market-ready" animals of this species approved in the CMIB);
- feeds for a particular species do not follow feeds containing medication that is not approved for that species **unless additional cleaning procedures are used** (e.g., flushing, physical clean out) **or unless otherwise authorized**; (e.g., a veterinary prescription is available for the batch of feed directly following the medication which authorizes this off-label use);
- feeds for a particular species do not follow feeds containing medications that are toxic to that species **unless additional cleaning procedures are used** (e.g., flushing, physical clean out); and
- the establishment must be following the written clean out procedures and have evidence which supports this, e.g., documentation.

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 18 — **Assess the validation procedures used to demonstrate the adequacy of additional cleaning procedures used in the previous task and supporting documentation**

Rating Type — **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

This task only applies to farms using the same equipment for receiving medicated feeds containing different medications or medicated and nonmedicated feeds

Standard — To receive a satisfactory rating, the establishment must have written clean out procedures which describe the validation of the receiving equipment clean out procedures which include the following information:

- date of the validation testing;
- production record for the validation test date (including sequence of feeds through equipment, type, amount and disposition of flush material (if applicable) or details of the clean out procedure being evaluated);
- details of the sampling procedures used;
- results of laboratory or other analytical testing; and
- evidence that the validation of clean out procedures was conducted in accordance with their written procedures.

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Area — **3.2 Storage and Distribution of Ingredients**

Task 19 — **Assess adequacy of written clean out procedures and production records for ingredient storage and handling equipment ("prohibited materials")**

Rating Type — **Compliance - *Health of Animals Regulations* Sections 91(3)(a) 170(1), 170(2) & 171(1)**

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

This task only applies to establishments that store and handle "prohibited materials"/feeds containing "prohibited materials" and who manufacture ruminant feeds.

Standard — To receive a satisfactory rating, the manufacturer must maintain written clean out procedures and production records for ingredient storage and handling equipment which contains the following information:

Production records

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

Equipment Cleanout Procedures

- written equipment clean out procedures must indicate that feeds must be sequenced such that ruminant feeds never immediately follow feeds containing "prohibited materials" unless the equipment is physically cleaned (swept/vacuumed) or flushed prior to manufacturing the ruminant feeds.

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 20 **Assess adequacy of production records for ingredient storage and handling equipment (medications)**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard **This task only applies to establishments using the same equipment to store and handle ingredients used in the manufacture of medicated feeds containing different medications or medicated and nonmedicated feeds.**

To receive a satisfactory rating, the manufacturer must maintain production records for ingredient storage and handling equipment which contains the following information:

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

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 21 **Assess the adequacy of written clean out procedures for ingredient storage and handling equipment (medications)**

Rating Type Compliance *Feeds Regulations* **Sections 14(b)**

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

This task only applies to establishments using the same equipment to store and handle ingredients used in the manufacture of medicated feeds containing different medications or medicated and nonmedicated feeds.

Standard To receive a satisfactory rating, written clean out procedures for ingredient storage and handling equipment must detail practices which prevent contamination of ingredients, including:

That feeds be sequenced such that:

- feeds intended for animals producing milk for human consumption, laying hens, finisher animals or other "market-ready" animals do not follow a feed containing a medication that has a withdrawal established for any use level **unless additional cleaning procedures are used** (e.g., flushing, physical clean out) **or unless otherwise authorized**; (e.g., use in "market-ready" animals of this species approved in the CMIB);
- feeds for a particular species do not follow feeds containing medication that is not approved for that species **unless additional cleaning procedures are used** (e.g., flushing, physical clean out) **or unless otherwise authorized**; (e.g., a veterinary prescription is available for the batch of feed directly following the medication which authorizes this off-label use);
- feeds for a particular species do not follow feeds containing medications that are toxic to that species **unless additional cleaning procedures are used** (e.g., flushing, physical clean out); and
- the establishment must be following the written clean out procedures and have evidence which supports this, e.g., documentation.

