Commercial Feed Mill Verification Task Procedures

Section: 1 Feed Facility Inspection
Subsection: 1 Commercial Feed Mill
Task: 1101 Drug Premixes
Task Frequency: Once per year for any facility manufacturing livestock feeds
Date Task Revised: 2013-04-01

Feeds Regulations Sections 5 and 14(b)

Commercial feed mill meets the regulatory requirements related to drug premixes used in the manufacture of feed in the facility.

File Review:

Select labels for drug premixes based on the number of drug premixes used in the manufacture of feeds at the facility as follows:

1-5 drug premixes = 1 label
6-15 drug premixes = 2 labels
>15 drug premixes = 3 labels

Go on-site:
Review labels for drug premixes used in the manufacture of feed at the facility and interview as necessary to verify that:

- labels for drug premixes contain a Drug Identification Number (DIN) or the drug premix is authorized by an emergency drug release
- drug premixes, labelled for use in the manufacture of feeds, at the facility have not passed their expiry date

Note:

1. ***Where concerns with a drug premix are identified, product control actions should be taken on feeds containing the drug premix.***

Inspection comments to include:

Activities Used to Assess Compliance

- information which clearly identifies the specific drug premix labels reviewed or an indication that there were no drug premixes used in the facility
  - brand name, generic name, code and lot number of drug premix
  - expiration date
  - Drug Identification Number, if applicable (if an Emergency Drug Release - capture details)
- information from staff interviews (include names and titles of staff interviewed) to determine whether there are any controls in place:
  - to ensure only approved drugs that have not expired are used in the facility
  - related to the disposal of expired drug premixes
- details of on-site observations used to determine whether unapproved or expired drugs were stored in the facility and/or used in the manufacture of feed
- information which clearly identifies the specific mixing records confirming that an unapproved or expired drug premix was used in the manufacture of feed
  - name, code and lot number (if available) of feed to which the mixing records correspond
  - brand name, generic name, code and lot number (if available) of unapproved or expired drug premix used in the manufacture of feed
  - date of manufacture of the feed containing the unapproved or expired drug premix

Non-compliant Objective Evidence

- identification of copies of documents obtained as evidence of a deviation
- any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility
- select the specific category of deviation observed from the list below (select all that apply):

1101.1. Use of unapproved drug premixes
1101.2. Use of expired drug premixes

Canada

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section: 1 Feed Facility Inspection
Subsection: 1 Commercial Feed Mill
Task: 1102 Ingredient Compliance – Domestic and Imported Rendered Products
Task Frequency: Once per year for any facility manufacturing livestock feeds and/or animal food
Date Task Revised: 2013-04-01

Feeds Regulations Sections 5, 14(a), 19(1)(d.3) and 26(8)
Health of Animals Regulations Sections 165(4), 166(1) and 167

Commercial feed mill meets the regulatory requirements related to domestic and imported rendered products used as ingredients in the manufacture of feed in the facility or offered for sale by the facility.

Review labels* for ALL incoming rendered products regardless of whether the facility is the importer of record.

Includes but is not limited to:

- **Meat and Bone meal (various types – ruminant, prohibited)**
- **Meat Meal (various types – ruminant, prohibited)**
- **Bone Meal (various)**
- **Feather Meal**
- **Fish Meal**
- **Poultry Meal**
- **Porcine Meal**
- **Hog Hair**
- **Hog Hair and Feather Meal Blend**
- **Blood Meal**
- **Animal Fat**
- **Tallow**
- **Animal Vegetable Fat Blend (also known as Yellow Grease)**
- **Fish Oil**
- **Blood Plasma**

***Note:**

1. ***The invoice or bill of sale may be the de facto label for rendered products shipped in bulk***

Go on-site:
Review labels for domestic and imported rendered products and interview as necessary to verify that:

- where the manufacturer of a rendered product is a Canadian rendering plant, verify that the rendering plant has a valid Permit to Operate using the CFIA_ACIA-#1244324-Feed - Index of Valid Rendering Plant Permit Numbers (*product control actions required)*
- where the facility is the importer of record for imported rendered products, imports are supported by valid import permits (*product control actions required)*

- rendered products used in the facility are listed in Part I of Schedule IV of the *Feeds Regulations* and labels for rendered products conform with the requirements of the ingredient definitions in Schedule IV

OR

- rendered products have a valid registration number as verified by CFIA's Product Registration System and the label conforms with the approved label on file (*product control actions required)*

NOTE: Currently Schedule IV & V are embedded into the *Feeds Regulations*. New single ingredient feeds (SIFs) are approved more frequently than the *Feeds Regulations* are officially updated. As a result, an administrative version of Schedule IV & V has been created and is maintained by Animal Feed Division. When determining if SIFs are approved for manufacture, import or sale for livestock, please refer to this document (RDIMS 706637).

- labels for animal fat derived from ruminants have a guarantee for insoluble impurities of no more than 0.15% (*product control actions required)*
- labels for yellow grease have a guarantee for insoluble impurities of no more than 0.15% (*product control actions required)*
- labels for prohibited material include the prescribed statement (*product control actions required)*

Commercial Feed Mill Verification Task Procedures

All Type A violations require product control actions to be initiated

Note: Where non-compliant feed labels are identified, follow-up with the original manufacturer of the non-compliant feed is also required.

Go on-site:
Observe procedures for the use of labels for feed ingredients offered for sale, review records (if available) and interview as necessary to verify that:

- the correct feed label is affixed to packaged products as required *(product control actions required where the feed contains prohibited material)*
- the correct feed label accompanies bulk shipments *(product control actions required where the feed contains prohibited material)*

Inspection comments to include:

Activities Used to Assess Compliance

- list of domestic rendered products assessed and permit number for domestic facilities or an indication that there were no domestic rendered products used in the facility or offered for sale by the facility
- list of imported rendered products assessed or an indication that there were no rendered products imported by the facility for their own use or sale
    - where the facility was the importer of record, include the corresponding import permit numbers for the rendered products
    - where the facility was not the importer of record, the name of the supplier from whom the rendered products were purchased
- information which clearly identifies the specific labels reviewed
    - name of rendered product
    - code and lot number of rendered product, if applicable
    - country of origin, if applicable
    - expiration date, if applicable
    - registration number, if applicable
- information from staff interviews (include names and titles of staff interviewed) to determine whether there are any controls in place to ensure that:
    - all rendered products used in the facility or offered for sale by the facility are approved and labelled correctly
- on-site observations

Non-compliant Objective Evidence

- identification of copies of documents obtained as evidence of a deviation
- any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility
    - Type of label non-compliance (Type A or Type B)
    - Specifics of the label non-compliance
- select the specific category of deviation observed from the list below (select all that apply):

1102.1. Use of unapproved domestic rendered product
1102.2. Use of unapproved imported rendered product
1102.3. Use of animal fat derived from ruminants or yellow grease with label guarantee > 0.15% insoluble impurities
1102.4. Labels reviewed have at least one Type A Violation
1102.5. Labels reviewed have at least one Type B Violation
1102.6. *Code no longer applicable*
1102.7. Corresponding feed labels are not provided with every bulk shipment of rendered product offered for sale by the facility
1102.8. Corresponding feed labels are not affixed to packaged rendered products offered for sale by the facility

Commercial Feed Mill Verification Task Procedures

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section:	1	Feed Facility Inspection
Subsection:	1	Commercial Feed Mill
Task:	1103	Incoming Ingredient Compliance - Mixed Feeds and Single Ingredient Feeds other than Rendered Products
Task Frequency:		Once per year for any facility manufacturing livestock feeds
Date Task Revised:		2013-04-01

Feeds Regulations Sections 5, 14, 16, 19, 20, 24 and 26 - 33
Health of Animals Regulations Section 169

Commercial feed mill meets the regulatory requirements related to incoming single ingredient feeds and mixed feeds used as ingredients in the manufacture of feed in the facility or offered for sale by the facility.

File Review:
Select labels for <u>imported</u> mixed feeds, regardless of whether the facility is the importer of record (including medicated premixes and supplements) based on the tonnage of the facility as follows:

0-1,000 tonnes = 1 label
1,001 – 30,000 tonnes = 2 labels
>30,000 tonnes = 3 labels

Select labels for <u>domestic</u> mixed feeds (including medicated premixes and supplements) based on the tonnage of the facility as follows:

0-1,000 tonnes = 1 label
1,001 – 30,000 tonnes = 2 labels
>30,000 tonnes = 3 labels

Select labels for incoming single ingredient feeds other than rendered products (domestic and imported) based on the tonnage of the facility as follows:

0-1,000 tonnes = 1 label
1,001 – 30,000 tonnes = 2 labels
>30,000 tonnes = 3 labels

Go On-Site:
Review labels for incoming single ingredient feeds and mixed feeds (e.g., supplements, premixes) used in the manufacture of feed at the facility and interview as necessary to verify that:

- incoming single ingredient feeds are approved and listed in Part I of Schedule IV or V and the label conforms with the requirements of the ingredient definition in Schedule IV or V (RDIMS 706637)

OR

- incoming single ingredient feeds are approved and listed in Part II of Schedule IV or V and have a valid registration number as verified by CFIA's Product Registration System and the label conforms with the approved label on file (*product control actions required)*

- labels for imported mixed feeds contain a valid registration number as verified by CFIA's Product Registration System (*product control actions required)*
- labels for imported mixed feeds include a valid registration number as verified by CFIA's Product Registration System and conform with the approved label on file
- labels for imported or domestic mixed feeds containing medicating ingredients that are used as ingredients in feeds manufactured in the facility are labelled as prescribed (*product control actions required for Type A violations)*
- labels for imported or domestic mixed feeds that contain prohibited material include the prescribed statement (*product control actions required)*
- domestic mixed feeds used as ingredients in feeds manufactured in the facility are exempt from registration or have a valid registration number as verified by CFIA's Product Registration System and are labelled as prescribed (a reader-friendly version of Table 4 is available – RDIMS 743797)
- registered products at the facility have not passed their expiry date, where the inclusion of an expiry date is a requirement of registration (e.g., forage additives and viable microbial products containing live microbes)

All Type A violations (e.g. non approved drug, drug incompatibility, improper drug level, improper or missing claim, improper or missing warning statement, improper or missing caution, directions for use) require product control actions to be initiated.

Note:

1. ***Where non-compliant feed labels are identified, follow-up with the original***

Commercial Feed Mill Verification Task Procedures

manufacturer of the non-compliant feed is also required.

