Feed & Feed Ingredient Manufacturing Committee

2023 AAFCO Annual
August 2, 2023
Baltimore, MD

Committee recommendations to Board and membership:

1. Committee recommends the Board of Directors disband the Nutrient Contaminant Workgroup or have the charge changed by the Board of Directors. It was discussed by the workgroup that they didn't want to re-invent the wheel. There is a lot of toxicology information out there and they were concerned that too much effort would be going into something that is already out there or taking place of contacting state veterinarian/toxicologist. (Does not go to BOD, just noted as an FYI)

2. Committee recommends sending the edited Official Guidelines for Contaminant Levels Permitted in Mineral Feed Ingredients to the Board of Directors for review and recommend the updated guidelines be published in Chapter Five of the AAFCO OP, Model Guidance Documents, following the Analytical Variations (AV). Updated document attached.

3. Committee recommends sending the updated review of Chapter 5, pg.258 – 263 of the 2023 AAFCO OP to the Board of Directors. All references to the VSIP were removed. Recommend changes to the next OP edit. Updated document attached.

Committee Action Items:

1. FSMA Implementation Task Force – Working Group 3
   Coordination with LMSC has slightly changed the survey frequency. Proposed sending the survey out every other year.

2. Working Group #4 – Inspector Training for Ingredient Manufacturing Inspections:
   Perform gap analysis of FSPCA training for inspectors to determine if AAFCO needs to provide additional training for state inspectors. It was proposed to change AITS reporting to Annual meeting after AITS. No report at Midyear meeting will be needed.

Committee Minutes 8/2/2023

Committee Participants
Members Present:
Charlie Hubenka – NE; (Co-Chair); Ken Bowers – KS (Co-Chair); Eric Brady – TN; Laura Scott – CFIA; George Ferguson – NC; Dr. Jonathon Roberts – LA; Jessica Gore – NC; Trish Dunn – IN; Doug Lueders – Life Member; Justin Henson – FDA; Linda Morrison – Life Member; Chad Witmer – PA.

Via Telephone: None

Advisors Present:
Pat Tovey – PFI; Louise Calderwood – AFIA; Charles Starkey - NARA; Matt Frederking – NGFA; James Emerson – US Poultry Association; Dan Frank – AFIA; Bill Bookout – APPA.

Committee Report/Minutes
Ken Bowers called the meeting to order 2:20 pm. Members and advisors in the room introduced themselves.

Introductions and Agenda Review, Ken Bowers, and Charles Hubenka

NEW MEMBERS: None

Review of Action Items
Mineral Guidelines Working Group – Brady

This was finalized and approved during business meeting of Annual Meeting in August 2022.

FSMA IMPLEMENTATION TASK FORCE UPDATES

Working Group #3 – Contaminant and Hazard Lab Strategy - Brady
Working Group Charge: Following the identification of contaminants and hazards by FSPCA/FDA, the group will determine action levels and enforcement strategies to provide guidance to the Lab Methods and Services Committee (LMSC) to develop a priority list of method development. This Working Group will work in consultation with the FSPCA, Enforcement Issues Committee, Inspection & Sampling Committee, Ingredient Definition Committee and the LMSC

Update on Contaminant and Hazard Lab Strategy
Communication with the Chairs of LMSC. LMSC has workgroups to address the methods and training needs returned by the survey.
The top 5 needs are:

1. Vitamins and Vet Drugs
   Vitamin D – Vitamin A – Vitamin E – Monensin – Lasolacid
2. Microbial Pathogens
   Salmonella – Listeria
3. Drug Residues
   Monensin – Lasolacid
4. Poisons/Toxins
   Mycotoxins – Pentobarbital – Dioxins
5. Pesticide Residues
   None Listed - Only performed on complaint basis.

AAFCO Regulatory Needs Yearly Survey
Coordination with LMSC has slightly changed the survey frequency. Instead of death by survey, we propose sending the survey out every other year, due to the fact that regulatory needs do not typically change annually.

Working Group #4 – Inspector Training for Ingredient Manufacturing Inspections - Brady
Working Group Charge: Review materials developed by FSPCA and FDA to determine whether training material for feed ingredient manufacturing from the FSPCA will meet the needs of Inspectors in regard to training. Working group will work in consultation with the Education & Training Committee and the Inspection & Sampling Committee

Brady - AITS 2023 update.

The seminar was held last month, June 13-15, in Denver, CO. We had 39 attendees, representing 14 states, Arizona, Arkansas, Colorado, Georgia, Indiana, Kentucky, Maryland, Michigan, North Carolina, Nebraska, New Mexico, Ohio, Pennsylvania, and Tennessee.
Cadre included Miriam Johnson, Chad Linton, Jamie Spencer, Jordan Mancini, Austin Therrell, and Eric Brady.

Training was conducted on topics that included Feed Stuffs, General Feed Manufacturing, cGMPs and Records Review, Advanced Feed Labeling, Veterinary Feed Directive Traceback and Trace forward, Ingredient Verification Tool and Ingredient Traceback, Medicated Feed Labeling Requirements and Drug Calculations, Aseptic Sampling, with the final day consisting of training led by the Council on Licensure, Enforcement, and Regulation.