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 22 — **Assess the validation procedures used to demonstrate the adequacy of additional cleaning procedures used in the previous task and supporting documentation**

Rating Type — **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

This task only applies to farms using the same equipment for handling medicated feeds containing different medications or medicated and nonmedicated feeds

Standard — To receive a satisfactory rating, the establishment must have written procedures which describe the validation of the storage and handling equipment clean out procedures which include the following information:

- date of the validation testing;
- production record for the validation test date (including sequence of feeds through equipment, type, amount and disposition of flush material (if applicable) or details of the clean out procedure being evaluated);
- details of the sampling procedures used;
- results of laboratory or other analytical testing; and
- evidence that the validation of clean out procedures was conducted in accordance with their written procedures.

Comments

ON-FARM FEED MILL INSPECTION		MCAP 2002
Section	**4. FEED MANUFACTURING**	
Area	**4.1 Handling and Processing of Ingredients**	
Task 23	**Assess written clean out procedures and production records for ingredient processing equipment ("prohibited materials")**	
Rating Type	**Compliance - *Health of Animals Regulations* Sections 91(3)(a) 170(1), 170(2) & 171(1)** All unsatisfactory ratings require a record of compliance action taken and/or a signed action plan for correction of noncompliance. **This task only applies to establishments that process "prohibited materials"/feeds containing "prohibited materials" and who manufacture ruminant feeds.**	
Standard	To receive a satisfactory rating, the manufacturer must maintain written clean out procedures and production records for ingredient processing equipment which contains the following information: **Production records** □ the name of the piece of equipment to which the production record refers; □ the manufacturing date(s); □ the name of the feeds in the order which they pass through the equipment; □ the information used to identify each lot of feed; □ the amount of each feed; □ include information as to whether the feed contains any "prohibited material"; □ details of any feed safety precautions taken between batches of feed, e.g., equipment clean out procedures including the amount and type of flush material; and □ copies of production records must be kept for a period of at least two years from the last date of manufacture of that feed. **Equipment Cleanout Procedures** □ written equipment clean out procedures must indicate that feeds must be sequenced such that ruminant feeds never immediately follow feeds containing "prohibited materials" unless the equipment is physically cleaned (swept/vacuumed) or flushed prior to manufacturing the ruminant feeds.	

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 24 **Assess adequacy of production records for ingredient processing equipment (medications)**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard **This task only applies to establishments using common equipment to process ingredients used in the manufacture of medicated feeds containing different medications or medicated and non-medicated feeds.**

To receive a satisfactory rating, the establishment must maintain a production record for all ingredient processing equipment which contains the following information:

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

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 25 **Assess the adequacy of written clean out procedures for ingredient processing equipment (medications)**

Rating Type Compliance *Feeds Regulations* **Sections 14(b)**

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

This task only applies to establishments using common equipment to process medicated feeds containing different medications or medicated and non-medicated feeds.

Standard To receive a satisfactory rating, written processing procedures must detail practices which prevent contamination of ingredients, including:

That feeds be sequenced such that:

- feeds intended for animals producing milk for human consumption, laying hens, finisher animals or other "market-ready" animals do not follow a feed containing a medication that has a withdrawal established for any use level **unless additional cleaning procedures are used** (e.g., flushing, physical clean out) **or unless otherwise authorized**; (e.g., use in "market-ready" animals of this species approved in the CMIB);
- feeds for a particular species do not follow feeds containing medication that is not approved for that species **unless additional cleaning procedures are used** (e.g., flushing, physical clean out) **or unless otherwise authorized**; (e.g., a veterinary prescription is available for the batch of feed directly following the medication which authorizes this off-label use);
- feeds for a particular species do not follow feeds containing medications that are toxic to that species **unless additional cleaning procedures are used** (e.g., flushing, physical clean out); and
- the establishment must be following the written clean out procedures and have evidence which supports this, e.g., documentation.