2. ***Where concerns with an expired registered product are identified, product control actions should be taken on feeds containing the expired registered product.***

Go on-site:

Observe procedures for the use of labels for feed ingredients (including mixed feeds intended for use as ingredients or offered for sale, e.g., premixes), review records (if available) and interview as necessary to verify that:

- the correct feed label is affixed to packaged feed and feed ingredients as required *(product control actions required where the feed contains prohibited material)*
- the correct feed label accompanies bulk shipments of feed and feed ingredients *(product control actions required where the feed contains prohibited material)*

Inspection comments to include:

Activities Used to Assess Compliance

- information which clearly identifies the specific domestic ingredient labels (single ingredient feeds and mixed feeds intended for further manufacturing) reviewed
  - name, code and lot number of ingredient as applicable
  - expiration date, if applicable
  - registration number, if applicable
- information which clearly identifies the specific imported ingredient labels (single ingredient feeds and mixed feeds intended for further manufacturing) reviewed or an indication that there were no imported ingredients used in the facility
  - name, code and lot number of ingredient as applicable
  - country of origin, if applicable
  - expiration date, if applicable
  - registration number, if applicable
- information from staff interviews (include names and titles of staff interviewed) to determine whether there are any controls in place:
  - to ensure that all incoming ingredients, other than rendered products, used in the facility or offered for sale by the facility are approved and labelled correctly; and
  - related to the disposal of expired registered products where the inclusion of an expiry date is a requirement of registration (e.g., forage additives and viable microbial products containing live microbes)
- on-site observations

Non-compliant Objective Evidence

- identification of copies of documents obtained as evidence of a deviation
- any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility
  - Type of label non-compliance (Type A or Type B)
  - Specifics of the label non-compliance
    - identify the specific Type A violations, e.g., non approved drug, drug incompatibility, improper drug level, improper or missing claim, improper or missing warning statement, improper or missing caution, directions for use, prescribed statement absent - PM feeds
    - identify the specific Type B violations, e.g., non approved single ingredient, outside Table 4 range of nutrients, Table 3 violation, Section 26 improper information on label, Section 32 Improper Name, Section 33 Units of measurement, prescribed statement present - non-PM feeds
- select the specific category of deviation observed from the list below (select all that apply):

1103.1. Use of unapproved single ingredient feeds (not in Schedule IV or V)
1103.2. Feed not registered as required (mixed feed or single ingredient feed)
1103.3. Required warning and/or caution statements related to medicating ingredients not on the label for a mixed feed
1103.4. Prescribed statement not on label for incoming mixed feed (used as an ingredient) containing prohibited material
1103.5. Labels reviewed have at least one Type A Violation
1103.6. Labels reviewed have at least one Type B Violation
1103.7. *Code no longer applicable*
1103.8. Use of expired registered products
1103.9. Corresponding feed labels are not provided with every bulk shipment of

	feed and feed ingredients offered for sale by the facility
1103.10.	Corresponding feed labels are not affixed to packaged feed and feed ingredients offered for sale by the facility

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section: 1 Feed Facility Inspection
Subsection: 1 Commercial Feed Mill
Task: 1104 Feeds for Further Manufacturing Containing Prohibited Material
Task Frequency: Once per year for any facility manufacturing animal food
Date Task Revised: 2013-04-01

Health of Animals Regulations Sections 164, 168, 169, 170(1), 170(2)(a) and 171(1)

Commercial feed mill meets the regulatory requirements related to the use of feeds for further manufacturing that contain prohibited material (includes but not exclusive to spillage, flush, dust collector material, returned feed and rework).

Obtain written procedures and verify that they include:

- a policy stating that returned feeds of unknown origin are not accepted (this is especially important for facilities that do not intentionally include prohibited materials in their formulations)
- a policy stating that returned feed including recalled feed, spillage, flush and dust collector material containing prohibited material that are deemed not suitable for further manufacturing are disposed of in a manner that prevents exposure of ruminants to the feed
- a policy stating that feeds suitable for further manufacturing that contain prohibited material are properly identified in the facility
- procedures are in place to prevent cross-contamination of ruminant feeds or other feed ingredients by feeds for further manufacturing that contain prohibited material when stored
- procedures are in place to ensure that feeds for further manufacturing that contain prohibited material are only used as ingredients in non-ruminant feeds that contain prohibited materials and are labelled with the prescribed statement

File Review:

Review production records to verify that procedures are followed regarding the storage, handling and use of:

- **returned feeds**
- **rework**
- **spillage**
- **flush material and**
- **dust collector material**

Note:

1. ***Select mixing formulae, mixing sheets, labels and production logs for equipment used in the manufacture and transportation of feeds containing the feed for further manufacture (with PM) as an ingredient (one feed including a lot of returned or reworked feed plus one feed containing flush material, spillage or dust collector material if available) for review under Tasks 1108, 1109, 1110, 1111, 1113, 1115 and 1117 (once per year). Verify that feeds for further manufacturing that contain PM are ONLY used as ingredients in feeds intended to contain prohibited material.***

Go on-site:
Observe the receipt, storage, handling and use of feeds for further manufacturing that contain prohibited material and interview as necessary to verify that:

- written procedures for accepting returned and recalled feeds that contain prohibited material are followed *(product control actions required)*
- written procedures for the disposal of returned or recalled feed, spillage, flush and dust collector material containing prohibited material that are deemed not suitable for further manufacturing are followed
- written procedures for preventing the cross-contamination of ruminant feeds or ingredients by feeds for further manufacturing containing prohibited material (during receiving, storage, handling and use) are followed *(product control actions required)*
- feeds suitable for further manufacturing that contain prohibited material are used only in non-ruminant feeds that are intended to contain prohibited materials and labelled with the prescribed statement *(product control actions required)*
- when feeds suitable for further manufacturing that contain prohibited material are used in the manufacture of non-ruminant feeds that contain prohibited materials they are labelled with the prescribed statement *(product control actions required)*
- feeds suitable for further manufacturing that contain prohibited material are properly identified *(product control actions required)*

Commercial Feed Mill Verification Task Procedures

Inspection comments to include:

Activities Used to Assess Compliance
• information which clearly identifies whether the facility accepts returned feeds of unknown origin
• information which clearly identifies the specific written policies and procedures reviewed
  o name/reference code of the relevant policy or procedure(s)
  o effective date
• information which clearly identifies the specific production records/files reviewed
  o days for which production records/files were reviewed
  o name, code and lot number of feed to which the mixing formula/mixing sheets/labels correspond
  o effective date/date of manufacture
• information from staff interviews (include names and titles of staff interviewed) to determine whether:
  o there are any controls in place relative to the identification, receiving and storage of returned feeds, including recalled feeds, containing prohibited material; and
  o they are familiar with and adhere to the facility's policies and procedures related to returned feeds and the use and disposal of returned feeds, recalled feed, spillage, flush and dust collector material containing prohibited material
• on-site observations

Non-compliant Objective Evidence • identification of copies of documents obtained as evidence of a deviation • any deviations identified (e.g., from record reviews, review of written policies and procedures, staff interviews or on-site observations)/product control measures taken by inspector or facility • select the specific category of deviation observed from the list below (select all that apply): 1104.1. Evidence of cross-contamination of ruminant feeds with prohibited material 1104.2. Evidence of cross-contamination with prohibited material of non-ruminant feeds not identified as containing prohibited material 1104.3. Required written procedures related to *Health of Animals Regulations* not available 1104.4. Required written procedures related to *Health of Animals Regulations* inadequate 1104.5. Required records related to *Health of Animals Regulations* not available 1104.6. Required records related to *Health of Animals Regulations* inadequate 1104.7. Evidence that written procedures *related to Health of Animals Regulations* are not being followed 1104.8. Evidence that returned or recalled feed, spillage, flush and dust collector material containing prohibited material that are deemed not suitable for further manufacturing are disposed of in a manner that does not prevent exposure of ruminants to the feed

Commercial Feed Mill Verification Task Procedures

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section: 1 Feed Facility Inspection
Subsection: 1 Commercial Feed Mill
Task: 1105 Feeds for Further Manufacturing containing Medications
Task Frequency: Once per year for any facility manufacturing livestock feeds
Date Task Revised: 2013-04-01

Feeds Regulations Sections 14(b), 19(1)(j) and (k)

Commercial feed mill meets the regulatory requirements related to the use of feeds suitable for further manufacturing and disposal of feeds not suitable for further manufacturing that contain medications (includes but not exclusive to spillage, flush, dust collector material, returned feed and rework).

Go on-site:
Review procedures and records (if available). Interview and observe as necessary to verify that:

- returned feeds including recalled feeds, rework, spillage, flush material and dust collector material that contain medication(s) are received, handled, stored and used in a manner that prevents cross contamination of medicated feed or non-medicated feed with medicating ingredients and ensures that medications are not present at levels other than those authorized by the CMIB or veterinary prescriptions.
    - feeds for further manufacturing that contain medications are ONLY used as ingredients in feeds intended to contain the same medication *(product control actions required)*
    - cross-contamination of feed and feed ingredients by feeds for further manufacturing that contain medications is prevented during receiving, storage and use *(product control actions required)*
- returned or recalled feed, spillage, flush and dust collector material containing medicating ingredients that are deemed not suitable for further manufacturing are disposed of in a manner that prevents exposure of livestock to the feed

Note:

1. ***Select mixing formulae, mixing sheets, labels and production logs for equipment used in the manufacture of feeds containing the medicated feed for further manufacture as an ingredient (one feed including a lot of returned or reworked feed plus one feed containing flush material, spillage or dust collector material if available) for review under Tasks 1108, 1109, 1110, 1111 and 1114 (once per year). Verify that feeds for further manufacturing that contain medications are ONLY used as ingredients in feeds intended to contain the same medication***

Commercial Feed Mill Verification Task Procedures

Inspection comments to include:

Activities Used to Assess Compliance

- information which clearly identifies whether the facility accepts returned feeds of unknown origin
- information which clearly identifies the specific written policies and procedures reviewed, if available or an indication that there were no feeds for further manufacturing containing medications used in the facility
    - name/reference code of the relevant policy or procedure
    - effective date
- information which clearly identifies the specific production records/files reviewed, if available
    - days for which production records/files were reviewed
    - name, code and lot number of feed to which the mixing formula/mixing sheets/labels correspond
    - effective date/date of manufacture
- information from staff interviews (include names and titles of staff interviewed) to determine whether:
    - there are any controls in place relative to the identification, receiving and storage of returned feeds, including recalled feeds, containing medications; and
    - they are familiar with and adhere to the facility's policies and procedures related to returned feeds and the use and disposal of returned feeds, recalled feed, spillage, flush and dust collector material containing medications
- on-site observations

Non-compliant Objective Evidence

- identification of copies of documents obtained as evidence of a deviation
- any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility
- select the specific category of deviation observed from the list below (select all that apply):

1105.1. Evidence that feeds containing medicating ingredients are used in the manufacture of feeds not intended to contain the same medicating ingredients

1105.2. Documentary evidence that feeds or feed ingredients have been contaminated with medicating ingredients other than those identified on the labels for these feeds

1105.3. Evidence that returned or damaged feed, spillage and flush, containing medications that are deemed not suitable for further manufacturing are disposed of in a manner that does not prevent exposure of livestock to the feed

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section: 1 Feed Facility Inspection
Subsection: 1 Commercial Feed Mill
Task: 1106 Customer Formula Feeds
Task Frequency: Once per year for any facility manufacturing livestock feeds
Date Task Revised: 2013-04-01

Feeds Regulations Sections 2, 14, 15(3) and 15(4)
Health of Animals Regulations Section 168

Commercial feed mill meets the regulatory requirements related to the manufacturing of customer formula feeds.

File Review:
Obtain the required number of written orders for the manufacture of customer formula feeds based on the number of written orders for the manufacture of customer formula received by the facility annually as follows:

1-5 written orders for the manufacture of customer formula feed = 2
6-50 written orders for the manufacture of customer formula feed = 4
>50 written orders for the manufacture of customer formula feed = 8

The written orders for the manufacture of customer formula feeds selected for review must include a minimum of one for each feed type of customer formula feed manufactured or distributed by this facility (e.g., complete feed, supplement, macro premix, micro premix). The written orders for the manufacture of customer formula reviewed should reflect the range of species for which customer formula feeds are manufactured.