AITS for 2024 will again be held in Denver, CO and is currently being scheduled for the week of June 10-14.

It was proposed to change AITS reporting to Annual meeting after AITS. No report at Midyear meeting will be needed.

Canadian Food Inspection Agency Update - Laura Scott

- The CFIA is continuing to work towards final publication of updated Canadian Feeds Regulations, with a target of Summer 2023.
- When the updated regulations are published some of the changes will come into effect right away, while others will be delayed.
- Changes respecting labelling, standards and product registration will come into effect immediately, but will have a one-year transition period that will allow regulated parties to follow either the old rules or the new ones.
- New requirements with respect to hazard analysis and preventive control plans will come into effect one year after publication of the regulations.
- New requirements with respect to licences will come into effect 18 months after publication of the regulations.
- The CFIA is preparing guidance and planning outreach activities to help support regulated parties with the updated regulations.
- The CFIA has also been working on several other activities.
    - The MyCFIA application portal has been fully launched. Applications for feed registration and approval can now be made on-line. Companies are encouraged to submit their applications here.
    - A database of registered products is in development and will be available on the web
    - Updated guidance on acid-based products and new guidance on data flexibility are available on the CFIA website.

Industry updates –
Pat Tovey PFI, -

- PFI has been discussing the possibility of changes to the regulatory environment.
- PFI is hosting the Globel Alliance in Minneapolis, MN June 20-24, 2024. IPPE - Will be hosting training along with sister associations, aiming to assist farms to generate USDA/APHIS inspection packages for trade.
- Nutrition subcommittee has drafted a manuscript entitled Challenging and Establishing Mineral Requirements in Dogs. Work addresses challenges regarding copper levels.
- Product safety regarding weather related concerns-mycotoxins in grains. Expanding to include more mycotoxins.

Louise Calderwood AFIA

- Recently published animal feed economic report on AFIA.org. Breaks all the economics down to the congressional level.
- Animal feed additives. Work has been done by FDA CVM to create new category of zootechnical animal food substances. These are non-nutritive substances that would have to ability to make marketing claims. Update next year.

Dave Fairfield NGFA

- Food Safety Preventive Controls Alliance – Standardized curriculum status. 2017 curriculum is current for animal food. FSPC is working towards providing additional resources to help instructors better describe enforcement discretion policies for the animal food rule. FSPC annual conference will be in Chicago Oct 17 and 18th, 2023. Lead instructor course will be offered Nov 28-30.
- PCQI courses are still being offered.

Charles Starkey NARA

- Well attended PCQI class with renderers.
- Annual convention in October.
- Fats and Proteins research foundation to fund additional work on heat sensitive pathogens to promote continued food safety.

Other Business:
Nutrient Contaminant Workgroup

Committee recommends the workgroup be disbanded.

The board in 2021 charged FFIM to put together some model contaminants and hazards so this workgroup was formed. Workgroup met 3 or 4 times and started with nutrients that if used at an excess of normal use level could be considered hazardous. They identified some nutrients that were tied to recalls. That's as far as the workgroup has gotten.

Tovey - Concerned that too much effort would be going into something that is already out there or taking place of contacting state veterinarian/toxicologist. Is there merit to going forward with this workgroup?

Industry seemed to not see the value.

Therrell – A focus around the workgroup was they didn't want to re-invent the wheel. There is a lot of toxicology information out there. Wanted to try and get this information in one spot for convenience. Committee needs to decide whether to continue.

Consideration to review the voluntary self-inspection program in Section 5 of the OP. Eric Brady moved to accept the workgroup report from the VSIP workgroup. Jessica Gore seconds. Motion carries.

Committee recommends sending the updated review of Chapter 5, pg.258 – 263 of the 2023 AAFCO OP to the Board of Directors. All references to the VSIP were removed. Recommend including changes to the next OP edit.

Workgroup disbanded.

NEW BUSINESS-

Edits in OP to Official Guidelines for Contaminants Levels Permitted in Mineral Feed Ingredients. Jennifer Kormos. Formed a work group to go over document to edit for clarity, not change content. Trish Dunn-IN, Cynthia Scholte-CVM, and Kevin Meyer-Intrepid Potash. Task completed. It was decided that these were still editorial changes and wouldn't need to go back through the membership. Recommend sending to the board and on to include the edits in the next OP update. Eric Brady-TN moved to accept the workgroup report and to move on to the AAFCO Board of Directors for placement in the OP. Trish Dunn-ID seconds. Motion carries. Jennifer to change Table 4 (mtl) before sending the final report. Work group disbanded.

Strategic Plan assignment for 2023 – 2025. Discussion/workgroups. EIC, Feed labeling and FFIM committees have formed a workgroup to address Chapter 5 edits.

3.1 Chairs from FFIMC, ISC, and EC will go through and align Chapter 5 with AFRPS. Once tasks are figured out Committee chairs will bring back assignments for workgroups.