Comments

Task 26 **Assess the validation procedures used to demonstrate the adequacy of additional cleaning procedures used in the previous task and supporting documentation**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

This task only applies to farms using the same equipment for processing medicated feeds containing different medications or medicated and nonmedicated feeds

Standard To receive a satisfactory rating, the establishment must have written procedures which describe the validation of the receiving equipment clean out procedures which include the following information:

- date of the validation testing;
- production record for the validation test date (including sequence of feeds through equipment, type, amount and disposition of flush material (if applicable) or details of the clean out procedure being evaluated);
- details of the sampling procedures used;
- results of laboratory or other analytical testing; and
- evidence that the validation of clean out procedures was conducted in accordance with their written procedures.

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Area 4.2 Feed Mixing Area

All Tasks in this Section should be repeated for each mixer used in the manufacture of feeds.

Task 27 **Evaluate condition of feed mixing area and equipment**

Rating Type **Good Manufacturing Practice**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating:

- the feed mixing area and equipment must be relatively free of accumulated material; and
- the mixer entry (hand adds) must be relatively free of accumulated material.

Accumulated material in the mixing area may be a visible indication of a potential problem. This material may contain medications, "prohibited material" or other contaminants. Where the mixer grate (for "hand-adds) is in-ground and uncovered or the cover is not clean, additional attention should be paid to making sure this area is clean.

Comments

Task 28 **Assess adequacy of written procedures used to test mixer performance and records**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating, the manufacturer must maintain mixer performance testing procedures and mixer records which contain the following information:

- the name or other information (e.g., model, serial number, etc.) which identifies the mixer to which the test record applies;
- the mixer performance testing date(s) - the mixer records must indicate that at a minimum mixing equipment performance has been tested at the time of installation (when installed after the Regulations have come into effect), after a major repair or modification and at least once/per year in accordance with their written procedures;
- details regarding the procedures that were used to assess the performance of mixing equipment (including information used to identify test feed (name, lot #), mixing sheet for test feed, the sequence of ingredient addition, batch size, mixing time, sampling procedures, etc.); and
- copies of mixer records must be kept for a period of at least three years from the date of testing.

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 29 **Evaluate performance of mixing equipment**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating, the establishment must have:

- evidence that the mixing equipment can produce feeds having a coefficient of variation within the critical limit for the particular type of feeds being manufactured using that mixer as defined in the *Feeds Regulations* (i.e., 5% for dilute drug premixes, 10% for micro or macro premixes and supplements and 15% for complete feeds and total mixed rations), including results of laboratory analysis for the level of selected test substance in test batches.

Comments

Task 30 **Assess adequacy of investigations of out of tolerance mixer performance testing results**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating, the establishment must have:

- written procedures detailing follow up procedures and corrective actions to be taken when mixer performance is outside of critical limits; and
- the establishment must have evidence documenting that these procedures have been followed.

Comments

ON-FARM FEED MILL INSPECTION		MCAP 2002
Task 31	**Assess adequacy of written cleaning procedures and production records for mixing equipment ("prohibited material")**	
Rating Type	**Compliance**	**Compliance - *Health of Animals Regulations* Sections 91(3)(a) 170(1), 170(2) & 171(1)**

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

This task only applies to establishments using common equipment to mix feeds containing "prohibited materials" and ruminant feeds.

Standard

To receive a satisfactory rating, the manufacturer must maintain written clean out procedures and production records for mixing equipment which contains the following information:

Production records

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

Equipment Cleanout Procedures

- written equipment clean out procedures must indicate that feeds must be sequenced such that ruminant feeds never immediately follow feeds containing "prohibited materials" unless the equipment is physically cleaned (swept/vacuumed) or flushed prior to manufacturing the ruminant feeds.

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 32 — **Assess adequacy of production records for mixing equipment (medications)**

Rating Type — **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

This task only applies to establishments using common equipment to mix medicated feeds containing different medications or medicated and nonmedicated feeds.

