Association Business Meeting Agenda

2024 AAFCO Midyear Meeting
Chattanooga Convention Center
Chattanooga, Tennessee
Tuesday, January 23, 2024
8:30–9:45 am EST

Agenda

1. **Meeting Called to Order < > CT**

2. **Welcome and Opening Remarks:** Josh Arbaugh, President

3. **Acknowledgement of Award:** Josh Arbaugh, President
   - Distinguished Service Award
   - Presidential
   - Appreciation Awards

4. **Roll Call:** Ashlee-Rose Ferguson, Secretary – Treasurer

5. **Acceptance of Committee Reports from:** Finance, Current Issues and Outreach, Education and Training, Feed and Feed Ingredient Manufacturing, Ingredient Definition, Inspection and Sampling, Laboratory Methods and Services, Proficiency Testing Program, Strategic Affairs, Feed Labeling, Pet Food Committee, Model Bill & Regulations, Enforcement Issues, Technology, and Ingredient Definition Committee E-Meeting (October 23, 2023) – Josh Arbaugh, President & Laura Scott, President-Elect
   (All open committee reports are published on the AAFCO website on the 2024 Midyear Meeting page, right side, under the heading "Committee Reports.")
   Board recommends acceptance. <> moves to accept committee reports. < > Seconds. Motion < >.
6. **Acceptance of Committee Recommendations:** Josh Arbaugh, President & Laura Scott, President-Elect
   a. **Ingredient Definition Committee Recommendations:**
      - IDC recommends changing T42.25 Grain Sorghum Protein Feed to OFFICIAL.
        42.25 Grain Sorghum Gluten Feed (Grain Sorghum Protein Feed) is that part of the grain of grain sorghums that remains after the extraction of the larger part of the starch and germ, by the processes employed in the wet milling manufacture of starch or syrup. Originally called Grain Sorghum Gluten Feed (adopted 1948, amended 1950). *Gluten name will be removed in 2025
        Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.
      - IDC recommends changing T42.35 Grain Sorghum Protein Meal to OFFICIAL
        42.35 Grain Sorghum Gluten Meal (Grain Sorghum Protein Meal) is the part of the grain of grain sorghums that remains after the extraction of the larger part of the starch and germ, and the separation of the bran by the processes employed in the wet milling manufacture of starch or syrup Originally called Grain Sorghum Gluten Meal (adopted 1948, amended 1950). *Gluten name will be removed in 2025
        Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.
      - IDC recommends changing T48.135 Corn Protein Feed to OFFICIAL
        48.135 Corn Gluten Feed (Corn Protein Feed) is that part of the commercial shelled corn that remains after the extraction of the larger portion of the starch, protein, and germ by the processes employed in the wet milling manufacture of corn starch or syrup. It may or may not contain one or more of the following: fermented corn extractives, corn germ meal. Originally called Corn Gluten Feed (adopted 1936, amended 1960). *Gluten name will be removed in 2025
        Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.
      - IDC recommends changing T48.145 Corn Protein Meal to OFFICIAL

T48.145 Corn Gluten Meal (Corn Protein Meal) is the dried residue from corn after the removal of the larger part of the starch and germ, and the separation of the bran by the process employed in the wet milling manufacture of corn starch or syrup, or by enzymatic treatment of the endosperm. It may contain fermented corn extractives and/or corn germ meal. Originally called corn gluten meal (adopted 1936, amended 1960). *Gluten name will be removed in 2025

Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.

- IDC recommends changing T73.200 Xanthum Gum to OFFICIAL

73.200 Xanthan Gum as per 21 CFR 573.1010 is classified as a food additive as a stabilizer, emulsifier, thickener, suspending agent, or bodying agent in calf milk replacer and liquid feed supplements. Also per informal review processes, it can be used in canned dog and cat foods **and as a suspending agent in plant inoculant products.** Maximum inclusion levels are 0.1% in calf milk replacers (as fed), and 0.25% in liquid feed supplements and canned dog and cat foods, **and 2% in plant inoculant products.** (Proposed 2013, Adopted 2015 rev. 1)

Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.