In addition, select mixing formulae, mixing sheets and labels corresponding to the written customer formulae requests reviewed in this task for review in Tasks 1108, 1109, 1110 and 1111 (once per year) based on the number of different customer formula feeds manufactured by the facility annually as follows:

1-5 customer formula feeds = 1 mixing formula/mixing sheet and 1 label
6-50 customer formula feeds= 2 mixing formulae/mixing sheets and 2 labels
>50 customer formula feeds = 3 mixing formulae/mixing sheets and 3 labels

Review the written orders for the manufacture of customer formula feeds to verify that:

- Customer formulae feeds manufactured in the facility conform to the definition of a customer formula feed:
  - A feed that is manufactured by a manufacturer for feeding to his own livestock
  - A feed that is manufactured by a manufacturer pursuant to a written order that is signed by a purchaser and that states the kind and amount of each single ingredient feed to be used in the manufacture of that feed
  - A feed that is manufactured by a manufacturer pursuant to a written order that is signed by a purchaser and that states the kind and amount of each single ingredient feed to be added to other mixed feeds that would be acceptable for registration, as a service to the purchaser
- Customer formula feeds are not used as ingredients in other customer formula feeds and are not sold to individuals other than the intended customer, e.g., the person who provided the signed customer formula
- Consultant formula feeds are not used as ingredients in customer formula feeds intended for resale
- Copies of signed customer formula, together with a list of each date on which the feed was manufactured are kept for a period of at least six months from the last date of manufacture of that feed

AND

- Signed customer formulae:
  - contain all information required to develop the mixing formula/mixing sheet and is at the facility before the feed is manufactured
  - list only single ingredient feeds found in Schedule IV or V of the *Feeds Regulations* (RDIMS 706637)
  - list only mixed feeds that are in compliance with the *Feeds Regulations* and not a customer formula feed
    - mixed feeds to which single ingredient feeds are to be added in accordance with the signed customer:
      - must be clearly identified using the unique name of the mixed feed

including the medication for medicated feeds)
- may be medicated only at the levels authorized by the CMIB or valid (compliant) veterinary prescription

- do not list prohibited material or feeds containing prohibited material as single ingredient feeds or as an ingredient in a mixed feed included in customer formula feeds destined for ruminants

Inspection comments to include:

Activities Used to Assess Compliance

- information which clearly identifies the specific written orders for the manufacture of customer formula feed reviewed or an indication that there are no customer formula feeds manufactured in the facility
  - name of the customer for whom the feed is manufactured
  - name and code of feed to which the written orders for the manufacture of customer formula correspond
  - effective date of the written order for the manufacture of customer formula feed (if available)
  - indicate the manner in which the feed meets the customer formula feed definition
- facility's policy relative to the retention time of required records
- information from staff interviews (include names and titles of staff interviewed) to determine whether there are any customer formula feeds manufactured in the facility and, if so, whether there are any controls related to the formulation, manufacture, labelling, storage and distribution of customer formula feeds
- on-site observations

Non-compliant Objective Evidence

- identification of copies of records (written orders for the manufacture of customer formula) obtained as evidence of a deviation
- any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility
- select the specific category of deviation observed from the list below (select all that apply):

1106.1. Required records related to Feeds Regulations (signed written orders for the manufacture of customer formula feed) not available
1106.2. Required records related to Feeds Regulations (signed written orders for the manufacture of customer formula feed) inadequate
1106.3. Use of prohibited material or feeds containing prohibited material as an ingredient in customer formula feed destined for ruminants
1106.4. Use of unapproved single ingredient feeds or mixed feeds not acceptable for registration in customer formula feed
1106.5. Use of unapproved medicating ingredients in customer formula feed
1106.6. Use of unapproved level/combination of medicating ingredients in customer formula feed
1106.7. Use of customer formula feed as an ingredient in customer formula feed intended for resale
1106.8. Use of consultant formula feed as an ingredient in customer formula feed intended for resale
1106.9. Sale of customer formula feed, including customer formula feeds manufactured for the facility, to an individual other than the customer for whom the feed was manufactured
1106.10. Required records related to Feeds Regulations (signed written orders for the manufacture of customer formula feed) are not maintained for the required time period

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section: 1 Feed Facility Inspection
Subsection: 1 Commercial Feed Mill
Task: 1107 Veterinary Prescription Feeds
Task Frequency: Once per year for any facility manufacturing livestock feeds
Date Task Revised: 2012-04-01

Feeds Regulations Sections 2, 5(2)(g), 15(1)(b) and 15(4)

Commercial feed mill meets the regulatory requirements related to the manufacturing of veterinary prescription feeds.

File Review:
Obtain the required number of veterinary prescriptions based on the number of veterinary prescriptions received by the facility annually as follows:

1-5 veterinary prescriptions received = 2
6-50 veterinary prescriptions received = 4
>50 veterinary prescriptions received = 8

The veterinary prescriptions selected for review must include a minimum of one for each type of veterinary prescription feed manufactured or distributed by this facility (e.g., complete feed, supplement, macro premix, micro premix). The veterinary prescriptions reviewed should reflect the range of species for which medicated feeds are manufactured.

In addition, select mixing formulae, mixing sheets and labels corresponding to the veterinary prescriptions reviewed in this task for review in Tasks 1108, 1109, 1110 and 1111 (once per year) based on the number of veterinary prescription feeds manufactured by the facility annually as follows:

1-5 veterinary prescription feeds = 1 mixing formula/mixing sheet and 1 label
6-50 veterinary prescription feeds = 2 mixing formulae/mixing sheets and 2 labels
>50 veterinary prescription feeds = 3 mixing formulae/mixing sheets and 3 labels

Review the selected veterinary prescriptions to verify that:

- The sale of such feed is authorized under section C.08.012 of the *Food and Drug Regulations*
- 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
- 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:
    - The date on which the prescription is written
    - The name and address of the person for whom the feed is to be manufactured and by whom it is intended to be used
    - The name and level of inclusion in the feed of the medicating ingredient prescribed by the veterinarian
    - The type and amount of feed to be manufactured
    - The number, kind, class and age or weight of the livestock intended to be fed the feed
    - Special manufacturing instructions including necessary mill clean up warnings, if any
    - Feeding instructions or directions for use of the feed including the period of time during which the feed is to be fed to the livestock and
    - Warning statements and caution statements where applicable

- A copy of the veterinary prescription is in the possession of the manufacturer of the feed **prior to the manufacture of the feed** except in the case of an emergency (product control actions required).
    - Where an emergency existed that precludes following normal procedures, the veterinary prescription must be in the possession of the manufacturer of the feed **prior to the delivery** of the feed along with a brief written description of the emergency which is signed by the veterinarian who issued the prescription.

- Copies of veterinary prescriptions (along with written description of emergency situation where applicable) and the formula for the manufacture of veterinary prescription feed, together with a list of each date on which the feed was manufactured are kept for a period of at least one year from the last date of manufacture of that feed.

Commercial Feed Mill Verification Task Procedures

Inspection comments to include:
Activities Used to Assess Compliance • information which clearly identifies the specific veterinary prescriptions and records reviewed or an indication that there are no veterinary prescription feeds manufactured in the facility o name of the customer for whom the feed is manufactured o name of the veterinarian who authorized the manufacture of the feed o name and code of feed to which the veterinary prescriptions and record(s) correspond o effective date of the veterinary prescription • facility's policy relative to the retention time of required records • information from staff interviews (include names and titles of staff interviewed) to determine whether there are any veterinary prescription feeds manufactured in the facility and, if so, whether there are any controls related to the formulation, manufacture, labelling, storage and distribution of veterinary prescription feeds • on-site observations
Non-compliant Objective Evidence • identification of copies of records (veterinary prescription) obtained as evidence of a deviation • any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility • select the specific category of deviation observed from the list below (select all that apply): 1107.1. Required records (signed veterinary prescription including written description of emergency situation where applicable) related to Feeds Regulations not available 1107.2. Required records (signed veterinary prescription including written description of emergency situation where applicable) related to Feeds Regulations inadequate 1107.3. Required records (signed veterinary prescription including written description of emergency situation where applicable) related to Feeds Regulations are not maintained for the required time period 1107.4. Sale of veterinary prescription feed to an individual other than the customer for whom the feed was manufactured

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section: 1 Feed Facility Inspection
Subsection: 1 Commercial Feed Mill
Task: 1108 Mixing Formulae and Mixing Sheets/Records for animal food **(feeds that contain animal products/by-products)**
Task Frequency: Per inspection for any facility manufacturing feed intended for feeding to ruminants, equines, porcines, chickens, turkeys, ducks, geese, ratites or game birds
Date Task Revised: 2013-04-01

***Health of Animals Regulations* Section 171(1)**

Commercial feed mill meets the regulatory requirements related to mixing formulae and mixing sheets/records.

File Review - Once per Year:

For facilities manufacturing feeds from rework, returns, spillage, flush or dust collector material etc, review the mixing formulae and mixing sheets/records selected in Task 1104 and/or Task 1105.

For facilities manufacturing customer formula and/or veterinary prescription feeds, review the mixing formulae and mixing sheets/records selected in Task 1106 and/or Task 1107.

Select the records required per inspection identified below.

In addition, select distribution records corresponding to the mixing formulae and mixing sheets/records assessed for this task for review in Task 1112 based on the number of feed formulae manufactured by the facility (in the last year) as follows:

1-10 feed formulae = 1 distribution record
11-150 feed formulae = 2 distribution records
> 150 feed formulae = 3 distribution records

File Review - Per Inspection*

Includes planned inspections under Program 37 and unplanned assessment of tasks associated with the identification of non-compliance when conducting other inspection activities

Obtain the required number of mixing formulae and mixing sheets/records for other animal food based on the number of feed formulae manufactured by the facility (in the last year) as follows:

1-10 feed formulae = 2 mixing formulae and corresponding mixing sheets/records
11-150 feed formulae = 4 mixing formulae and corresponding mixing sheets/records
> 150 feed formulae = 8 mixing formulae and corresponding mixing sheets/records

The mixing formulae and mixing sheets/records selected for review must include a minimum of one mixing formula and associated mixing sheet/record for each feed type manufactured by this facility (e.g., complete feed, supplement, macro premix, micro premix). Where the facility has more than one mixer, the records selected should include records for feeds made in each mixer. For facilities manufacturing ruminant and non-ruminant feeds, the mixing formulae and mixing sheets/records reviewed should include an equal number of each. For facilities manufacturing medicated feeds, the mixing formulae and mixing sheets/records reviewed should include both medicated feeds and non-medicated feeds.

Notes:

1. ***Mixing formulae and mixing sheets/records (for livestock feeds) assessed for Task 1108 must also be reviewed for Task 1109.***
2. ***Labels corresponding to mixing formulae and mixing sheets/records reviewed for Task 1108 must be reviewed for Task 1110.***

Commercial Feed Mill Verification Task Procedures

Review mixing formulae and mixing sheets/records to verify that they:

Include:

- The name and weight of each ingredient used in the manufacture of each lot of animal food (mixing formula only)
- The date of preparation of the animal food (mixing sheets/records only)
- The lot number **and** any other information used to identify each lot of animal food (mixing sheets/records only)
- Information that clearly identifies whether an animal food contains prohibited material
- The prescribed statement **OR** terms such as "prohibited material", "bovine MBM", or "mixed MBM", other words, abbreviations, symbols can be used in lieu of the prescribed statement to identify that a product contains prohibited material, providing that:
    - the means of identification is explained in the facility's written procedures;
    - the written procedures are understood and consistently applied by employees involved in the manufacture of feed; and
    - records reflect the means described and applied in the manufacture of feed containing prohibited material

AND

- Do not list prohibited material or feed containing prohibited material as an ingredient in ruminant feeds

Review mixing records to verify that the composition of the lot reflects the mixing formula.

- **For facilities whose mixing record is a mixing sheet**, verify that mixing sheets show that each batch of feed in a lot has been produced in accordance with the mixing formula
    - All ingredients identified on the mixing formula are included in the feed as indicated on the mixing sheet or ingredient substitutions are authorized by the person who develops mixing formulae
    - Mixing sheets indicate the name and actual weight of each ingredient used in the manufacture of each batch of feed in the lot

OR

- **For facilities who use a check-off system to identify the ingredients and amounts of some or all ingredients added to individual batches of feed** (i.e. do not have a mixing sheet which identifies the name and actual weight of each ingredient used in the manufacture of each batch of feed) written procedures are required.