3.2 Coordination with LMSC has slightly changed the survey frequency. LMSC and FFIMC has proposed sending the survey out every other year, due to the fact that regulatory needs do not typically change annually.

Responsible	Item	Action	Timing / Status
Mineral Guidelines Working Group	Mineral Guidelines	To review and revise the "Official Guidelines for Contaminant Levels Permitted in Mineral Feed Ingredients". Working Group: Bill Burkholder (lead)	Approved
FSMA Implementation	Hazard & Contaminant	Work with FSPCA, EIC, ISC, IDC and LMSC to develop a prioritized list of method	Update: August 2024

Responsible	Item	Action	Timing / Status
Task Force – Working Group 3	Action Levels and Lab and Enforcement Strategies	development once list of contaminants and hazards has been identified by the FSPCA and FDA. A plan of action should be created by the working group to determine the processes of implementing the decision making and method development.	
FSMA Implementation Task Force – Working Group 4	Inspector Training Development	Gap Analysis performed on FSCPA training to determine if there is any missing education that should be provided to inspectors who perform feed ingredient manufacturing inspections	Update: August 2024

Meeting Adjourned.

Official Guidelines for Contaminant Levels Permitted in Mineral Feed Ingredients

Section Editor—Jennifer Kormos, Canada

The Mineral Investigation Committee considered the matter of contaminants in mineral feed ingredients for several years before adopting an approach to the problem as reported in the 1978 AAFCO Official Publication~~*Official Publication*~~. The original approach was combined with toxicity data in the 1980 National Academy of Sciences (NAS), National Research Council (NRC) *Mineral Tolerance of Domestic Animals* [National Academy of Sciences, National Research Council. *Mineral Tolerance of Domestic Animals* (1980). National Academy Press, Washington, D.C. 20001] to produce the guidelines appearing in the AAFCO Official Publication~~*Official Publication*~~ through 2021. Updates to the AAFCO ~~Official~~ Mineral Guidelines in 2022 were derived from multiple sources including the 2005 National Academy of Sciences (NAS), National Research Council (NRC) *Mineral Tolerance of Animals*~~2005 NRC *Mineral Tolerance of Animals*~~ [National Academy of Sciences, National Research Council. *Mineral Tolerance of Animals Second Revised Edition*, (2005). National Academy Press, Washington, D.C.
20001]. The 2005 *Mineral Tolerance of Animals* indicates that the 2005 NRC Expert Subcommittee ~~expert subcommittee~~ did not consider tissue residues of mineral contaminants with regard to human food safety when setting the various maximum tolerance~~ble~~ levels (MTL or tolerance) for minerals.
Given the lack of consideration for human food safety by the 2005 NRC Expert Subcommittee~~NRC expert subcommittee~~, the AAFCO Mineral Guidelines Work Group that updated these ~~Official~~ AAFCO Mineral Guidelines took the approach that if a tolerance for a given mineral was reduced by the 2005 NRC Expert Subcommittee ~~2005 NRC expert subcommittee~~ from the tolerance stated in the 1980 *Mineral Tolerance of Domestic Animals*, the AAFCO Mineral Guidelines Work Group accepted the reduced amount in the 2005 *Mineral Tolerance of Animals*. If, however, the 2005 NRC Expert Subcommittee ~~2005 NRC expert subcommittee~~ increased a tolerance for a given mineral, the AAFCO Mineral Guidelines Work Group retained the lesser tolerance from the 1980 *Mineral Tolerance of Domestic Animals*.

The mineral products section (section #57) of the 2022 AAFCO Official Publication contains 142~~1~~ mineral ingredient definitions for sources of 15 elements to consider in drafting guidelines to limit contaminants. Variables considered and used in guideline development included:

(1) Differing nutrient requirements between species and within species, e.g., young vs. mature, lactating vs. non-lactating, and layers vs. broilers.
(2) Whether the toxicity of a contaminant varies between and within species.
(3) The concentration of a nutrient varies between several ingredient sources. For example, magnesium oxide (MgO) contains 6 times the magnesium (Mg) to an equivalent weight of magnesium sulfate heptahydrate ($MgSO_4$-$7H_2O$), and thus, could contain 6 times the contaminant level compared to magnesium sulfate for an equivalent contaminate burden in a finished product since only one-sixth as much magnesium oxide would be needed to meet a given amount of magnesium.
(4) The range between a nutrient requirement and toxicity for a given element varies greatly. Manganese, for example, is required at about 50 ppm but levels as high as 1,000 to 2,000 ppm can be tolerated.
(5) Knowledge of nutrient requirements and toxicities is incomplete and/or imprecise in many cases.

If the variables are acknowledged, it becomes apparent that precise contaminant limits, fixed at the very brink of toxicity, are impractical. Rather, we must work in much

more general and conservative terms, using scientific data to limit, but not exclude some subjective decisions based upon common sense. Safety factors, for example, would be included in the latter category.

With the above ~~factors~~ variables in mind, the following approach was used in developing the overall recommendations for handling contaminants in mineral feed ingredients proposed in this report.