- IDC recommends adding AGRN-60 Dried Fermentation Biomass to the GRAS Table 101.1

AGRN (select for detailed record)	Notifier	Substance	Common or Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
60 (PDF - 305 pages)	Calysta, Inc.	Dried *Methylococcus capsulatus* product	Dried Fermentation Biomass	To be used as a source of protein in food for salmonid species at a level up to 18% of the diet.	Salmonid species	6/2/22	FDA has no questions. (PDF - 3 pages)

Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.

- IDC recommends adding AGRN-59 Porcine Oligosaccharides peptide complex to the GRAS Table 101.1

AGRN (select for detailed record)	Notifier	Substance	Common or Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
59 (PDF - 779 pages)	Gnubiotics Sciences SA	Porcine oligosaccharides-peptides complex	Porcine oligosaccharides-peptides complex	To be used as a source of amino acids, peptides and glycopeptides in food for cats and dogs at a level not to exceed 1.5% by weight/complete feed	Cats and dogs	5/11/22	FDA has no questions. (PDF - 3 pages)

Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.

- IDC recommends adding a new Tentative Definition T60.117 Dried Black Soldier Fly Larvae

T60.117(A) Black Soldier Fly Larvae is the dried larvae of the Black Soldier Fly, *Hermetia illucens*, with or without mechanical extraction of part of the oil, that has been raised on feedstock composed exclusively of feed grade materials. The ingredient must be labeled for guarantees for minimum crude protein and minimum crude fat on an as-fed basis. If oil is mechanically extracted, maximum crude fat must also be guaranteed on the ingredient label. The ingredient is dried by artificial means to no more than 10% moisture. It is for use in ~~salmonid~~ **finfish**, poultry, and swine feed and in adult dog food as a source of protein and fat consistent with good feeding practices. (Proposed 2022, Amended 2023)

Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.

- IDC recommends adding a new Tentative Definition T60.120 Dried Chicory Root Pulp

  T60.120 Dried Chicory Root Pulp is the dried pulp produced as a byproduct of inulin extraction from the root of *Cichorium intybus* L., intended as a source of fiber. It shall contain no more than 10% inulin, no less than 60% total dietary fiber, and no more than 13% moisture.

  Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.
- IDC recommends adding a new Tentative Definition T60.121 Dried Mealworm Meal

  T60.121 Dried Mealworm Meal is obtained from the dried larvae of the yellow mealworm beetle (*Tenebrio molitor*) which has been raised on a feedstock composed exclusively of feed grade materials and from which part of the oil has been extracted using a mechanical process. The ingredient must be labeled with guarantees for minimum crude protein, and minimum and maximum crude fat. The ingredient is artificially dried to no more that 8% moisture. It is for use in adult dog food as a source of protein at a level not to exceed 30% on an as-fed basis.

  Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.
- IDC recommends adding a new Tentative Definition T40.100(A) Recovered Retail Food

  T40.100(A) Recovered Retail Food is composed of edible human food products safe and suitable for livestock feed <u>and poultry feed</u> that are collected from retail food establishments, domestic holding facilities, and domestic packing facilities. Permitted recovered retail foods are products from overstocks, lacking consumer acceptance, or beyond their sell-by date that include items such as bruised, cut, or overly ripe product (fruit and vegetables), bakery goods, eggs, and dairy products. It shall be safe and appropriately labeled for its intended use <u>in accordance with good feeding practices</u> and shall be free of material harmful to animals. Materials excluded from this definition include pet foods and products containing beef, lamb, pork, poultry, fish, or shellfish. It must not contain packaging materials (e.g. plastics, glass, metal, string, ~~Stryofoam~~, polystyrene, cardboard, and similar materials), flowers, potted plants, or potting soil. The recovered foods shall be collected and intermixed in secure holding containers to exclude unauthorized addition of trash, materials harmful to animals, or infestation and adulteration by pests. Egg and dairy products (and other products ordinarily held at refrigerator temperatures) must be kept in cold storage until the scheduled pick-up. To minimize spoilage, the recovered retail food shall be collected at least weekly, or more frequently if necessary. The establishment should have a sanitation plan in place, and the containers should be cleaned and sanitized as necessary. The collected material may be further processed or delivered as is to an animal feeding facility. The product must be handled to preserve its safety and nutritional value. (Proposed 2017, Adopted 2019)
  **Double underlines and strike throughs represent changes.*

  Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.
- IDC recommends adding a new Tentative Definition T33.29(B) Black Soldier Fly Larvae Oil

  T33.29(B) Black Soldier Fly Larvae Oil is the product obtained by mechanically extracting the oil from dried larvae of Black Soldier Fly, *Hermetia illucens*, that have been raised on a feedstock composed exclusively of feed grade materials. It is intended for use in swine and finfish feed, and adult dog <u>and adult cat food</u> as a source of energy consistent with good feeding practices. It consists predominantly of glyceride esters of fatty acids and contains no additions of free fatty acids or other materials obtained from fats. It must contain, and be guaranteed for, not less than 90% total fatty acids, not more than 2% unsaponifiable matter and not more than 1% insoluble impurities. Maximum free

fatty acids and moisture must also be guaranteed. If an antioxidant(s) is used, the common name or names must be indicated, followed by the words "used as a preservative." (Proposed 2022, Adopted 2022)
**Double underlines represent changes.*
Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.

- IDC recommends a nomenclature Change 36.14 Direct-Fed Microorganism, add *Weissella confusa*
  36.14 Weissella confusa Section 36.14 will be edited to include *Weissella confusa*. One of the strains thought to have belonged to the *Lactobacillus acidophilus* genus species has been determined to actually belong to *Weissella confusa*. This results in adding *W. confusa* to 36.14. Both ***Lactobacillus acidophilus*** and ***Weissella confusa*** will be included in the 36.14, and **no microorganism will be removed from 36.14.**
  Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.
- IDC recommends publishing a tentative definition T71.41 LG HEAR Meal to OFFICIAL status as 71.41.
  71.41 Low Glucosinolate High Erucic Acid Rapeseed Meal, Mechanically Extracted,** is the meal obtained after the removal of most of the oil by mechanical extraction of whole seeds obtained from the genus Brassica [*Brassica napus*, *Brassica rapa*, or *Brassica juncea*] from which the oil shall contain more than 2% erucic acid and the solid component shall contain less than 30 micromoles of any one or any mixture of 3-butenyl glucosinolate, 4-pentenyl glucosinolate, 2-hydroxy-3-butenyl glucosinolate, 2-hydroxy-4-pentenyl glucosinolate, and allyl glucosinolate per gram of air dry, oil free solid. When produced from *Brassica juncea* it must also contain less than 5 micromoles of allyl glucosinolates per gram of air dry, oil free solid. It must contain a maximum of 6% erucic acid, a maximum of 12% crude fiber, and a maximum of 30 micromoles of glucosinolates per gram. It is used in the diets of animals as a source of protein, not to exceed a 5% inclusion rate.
  Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.
- IDC recommends publishing tentative definition T36.11a Dried ____ Fermentation Products to OFFICIAL status, replacing the current official definition 36.11.
  T36.11a Dried _____Fermentation Product is the product derived by culturing _____on appropriate nutrient media for the production of one or more of the following: enzymes, fermentation substances, or other microbial metabolites, and dried in accordance with approved methods and good manufacturing practices. Protein, amino acids, fat, fiber, cell count, enzyme activity or nutrient metabolite level shall be guaranteed where applicable. Use of *Lactobacillus buchneri*, *Lactobacillus diolivorans*, and *Lentilactobacillus hilgardii* is limited to silage and high moisture corn grain in plant inoculant products. [For label identification the source must be indicated such as *Bacillus subtilis*, *Aspergillus oryzae*, *Aspergillus niger*, *Lactobacillus acidophilus*, *Lactobacillus buchneri*, *Lactobacillus diolivorans*, *Lentilactobacillus hilgardii*, *Lactobacillus delbrueckii* or *Enterococcus faecium*, or as permitted by FDA.] (Proposed 1976, Adopted 1983, Amended 1997, Amended 1999, Amended 2001, Adopted 2003, Amended 2010, Adopted 2014 rev.1, Amended 2022)
  Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.
- IDC recommends publishing a new TENTATIVE definition T51.17 Clam Meal
  T51.17 Clam Meal is the undecomposed, dried byproducts from shucking and processing operations of *Spisula solidissima* and/or *Arctica islandica*. The ingredient is derived from all or part of the meat, liquid and viscera of the clam. It must contain not less than 60% crude protein and not more than 12% moisture. It is for use in non-salmonid finfish feed as a source of protein consistent with good feeding practices
  Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.
- IDC recommends publishing a new TENTATIVE definition T60.119 Dried Crickets
  T60.119 Dried Crickets are nymph through adult stage crickets, *Acheta domesticus*, manufactured either by roasting or wet milling. Crickets are raised on feedstock composed exclusively of feed grade materials. Post-harvest processing of crickets shall incorporate a microbial kill step. The ingredient must be labelled with guarantees for minimum crude protein and minimum crude fat on an as-fed basis. The ingredient is dried to no more than 6% moisture. The ingredient must contain no more than 7.5% chitin.[1] It is