Standard — To receive a satisfactory rating, the manufacturer must maintain production records for mixing equipment which contains the following information:

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

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 33 **Assess the adequacy of written clean out procedures for mixing equipment (medications)**

Rating Type Compliance *Feeds Regulations* **Sections 14(b)**

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

This task only applies to establishments using the same equipment to mix medicated feeds containing different medications or medicated and nonmedicated feeds.

Standard To receive a satisfactory rating, written clean out procedures for mixing equipment must detail practices which prevent cross-contamination of feeds, including:

That feeds be sequenced such that:

- feeds intended for animals producing milk for human consumption, laying hens, finisher animals or other "market-ready" animals do not follow a feed containing a medication that has a withdrawal established for any use level **unless additional cleaning procedures are used** (e.g., flushing, physical clean out) **or unless otherwise authorized**; (e.g., use in "market-ready" animals of this species approved in the CMIB);
- feeds for a particular species do not follow feeds containing medication that is not approved for that species **unless additional cleaning procedures are used** (e.g., flushing, physical clean out) **or unless otherwise authorized**; (e.g., a veterinary prescription is available for the batch of feed directly following the medication which authorizes this off-label use);
- feeds for a particular species do not follow feeds containing medications that are toxic to that species **unless additional cleaning procedures are used** (e.g., flushing, physical clean out); and
- the establishment must be following the written procedures and have evidence which supports this, e.g., documentation.

Comments

Task 34 **Assess the validation procedures used to demonstrate the adequacy of additional cleaning procedures used in the previous task and supporting documentation**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

This task only applies to farms using the same equipment for mixing medicated feeds containing different medications or medicated and nonmedicated feeds

Standard To receive a satisfactory rating, the establishment must have written procedures which describe the validation of the receiving equipment clean out procedures which include the following information:

- date of the validation testing;
- production record for the validation test date (including sequence of feeds through equipment, type, amount and disposition of flush material (if applicable) or details of the clean out procedure being evaluated);
- details of the sampling procedures used;
- results of laboratory or other analytical testing; and
- evidence that the validation of clean out procedures was conducted in accordance with their written procedures.

Comments

ON-FARM FEED MILL INSPECTION **MCAP 2002**

Task 35 **Assess suitability of all scales in this area**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating, all scales used in the manufacture of feeds must:

- have a capacity suitable for its intended purpose (i.e., *quantity measured must not exceed scale capacity);*
- have a sensitivity suitable for its intended purpose (i.e., *scale must not be used to weigh ingredient(s) in quantities lower than the sensitivity of the instrument. For example, a scale with 100 g sensitivity can not be used to weigh 50 g); and*
- have a graduation suitable for its intended purpose (i.e., *scale must not be used to weigh quantities more precisely than the instrument allows. For example, a scale with 1 kg graduations must not be used to weigh 1.5 kg of an ingredient).*

Comments

Task 36 **Assess suitability of all metering devices in this area**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating, all metering devices used in the manufacture of feeds must:

- have a sensitivity suitable for its intended purpose (i.e., *metering devices must not be used to add ingredient(s) in a quantity lower than it's sensitivity. For example, a metering device that is adding an ingredient at a rate of 2 kg/tonne at it's lowest setting can not be used to add an ingredient at a rate of 1 kg/tonne); and*

- have a graduation suitable for its intended purpose (i.e., *metering devices must not be used to dispense more precisely than the instrument allows. For example, a metering device that increases inclusion of an ingredient at a rate of 2 kg/tonne per increase in graduation setting can not be used to increase inclusion at a rate of 0.5 kg/tonne).*

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 37 — **Assess adequacy of written scale and metering device verification procedures and records**

Rating Type — **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard — **This task should be repeated for each scale or metering device used in the manufacture of medicated feed**

To receive a satisfactory rating, the establishment must have written scale and metering device verification procedures and records for each scale or metering device used in the manufacture of medicated feed which contain the following information:

- the name or other information (e.g., model, serial number, location etc.) which identifies the scale/metering device to which the test record applies;
- the scale/metering device verification testing date(s) - the scale/metering device verification records must indicate that, at a minimum, scales/metering devices have been tested at the time of installation (when installed after the Regulations have come into effect), after a major repair or modification and at least once/per year in accordance with their written procedures;
- details regarding the procedures that were used to verify the performance of scale (including information on the number of test weights used, the sequence of addition and removal of the test weights from the scale, location where test weights were placed, etc.); or
- details regarding the procedures that were used to verify the performance of metering device accuracy (including information on the time/volume/weight of the material delivered by the metering device and a comparison of theoretical versus actual addition); and
- copies of records must be kept for a period of at least three years from the date of testing.

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 38 **Evaluate performance of scales/metering devices used in the manufacture of medicated feed in this area**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard **This task should be repeated for each scale or metering device used in the manufacture of medicated feed**

To receive a satisfactory rating, the establishment must maintain a verification record for each scale and metering device verification record must contain the following information:

- evidence that the scale is accurate (e.g., records showing that the scale can weigh given test weights within 0.2% of the capacity of the scale or ± one graduation whichever is more); and
- evidence that the metering device is accurate (e.g., records showing test batches are within 5% of the intended formulation or ± one graduation whichever is more).

Comments

Task 39 **Assess adequacy of investigations of out of tolerance scale/metering device testing results**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating, the establishment must have:

- written procedures detailing follow up procedures and corrective actions to be taken when scale/metering device performance is outside of critical limits which indicate that
  - the manufacturer must stop using the scale/metering device until its' accuracy is within critical limits;
  - the manufacturer must stop using all lots of animal food that are likely to be affected by the discrepancy;
- must promptly conduct an investigation and take the necessary corrective measures; and
- the establishment must have evidence documenting that these procedures have been followed.

Comments

ON-FARM FEED MILL INSPECTION		MCAP 2002
Section	**5. STORAGE AND HANDLING OF MEDICATING INGREDIENTS**	
Area	**5.1 Storage of Medications**	
Task 40	**Evaluate condition of medication storage area**	
Rating Type	**Good Manufacturing Practice**	
	All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.	
Standard	To receive a satisfactory rating, the medication storage area must be relatively free of accumulated material.	
	Accumulated material in the medication storage area may be a visible indication of a potential problem. This material will contain medications and may be carried throughout the mill on the footwear of the mill staff and any visitors. Again, where mixer grates (for "hand-adds) are in-ground and uncovered, additional attention should be paid to making sure this area is clean.	

Comments

Area	**5.2 Handling and Identification of Medications**	
Task 41	**Evaluate condition of medication handling area**	
Rating Type	**Good Manufacturing Practice**	
	All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.	
Standard	To receive a satisfactory rating, the medication handling area must be relatively free of accumulated material.	
	Accumulated material in the medication handling area may be a visible indication of a potential problem. This material will contain medications and may be carried throughout the mill on the footwear of the mill staff and any visitors. Again, where mixer grates (for "hand-adds) are in-ground and uncovered, additional attention should be paid to making sure this area is clean.	

Comments

ON-FARM FEED MILL INSPECTION **MCAP 2002**

Task 42 **Evaluate condition of medication handling equipment**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating:

- separate medication handling equipment (e.g., scoops, pails, etc.) must be used for each medication; or
- the medication handling equipment must be thoroughly cleaned between medications.

Accumulated material on the medication handling equipment may be a visible indication of a potential problem. This material will contain medications and may become an unintended ingredient in other medicated feeds. To reduce the risk of residues, medication handling equipment should at a minimum be cleaned between medications.

Comments

Task 43 **Assess adequacy of written medication handling procedures**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating, written procedures should indicate that medications be handled such that:

- the identity of the medication is maintained at all times;
- the integrity of the medication is maintained (no cross-contamination); and
- the establishment must be following the written procedures and have evidence which supports this, e.g., documentation.