(1) Determine the all-species average requirement for each of the 15 elements included in the AAFCO mineral product definitions if a requirement has been established. [Chromium is believed to be essential, but no minimum requirement has been established for any species, thus, chromium does not appear in Table 1.] These values (Table 1) were adapted from the NRC nutrient requirement recommendations for the species listed in Table 1.

(2) Determine the all-source average content for each element.

(3) Calculate, from the data in (1) and (2) above, the dilution factor needed to meet NRC recommended amounts for each element (Table 2). Example: If the average calcium content from all AAFCO sources is 32% and the NRC recommendation is 1.55%, the dilution factor is 21.
In other words, the calcium source will be diluted by a factor of 21 on a complete feed basis. [Complete feed. A nutritionally adequate feed for animals other than man; by specific formula is compounded to be fed as the sole ration and is capable of maintaining life and/or promoting production without any additional substance being consumed except water.] ~~[A Complete Feed is a multi-ingredient product fed to an animal. Examples include, but are not necessarily limited to, total mixed rations, sweet feeds, pelleted feeds or grain mixes. It also can be the summation of the total amount of feedstuffs fed separately at various locations or times within a 24-hour period.]~~

(4) Come up with a safety factor, which is 2.5 in this report.

(5) Group contaminants according to toxicity following the general guidelines proposed in the 2021 report by the AAFCO Mineral Guidelines Work Group ~~2021 report of the Work Group~~ to this Committee. Five groups, labeled 1 through 5, ordered from least to greatest tolerance, were recommended by the AAFCO Mineral Guidelines Work Group ~~Work Group~~ based on the MTL in c~~C~~omplete f~~F~~eed (Table 3).

(6) Set limits *within each group* as follows:
   a. Level for contaminants below which no declaration or labeling for the contaminants is required or deemed appropriate.
   b. A range of contaminants' levels permitted in feed ingredients if, but only if, the product is labeled as to the contaminants' levels. "Labeling" here and elsewhere is considered in the broader sense, e.g., "Typical Analysis Specification Sheet" or similar information supplied by the manufacturer to customers.
   c. Contaminants' levels above which the product's use as a feed ingredient is prohibited. This guidance does not apply to the primary nutritional element(s) of defined mineral ingredients. Definition 57.119 sodium selenite contains selenium at 460,000 ppm, but selenium from sodium selenite is a primary nutritional element.

(7) Select a dilution factor (see item (3) above) to be used in setting the maximum contaminant level permitted in a feed ingredient without labeling the amount present. A dilution factor of 21 is recommended and was used in arriving at the values in Table 3. This is the lowest value in Table 2 (for calcium) and thus provides the greatest margin of safety.

(8) Calculate the maximum level permitted in ingredients, without labeling, for each of the 5 groups, using the following equation:

$$MLP = (CFL \times DF)/SF,$$

where
MLP is Maximum Level Permitted without labeling (on "Typical Composition Specification Sheets" for example)

CHAPTER FIVE

Commented [KJ(1]: Replace with the defined term for complete feed in Chapter 6 of the OP:

Complete feed. A nutritionally adequate feed for animals other than man; by specific formula is compounded to be fed as the sole ration and is capable of maintaining life and/or promoting production without any additional substance being consumed except water.

CFL is NAS recommended maximum Continuous Feeding Level for the most toxic element in the group

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DF is Dilution Factor SF is Safety Factor
Example:
In Group 1 (Table 3) of inorganic mercury, cadmium, and selenium, inorganic mercury has the least daily tolerance in complete feed at 0.2 ppm. Therefore, if DF = 21 and SF = 2.5, MLP = (0.2 ppm × 21) / 2.5 = 1.7 ppm. Thus, ingredients containing 1.7 (~2) ppm or less of Group 1 contaminants will not raise the level in the total ration above the MTL for any of the contaminants in Group 1.
The MLP values for the other 4 groups were determined similarly.

(9) Determine range of contaminant levels permitted, **by group**, if levels are stated in the labeling. This is a judgment decision.

(10) Determine contaminant levels, **by group**, above which an ingredient would be excluded from use in a feed. This is also a judgment decision.

The procedure recommended above provides a systematic approach to establishing contaminant limits in feed ingredients based upon toxicity data in the NRC publications for mineral tolerances of animals and other publicly available information. The equation used to set the limits is designed to handle worst case situations, since it is based upon the most toxic element in each group and assumes the lowest dilution of the ingredient (dilution factor of 21). Thus, an additional margin of safety is provided automatically for all but the most toxic contaminants in each group and the greatest nutrient requirements. This margin of safety comes not just from focusing on the MTL for the most toxic element in the group, but also because the values in the last three columns of Table 3 represent the total amount, that is the sum of the content, of all elements within the Group. That these values represent the sum of the Group, and not just the amount of an individual element within the group, has been a source of confusion by users of the former versions of Table 3. However, a reading of the 1978 minutes of the former AAFCO Mineral Investigation Committee reveals that this is in fact the approach and intent of the group that originally established these guidelines. Table 3 has been reorganized to try and clarify this aspect of the guidelines. In addition, a new table (Table 4) has been created that contains species-specific MTLs for certain minerals that previously was found in the footnotes of Table 3.