for use in adult dog food as a source of protein and fat consistent with good feeding practices.
[1]Narguess H. Marei, Emtithal Abd El-Samie, Taher Salah, Gamal R. Saad, Ahmed H.M. Elwahy, Isolation and characterization of chitosan from different local insects in Egypt, International Journal of Biological Macromolecules, Volume 82, 2016, Pages 871-877, ISSN 0141-8130, https://doi.org/10.1016/j.ijbiomac.2015.10.024.
Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.

- IDC recommends publishing a new TENTATIVE definition T40.113 Dried Recovered Household Food.
  T40.113 Dried Recovered Household Food is composed of only non-spoiled materials originally intended for or derived from food for human consumption and collected from households. Materials are dried daily in the home to 12% or less moisture to enable safe storage and transport. These materials must be safe and suitable for use in animal food. The materials shall be collected, evaluated, and further processed by the manufacturer to confirm that only acceptable materials have been added by households. To help ensure safety, a manufacturer of Dried Recovered Household Food must maintain a relationship with participating households to support training and accountability regarding acceptable material. Dried Recovered Household Food is intended for use in poultry diets in accordance with good feeding practices. The guaranteed analysis shall include the maximum moisture which shall be no more than 12%.
  Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.
- IDC recommends adding AGRN 55 Phytase to the GRAS Table 101.1.

AGRN (select for detailed record)	Notifier	Substance	Common or Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
55	BASF Enzymes LLC	Phytase Enzyme Produced By *Pseudomonas Flourescens* Strain BD50104 Expressing An Altered Appa 6-Phytase Gene From *Escherichia Coli* Strain K12	phytase	To increase the availability of phytin-bound phosphorus in poultry diets at 500-2,000 U/kg in complete feed	Poultry	1/20/22	FDA has no questions. (PDF, 4 pages)

Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.

- IDC Recommends new GRAS Table 101.1 addition AGRN 45 *Succinivibrio dextrinosolvens*

AGRN (select for detailed record)	Notifier	Substance	Common or Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
45 (PDF, 821 pages)	Native Microbials, Inc.	Dried fat encapsulated *Succinivibrio dextrinosolvens* strain	Dried *Succinivibrio dextrinosolvens* Fermentation Product	To be used as a viable microorganism in diets of beef cattle at an	Beef Cattle	3/16/21	FDA has no questions. (PDF, 3 pages)

		ASCUSBF53 (NRRL B-67550)		intended use rate of 1x108 colony forming units (CFU)/head/day.			

Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.

- IDC recommends revising Table 101.1 Section Header in the OP by inserting the following language at the end of the current section language: "AGRN's may be presented to the IDC for inclusion in section 101 at the next scheduled IDC meeting after FDA has posted their no questions letter, without regard for the redacted notice."

Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.

b. Feed Labeling Recommendation:

- Feed Labeling Committee recommends updating the label for "Your Pasture Horse Mineral". This should be inserted between pages 248 and 249 of the 2023 OP. This same label should replace the label on Page 31 of the 2020 feed labeling guide of the stand-alone document

Feed Labeling Guide 1
Equine Mineral Supplement Feeds
YOUR PASTURE HORSE MINERAL
For maintenance of mature horses
Guaranteed Analysis

Calcium (min)	12.0%
Calcium (max)	14.0%
Phosphorus (min)	12.0%
Salt (min)	4.5%
Salt (max)	5.5%
Sodium (min)	1.7%
Sodium (max)	2.2%
Copper (min)	860 ppm
Selenium (min)	0.20 ppm
Zinc (min)	3,400 ppm
Vitamin A (min)	80,000 IU/lb.

Ingredient Statement

Calcium Carbonate, Dicalcium Phosphate, Salt, Copper Sulfate, Manganous Oxide, Molasses Products, Zinc Oxide, Ferrous Sulfate, Cobalt Carbonate, Calcium Iodate, Vitamin A Supplement, Processed Grain By-Products, Choline Chloride, Animal Fat, Ethoxyquin (a preservative), Sodium Selenite.

Feeding Directions:

Feed free-choice at an approximate rate of 2 oz/head/day. Provide fresh, clean water.

Manufactured By:
YOUR NAME FEEDS
City, State Zip

NET Wt.: 50 lb. (22.67 kg)

Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.

c. **Model Bill and Regulations Recommendations:**

- MBRC states that given that registration and labeling of silage additives is covered on page 113 of the 2022 OP under the definition of commercial feed in Section 3(b) of the Model Bill, SUIP #5 Registration and Labeling of Silage Additive Products should be deleted.

Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.

- MBRC recommends revise Section 3(b) of the Model Bill as follows for clarity –
  Section 3(b) The term "commercial feed" means all materials or combination of materials which are distributed or intended for distribution for use as feed or for mixing in feed, unless such materials are specifically exempted.
  - Unmixed whole seeds and physically altered entire unmixed seeds, when such whole or physically altered seeds are not chemically changed or are not adulterated within the meaning of Section 7(a) of this Act, are exempt.
  - The _____ by rule may exempt from this definition, or from specific provisions of this Act, commodities such as hay, straw, stover, silage, cobs, husks, hulls, and individual chemical compounds or substances when such commodities, compounds or substances are not inter–mixed with other materials, and are not adulterated within the meaning of Section 7(a) of this Act.

  **The bullets are the points of clarity, otherwise nothing new has been added.*

  Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.

d. ***Feed and Feed Ingredient Manufacturing***

- FFIM recommends updating Chapter 5, pg.258 – 263 of the 2023 AAFCO OP where all references to the VSIP were removed. Appendix A.

  Board Recommends Acceptance. <> moves, <> Seconds, Motion <>.

This concludes committee and board recommendations needing membership approval.

7. Credential Report: FASS
   Number of voting states represented:
   Number of members present:
   Number of countries:
   Number of FDA representatives:
   Number of life members:
   Total meeting attendance:
   In-Person:
   Zoom:
8. **Meeting Concluded at <> CT.**

AAFCO Model National Medicated Feed Program

Section Editor—FASS

Mission

To provide US and world consumers with a safe, wholesome and affordable supply of meat, milk and eggs free of unsafe drug residues, and to protect the health of animals.

Objectives

The objectives of the Model National Medicated Feed Program are to:

(1) Provide a credible, visible and cost-effective method for ensuring the use of prudent feed manufacturing practices.
(2) Promote self-regulation and implementation of quality-assurance principles by all sectors of the regulated industry.
(3) Enable FDA and State Regulatory Authorities to focus and prioritize regulatory compliance and inspection efforts to enhance efficiency and cost-effectiveness.
(4) Foster a uniform regulatory environment among the regulated industry.
(5) Enhance compliance by providing ongoing education and consultation with the regulated industry.
(6) Promote expeditious, equitable and consistent application of enforcement of the regulated industry.