- Verify that the required written procedures clearly describe the system (e.g., initials, check marks) used to determine whether the amount of each ingredient in a specific batch of feed is within the tolerances identified below:
    - Acceptable tolerance for medicating ingredients and/or feeds containing medicating ingredients does not exceed ± 5% of the intended amounts per batch (*product control actions required)*
    - Acceptable tolerance for non-medicating ingredients does not exceed ± 10% of the intended amounts per lot
    - Acceptable tolerance for actual batch sizes does not exceed ± 5% of the intended or theoretical batch sizes for medicated feeds (*product control action required)*
- Verify that mixing records show that each batch of feed in a lot has been produced in accordance with the mixing formula
    - All ingredients identified on the mixing formula are included in the feed as indicated on the mixing record or ingredient substitutions are authorized by the person who develops mixing formulae
    - Mixing records indicate the name of each ingredient used in the manufacture of each batch of feed in the lot and the verification of amount is recorded according to their written procedures

File Review:
Review records and interview as necessary to verify that:

- Mixing formulae and mixing sheets/records have been maintained for the minimum time required by the *Health of Animals Regulations* (ten years or at least since February 1, 2005).

Commercial Feed Mill Verification Task Procedures

Go on-site:
Observe the mixing process and interview as necessary to verify that:

- The ingredients added to one lot of feed are those indicated on the mixing sheet/record (mixing formula)
- The employee understands and applies written procedures used by the facility related to the identification of mixing formulae and mixing sheets/records for feeds containing prohibited material
- For facilities using a check-off system, required written procedures are being followed and that the feed is being made in accordance with the formula (i.e., all ingredients identified on the mixing formula are included in the feed as indicated on mixing records) and tolerances are respected *(product control actions required for medicated feeds)*

Inspection comments to include:

Activities Used to Assess Compliance

- provide information as to whether the mixing sheet identifies actual weights for all ingredients (mixing sheet) or a check-off system is used
- information which clearly identifies the specific written procedures reviewed
  - name/reference code of the relevant procedure(s)
  - effective date
- information which clearly identifies the specific mixing formulae and mixing sheets/mixing records reviewed and the location where they are stored
  - name, code and lot numbers (mixing sheets/records only) of feeds to which the mixing formulae and mixing sheets/mixing records correspond
  - effective date of manufacture
- facility's policy relative to the retention time of required records
- information from staff interviews (include name and title of staff interviewed) to determine what controls are in place when:
  - deviations related to the actual versus theoretical inclusion rate of medicating and non-medicating ingredients or actual versus theoretical batch weight are identified (in facilities using a check-off system only)
  - ingredient substitutions are made
  - completion of mixing sheets/records (identify how the records are completed and by whom)
- on-site observations

Non-compliant Objective Evidence

- identification of copies of records obtained as evidence of a deviation
- any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility
- select the specific category of deviation observed from the list below (select all that apply):

1108.1. Required records (mixing formulae and mixing sheets/records) related to *Health of Animals Regulations* not available
1108.2. Required records (mixing formulae and mixing sheets/records) related to *Health of Animals Regulations* inadequate
1108.3. Required records (mixing formulae and mixing sheets/records) related to *Health of Animals Regulations* are not maintained for the required time period
1108.4. Required written procedures related to *Health of Animals Regulations* not available
1108.5. Required written procedures related to *Health of Animals Regulations* inadequate
1108.6. Evidence that written procedures related to *Health of Animals Regulations* are not being followed
1108.7. Use of prohibited material or feed containing prohibited material as an ingredient in ruminant feeds
1108.8. Records (mixing formulae and mixing sheets/records) reviewed at facility do not have prescribed statement or alternative when PM is present
1108.9. Records (mixing formulae and mixing sheets/records) reviewed at facility have prescribed statement or alternative when PM is not present
1108.10. Mixing sheet/record does not accurately reflect mixing formula

Commercial Feed Mill Verification Task Procedures

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section: 1 Feed Facility Inspection
Subsection: 1 Commercial Feed Mill
Task: 1109 Mixing Formulae and Mixing Sheets
Task Frequency: Per inspection for any facility manufacturing livestock feeds
Date Task Revised: 2013-04-01

Feeds Regulations Sections 2, 14(a), 14(b), 15(1), 15(3), 16, 19(1)(j) and (k), 20 and 26(1)(g)

Commercial feed mill meets the regulatory requirements related to mixing formulae and mixing sheets.

File Review - Once per Year:

For facilities manufacturing feeds from rework, returns, spillage, flush or dust collector material etc, review the mixing formulae and mixing sheets selected in Task 1104 and/or Task 1105.

For facilities manufacturing customer formula and/or veterinary prescription feeds, review the mixing formulae and mixing sheets selected in Task 1106 and 1107.

In addition select the records required per inspection identified below.

File Review - Per Inspection*

Includes planned inspections under Program 37 and unplanned assessment of tasks associated with the identification of non-compliance when conducting other inspection activities

Obtain the required number of mixing formulae and mixing sheets for other feeds based on the number of feed formulae manufactured by the facility (in the last year) taking into consideration the records already selected in Task 1108 as follows:

1-10 feed formulae = 2 mixing formulae and corresponding mixing sheets
11-150 feed formulae = 4 mixing formulae and corresponding mixing sheets
>150 feed formulae = 8 mixing formulae and corresponding mixing sheets

The mixing formulae and mixing sheets selected for review must include a minimum of one mixing formula and associated mixing sheet for each feed type manufactured or distributed by this facility (e.g., complete feed, supplement, macro premix, micro premix). Where the facility has more than one mixer, the records selected should include records for feeds made in each mixer. For facilities manufacturing ruminant and non-ruminant feeds, the mixing formulae and mixing sheets reviewed should include an equal number of each. For facilities manufacturing medicated feeds, the mixing formulae and mixing sheets reviewed should include both medicated feeds and non-medicated feeds.

Notes:

1. ***Mixing formulae and mixing sheets (for animal food) assessed for Task 1109 must also be reviewed for Task 1108.***
2. ***Labels corresponding to mixing formulae and mixing sheets reviewed for Task 1109 must be reviewed for Task 1111.***

Review mixing formulae and mixing sheets to verify that they:

- List only non-medicating ingredients that are approved, authorized and/or registered as required
- List only medicating ingredients of a type or brand authorized by the CMIB or veterinary prescription (identified with a Drug Identification Number (DIN)) for the intended purpose and species *(product control actions required on any feed containing an unapproved medicating ingredient)*
- Provide medicating ingredients at levels authorized by the CMIB or a valid (compliant) veterinary prescription and guaranteed on the product label *(product control actions required on any feed containing an unapproved level of a medicating ingredient)*

Review mixing sheets (if available) to verify that the composition of the batch reflects the mixing formula.

- Mixing sheets show that each batch of medicated feed has been produced in accordance with the mixing formula
    - Acceptable tolerance for medicating ingredients and/or feeds containing medicating ingredients is ± 5% of the intended amounts per batch (*product control action required)*
    - Actual batch sizes are within ± 5% of the intended or theoretical batch sizes for medicated feeds (*product control action required)*

Commercial Feed Mill Verification Task Procedures

Go on-site:
Observe the mixing process for a batch of livestock feed and, if possible, a batch of customer formula feed as well as a batch of veterinary prescription feed and interview as necessary to verify that:

Livestock Feed

- The composition of the feed is as stipulated by the mixing formula
    - The ingredients (including medicating ingredients for medicated feeds) added to one batch of livestock feed are those indicated on the mixing formulae
    - The amounts of ingredients (including medicating ingredients for medicated feeds) added to one batch of livestock feed are those indicated on the mixing formulae
    - For medicated feeds, the medicating ingredients added to the batch of livestock feed has a Drug Identification Number (DIN) (product control actions required)
    - For medicated livestock feeds, the amounts of medicating ingredients and/or feeds containing medicating ingredients is at an approved level (pursuant to the CMIB) taking into consideration the acceptable tolerance of ± 5% of the intended amount *(product control actions required)*.
    - Mixing records provide evidence that actual batch sizes are within ± 5% of the intended or theoretical batch sizes (*product control actions required)*

Customer Formula Feed

- Review written orders and the list of dates customer formula feeds were manufactured and verify that the composition of the customer formula feed is as stipulated by the signed customer formula:
    - The ingredients added to one batch of customer formula feed are those indicated on the written order (and mixing record)
    - The amounts of each ingredient added to one batch of customer formula feed are those indicated on the written order (and mixing record) taking into consideration the acceptable tolerances of ± 5% of the intended amounts for medicating ingredients (as per medicated feed formulas) and/or feeds containing medicating ingredients (*product control action required)*
    - Mixing records provide evidence that actual batch sizes are within ± 5% of the intended or theoretical batch sizes for medicated feeds (*product control action required)*
    - Customer formula feeds are manufactured in the quantity specified on written customer orders for that specific formulation received **prior to the date of manufacture**, i.e., the customer formula feed is not floor-stocked

Veterinary Prescription Feed

- Review veterinary prescriptions and the list of dates veterinary prescription feeds were manufactured and verify that the composition of the feed is as stipulated by the veterinary prescription:
    - The medicating ingredients added to one batch of veterinary prescription feed are those indicated on the veterinary prescription (and mixing formulae) (product control actions required)
    - The amounts of medicating ingredient added to one batch of veterinary prescription feed are those indicated on the veterinary prescription (and mixing formulae) (product control actions required) taking into consideration the acceptable tolerances of ± 5% of the intended amounts for medicating ingredients and/or feeds containing medicating ingredients (as per veterinary prescriptions) (*product control action required)*
    - Mixing records provide evidence that actual batch sizes are within ± 5% of the intended or theoretical batch sizes (*product control action required)*
    - The medicating ingredients added to one batch of veterinary prescription feed has a Drug Identification Number (DIN) (product control actions required)
    - Veterinary prescription feeds are manufactured in the quantity specified on customer orders for that specific formulation received **prior to the date of manufacture**, i.e., the veterinary prescription feed is not floor-stocked

File Review:
Review records and interview as necessary to verify that:

- Mixing formulae have been maintained for the minimum time required by the *Feeds Regulations* as follows:
    - for Veterinary Prescription Feeds (one year from the last date of manufacture)
    - for Customer Formula Feeds (6 months from the last date of manufacture)
    - for Consultant Formula Feeds (6 months from the last date of manufacture)
    - for Feeds exempt from registration (6 months from the last date of manufacture)

Commercial Feed Mill Verification Task Procedures

Inspection comments to include:

Activities Used to Assess Compliance

- provide information as to whether the mixing sheet identifies actual weights for all ingredients (mixing sheet) or a check-off system is used
- **For facilities using mixing sheets that identify actual weights for all ingredients:**
  - summarize facility standards for acceptable deviations from theoretical weights (formulae) to actual weights for medicating ingredients
  - summarize facility standard for acceptable deviation from theoretical batch weights
- information which clearly identifies the specific mixing formulae and mixing sheets reviewed and the location where they are stored
  - name, code and lot numbers (mixing sheets only) of feed to which the mixing formulae and mixing sheets correspond
  - effective date/date of manufacture
- facility's policy relative to the retention time of required records
- information from staff interviews (include name and title of staff interviewed) to determine what controls are in place when:
  - deviations related to the actual versus theoretical inclusion rate of medicating ingredients or actual versus theoretical batch weight are identified
  - ingredient substitutions are made
  - completion of mixing sheets/records (identify how the records are completed and by whom)
- on-site observations

Non-compliant Objective Evidence

- identification of copies of records obtained as evidence of a deviation
- any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility
- select the specific category of deviation observed from the list below (select all that apply):

1109.1.	Mixing formula does not accurately reflect authorized levels of medicating ingredients and/or label guarantees for medicating ingredients
1109.2.	Mixing sheet does not accurately reflect authorized levels of medicating ingredients and/or label guarantees for medicating ingredients
1109.3.	*Code no longer applicable*
1109.4.	Mixing formulae/sheet does not accurately reflect customer formula request
1109.5.	Mixing formulae/sheet does not accurately reflect veterinary prescription order
1109.6.	Use of unapproved medicating ingredients
1109.7.	Use of unapproved source of medicating ingredients (no DIN)
1109.8.	Use of unapproved level/combination of medicating ingredients
1109.9.	Use of feeds containing medicating ingredients in feeds not intended to contain the same medicating ingredients
1109.10.	Use of unapproved ingredients other than medicating ingredients
1109.11.	Required records (mixing formulae) related to Feeds Regulations not available
1109.12.	Required records (mixing formulae) related to Feeds Regulations inadequate
1109.13.	Required records (mixing formulae) related to *Feeds Regulations* are not maintained for the required time period
1109.14.	The quantity of customer formula feed manufactured exceeds the amount specified on written orders for that specific formulation received prior to the date of manufacturing
1109.15.	The quantity of veterinary prescription feed manufactured exceeds the amount specified on customer orders for that specific formulation received prior to the date of manufacturing

Commercial Feed Mill Verification Task Procedures

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section: 1 Feed Facility Inspection
Subsection: 1 Commercial Feed Mill
Task: 1110 Labels for Feeds Manufactured in the Facility – Prohibited material
Task Frequency: Per inspection for any facility manufacturing feed intended for feeding to ruminants, equines, porcines, chickens, turkeys, ducks, geese, ratites or game birds
Date Task Revised: 2013-04-01

Health of Animals Regulations Sections 165(4), 167 and 169
Feeds Regulations Sections 19(1)(d) and (f), 26 (1)(i) and 28(b)

Commercial feed mill meets the regulatory requirements related to compliance of labels for feeds they manufacture.