Finally, fluorine is not included in Table 3 because fluorine is closely associated with phosphate ingredients and has been handled successfully for many years by requiring the phosphorus:fluorine ratio to be not less than 100:1. It is recommended this policy continue unchanged.

Commented [KJ(2]: The WG created a new table (Table 4) that contains information in the footnotes (MTLs for certain minerals) in Table 3.

Instead of having a number of footnotes in Table 3, this information is now found in table 4.

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Table 1. Approximate Mineral Requirements (Total Diet Basis–Greatest Concentration)[a]

Mineral	Swine	Dairy	Beef	Poultry	Aquaculture	Sheep	Goats	All-Species Average
Calcium (%)	0.85	0.8	0.71	5	2	0.67	0.79	1.55
Phosphorus (%)	0.7	0.44	0.34	0.6	2	0.45	0.45	0.71
Potassium (%)	0.3	1.35	0.7	1	1.2	0.59	0.78	0.85
Magnesium (%)	0.06	0.4	0.2	0.5	0.35	0.16	0.15	0.26
Sodium (%)	0.4	0.34	0.1	0.23	0.15	0.08	0.12	0.20
Chloride (%)	0.5	1.2	–	0.35	–	0.18	0.29	0.50
Sulfur (%)	–	0.4	0.15	–	–	0.18	0.26	0.25
Cobalt (ppm)	–	0.11	0.1	–	–	0.2	0.12	0.13
Copper (ppm)	10	18	10	16	53	6	26	19.86
Iron (ppm)	100	26	50	80	199	83	71	87.00
Iodine (ppm)	0.14	0.88	0.5	1.7	1.1	0.83	0.81	0.85
Manganese (ppm)	25	24	40	120	13	34	29	40.71
Selenium (ppm)	0.3[b]	0.3[b]	0.3[b]	0.3[b]	0.7[c]	0.3[b]	0.3[b]	0.30
Zinc (ppm)	100	73	30	100	200	55	71	89.86

[a] 2005 National Academy of Sciences (NAS), National Research Council (NRC) Mineral Tolerance of Animals~~Updated and adopted from National Academy of Sciences, Engineering, and Mathematics, National Research Council (NAS/NRC) recommendations as of 2015.~~

[b]FDA approved concentration.

[c]Aquaculture species are not included in the selenium food additive regulation.

CHAPTER FIVE

Table 2. Approximate Dilution Factors and Typical Contaminate Levels of AAFCO Defined Mineral Feed Ingredients

Mineral Feed Ingredient	Recommended Level NAS/ NRC[a]	Approximate Dilution to Meet ReeRecommended Level[b]	Typical Contamination Levels (ppm)[c]					
			Arsenic	Lead	Mercury	Cadmium	Nickel	Antimony
Calcium	1.55%	2.1×10^1	2.5	5–30	0.05	5–10	–	–
Phosphorus	0.71%	3.5×10^1	2–5	5–30	0.05	5–10	–	–
Potassium	0.85%	5.2×10^1	1	1	1	–	–	–
Magnesium	0.26%	1.1×10^2	1–10	1–20	0.1–5	1	–	–
Sodium	0.20%	1.6×10^2	–	–	0	–	–	–
Chloride	0.50%	8.9×10^1						
Sulfur	0.25%	1.8×10^2	1	1	1	–	–	–
Cobalt	0.13 ppm	2.8×10^6	2–20	1–20	1–20	2–200	800	–
Copper	19.86 ppm	2.5×10^4	3–100	9–600	1	2–100	100	0–20
Iron	87 ppm	2.3×10^3	1–50	1–90	1	–	–	–
Iodine	0.85 ppm	8.5×10^5	2	3	2	1	–	–
Manganese	40.71 ppm	5.1×10^3	1–10	1–90	–	1–20	–	70–200
Selenium	0.3 ppm	1.3×10^6	–	–	1	1–5	1–5	–
Zinc	89.86 ppm	6.0×10^3	10–800	100–2,000	1	80–500	–	10

[a] Values from Table 1, including goats and aquaculture All-species average NAS/NRC nutrient requirement recommended levels from Table 1. NAS stands for National Academy of Sciences, Engineering and Mathematics, and NRC stands for National Research Council. NAS/NRC stands for National Academy of Sciences, Engineering, and Mathematics, National Research Council.

[b] Dilution factor calculated using mineral ingredient values from the NRC Nutrient Requirements for Dairy Cattle Seventh Revised Edition, 2001, NRC of the National Academes, Nutrient Requirements for Small Ruminants, Sheep, Goats, Cervids and New World Camelids, Animal Nutrition Series, 2007the NAS/NRC Nutrient Requirements of Dairy Cattle, Nutrient Requirements of Small Ruminants, and information available to the work group.

[c] Typical contaminate levels found in mineral-based feed ingredients. Unchanged as aAdapted from "NFIA Mineral Ingredient Handbook," National Feed

Commented [KJ(3]: Suggest: All-species average NAS/NRC nutrient requirement recommended values.

