Final 9/14/21 version 2

# Ingredient Definitions Committee Report
# Annual Meeting via Webinar

**(3 sessions )**
August 2, 2021, 3:30PM – 5:00PM Eastern
August 3, 2021 3:30PM – 5:00PM Eastern
August 5, 2021 11:30AM – 12:30PM Eastern

Minutes approved by committee September 16, 2021
Video recording of the meeting is posted on the performedia site for the annual meeting: https://www.aafco.org/Meetings/Annual/2021
Video recording of the 8/5 meeting is posted in the BIN at:
https://aafco.mocaworks.com/viewer/?eID=1955665

## Recommendations to the Board and Association membership:

*When needed, text is presented in appendix A .*

1) Publish a tentative definition: **T**12.8 **Barley Protein Concentrate** and withdraw **12.6 Barley Distillers Protein concentrate** if T12.8 is accepted by Association Membership.

2) Publish a tentative definition: **T33.29(A) Black Soldier Fly Larvae Oil** (T33.29 to remain in place)

3) Add to table 101.1: AGRN 36 **Marine Microalgae Oil (**for dogs)

4) Add to table 101.1: AGRN 37 **Marine Microalgae Oil** (for cats)

5) Publish a new **table 90.27** concerning vitamin names in ingredient statements on finished pet foods. Insert at 2021 OP rev 1 page 508 after table 90.26 foot notes.

6) Make the following changes in ODI: (tentative changes do not go into ODI) **

| ODI Action | Name | Reference | Comments |
|---|---|---|---|
| Delete Ingredient Name<br>Delete Reference | Barley Distillers Protein Concentrate | 12.6 | Business meeting xx/xx/xxxx |
| Add Ingredient name //add reference | Marine Microalgae Oil | Table 101.1 | Business meeting xx/xx/xxxx |

| ODI Action | Name | Reference | Comments |
|---|---|---|---|
| Add Ingredient name // add reference | Vitamin A (Vitamin A Acetate) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin A (Vitamin A Palmitate) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin A (Vitamin A Propionate) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin $B_1$ (Thiamine Hydrochloride) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin $B_1$ (Thiamine Mononitrate) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin $B_2$ (Riboflavin) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin $B_2$ (Riboflavin-5-phosphate) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin $B_3$ (Niacin) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin $B_3$ (Niacinamide) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Choline (Choline Pantothenate) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Choline (Choline Chloride) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Choline (Choline Bitartrate) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Choline (Ferric Choline Citrate) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin $B_5$ ( Calcium Pantothenate) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin $B_5$ (Choline Pantothenate) | Table 90.27 | Business meeting xx/xx/xxxx |

| ODI Action | Name | Reference | Comments |
|---|---|---|---|
| Add Ingredient name // add reference | Vitamin $B_5$ (D-Pantothenyl Alcohol) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin $B_5$ (Sodium Pantothenate) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin $B_6$ (Pyridoxine Hydrochloride) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin $B_7$ ( Biotin) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin $B_9$ (Folic Acid) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin C (Ascorbic Acid) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin C (L-Ascorbyl-2-polyphosphate) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin C (Calcium Ascorbate)* | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin C (Calcium L-Ascorbyl-2-Monophosphate) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin C (Erythorbic Acid) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin $D_2$ (Ergocalciferol) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin $D_3$ ( Cholecalciferol) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin E (α-Tocopherol Acetate) | Table 90.27 | Business meeting xx/xx/xxxx |
| Add Ingredient name // add reference | Vitamin E (Tocopherols) | Table 90.27 | Business meeting xx/xx/xxxx |

**Board Action:**

To be considered in November 2021

**Association Action:**

To be considered in January 2022

## Recommendations not needing further Association review

**a)** Edit an official definition for **57.168 Selenomethionine Hydroxy Analogue** to align with the CFR revisions.

b) Edit an Official definition for **87.20 <u>Guanidinoacetic Acid</u>** to align with the CFR revisions.