Medications should be handled in such a way that the potential for cross-contamination of one product with another is minimized. For example, making sure that lids are replaced on storage bins when scooping medications out of nearby containers will limit the spillage into the medication stored in the bin not being used for that batch.

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 44 **Assess suitability of all scales in this area**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating, all scales used in the manufacture of feeds must:

- have a capacity suitable for its intended purpose (i.e., *quantity measured must not exceed scale capacity);*
- have a sensitivity suitable for its intended purpose (i.e., *scale must not be used to weigh ingredient(s) in quantities lower than the sensitivity of the instrument. For example, a scale with 100 g sensitivity can not be used to weigh 50 g); and*
- have a graduation suitable for its intended purpose (i.e., *scale must not be used to weigh quantities more precisely than the instrument allows. For example, a scale with 1 kg graduations must not be used to weigh 1.5 kg of an ingredient).*

Comments

Task 45 **Assess suitability of all metering devices in this area**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating, all metering devices used in the manufacture of feeds must:

- have a sensitivity suitable for its intended purpose (i.e., *metering devices must not be used to add ingredient(s) in a quantity lower than it's sensitivity. For example, a metering device that is adding an ingredient at a rate of 2 kg/tonne at it's lowest setting can not be used to add an ingredient at a rate of 1 kg/tonne); and*
- have a graduation suitable for its intended purpose (i.e., *metering devices must not be used to dispense more precisely than the instrument allows. For example, a metering device that increases inclusion of an ingredient at a rate of 2 kg/tonne per increase in graduation setting can not be used to increase inclusion at a rate of 0.5 kg/tonne).*

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 46 **Assess adequacy of written scale and metering device verification procedures**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating, the establishment must have written scale and metering device verification procedures and records for each scale or metering device used in the manufacture of medicated feed which contain the following information:

- the name or other information (e.g., model, serial number, location etc.) which identifies the scale/metering device to which the test record applies;
- the scale/metering device verification testing date(s) - the scale/metering device verification records must indicate that, at a minimum, scales/metering devices have been tested at the time of installation (when installed after the Regulations have come into effect), after a major repair or modification and at least once/per year in accordance with their written procedures;
- details regarding the procedures that were used to verify the performance of scale (including information on the number of test weights used, the sequence of addition and removal of the test weights from the scale, location where test weights were placed, etc.); or
- details regarding the procedures that were used to verify the performance of metering device accuracy (including information on the time/volume/weight of the material delivered by the metering device and a comparison of theoretical versus actual addition); and
- copies of records must be kept for a period of at least three years from the date of testing.

Comments

Task 47 **Evaluate performance of scales/metering devices used in the manufacture of medicated feed in this area**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard **This task should be repeated for each scale or metering device used in the manufacture of medicated feed**

To receive a satisfactory rating, the establishment must maintain a verification record for each scale and metering device verification record must contain the following information:

- evidence that the scale is accurate (e.g., records showing that the scale can weigh given test weights within 0.2% of the capacity of the scale or ± one graduation whichever is more);and
- evidence that the metering device is accurate (e.g., records showing test batches are within 5% of the intended formulation or ± one graduation whichever is more).

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 48 **Assess adequacy of investigations of out of tolerance scale/metering device testing results**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating, the establishment must have:

- written procedures detailing follow up procedures and corrective actions to be taken when scale/metering device performance is outside of critical limits which indicate that
  - the manufacturer must stop using the scale/metering device until its' accuracy is within critical limits;
  - the manufacturer must using all lots of animal food that are likely to be affected by the discrepancy;
  - must promptly conduct an investigation and take the necessary corrective measures; and
- the establishment must have evidence documenting that these procedures have been followed.