Use the above title if it can fit in the table. If not, the current title is fine.

Commented [KJ(4]: Suggest to spell the column heading out in full.

If it does not fit, the current title is fine.

ingredient Association, 1979 edition, and from “AFIA Feed Ingredient Guide,” American Feed Industry Association Inc.

Table 3. Official Guidelines Suggested for Contaminants in Individual Mineral Feed Ingredients

Contaminant Group[a]	Maximum Tolerance~~ble~~ Level in Complete Feed (ppm)	Total Level of Group Permitted Without Labeling (collectively, ppm)[b,c]	Labeling Required Between Indicated Range (collectively, ppm)[b]	Use Prohibited at Levels Above (collectively ppm)[b]
Group 1[d]	**0 to less than ~~<~~5**	**2**	**2–500**	**500**
Mercury (inorganic)	0.2			
Cadmium	0.5			
Selenium	2			
Group 2	**5 to less than ~~<~~15**	**42**	**42–1,000**	**1,000**
Arsenic	5~~e~~			
Iodine	5~~f~~			
Molybdenum	5g			
Cobalt	10			
Lead	10			
Vanadium	10			
Group 3	**15 to less than ~~<~~50**	**126**	**126–1,500**	**1,500**
Copper	15~~h~~			
Barium	20			
Tungsten	20			
Lithium	25			
Group 4	**50 to less than ~~<~~150**	**420**	**420–2,000**	**2,000**
Nickel	50~~i~~			
Antimony	70~~j~~			
Chromium	100~~jk~~			
Tin	100			
Group 5	**150 or greater than 150~~>~~**	**1,260**	**>1,260**	**No Limit**
Boron	150			
Aluminum	200			
Bromine	200			
Zinc	250~~l~~			
Bismuth	400			
Manganese	400~~m~~			
Iron	500			

[a]Ordered from most to least toxic within Group.

[b]Values in column represent the total (i.e., the sum) of the content of all elements in the Group.

[c]Calculated as (NRC MTL for most toxic element in the Group × dilution factor of 21)/ safety factor of 2.5.
[d]Fluorine is not included in Table 32 because fluorine is closely associated with phosphate ingredients and has been handled successfully for many years by requiring the phosphorus:fluorine ratio to be not less than 100:1.
~~[e]Arsenic 5 for fish, 30 for all other species.~~
~~[f]Iodine 5 for horses, 50 for cattle and sheep.~~
~~[g]Molybdenum 5 for horse, cattle, and sheep.~~
~~[h]Copper MTL's are species dependent. MTL's are: 15 for sheep, 40 for cattle, 100 for fish and ducks, 250 for other poultry species, horses, and swine.~~
~~[i]Nickel MTL for horse, rodent, and fish, unchanged from previous.~~
~~[j]Antimony MTL for rodents only, unchanged from previous.~~
[ek]Values for chromium III (Cr^{+3}). Chromium VI (Cr^{+6}) is carcinogenic and typically not incorporated or found in mineral ingredients.
~~[l]Zinc 250 for fish, 500 for horse, cattle, poultry, rodents.~~
~~[m]Manganese 400 for horse, 1,000 for swine.~~

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Table 4. Species-specific Maximum Tolerance~~able~~ Levels of Minerals, including Contaminants, in Complete Feed (ppm dry matter)[ab][c]

Commented [KJ(5]: New Table (table 4) includes the MTLs found in the footnotes e to j, l and m in table 3.

Mineral	Cattle	Horse	Swine	Fish	Sheep	Poultry	Rodents
Antimony	---	---	---	---	---	---	70-150
Arsenic	30	30	30	5	30	30	30
Copper	40[de]	250	250	100	15[de]	250; 100 for ducks	500
Iodine	50	5	400	---	50	300	---
Molybdenum	5	5	150	10	5	100	7
Manganese	2,000	400	1,000	---	2,000	2,000	2,000
Nickel	100	50	250	50	100	250	50
Zinc	500	500	1,000	250	300	500	500

[a]2005 National Academy of Sciences (NAS), National Research Council (NRC) Mineral Tolerance of Animals
[b]If there is no MTL, use the most sensitive species (lowest MTL) for that mineral.
[c]Minerals (including contaminants) not listed have the same MTL across all species (as listed in Table 3).
[ed]Assuming normal concentrations of molybdenum (1–2 mg/kg diet) and sulfur (0.15–0.25%). At molybdenum and sulfur concentrations below these, copper may become toxic at lower levels.

Dashes indicate that data were insufficient to set a MTL.

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[Agency Letterhead]

EXPORT CERTIFICATE - MANUFACTURER

MANUFACTURER: Name: _____

Address: _____

_____

_____

This is to certify that the above named manufacturing facility located at _____ _____, is duly registered with the _____ Department of Agriculture as required by the Commercial Feed Law. The registration number of this establishment is _____. The above mentioned company is subject to the applicable laws and rules and routine inspection in _____.

This establishment is random/periodically inspected by the _____ Department of Agriculture. A copy of the most recent inspection results/form (signed and dated) is attached hereto.