File Review - Once per Year:

Review the labels (for animal food) selected in Tasks 1104, 1105, 1106 and 1107.

In addition select the records required per inspection identified below.

File Review - Per Inspection*

Includes only planned inspections under Program 37.

Review the labels (for animal food) selected in Tasks 1108 and 1109.

Note:

1. ***Labels (for livestock feeds) assessed for Task 1110 must also be reviewed for Task 1111.***
2. ***For unplanned assessment of tasks associated with the identification of non-compliance when conducting other inspection activities, use the appropriate labelling verification task(s) 2301, 2302 or 2303 to assess compliance of feed labels based on the number of formulae manufactured in the past year as follows:***

1-10 feed formulae = 2 labels
11-150 feed formulae = 4 labels
> 150 feed formulae = 8 labels

Review the labels and production records selected to confirm appropriate use of the prescribed statement. Verify that:

- where the facility handles prohibited material without procedures in place to prevent cross contamination (e.g., ingredient receiving), and does not manufacture or handle feeds for ruminants, all feeds must be labelled with the prescribed statement (*product control actions required*)
- where the mixing sheet/record provides evidence that the feed intentionally contains prohibited material, the label includes the prescribed statement (*product control actions required*)
- where the production records for at least one piece of cross-utilized equipment provide evidence that the feed contains prohibited material because no procedures were used to prevent contamination from a preceding batch that contained prohibited material, the label includes the prescribed statement (*product control actions required*)
- where the mixing sheet/record and/or production records provide evidence that the feed does not contain prohibited material, the label does not include the prescribed statement

All Type A violations require product control actions to be initiated

Go on-site:
Observe procedures for the use of labels, review records (if available) and interview as necessary to verify that:

- the correct feed label is affixed to packaged products as required *(product control actions required where the feed contains prohibited material)*
- the correct feed label accompanies bulk shipments *(product control actions required where the feed contains prohibited material)*

Commercial Feed Mill Verification Task Procedures

Inspection comments to include:

Activities Used to Assess Compliance

- information which clearly identifies the specific labels reviewed
  - name, code and lot number of feed to which the label corresponds
  - registration number, if applicable
- information which clearly identifies the specific production records reviewed (including the specific types of cross-utilized equipment to which they apply)
  - name of the specific records reviewed and the piece(s) of equipment to which it applies
  - dates for which production records were reviewed
- information from staff interviews (include names and titles of staff interviewed) to determine what controls are in place related to:
  - the development of labels that are in compliance with the regulations
  - the selection of correct label to attach to packaged feeds or accompany bulk feeds
  - ensuring that the prescribed statement is used appropriately
  - the regular review of labels as applicable and disposition of outdated and/or non-compliant labels
  - the completion of production records for cross-utilized equipment (identify how the records are completed and by whom)
- on-site observations **including** observation of procedures followed in relation to:
  - the completion of production records for each piece of cross-utilized equipment
  - the selection of labels to be affixed to packaged feed
  - the selection of labels to accompany shipments of feeds in bulk

Non-compliant Objective Evidence

- identification of copies of labels, mixing sheets/records and production records obtained as evidence of a deviation
- any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility
  - Type of label non-compliance (Type A or Type B)
  - Specifics of the label non-compliance
- select the specific category of deviation observed from the list below (select all that apply):

1110.1. Labels reviewed at facility do not have prescribed statement when PM is present (Type A Violation)
1110.2. Labels reviewed at facility have prescribed statement when PM is not present (Type B Violation)
1110.3. Corresponding feed labels are not provided with every bulk shipment of feed
1110.4. Corresponding feed labels are not affixed to packaged feeds
1110.5. *Code no longer applicable*

Commercial Feed Mill Verification Task Procedures

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section: 1 Feed Facility Inspection
Subsection: 1 Commercial Feed Mill
Task: 1111 Labels for Feeds Manufactured in the Facility
Task Frequency: Per inspection for any facility manufacturing livestock feeds
Date Task Revised: 2013-04-01

Feeds Regulations Sections 5, 14, 16, 19, 24 and 26-33
Health of Animals Regulations Section 169

Commercial feed mill meets the regulatory requirements related to compliance of labels for feeds they manufacture.

File Review - Once per Year:

Review the labels selected in Tasks 1104, 1105, 1106 and 1107.

In addition select the records required per inspection identified below.

File Review - Per Inspection*

Includes only planned inspections under Program 37

Review the labels (for animal food) selected in Tasks 1108 and 1109.

Note:

1. ***Labels (for livestock feeds) assessed for Task 1110 must also be reviewed for Task 1111.***
2. ***For unplanned assessment of tasks associated with the identification of non-compliance when conducting other inspection activities, use the appropriate labelling verification task(s) 2301, 2302 or 2303 to assess compliance of feed labels based on the number of formulae manufactured in the past year as follows:***

1-10 feed formulae = 2 labels
11-150 feed formulae = 4 labels
> 150 feed formulae = 8 labels

Record Review:

Review the labels selected and verify that:

- feed labels are in compliance with the *Feeds Regulations*
  - inspection staff must consider the requirements for floor-stock feds, registered feeds, as well as, specific requirements for consultant, customer formula and veterinarian prescription feeds. Regulatory Guidance (RG-1), Chapter 4 Labelling and Guarantees is a useful reference tool
  - a reader-friendly version of Table 4 is available (RDIMS 743797)

For livestock feeds containing medicating ingredients verify that:

- the label includes the required guarantee and claim for the medicating ingredients as well as any required warnings and cautions (*product control actions required*)

For livestock feeds intended for feeding to animals other than ruminants, equines, porcines, chickens, turkeys, ducks, geese, ratites or game birds review the labels, mixing sheets/records and production records selected to confirm appropriate use of the prescribed statement. Verify that:

- where the facility handles prohibited material without procedures in place to prevent cross contamination (e.g., ingredient receiving), and does not manufacture or handle feeds for ruminants, all feeds must be labelled with the prescribed statement (*product control actions required*)
- where the mixing sheet/record provides evidence that the feed intentionally contains prohibited material, the label includes the prescribed statement (*product control actions required*)
- where production records for at least one piece of cross-utilized equipment provide evidence that the feed contains prohibited material because no procedures were used to prevent contamination (from a preceding batch that contained prohibited material, the label includes the prescribed statement (*product control actions required*)
- where the mixing sheet/records and/or production record provide evidence that the livestock feed does not contain prohibited material, the label does not include the prescribed statement

All Type A violations (e.g. non approved drug, drug incompatibility, improper drug level, improper or missing claim, improper or missing warning statement, improper or missing caution, directions for use) require product control actions to be initiated.

Commercial Feed Mill Verification Task Procedures

Go on-site:
Observe procedures for the use of labels, review records (if available) and interview as necessary to verify that:

- the correct feed label is affixed to packaged products as required *(product control actions required where the feed contains prohibited material or medications)*
- the correct feed label accompanies bulk shipments *(product control actions required where the feed contains prohibited material or medications)*

Inspection comments to include:

Activities Used to Assess Compliance

- information which clearly identifies the specific labels reviewed
  - name, code and lot number (if associated with a specific batch) of feed to which the label corresponds
  - registration number, if applicable
- information which clearly identifies the specific production records reviewed (including the specific types of cross-utilized equipment to which they apply)
  - name of the specific records reviewed and the piece(s) of equipment to which it applies
  - dates for which production records were reviewed
- information from staff interviews (include names and titles of staff interviewed) to determine what controls are in place related to:
  - the development of labels that are in compliance with the regulations
  - the selection of correct label to attach to packaged feeds or accompany bulk feeds
  - ensuring that the prescribed statement is used appropriately
  - the regular review of labels and disposition of outdated and/or non-compliant labels
  - the completion of production records for cross-utilized equipment (identify how the records are completed and by whom)
- on-site observations **including** observation of procedures in relation to:
  - the completion of production records for each piece of cross-utilized equipment
  - the selection of labels to be affixed to packaged feed
  - the selection of labels to accompany shipments of feeds in bulk

Non-compliant Objective Evidence

- identification of copies of labels obtained as evidence of a deviation
- any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility
  - Type of label non-compliance (Type A or Type B)
  - Specifics of the label non-compliance
    - identify the specific Type A violations, e.g., non approved drug, drug incompatibility, improper drug level, improper or missing claim, improper or missing warning statement, improper or missing caution, directions for use, prescribed statement absent - PM feeds
    - identify the specific Type B violations, e.g., non approved single ingredient, outside Table 4 range of nutrients, Table 3 violation, Section 26 improper information on label, Section 32 Improper Name, Section 33 Units of measurement, prescribed statement present - non-PM feeds
- select the specific category of deviation observed from the list below (select all that apply):

1111.1. Labels reviewed have at least one Type A Violation
1111.2. Labels reviewed at the facility do not contain required warning or caution statements related to medicating ingredients
1111.3. Labels reviewed at facility do not have prescribed statement when PM is present
1111.4. Labels reviewed have at least one Type B Violation
1111.5. Labels reviewed at facility have prescribed statement when PM is not present
1111.6. *Code no longer applicable*
1111.7. Corresponding feed labels are not provided with every bulk shipment of feed
1111.8. Corresponding feed labels are not affixed to packaged feeds

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section: 1 Feed Facility Inspection
Subsection: 1 Commercial Feed Mill
Task: 1112 Distribution Records – ruminants, equines, porcines, chickens, turkeys, ducks, geese, ratites or game birds
Task Frequency: Per inspection for any facility manufacturing feed intended for feeding to ruminants, equines, porcines, chickens, turkeys, ducks, geese, ratites or game birds
Date Task Revised: 2013-04-01

Health of Animals Regulations Sections 168, 170(1) and 171

Commercial feed mill meets the regulatory requirements related to distribution records (documents that identify the name and address of the person to whom the feed was distributed or sold and provide a description of the feed and quantity purchased).

File Review - Once per Year:

Review the distribution records selected in Task 1108.

In addition select the records required per inspection identified below.

File Review - Per Inspection*

Includes planned inspections under Program 37 and unplanned assessment of tasks associated with the identification of non-compliance when conducting other inspection activities

Select distribution records based on the number of feed formulae manufactured by the facility (in the last year) as follows:

1-10 feed formulae = 1 distribution record
11-150 feed formulae = 2 distribution records
> 150 feed formulae = 3 distribution records

Note:

1. ***For planned inspections – select distribution records including records for cash sales.***
2. ***For unplanned assessment of tasks – select distribution records for the type of non-compliance identified (cash sales and/or invoices).***

Review the distribution records selected to verify that they include or are linked to other records that include:

- the name, the lot number and any other information used to identify the animal food
- the name and address of the person to whom the animal food is distributed or sold and a description of the animal food, including the name and quantity
- information as to whether or not the animal food contains any prohibited material

NOTE:

An address is a collection of information used for describing the location of a building, other structure or a plot of land, generally using political boundaries and street names as references, along with other identifiers such as street numbers. Some addresses also contain special codes to aid routing of mail and packages, such as a postal code

File Review:
Review records and interview as necessary to verify that:

Distribution records have been maintained for the minimum time required by the *Health of Animals Regulations* (ten years or at least since February 1, 2005).