Inspection

Scope and Purpose

Current Good Manufacturing Practices regulations (CGMP) [Title 21, Code of Federal Regulations, Part 225] for feed manufacturing are regulations developed by FDA and adopted by most states in the same or very similar language. Inspections conducted to determine compliance with these regulations apply to all medicated feed manufacturing establishments (FDA licensed and non-FDA-licensed, commercial and on-farm mixer/feeder establishments). Inspections enhance animal and public health protection by assuring that the applicable regulations are understood and followed by each manufacturing establishment.

It is critical that all regulatory agencies (federal and state) involved in the control of feed manufacturing are operating from the same understanding and knowledge base that communication is extensive, and their efforts and activities are coordinated. Cooperative Agreements between FDA and State Feed Control Authorities are the preferred method for conducting CGMP inspections.

To ensure a viable, effective inspection program is maintained, the following concepts are needed:

(1) To the extent practicable, only trained inspectors trained and specializing in examinations of medicated feed manufacturing establishments should be utilized in conducting such inspections.
(2) "Hands-on" inspection training, preferably on a regional basis, to enhance consistency and uniformity of CGMP inspections should be available. FDA, State Feed Control Authorities, and the regulated industry should participate in developing and conducting the training programs.
(3) Joint FDA and State inspections should be conducted concurrently to provide oversight of the adequacy of training, experience, and inspectional methods performed by State Feed Control Authorities and FDA inspectors.

(4) A consistent model should be developed that both FDA and State Feed Control Authorities can use to ensure the randomness of routine, programmed inspections, and avoidance of duplicative inspectional efforts.

(5) ~~A voluntary self-inspection program (VSIP), whereby medicated feed manufacturing establishments (FDA licensed and non-FDA-licensed, commercial and on-farm mixer/feeder establishments) conduct "self inspections" to determine compliance with the CGMP regulations, should be implemented.~~

Categories of Establishments

Licensed. Medicated feed manufacturing establishments using Category II Type A medicated articles are required to have an approved FDA Medicated Feed Mill License and are required to be registered with FDA as a drug establishment. Licensed and registered firms are subject to a periodic CGMP inspection by FDA. A license is also required for manufacture of free-choice and/or liquid medicated feeds that follow an approved proprietary formula or specifications or include a Category II drug.

Non-Licensed. Medicated feed manufacturing establishments using Category I Type A medicated articles or medicated feeds to manufacture other medicated feeds, or manufacture free-choice and/or liquid medicated feeds, containing a Category I drug, following a published formula or specifications, are not required to be licensed or registered with FDA, and are not required to be registered as a drug establishment. These establishments are subject to random audit and for-cause inspections by FDA and State Feed Control Authorities, and may be subject to CGMP inspections conducted by State Feed Control Authorities.

Type of Inspections

(1) **Pre-approval Inspection for License.** A pre-approval inspection is required for new applicants for a FDA Medicated Feed License. These inspections should be conducted by Certified Inspectors.

(2) **Licensed Establishment CGMP Inspection.** Required CGMP inspections for registered drug establishments should be conducted by Certified Inspectors.

(3) **Non-Licensed Establishment CGMP Inspections.** Inspections of non-licensed medicated feed establishments ~~that do not participate in VSIP~~ should be conducted by Certified Inspectors.

(4) **For-Cause Inspection.** For-cause inspections for licensed, non-licensed ~~and VSIP~~ establishments should be conducted by Certified Inspectors based on information that raises questions, concerns, or problems with a regulated firm or commodity

(5) **Random Inspector Audits.** Random inspector audits should be conducted by Certified Auditors.

~~(6) **VSIP Audits.** VSIP audits should be conducted by Certified Inspectors.~~

~~(7) **Voluntary Self-Inspection Program (VSIP).** VSIP is a program in which a medicated feed manufacturing establishment conducts its own inspection (a "self inspection") for compliance with CGMP regulations. Medicated feed manufacturing establishments under this category may include FDA licensed and non-FDA-licensed, commercial and on-farm mixer/feeder establishments.~~

~~VSIP is voluntary. Its purpose is to enhance public health by providing increased assurance to regulatory authorities of a medicated feed manufacturing establishment's compliance with CGMPs through means other than routine~~

agency inspections. The goals of the program are to improve compliance with CGMP regulations and to increase animal and public health protection. It may also allow a regulatory authority to prioritize resources to focus on animal and public health inspection needs. The program achieves this through the medicated feed establishment meeting the criteria for participation in the self-inspection program, coupled with yearly reports of continued CGMP compliance.