Products manufactured at this establishment are random/periodically inspected, sampled and tested by the _____ Department of Agriculture. Commercial feed products that are in compliance with applicable laws may be in distribution throughout _____ _____.

This certificate should not be construed as a warranty or guarantee (expressed or implied) for the above mentioned manufacturer; nor should it be used for promotional purposes.

Signature: _____

_____Department of Agriculture

Date: _____

The foregoing instrument was acknowledged before me.

_____

(Notary Public)

Signed this _____ day of _____, 20_____

[Agency Letterhead]

EXPORT CERTIFICATE - PRODUCT

MANUFACTURER: Name: _____

Address: _____

_____

_____

This is to certify that the label(s) of the following commercial feed(s) is (are) approved/registered with the _____ Department of Agriculture and may be in distribution through out _____

_____

_____

A photocopy of the feed label(s) (signed and dated) for the above named feed(s) as approved/registered is (are) enclosed. The ingredients and terms listed on the label(s) of the above commercial feed(s) are defined in the current publication of the *Association of American Feed Control Officials* (AAFCO). The manufacturer has certified to the Department that all the ingredients contained in the above named feeds are approved for use in these feeds in a regulation of AAFCO or the United States Food and Drug Administration.

The above mentioned company is subject to the applicable laws and rules and routine inspection ___ _____.

This certificate should not be construed as a warranty or guarantee (expressed or implied) for the product(s) of the above mentioned manufacturer; neither should it be used for promotional purposes.

Signature: _____

_____Department of Agriculture

Date: _____

The foregoing instrument was acknowledged before me.

_____

(Notary Public)

Signed this _____ day of _____, 20_____

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

responsible for the operation of the certification program. The CB will consist of selected State and Federal officials, who will be determined by AAFCO and FDA.

The responsibilities of the CB are as follows:

(1) Establish minimum criteria for the CO to include; training curricula, processes for audit, re-certification and de-certification of inspectors, and reporting/notification requirements.
(2) Establish initial standards for certification of inspectors.
(3) Review the development of testing, certification, re-certification and de-certification procedures.
(4) Provide oversight for certification program development and implementation.
(5) Establish and conduct periodic audits of the CO.
(6) Provide input for developing initial re-certification criteria for inspectors.
(7) Serve as a pool of qualified faculty to serve as instructors for education and training programs for certifying and re-certifying inspectors.

Responsibilities of the Certifying Organization (CO)

A Certifying Organization (CO) is an independent organization selected by the CB to develop, implement and maintain the certification program. The responsibilities of the CO are as follows:

(1) Provide periodic education and training programs to enable inspectors to meet the certification and re-certification requirements.
    - Prepare and select course manuals for each level of certification.
    - Provide district, regional and national training.
    - Select qualified faculty from among FDA, State Inspection Authorities, industry experts and other qualified individuals knowledgeable about the regulations governing the manufacture of medicated feed.
    - Distribute information and educational materials to all certified inspectors and auditors.
(2) Develop, implement and maintain certification procedures, including the following:
    - Develop and implement written testing and proficiency standards for various levels of certification.
    - Certify inspectors and auditors, and maintain a registry of such personnel.
    - Develop, implement and maintain an appeals process.
    - Modify Certification Program requirements, as needed, based upon audits of Certified inspectors, as well as changes and technological developments in the regulated industry.
(3) Certify inspectors and auditors, and maintain a registry of such personnel. The CO will accept as second-level (certified) inspectors:
    - FDA inspectors that FDA believes are qualified to perform medicated CGMP inspections; and
    - State inspectors commissioned by FDA to conduct medicated feed CGMP inspections.
(4) Re-certify inspectors every two years under standards developed by the CO. The CO is strongly encouraged to require that certified inspectors attend an education training course and conduct an adequate number of satisfactory inspections, as determined by the (CO), prior to being re-certified.
(5) Develop, in conjunction with FDA, procedures through which certified inspectors and auditors will be de-certified for cause (e.g., conflict of interest, incompetence, malfeasance, etc.).

Training for Regulatory Program Staff

The amount and type of training received, and competence demonstrated, will determine the inspector level achieved. FDA is to provide funding for training FDA personnel, and, when available, for State personnel.

(1) **First-Level Inspectors.** Have received State or Federal training for inspecting medicated feed establishments. These inspectors are to be accompanied by a Certified Inspector when performing CGMP inspections.

(2) **Second-level (Certified) Inspectors.** Have completed two levels of training satisfactory to the Certification Organization (CO). Certified inspectors are qualified to conduct unaccompanied CGMP inspections of medicated feed establishments.

(3) **Third-Level Inspectors (Auditors).** Meet criteria established by the CO and are qualified to evaluate the competence of certified inspectors. Auditors may verify the performance of Certified Inspectors through periodic, random follow-up inspections of medicated feed establishments.

Education/Information to Assist Compliance

(1) Joint CGMP compliance education workshops involving—and funded by—FDA, States and industry and other affected parties (e.g., on-farm/mixer-feeders) should be conducted on a regular basis to foster a high level of understanding and compliance with CGMP regulations governing medicated feed establishments.