Go on-site:
Observe the shipping of feeds and interview as necessary to verify:

- complete distribution records are available for bulk shipments *(product control actions required where the feed contains prohibited material)*
- complete feed distribution records are available for shipments of packaged feeds *(product control actions required where the feed contains prohibited material)*
- complete feed distribution records are available for cash sales of animal food *(product control actions required where the feed contains prohibited material)*
- distribution records accurately identify whether the feed is or contains any prohibited material *(product control actions required where the feed contains prohibited material and the prescribed statement or acceptable alternative is not on the records)*

Commercial Feed Mill Verification Task Procedures

Inspection comments to include:

Activities Used to Assess Compliance
• information which clearly identifies the specific distribution records reviewed
  o name, code and lot number of feed to which the distribution record(s) correspond
  o distribution record number
  o date of shipping/manufacture
  o name of the customer purchasing the feed
• facility's policy relative to the retention time of required records
• information from staff interviews (include names and titles of staff interviewed) to determine what the record-keeping requirements are for cash sales and where these and other distribution records are stored
• on-site observations

Non-compliant Objective Evidence • identification of copies of documents obtained as evidence of a deviation • any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility • select the specific category of deviation observed from the list below (select all that apply): 1112.1. Required records related to *Health of Animals Regulations* not available 1112.2. Required records related to *Health of Animals Regulations* inadequate 1112.3. Required records related to *Health of Animals Regulations* are not maintained for the required time period

Commercial Feed Mill Verification Task Procedures

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section:	1	Feed Facility Inspection
Subsection:	1	Commercial Feed Mill
Task:	1113	Cross contamination of manufacturing equipment with Prohibited Material
Task Frequency:		Per inspection for any facility manufacturing animal food and using prohibited material in the manufacture of feeds in the facility or accepting returned feeds of unknown origin
Date Task Revised:		2012-04-01

Health of Animals Regulations Sections 168, 170(1), 170(2), 170(3) and 171

Commercial feed mill meets the regulatory requirements related to preventing cross-contamination of ruminant feeds with prohibited material during the manufacture of feeds.

File Review - Obtain written procedures intended to prevent the contamination of ruminant feeds or feeds not identified as containing prohibited material with prohibited material where equipment is cross-utilized and verify that:

Written procedures indicate and records confirm that:

- Prohibited material is identified during receiving, storage, handling and manufacturing
- Precautions are taken to prevent cross-contamination of ruminant feeds with prohibited material during receiving, storage, handling and manufacturing including controls on the reuse of packaging for storage of ingredient and finished feed
- Controls are in place that prevent contamination of ruminant feed or feeds not identified as containing prohibited material with prohibited material for any cross-utilized equipment used for receiving, ingredient storage and handling, ingredient processing, mixing, pelleting, packaging, finished feed storage and handling including:
    - Equipment intended to prevent the unintended introduction of prohibited material is maintained
- For all facilities identified as high risk for TSEs (e.g., manufacture ruminant feeds and feeds containing prohibited material using the same equipment), written procedures identify that the flushing or physical cleanout procedures used to prevent cross-contamination must be validated for effectiveness. Validation procedures must meet the following standards:
    - **Be conducted for every piece of cross-utilized equipment used in the manufacture of feed where these additional cleanout procedures are used to prevent cross-contamination of ruminant feeds with prohibited material**.
    - Be conducted once initially and repeated when there are changes in equipment, manufacturing procedures or equipment clean out procedures.
    - Verify that there are no detectable levels of the selected tracer in the first 50 to 100 kg of the batch immediately following the feed for which the cleanout is being validated.
- Records are available documenting that the validation testing was performed according to the written procedures and confirming that the cleanout procedures were effective

***Note*:**

1. ***Use of soft packaging material such as totes and bags are assessed and subject to the standards prescribed under Task 1115.***

File Review – Once per Year:

For facilities manufacturing feeds from returned feeds, rework, spillage, flush or dust collection material etc. that may contain prohibited material, the production records selected in Task 1104 must be reviewed.

In addition select the records required for inspection.

File Review - Per Inspection*

Includes planned inspections under Program 37 and unplanned assessment of tasks associated with the identification of non-compliance when conducting other inspection activities

To verify that ruminant feeds or other feeds not identified as containing prohibited material have not been contaminated with prohibited material, select production records for each piece of cross-utilized equipment, since the date of the previous inspection, based on the number of feed formulae manufactured by the facility in the last year as follows:

1-10 feed formulae = 1 production record/piece of cross-utilized equipment
11-150 feed formulae = 2 production records/piece of cross-utilized equipment
>150 feed formulae = 3 production records/piece of cross-utilized equipment

Commercial Feed Mill Verification Task Procedures

Review production records to verify that:

- written procedures are being followed *(product control actions required)*
- records are complete and contain the following information:
  - name or other information used to identify each batch of feed in the order which they pass through the equipment *(product control actions required)*
  - amount of each feed
  - whether feed is or contains prohibited material
  - details of feed safety precautions taken between batches of feed (e.g., flushing, physical clean out) *(product control actions required)*
  - name of the piece of equipment
  - production date

File Review:
Review production records and interview as necessary to verify that:

Production records have been maintained for the minimum time required by the *Health of Animals Regulations* (ten years or at least since February 1, 2005).

Go on-site:
Observe and interview as necessary to verify:

- Written procedures are being followed for all equipment (receiving, ingredient storage and handling, ingredient processing, mixing, pelleting and extruding, packaging, bulk finished feed storage and handling. (*product control required*)

Inspection comments to include:

Activities Used to Assess Compliance

- information which clearly identifies the specific written procedures reviewed and the specific types of cross-utilized equipment to which they apply (e.g., receiving equipment, ingredient storage and handling equipment, ingredient processing equipment, mixing equipment, pelleting and extruding equipment, packaging equipment, bulk finished feed storage and handling equipment)including information which clearly identifies the specific written procedures for validation of cleanout procedures for every piece of cross-utilized equipment used in the manufacture of feed or an indication that the facility does not use prohibited material in the manufacture of feeds
  - name/reference code of the relevant procedure(s)
  - effective date
- information which clearly identifies the specific production records reviewed and the specific types of cross-utilized equipment to which they apply
  - name of the record reviewed and the piece(s) of equipment to which it applies
  - dates for which production records were reviewed
- facility's policy relative to the retention time of required records
- information from staff interviews (include names and titles of staff interviewed) to identify how the production records for cross-utilized equipment are completed and by whom
- on-site observations **including** observation of procedures followed and the completion of production records for each piece of cross-utilized equipment

Non-compliant Objective Evidence

- any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility
- identification of copies of documents obtained as evidence of a deviation
- select the specific category of deviation observed from the list below (select all that apply):

1113.1. Evidence of cross-contamination of ruminant feeds with prohibited material
1113.2. Evidence that non-ruminant feeds not identified as containing prohibited material have been contaminated with prohibited material
1113.3. Required written procedures related to *Health of Animals Regulations* not available
1113.4. Required written procedures related to *Health of Animals Regulations* inadequate
1113.5. Required records related to *Health of Animals Regulations* not available
1113.6. Required records related to *Health of Animals Regulations* inadequate
1113.7. Required records related to *Health of Animals Regulations* are not maintained for the required time period

Commercial Feed Mill Verification Task Procedures

1113.8.	Evidence that required written procedures related to *Health of Animals Regulations* are not being followed
1113.9.	Evidence that equipment cleanout procedures other than sequencing have not been proven effective (validated) for each cross-utilized piece of equipment using appropriate sampling methodology in a facility identified as high risk for TSEs

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section:	1	Feed Facility Inspection
Subsection:	1	Commercial Feed Mill
Task:	1114	Cross contamination of manufacturing equipment within the facility with Medications
Task Frequency:		Per inspection for any facility manufacturing medicated livestock feeds or accepting returned feeds of unknown origin
Date Task Revised:		2013-04-01

Feeds Regulations Sections 14(b), 19(1)(j) and (k)

Commercial feed mill meets the regulatory requirements related to preventing cross-contamination of livestock feeds with medications that could negatively impact on animal or human health during the manufacture of feeds.

File Review - Once per Year:

For facilities manufacturing feeds from rework, returns, spillage, flush or dust collector material etc, that may contain medications, review the production records selected in Task 1105.

In addition select the records required per inspection identified below.

File Review - Per Inspection*

Includes planned inspections under Program 37 and unplanned assessment of tasks associated with the identification of non-compliance when conducting other inspection activities

To verify that livestock feeds have not been cross-contaminated with medications (such that animal or human health will be negatively impacted), select production records for each piece of cross-utilized equipment, since the date of the previous inspection, based on the number of feed formulae manufactured by the facility in the last year as follows:

1-10 feed formulae = 1 production record/piece of cross-utilized equipment
11-150 feed formulae = 2 production records/piece of cross-utilized equipment
>150 feed formulae = 3 production records/piece of cross-utilized equipment

Go on-site:
Review written procedures and records (if available). Interview and observe as necessary to verify that:

- Controls are in place that prevent the carryover of drugs that may negatively impact on animal or human health required for all cross-utilized equipment used for receiving, ingredient storage and handling, ingredient processing, medication storage and handling (including scoops, pails, tubs, etc.), mixing, pelleting, packaging, finished feed storage and handling and the reuse of packaging for storage of ingredient and finished feed including:
    - Prevention of carryover of drugs that have a withdrawal requirement at any use level in feeds for market-ready animals
    - Prevention of the carryover of drugs not approved for a particular species or class of animals in feeds intended for their consumption
    - Prevention of the carryover of drugs from returned feeds for facilities not manufacturing medicated feeds

Verify using the current version of the Medication Sequencing Guide published by the CFIA. Companies wishing to use other sequences should consult the policy entitled "Validation Studies for Modification of Sequencing Guidelines Verification Task 1114" for details of the scientific support required in their validation studies.

Note: If the above requirements are not being met, product control actions are required.

Commercial Feed Mill Verification Task Procedures

The facility's sequencing and flushing procedures for medicating ingredients include:

- A written or verbal indication that when they cannot sequence after medicated feed, the facility flushes or physically cleans out equipment prior to manufacturing the next feed. This flush may follow the feed manufactured and be included as part of the batch it was used to flush, be reworked (e.g. added to batch intended to contain the same medication) or be disposed of in an appropriate manner.
- A written or verbal indication that the medication level and dilution rates of feeds are taken into consideration when developing sequencing procedures (e.g., facility appropriately addresses the risks related to manufacturing different types of feeds (micro-premixes, macro-premixes, supplements and complete feeds) using the same equipment.
- A written or verbal indication that the flushing or physical cleanout procedures were validated for effectiveness
    - For all facilities identified as low risk for TSEs (e.g., do not manufacture ruminant feeds and feeds containing prohibited material using the same equipment), validation of equipment cleanout procedures at the exit of each processing stream (e.g., processing stream 1 = mixer ➔pellet mill ➔ bagger, processing stream 2 = mixer ➔ bagger, processing stream 3 = mixer ➔ loadout, processing stream 4 = mixer ➔ pellet mill ➔loadout) is necessary. In addition, ingredient receiving equipment should be validated as close to the discharge as possible where medicated feeds or medicated feed ingredients (including returned feeds) are received in bulk at the facility.

    - Validation to be conducted once initially and repeated when there are changes in equipment, manufacturing procedures or equipment clean out procedures by verifying that the level of medication carryover does not exceed the residue method limit of quantification (rLoQ) or action limit (whichever is higher) for drug residues as indicated in Appendix IA of the I-3-93 in the batch immediately following the feed for which the cleanout is being validated.