The following are criteria for a medicated feed manufacturing establishment to participate in VSIP:

- The establishment provides written notification to the appropriate regulatory authority of its intent to participate in the program. The notification should include:
  (1) Name and address of the establishment
  (2) Name and title of responsible party at the establishment
  (3) A statement that the establishment will operate in full compliance with CGMPs.
- The establishment has implemented a written company or industry-based quality assurance program that meets FDA's CGMP requirements. The establishment has a "passed" inspection status based on an inspection for CGMP compliance conducted by the appropriate regulatory authority within two (2) years prior to the date of notification that the firm desires to participate in the program.
- Establishments that have a "failed" inspection status within two (2) years prior to the date of notification to participate in the program, or establishments that have not had a CGMP compliance inspection within two (2) years prior to the date of notification to participate in the program, may request a pre-approval inspection to verify current compliance with CGMPs.
- The establishment conducts the self inspection at least once a year using either:
  (1) Attachment B (Form FDA 2481), the "Medicated Feeds Inspection Report" of Compliance Program 7371.004, Medicated Feeds Program, found in FDA's Compliance Program Guidance Manual (should be used for FDA licensed establishments) [Note: CVM has issued a single Comprehensive Animal Food Inspection Compliance Program (7371.000) and has revoked the CPs for Medicated Feed Manufacturing (7371.004) and BSE (7371.009). The FDA 2481 is still in use but is not directly included in the CP. The form can be accessed on the FDA.gov, FDA Forms page, https://www.fda.gov/about-fda/reports-manuals-forms/forms]; or,
  (2) The "Non-Licensed Medicated Feed Establishment Inspection Form," found in AAFCO's *Official Publication* (should be used for non-FDA licensed establishments).

Establishments participating in VSIP will conduct self-inspections using individuals who have a thorough understanding of medicated feed manufacturing and the applicable CGMPs, and are knowledgeable in conducting medicated feed inspections. These inspectors must be given ready access to all facilities, records, and documents necessary for the conduct of a complete CGMP inspection at the VSIP establishment.

If the establishment received a CGMP inspection by a Certified Inspector from an appropriate regulatory authority during the year, that inspection may serve as the self-inspection.

The self-inspection should include a review of any previous inspection to determine that corrective action was taken as promised. A responsible person for the establishment

~~should review all observations on the inspection form, formulate corrective action to be taken if necessary, and establish a target date for resolution of any deficient areas. Types of deficiencies could include:~~

~~(1) Deficiencies correctable at the time of inspection.~~
~~(2) Deficiencies requiring changes in procedures to ensure compliance.~~
~~(3) Deficiencies requiring additional employee training or employee changes to ensure compliance.~~
~~(4) Deficiencies that have been ongoing and continue to occur.~~

~~An establishment that has deficiencies that have been ongoing and continue to occur should be self-re-inspected within ninety (90) days to ensure the deficiencies have been corrected.~~

~~Within sixty (60) days of the self-inspection, a responsible person for the establishment submits a **Facility Annual Inspection Report (FAIR)** to the appropriate regulatory authority. The FAIR should include the following:~~

~~(1) The name and title of the person who conducted the self-inspection.~~
~~(2) The date(s) of the inspection.~~
~~(3) Statement that the establishment's quality assurance program meets the requirements established by the CGMPs~~
~~(4) A copy of the completed inspection report. If deficiencies are found, a narrative describing corrective action taken.~~
~~(5) A report of any deficiencies that have been ongoing and continue to occur. The establishment must explain the corrective action that is to be taken to ensure that the deficiency will be corrected and will not continue to occur. The results of the 90-day follow-up inspection should be submitted as a supplement to the FAIR.~~