Comments

ON-FARM FEED MILL INSPECTION		MCAP 2002
Section	**6. STORAGE AND HANDLING OF FINISHED PRODUCTS**	
Area	**6.1 Storage of Finished Feeds**	
Task 49	**Assess adequacy of written clean out procedures and production records for finished feed storage and handling equipment- "prohibited materials".**	
Rating Type	Compliance	Compliance - ***Health of Animals Regulations*** **Sections 91(3)(a) 170(1), 170(2) & 171(1)**

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

This task only applies to establishments using the same equipment to store and handle feeds containing "prohibited materials" and ruminant feeds.

Standard

To receive a satisfactory rating, the manufacturer must maintain written clean out procedures and production records for storage and handling equipment which contains the following information:

Production records

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

Equipment Cleanout Procedures

- written equipment clean out procedures must indicate that feeds must be sequenced such that ruminant feeds never immediately follow feeds containing "prohibited materials" unless the equipment is physically cleaned (swept/vacuumed) or flushed prior to manufacturing the ruminant feeds.

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 50 **Assess adequacy of production records for finished feed storage and handling equipment (medications)**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard **This task only applies to establishments using common equipment to store and handle medicated feeds containing different medications or medicated and non-medicated feeds.**

To receive a satisfactory rating, the establishment must maintain a production record for all pieces of equipment used to store/handle medicated feeds containing different medications or medicated and non-medicated feeds.

To receive a satisfactory rating, the required daily production records log must include the following information:

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

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 51 **Assess the adequacy of written clean out procedures for storage and handling equipment (medications)**

Rating Type Compliance *Feeds Regulations* **Sections 14(b)**

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

This task only applies to establishments using the same equipment to store and handle medicated feeds containing different medications or medicated and nonmedicated feeds.

Standard To receive a satisfactory rating, written clean out procedures for storage and handling equipment must detail practices which prevent contamination of ingredients, including:

That feeds be sequenced such that:

- feeds intended for animals producing milk for human consumption, laying hens, finisher animals or other "market-ready" animals do not follow a feed containing a medication that has a withdrawal established for any use level **unless additional cleaning procedures are used** (e.g., flushing, physical clean out) **or unless otherwise authorized**; (e.g., use in "market-ready" animals of this species approved in the CMIB);
- feeds for a particular species do not follow feeds containing medication that is not approved for that species **unless additional cleaning procedures are used** (e.g., flushing, physical clean out) **or unless otherwise authorized**; (e.g., a veterinary prescription is available for the batch of feed directly following the medication which authorizes this off-label use);
- feeds for a particular species do not follow feeds containing medications that are toxic to that species **unless additional cleaning procedures are used** (e.g., flushing, physical clean out); and
- the establishment must be following the written clean out procedures and have evidence which supports this, e.g., documentation.

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 52 **Assess the validation procedures used to demonstrate the adequacy of additional cleaning procedures used in the previous task and supporting documentation**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

This task only applies to farms using the same equipment for handling medicated feeds containing different medications or medicated and nonmedicated feeds

Standard To receive a satisfactory rating, the establishment must have written procedures which describe the validation of the receiving equipment clean out procedures which include the following information:

- date of the validation testing;
- production record for the validation test date (including sequence of feeds through equipment, type, amount and disposition of flush material (if applicable) or details of the clean out procedure being evaluated);
- details of the sampling procedures used;
- results of laboratory or other analytical testing; and
- evidence that the validation of clean out procedures was conducted in accordance with their written procedures.

Comments

Area **6.2 Feed Delivery/Shipping Area**

Task 53 **Evaluate condition of delivery vehicles**

Rating Type **Good Manufacturing Practice (will be requirement of Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard To receive a satisfactory rating, delivery vehicles must;

- be relatively free of accumulated material;
- have no leaks/holes; and
- have intact, tight fitting separating walls which minimize cross-contamination between compartments.