    - Validation of the equipment cleanout procedures does not have to be completed for each medication used in a facility. Where possible, a "higher risk" scenario typical for the facility should be evaluated to ensure that drug carryover is adequately controlled. Additionally, consideration needs to be given to the detection level of medications used in the facility or the use of tracers.

    - Facilities identified as low risk for TSEs may choose to use the validation procedures identified in Task 1113 in lieu of the validation procedure identified above.

- Details of how medicated feed is identified during receiving, storage, handling and manufacturing and precautions taken to prevent cross-contamination.
- Equipment is maintained such that the unintended introduction of medicated feed is prevented.

***Note*:**

1. ***Use of soft packaging material such as totes and bags are assessed and subject to the standards prescribed under Task 1115.***

Commercial Feed Mill Verification Task Procedures

Inspection comments to include:
Activities Used to Assess Compliance • information which clearly identifies the specific written procedures reviewed and the specific types of cross-utilized equipment to which they apply (e.g., receiving equipment, ingredient storage and handling equipment, ingredient processing equipment, mixing equipment, pelleting and extruding equipment, packaging equipment, bulk finished feed storage and handling equipment) including information which clearly identifies the specific written procedures for validation of cleanout procedures or an indication that the facility does not use medications in the manufacture of feeds o name/reference code of the relevant procedure(s) o effective date • information which clearly identifies the specific production records reviewed and the specific types of cross-utilized equipment to which they apply o name of the record reviewed and the piece(s) of equipment to which it applies o dates for which production records were reviewed • facility's policy relative to the retention time of required records • information from staff interviews (include names and titles of staff interviewed) to identify how the production records for cross-utilized equipment are completed and by whom • on-site observations **including** observation of procedures followed and the completion of production records for each piece of cross-utilized equipment
Non-compliant Objective Evidence • any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility • identification of copies of documents obtained as evidence of a deviation • select the specific category of deviation observed from the list below (select all that apply): 1114.1. Documentary evidence that feeds have been contaminated with medicating ingredients other than those identified on the labels for these feeds. 1114.2. Insufficient controls in place to effectively manage cross-contamination of feeds with medicating ingredients other than those identified on the labels for these feeds.

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section: 1 Feed Facility Inspection
Subsection: 1 Commercial Feed Mill
Task: 1115 Reuse of Packaging – Prohibited Material
Task Frequency: Per inspection for any facility manufacturing animal food
Date Task Revised: 2012-04-01

Health of Animals Regulations Sections 168, 170(1), 170(2), 170(3) and 171(1)

Commercial feed mill meets the regulatory requirements to prevent the contamination of ruminant feeds with prohibited material during packaging.

File Review:
Obtain written procedures that prevent the contamination of packaging for ruminant feeds with prohibited material. Review written procedures to verify that:

- a program is described which prevents the reuse of packaging of unknown origin (e.g., no label available for the feed) or stipulates no reuse of packaging
- a program is described which permits reuse of packaging that contained prohibited material only for packing non-ruminant feeds that contain prohibited material

File Review - Once per Year:

For facilities manufacturing feeds from rework, returns, spillage, flush or dust collector material etc, that may contain prohibited material, review the production records selected in Task 1104.

In addition select the records required per inspection identified below.

File Review - Per Inspection*

Includes planned inspections under Program 37 and unplanned assessment of tasks associated with the identification of non-compliance when conducting other inspection activities

Select the required number of production records based on the number of feed formulae manufactured by the facility (in the last year) as follows:

1-10 feed formulae = 1 production record
11-150 feed formulae = 2 production records
>150 feed formulae = 3 production records

Review production records to verify that they include:

- the origin of the used packaging *(product control actions required)*
- where the packaging had previously contained prohibited material, it has only been used for packaging non-ruminant feeds that contain prohibited material *(product control actions required)*
- the name or other information used to identify previous batch of feed packed in used packaging *(product control actions required)*
- the amount of each feed packed in used packaging

File Review:
Review records and interview as necessary to verify that:

Records have been maintained for the minimum time required by the *Health of Animals Regulations* (ten years or at least since February 1, 2005).

Go on-site:
Observe and interview as necessary to verify:

- written procedures are being followed *(product control actions required)*
- records are complete and contain the following information:
  - verification of the origin of the used packaging *(product control actions required)*
  - verification of whether the previous feed contained prohibited material *(product control actions required)*
  - name or other information used to identify each batch of feed packed in used packaging *(product control actions required)*
  - amount of each feed packed in used packaging
  - packaging date

Commercial Feed Mill Verification Task Procedures

Inspection comments to include:

Activities Used to Assess Compliance
• information which clearly identifies the specific written procedures reviewed or an indication that packaging is not reused in this facility
  o name/reference code of the relevant procedure(s)
  o effective date
• information which clearly identifies the specific production records reviewed
  o name of record reviewed
  o dates for which production records were reviewed
• facility's policy relative to the retention time of required records
• information from staff interviews (include names and titles of staff interviewed) to determine the disposition of used packaging
• on-site observations **including** identification of the locations where used packaging is stored in the facility

Non-compliant Objective Evidence • identification of copies of documents obtained as evidence of a deviation • any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility • select the specific category of deviation observed from the list below (select all that apply): 1115.1. Reuse of packaging materials of unknown origin 1115.2. Evidence of cross-contamination with prohibited material 1115.3. Required written procedures related to *Health of Animals Regulations* not available 1115.4. Required written procedures related to *Health of Animals Regulations* inadequate 1115.5. Required records related to *Health of Animals Regulations* not available 1115.6. Required records related to *Health of Animals Regulations* inadequate 1115.7. Required records related to *Health of Animals Regulations* are not maintained for the required time period

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section: 1 Feed Facility Inspection
Subsection: 1 Commercial Feed Mill
Task: 1116 Reuse of Packaging – Medications/Chemical Contaminants
Task Frequency: Once per year for any facility manufacturing livestock feeds
Date Task Revised: 2012-04-01

Feeds Regulations Sections 14(b), 19 (1)(j) and (k)

Commercial feed mill meets the regulatory requirements to prevent the contamination of livestock feeds with medications or other chemical contaminants that could negatively impact animal or human health when reusing packaging for feeds.

Go on-site:
Review written procedures and records (if available). Interview and observe as necessary to verify that:

- the facility provides a verbal or written indication that they have appropriate controls in place to ensure that cross-contamination of feed with medications that could negatively impact on animal or human health include:
  - procedures that prevent the reuse of packaging of unknown origin (e.g., no label available for the feed)
  - packaging that previously contained a medicated feed is used only for feeds containing the same medication
  - if packaging that previously contained a medicated feed is used to package feeds not containing the same medication, an effective cleanout procedure was used
  - packaging that previously contained pesticides, fertilizers or other chemical hazards are not used to repackage feeds

Product control actions are required for any feeds in the facility that are contaminated with medications or other chemical contaminants resulting from the failure to follow appropriate procedures.

Inspection comments to include:

Activities Used to Assess Compliance

- information which clearly identifies the specific written procedures reviewed, if available
  - name/reference code of the relevant procedure(s)
  - effective date
- information which clearly identifies the specific production records reviewed, if applicable
  - name of the record reviewed
  - dates for which production records were reviewed
- information from staff interviews (include names and titles of staff interviewed) to determine the disposition of used packaging
- on-site observations including identification of the locations where used packaging is stored in the facility

Non-compliant Objective Evidence

- identification of copies of documents obtained as evidence of a deviation
- any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility
- select the specific category of deviation observed from the list below (select all that apply):

1116.1.	Documentary evidence that feeds have been contaminated with medicating ingredients or other chemical hazards as a result of the re-use of packaging.
1116.2.	Insufficient controls in place to prevent the cross-contamination of feeds with medicating ingredients or other chemical hazards from used packaging.

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section: 1 Feed Facility Inspection
Subsection: 1 Commercial Feed Mill
Task: 1117 Conveyances Distributing Feed Manufactured in the Facility – Prohibited Material
Task Frequency: Per inspection for any facility manufacturing animal food and using company-owned conveyances to distribute feed
Date Task Revised: 2013-04-01

Health of Animals Regulations Sections 168, 170(1), 170(2) 170(3) and 171

Commercial feed mill meets the regulatory requirements related to preventing cross-contamination of ruminant feeds with prohibited material during the distribution of bulk feed.

File Review - Obtain written procedures for conveyances distributing feed containing prohibited material and verify that:

- there is a program available that fully describes the precautions taken to prevent cross-contamination of ruminant feeds with prohibited material and feeds containing prohibited material during transportation of bulk feed *(product control actions required).*
- there is a program available that fully describes the controls in place to prevent contamination of ruminant feed with prohibited material in any cross-utilized equipment (including compartment and on-board transfer equipment) used during transportation and loading/unloading of bulk feed. *(product control actions required).*
- such controls must include procedures to ensure that:
  - the material previously transported by the conveyance has not resulted in contamination of feed
  - the correct feed is loaded on truck *(product control actions required)*
  - product overflow is prevented in multi-compartment trucks when a truck is loaded *(product control actions required)*
- there is a regular maintenance program available for equipment that prevents the unintended introduction of prohibited material.

OR

- there is a program available that fully describes how prohibited material and bulk feeds containing prohibited material will not be transported on the same conveyances as ruminant feeds *(product control actions required).*

File Review - Once per Year:

For facilities manufacturing feeds from rework, returns, spillage, flush or dust collector material etc, that may contain prohibited material, review the production records selected in Task 1104.

In addition select the records required per inspection identified below.

File Review - Per Inspection*

Includes planned inspections under Program 37 and unplanned assessment of tasks associated with the identification of non-compliance when conducting other inspection activities

To verify that ruminant feed or other feeds not identified as containing prohibited material have not been contaminated with prohibited material, select production records for cross-utilized and dedicated conveyances, since the date of the previous inspection, based on the number of conveyances used by the facility to deliver feed as follows:

1-2 conveyances = 1 production records
3-5 conveyances = 2 production records
>5 conveyances = 3 production records

Note:

1. ***Where the company operates different types of conveyances (e.g., trucks with delivery auger, trucks with pneumatic unloading (blower trucks)), the records selected should reflect the range of company-owned conveyances used.***

Commercial Feed Mill Verification Task Procedures

Review records to verify that:

- written procedures are being followed *(product control actions required)*
- records are complete and contain the following information:
  - name or other information used to identify each batch of bulk feed in the order which they pass through the conveyance (truck/compartment & or loading/unloading equipment) *(product control actions required)*
  - amount of each bulk feed
  - whether bulk feed is or contains prohibited material
  - details of feed safety precautions taken between batches of bulk feed (e.g., flushing, physical clean out) *(product control actions required)*
  - name of the piece of equipment
  - transportation date

File Review:
Review records and interview as necessary to verify that:

Records have been maintained for the minimum time required by the *Health of Animals Regulations* (ten years or at least since February 1, 2005).