~~An establishment participating in the VSIP program may be subject to VSIP Audit and For-Cause inspections by an appropriate regulatory authority. Inspectors should have access to the following:~~

~~(1) Records and copies of records as permitted by 21 CFR Part 225;~~
~~(2) Additional records and copies of records as permitted by the Federal Food, Drug, and Cosmetic Act (the Act) and the regulatory authority;~~
~~(3) The FAIRs that have been filed with the appropriate regulatory authority by the establishment and;~~
~~(4) The person who conducted the self-inspection to answer questions about how the self-inspection was done. This may be done by telephone.~~

~~An establishment's records, not addressed by the Act or regulations as noted above, and internal audit forms, are not subject to inspection by Certified Inspectors or auditors in this program. In the case of criminal action against the establishment, such records may be subpoenaed.~~

~~Participation in VSIP does not change the requirements for reporting under Title 21, Code of Federal Regulations, Part 510.301 for sponsors of new animal drugs used in feed.~~

~~An establishment's continued participation in the program will be based on its ability to continue to meet the criteria for participation.~~

~~Note: Medicated feed manufacturing establishments retain the option of voluntarily withdrawing from the program at any time.~~

Reports

(1) Establishments that become aware of a hazard that poses an imminent threat to human or animal health or safety should report the applicable information to

the appropriate regulatory authority.

(2) **Establishment Inspection Report (EIR).** The EIR will be used by Certified Inspectors for pre-approval, routine, for-cause and audit inspections.

(3) **FDA 2481 (Inspection Checklist).** This inspection checklist will be used by Certified Inspectors for establishments that are registered and have a Medicated Feed License. ~~VSIP establishments that are licensed and registered with FDA should use this checklist for the annual self-inspection (FAIR).~~

(4) **AAFCO Non-licensed Checklist.** Certified Inspectors will use this inspection checklist for establishments that are not required to be licensed and registered. ~~VSIP establishments that are not licensed and registered with FDA should use this form for their annual self-inspection (FAIR).~~

~~(5) **Facility Annual Inspection Report (FAIR).** Participants in VSIP are required to have a responsible person for each establishment file an annual report with the appropriate regulatory authority. A copy of the report is to be maintained by the establishment for a minimum of two years. The report is to include the following:~~

- ~~The name and title of the person(s) who conducted the self inspection and the date of the inspection;~~
- ~~Certification that the establishment's quality assurance program meets CGMP requirements;~~
- ~~A copy of the completed inspection checklist (FDA 2481 or AAFCO). If discrepancies are found, a report describing corrective action(s) taken; and~~
- ~~A report of any deficiencies that have been ongoing and continue to occur. The establishment must explain the corrective action that is to be taken to ensure that the deficiency will be corrected and will not continue to occur. A follow-up self-inspection is to be conducted within 90 days to ensure all deficiencies have been corrected as promised.~~

(6) **Notice of Inspection.** A written notice of inspection will be issued for all inspections, ~~except a notice of inspection is not required for a VSIP establishment conducting a self-inspection.~~

(7) **Inspectional Observations.** A report listing all deficiencies will be issued for any CGMP deviation revealed during any inspection by Certified Inspectors.

Education and Training

Scope and Purpose

Persons responsible for regulating and inspecting medicated feeds, as well as those who manufacture such feeds, are to be proficient in their knowledge, understanding and application of the regulations governing medicated feed establishments. This is accomplished through the use of innovative and creative approaches to continuing education and training, as well as a service-oriented approach to regulation.

To promote a uniform regulatory environment for the regulated industry and provide a high quality, cost effective, food safety initiative for enforcing the Federal Food, Drug, and Cosmetic Act, the Medicated Feed Current Good Manufacturing Practice regulations (CGMPs) and State Feed Laws, the National Medicated Feed Program proposes a performance-based certification process.

Responsibilities of the Certifying Body (CB)

To implement the certification process, a Certifying Body (CB) is to be established to set minimum criteria and provide oversight to a Certifying Organization (CO) that is