Comments

ON-FARM FEED MILL INSPECTION		MCAP 2002
Task 54	**Assess adequacy of written clean out procedures and production records for loading/unloading of bulk delivery vehicles ("prohibited materials")**	
Rating Type	**Compliance**	**Compliance - *Health of Animals Regulations* Sections 91(3)(a) 170(1), 170(2) & 171(1)**

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

This task only applies to establishments using the same bulk delivery vehicles for loading/unloading both "prohibited materials"/feeds containing "prohibited materials" and ruminant feeds.

Standard

To receive a satisfactory rating, the manufacturer must maintain written clean out procedures and production records for bulk delivery vehicles which contains the following information:

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

Equipment Cleanout Procedures

- written equipment clean out procedures must indicate that feeds must be sequenced such that ruminant feeds never immediately follow feeds containing "prohibited materials" unless the equipment is physically cleaned (swept/vacuumed) or flushed prior to manufacturing the ruminant feeds.

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 55 **Assess adequacy of production records for loading/unloading of bulk delivery vehicles (medications)**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

Standard **This task only applies to establishments using common equipment to load/unload medicated feeds containing different medications or medicated and non-medicated feeds delivered in bulk.**

To receive a satisfactory rating, the manufacturer must maintain production records for bulk delivery vehicles which contains the following information:

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

Comments

ON-FARM FEED MILL INSPECTION	MCAP 2002

Task 56 **Assess the adequacy of written clean out procedures for bulk delivery vehicles (medications)**

Rating Type Compliance *Feeds Regulations* **Sections 14(b)**

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

This task only applies to establishments using the same bulk delivery vehicles to deliver medicated feeds containing different medications or medicated and nonmedicated feeds.

Standard To receive a satisfactory rating, written delivery procedures must detail practices which prevent contamination of feeds, including:

That feeds be sequenced such that:

- feeds intended for animals producing milk for human consumption, laying hens, finisher animals or other "market-ready" animals do not follow a feed containing a medication that has a withdrawal established for any use level **unless additional cleaning procedures are used** (e.g., flushing, physical clean out) **or unless otherwise authorized**; (e.g., use in "market-ready" animals of this species approved in the CMIB);
- feeds for a particular species do not follow feeds containing medication that is not approved for that species **unless additional cleaning procedures are used** (e.g., flushing, physical clean out) **or unless otherwise authorized**; (e.g., a veterinary prescription is available for the batch of feed directly following the medication which authorizes this off-label use);
- feeds for a particular species do not follow feeds containing medications that are toxic to that species **unless additional cleaning procedures are used** (e.g., flushing, physical clean out); and
- the establishment must be following the written clean out procedures and have evidence which supports this, e.g., documentation.

Comments

Task 57 **Assess the validation procedures used to demonstrate the adequacy of additional cleaning procedures used in the previous task and supporting documentation**

Rating Type **Good Manufacturing Practice (will be a requirement of the Medicated Feed Regulations)**

All unsatisfactory ratings require a comment and/or a signed action plan for correction of deficiency.

This task only applies to farms using the same equipment for handling medicated feeds containing different medications or medicated and nonmedicated feeds

Standard To receive a satisfactory rating, the establishment must have written procedures which describe the validation of the receiving equipment clean out procedures which include the following information:

- date of the validation testing;
- production record for the validation test date (including sequence of feeds through equipment, type, amount and disposition of flush material (if applicable) or details of the clean out procedure being evaluated);
- details of the sampling procedures used;
- results of laboratory or other analytical testing; and
- evidence that the validation of clean out procedures was conducted in accordance with their written procedures.

Comments

ON-FARM FEED MILL INSPECTION **MCAP 2002**

Section 7. SUMMARY AND COMMENTS

Task 58 **Additional Comments from Inspector**

Rating Type **N/A**

Standard Inspection staff should capture any additional comments on the facility in the comment field provided for future reference.

Comments

Task 59 **Feedback from Mill Management**

Rating Type **N/A**

Standard Inspection staff should capture any feedback received from establishment personnel in the comment field provided for future reference.

Comments

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