Go on-site:
Observe and interview as necessary to verify:

- Written procedures are being followed for all conveyances transporting bulk feeds. *(product control actions required)*

Inspection comments to include:

Activities Used to Assess Compliance

- information which clearly identifies whether the facility uses company-owned conveyances to distribute bulk feed
- information which clearly identifies the specific written procedures reviewed and the specific types of cross-utilized conveyances to which they apply
  - name/reference code of the relevant procedure(s)
  - effective date
- information which clearly identifies the specific production records reviewed and the specific types of cross-utilized conveyances to which they apply
  - name of the record review and the conveyance to which it corresponds
  - dates for which production records were reviewed
- facility's policy relative to the retention time of required records
- information from staff interviews (include names and titles of staff interviewed) to determine the procedures used to prevent cross-contamination during loading, unloading and transport including the amount flush material used if any and its disposition
- on-site observations

Non-compliant Objective Evidence

- any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility
- identification of copies of documents obtained as evidence of a deviation
- select the specific category of deviation observed from the list below (select all that apply):

1117.1.	Evidence of cross-contamination of ruminant feeds with prohibited material
1117.2.	Required written procedures *related to Health of Animals Regulations* not available
1117.3.	Required written procedures *related to Health of Animals Regulations* inadequate
1117.4.	Required records related to *Health of Animals Regulations* not available
1117.5.	Required records related to *Health of Animals Regulations* inadequate
1117.6.	Required records related to *Health of Animals Regulations* are not maintained for the required time period
1117.7.	Evidence that required written procedures related to *Health of Animals Regulations* are not being followed

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section: 1 Feed Facility Inspection
Subsection: 1 Commercial Feed Mill
Task: 1118 Uniformity of Mix
Task Frequency: Once per year for any facility manufacturing livestock feeds
Date Task Revised: 2013-04-01

Feeds Regulations Section 20

Feeds manufactured in the commercial feed mill meet the regulatory requirements for uniformity of mix. Every feed shall have the uniformity of mix, the chemical composition and the physical composition necessary for it to be efficacious for the purpose for which it is manufactured, sold or represented.

Go on-site:
Review written procedures and records (if available). Interview as necessary to verify that:

- The facility can demonstrate that all feed manufactured in the facility is of a uniform mix
  - If the facility uses mixer performance testing to demonstrate the capability of equipment to achieve the desired outcome, **testing is conducted at least once every three years**, mixing time and fill should reflect standard operating procedures and test results should meet the critical limits for uniformity with coefficients of variation (CV) as follows:
    - 5% for dilute drug premixes
    - 10% for micro or macro premixes and supplements
    - 15% for complete feeds and total mixed rations
  - If the facility uses other methodologies to achieve the desired outcome, this should be brought to the attention of Feed Program Staff for a decision on acceptability and next steps. As additional acceptable procedures are identified, these will be communicated to inspection staff and industry on a National basis.

Note:

1. ***Mixer performance testing or other methodologies used to demonstrate uniformity of mix must be conducted for all mixing equipment used by the facility.***

Inspection comments to include:

Activities Used to Assess Compliance

- information which clearly identifies the specific written procedures reviewed if available
  - name/reference code of the relevant procedure(s) if available
  - effective date
- date of last mixer performance test and the CV determined (for each mixer)
- information which clearly identifies the specific records reviewed
  - name of record reviewed and the mixer to which it corresponds
  - dates for which records were reviewed
- information from staff interviews (include names and titles of staff interviewed) to determine whether the written procedures relative to sequence of addition of ingredients to the mixer, mixer fill and mixing time are followed
- on-site observations

Non-compliant Objective Evidence

- identification of copies of documents obtained as evidence of a deviation
- any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility
- select the specific category of deviation observed from the list below (select all that apply):

1118.1. Insufficient evidence to demonstrate uniformity of mix for the feed types manufactured.
1118.2. Documentary evidence demonstrating a lack of uniformity of mix for the feed types manufactured.

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section: 1 Feed Facility Inspection
Subsection: 1 Commercial Feed Mill
Task: 1119 Chemical Composition/Accurate Statement of Analysis (Scales)
Task Frequency: Once per year for any facility manufacturing livestock feeds
Date Task Revised: 2013-04-01

Feeds Regulations Sections 20 and 26(1)(g)

Feeds manufactured in the commercial feed mill meet the regulatory requirements for chemical composition and an accurate statement of analysis. Every feed has the uniformity of mix, the chemical composition and the physical composition necessary for it to be efficacious for the purpose for which it is manufactured, sold or represented. Feed labels contain an accurate statement of guaranteed analysis.

Go on-site:
Review written procedures and records (if available). Interview and observe as necessary to verify that:

- The facility can demonstrate that feed manufactured in the facility has an acceptable chemical composition/meets label guarantees
  - Facility ensures that equipment has a suitable capacity and graduation for the feeds manufactured (review mixing sheets)
  - **Facility tests scales and metering devices at least once every year** to achieve the desired outcome in terms of chemical composition/meeting label guarantees **OR** the facility tests a statistical sample of feed manufactured in the facility to achieve a 95% confidence interval that guarantees for medication are met
  - If the facility uses other methodologies to achieve the desired outcome, this should be brought to the attention of Feed Program Staff for a decision on acceptability and next steps. As additional acceptable procedures are identified, these will be communicated to inspection staff and industry on a National basis.

Inspection comments to include:

Activities Used to Assess Compliance

- information which clearly identifies the specific written procedures reviewed, if available
  - name/reference code of the relevant procedure(s)
  - effective date
- date of last scale and metering device test and the test results
- information which clearly identifies the specific records reviewed
  - name of the record and the identity of the scale or metering device to which it corresponds
  - dates for which records were reviewed
- information from staff interviews (include names and titles of staff interviewed) to determine whether the scale and metering device testing is conducted by facility staff or a third-party provider and the frequency of testing for each scale and metering device
- on-site observations

Non-compliant Objective Evidence

- identification of copies of documents obtained as evidence of a deviation
- any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility
- select the specific category of deviation observed from the list below (select all that apply):

1119.1. Insufficient evidence to demonstrate the chemical composition of the feed supports label guarantees
1119.2. Scales are used to weigh amounts in excess of their rated capacity
1119.3. Scales and metering devices are used to weigh/meter amounts of ingredients that are more precise than the graduations of the equipment permits

Commercial Feed Mill Verification Task Procedures

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section: 1 Feed Facility Inspection
Subsection: 1 Commercial Feed Mill
Task: 1120 Water Treatment Chemicals, Pest Control Products and Other Chemicals
Task Frequency: Once per year for any facility manufacturing livestock feeds
Date Task Revised: 2012-04-01

Feeds Regulations Sections 14(a), 19(1) (j) and (k)

Feeds manufactured in the commercial feed mill meet the regulatory requirements for freedom from chemical contaminants that can negatively impact on animal or human health.

Go on-site:
Review written procedures and records (if available). Interview and observe as necessary to verify that:

- treatment compounds that are used in water **that comes into direct contact with feeds** (e.g., conditioning, pelleting, steam flaking, etc.) are approved (e.g., listed on the *Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products – Category Water Treatment Compound, Sub-Category: May come in contact with food products(w1)* http://active.inspection.gc.ca/scripts/fssa/reference/refresults.asp?lang=e&cmd=4&cat=24&subcat=103&pnb=2 , are listed in Schedule IV, Part I or have a valid feed registration number).
- pesticides and other chemicals are stored and used in a manner which prevents the cross-contamination of feed and feed ingredients

Inspection comments to include:

Activities Used to Assess Compliance

- information which clearly identifies the specific written procedures reviewed, if available
  - name/reference code of the relevant procedure(s)
  - effective date
- information which clearly identifies the specific records reviewed, if available
  - name of the record reviewed
  - name of the water treatment compound(s) used
  - dates for which records were reviewed
- information from staff interviews (include names and titles of staff interviewed) to determine whether water treatment compounds are used (which ones and how) and confirm how pesticides and other chemicals are stored and used in the facility
- on-site observations

Non-compliant Objective Evidence

- identification of copies of documents obtained as evidence of a deviation
- any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility
- select the specific category of deviation observed from the list below (select all that apply):

1120.1. Use of unapproved ingredients (e.g., water treatment compounds)
1120.2. Insufficient controls in place to prevent contamination of feeds with pesticides or other chemicals due to improper storage
1120.3. Insufficient controls in place to prevent contamination of feeds with pesticides or other chemicals due to misuse

Inspection Observations – Rough Notes

Commercial Feed Mill Verification Task Procedures

Section: 1 Feed Facility Inspection
Subsection: 1 Commercial Feed Mill
Task: 1121 Recall Procedures – *Health of Animals Regulations*
Task Frequency: Once a year for any facility manufacturing animal food intended for feeding to ruminants, equines, porcines, chickens, turkeys, ducks, geese, ratites or game birds
Date Task Revised: 2013-04-01

Health of Animals Regulations Sections 91.3, 170 (3), 170.1, 171(1) and 171(2)

Commercial feed mill meets the regulatory requirements related to recall procedures.

File Review:
Obtain written feed recall procedures. Review written procedures to verify that they include:

- the requirement to establish and maintain records that provide details of situations where ruminant feeds were contaminated with prohibited material or where ruminants were exposed to non-ruminant feeds containing prohibited material as a result of manufacturing or distribution errors
  - these contamination events may be identified either directly by the facility or indirectly through a customer complaint or information received from a supplier
- details of the food safety/animal health assessment process to be used to identify whether a recall is required
  - the criteria for a recall to be implemented
  - the criteria for contacting the CFIA and/or other competent authority
- method to identify, locate and control recalled product
  - a system of records and procedures that ensure that lots of feed ingredients can be linked to their supplier
  - details of the amount of feed produced, in inventory and distributed; name and lot identification of recalled feed; reason for the recall; area of distribution of the affected feed – local, national, international
  - handling procedures for affected feed
  - a requirement to investigate other products that may be affected and that should be included in the recall
- procedures to verify and document the effectiveness of recalls conducted, e.g., capability to rapidly identify and control a lot of potentially affected product and reconcile the amount of product produced, in inventory and in distribution, e.g.:
  - Notification efficiency 100% of customers notified
  - Traceability efficiency 100% of product traced
  - Identification of target recovery efficiency % of product recovered, time based
- details of the records to be maintained in the event that a feed is recalled

File Review:
Obtain records of recalls, including mock recalls, conducted since the last inspection, if any. Review records and interview as necessary to verify that:

- If a recall or a mock recall was conducted since the last inspection, the following actions were taken:
  - manufacturing errors/complaints were assessed to determine whether the recall was required using food safety/animal health assessment process identified in their written recall procedures
  - written recall procedures were followed and were effective
  - any deficiencies identified in the written recall procedures were corrected
- Records of recalls have been maintained for the minimum time required (two years) by the *Health of Animals Regulations*.

If a recall or a mock recall has not been conducted in the last year, verify the availability of records required to conduct a recall and effectiveness of the facility's recall procedures as follows:

Select a lot of feed manufactured five (5) working days prior to the date of the inspection and request that the facility gather the records necessary to identify the names and addresses, and, if available phone numbers of all customers receiving that feed and the amount of that feed that each customer received. A feed that has between three (3) and twenty (20) customers should be selected for assessment.

- Confirm that the facility records support the rapid (within one working day) identification of:
  - the names and contact information of ALL customers receiving the selected lot of feed
  - the amount of the selected lot of feed shipped to EACH customer
  - the amount remaining in inventory if any
- Determine the possible notification and traceability efficiencies (should be 100% for both) by comparing initial lot size with the amount of product traced

Commercial Feed Mill Verification Task Procedures

Inspection comments to include:

Activities Used to Assess Compliance
• information which clearly identifies the specific written procedures reviewed
  o name/reference code of the relevant procedure(s)
  o effective date
• information which clearly identifies the specific recall, mock recall, or selected lot records reviewed
  o names of the records reviewed
  o dates for which recall or mock recall records were reviewed
• information from staff interviews (include names and titles of staff interviewed)

Non-compliant Objective Evidence • any deviations identified (e.g., from record reviews, staff interviews or on-site observations)/product control measures taken by inspector or facility • identification of copies of documents obtained as evidence of a deviation • select the specific category of deviation observed from the list below (select all that apply): **For all facilities assessed** 1121.1. Written procedures for recall not available 1121.2. Written procedures for recall inadequate 1121.3. Sufficient records were not available to support an effective recall 1121.4. *Code no longer applicable* **Where a recall including a mock recall was conducted:** 1121.5. Required records related to *Health of Animals Regulations* are not maintained for the required time period 1121.6. Evidence that recall procedures were not followed 1121.7. Evidence that recall procedures were not effective 1121.8. Evidence that deficiencies identified in recall or mock recall were not corrected

Commercial Feed Mill Verification Task Procedures

Inspection Observations – Rough Notes