(2) Other means of providing the latest information on regulatory aspects of medicated feed manufacturing should be pursued. A world wide web site should be established through which FDA could provide current news about drug approvals and new or amended policies. The web site also could provide an opportunity for regulators and the regulated industries to post questions for response by qualified FDA, State and industry representatives.

(3) The FDA's Compliance Program Guidance Manual should continue to be updated and available, as it represents an effective source of interpretation of CGMP compliance.
- To the extent practicable, revisions to the manual should occur after States and industry have had the opportunity to review and comment.
- A reliable means for distributing the manual to States and the regulated industry is to be developed.

Enforcement

Scope and Purpose

The goals of the enforcement program are to:

(1) Reinforce regulatory programs that safeguard human, animal and plant health;

(2) Provide effective and uniform administration of laws and rules which will assist in facilitating national and international trade;

(3) Facilitate voluntary compliance with requirements through education and promotion of industry-sponsored voluntary inspection programs; and

(4) Increase consumer confidence in the global marketplace through strong and effective enforcement.

Tools

Enforcement tools should be used by state and federal regulatory agencies in a judicious manner utilizing the most appropriate enforcement tool necessary to facilitate

compliance in a particular situation. The following state enforcement tools, some which may not be available to all state regulatory programs, are intended to serve as a guide.

(1) **Informational Letter.** Provides the regulated establishment with the information necessary to know what is needed to achieve compliance. This tool should be used when the violation is neither chronic in nature nor threatens animal or human health or safety.

(2) **Warning Letter.** Provides the regulated establishment with information specifically outlining a violation that has occurred and demands compliance. This tool should be used when a violation has the potential to threaten animal or human health or safety, but no specific incident has occurred.

(3) **Withdrawal From Distribution Order.** Directs the regulated establishment to remove a product from use or distribution until corrective action has been accomplished and confirmed. This tool should be used when animal or human health, safety, or animal productivity may be adversely affected. This tool may be used in conjunction with an informational letter, warning letter, or informal hearing/meeting.

(4) **Informal Hearing/Meeting.** Provides the regulated establishment with an opportunity to discuss and understand the information necessary to achieve compliance. This tool should be used when a violation is neither chronic in nature nor threatens animal or human health or safety. This tool may be used in conjunction with an informational letter, warning letter or withdrawal from distribution order.

(5) **Condemnation and Confiscation.** Any lot of commercial feed not in compliance may be subject to seizure by a court of competent jurisdiction in the area in which the commercial feed is located. The court may find the commercial feed to be in violation and order condemnation and disposition of the feed after first giving the claimant/manufacturer an opportunity to apply for the release of the commercial feed or to request permission to process or re-label the commercial feed to bring it into compliance. This tool should be used when a practice or product threatens health or safety; or when a violation is chronic in nature.

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

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

(8) **Criminal Prosecution.** Prosecution may be pursued in a court of competent jurisdiction against any firm and/or any person that impedes, obstructs, hinders or otherwise prevents or attempts to prevent enforcement of commercial feed regulations. This tool should be used when the violation seriously compromised animal or public health or significant monetary loss occurred resulting from economic fraud, and the act was done willfully.

(9) **Injunction.** Restrains a regulated establishment from engaging in any or all violations. This tool should be used when the establishment is engaging in conduct that causes immediate or irreparable harm to the public. In addition to an injunction, civil penalty or criminal prosecution may be levied.

The federal regulatory tools available to FDA are found in the following chapters of the FDA/ORA Regulatory Procedures Manual. For a complete description and text of federal enforcement tools, refer to the FDA/ORA Regulatory Procedures Manual. This document is available on FDA's home page at: http://www.fda.gov/ora/compliance_ref/rpm/default.htm

(1) **Chapter 4—Advisory Actions.** Under this chapter are found the advisory tools, Warning Letters and Untitled Letters which are applicable to all FDA regulated products.
(2) **Chapter 5—Administrative Actions.** Under this chapter are found the administrative tools; Citations, Detentions and Section 305 Meeting (the required hearing in a citation). This chapter also contains the enforcement tool of license revocation which is not currently applicable to all FDA regulated products.
(3) **Chapter 6—Judicial Actions.** Under this chapter are found the judicial tools; Seizure, Injunction, Inspection Warrants, Search Warrants (criminal situation only) and Prosecutions that are applicable to all FDA regulated products.

State and federal enforcement tools may appear to be similar in title and definition but may have very different regulatory intent. Even though both state and federal enforcement tools may be applicable, a clear distinction must be made between the two.

Compliance Assistance

Corrections to CGMP violations should be permitted while the Certified Inspector is on-site. Violations so corrected should be included and noted as corrected on the forms left by Certified Inspectors with establishment management when the inspection is completed.

CGMP violations not corrected while the Certified Inspector is on-site should be described on the forms left by the Certified Inspectors with establishment management when the inspection is completed. A follow-up inspection may be scheduled to determine that the violations have been corrected. Proof of correction using other means (e.g., by letter) is to be considered.