## Referrals to other AAFCO committees:

A. -none-

## Minutes IDC August 2-5, 2021

## Session 1:

Committee met virtually. Committee member roll call on Google Doc was Displayed by Kent Kitade. A quorum was present. All 23 voting members were present. The chair asked if any regulators would like to join the committee. No volunteers came forward.

***ODI updating—in order to add transparency of the impact of committee decisions on the Online Database of Ingredients (ODI) label validation tool, the committee recommendations will include a table of the anticipated changes to ODI to reflect changes to common or usual names and/or references in the OP. It is anticipated this table will also appear in the front of the OP with the dates of adoption by the Association Membership. OP section editors are responsible for the accuracy of the ODI updates.*

1) *Hemp Update – Falina Hutchinson, MT Ingredient definition was submitted in February in 2021. CVM has asked the firm some questions. The BOD would like to do a round table discussion, preferably in person

2) Publish a new tentative definition **T12.8 Barley Protein Concentrate**. CVM recommended publishing the definition but indicated that the old definition language (12.6) be deleted concurrently. The new definition indicates a different manufacturing process. Discussion was held on use of the old definition. CVM indicated that it had reached out to several stakeholders and did not find that there is anyone marketing under the existing definition. The intended use only covers fish (not pets). Dan King moved to publish the tentative definition and delete 12.6. Jacob Fleig seconded. Motion passed with no objections.

3) Withdraw 12.6 Barley Distillers Protein Concentrate , covered in the motion in agenda item #2 – Dan King

4) Edit a tentative definition **T33.29 Black Soldier Fly Larvae Oil**. The change was to add adult dog food in the intended use. This includes treats for adult dogs. Discussion was held on using the edit process to add new species to the intended use. Bernadette Mundo moved to edit the tentative definition T33.29, Mark LeBlanc seconded. After discussion , voting 6 aye /FDA abstained/ 12 nay. *Motion failed.* Definitions adding new species should go in front of Association Membership.

   Bernadette Moved to add a new tentative definition **T33.29(A)** as displayed on the screen ( see appendix A) Brett Groves seconded. Motion passes with one nay. Existing tentative to remain in place

5) Edit an Official Definition for **57.168 Selenomethionine Hydroxy Analogue** (CFR amendment) – Motion to edit 57.168 to align with the recently updated CFR regulation. Language adds use for complete feed for beef cattle and dairy cattle, limit feeding to beef cattle, and free-choice feeding for beef cattle. Mark LeBlanc moved to edit 57.168 as displayed Stan Cook seconded. Motion passes unanimously.

6) Edit an Official Definition for **87.20 Guanidinoacetic Acid**- CVM moved to edit 87.20 as displayed on the screen, amendment changed broiler chicken and turkey to poultry. Mark LeBlanc seconded. Poultry means the same as in Title 7 of the CFR (any kind of domesticated bird, including, but not being limited to, chickens, turkeys, ducks, geese, pigeons, and guineas). Motion passes unanimously.

7) Add to table 101.1: AGRN 36- Nathan Price moved to add AGRN 36 **Marine Microalgae Oil** Mark LeBlanc seconds. This entry is for dogs. FDA letter restricts use rate and species. Motion passes unanimously.

8) Add to table 101.1: AGRN 37- Nathan Price moved to add AGRN 37 **Marine Microalgae Oil** Brett Groves seconds. This entry is for cats. FDA letter restricts use rate and species. Motion passes unanimously.

9) ~~Add to table 101.1: AGRN XX- Nathan Price (5 min)~~

10) **90.27 (NEW Table)** Pet food parenthetical Vitamin common name table Tom Phillips moved to publish new table 90.27 (version 4 was displayed) in the OP. Jacob seconded. Discussion covered MSBC, Inositol and other vitamins. Session 1 time ran out and the committee recessed until the next day. Tom will update the table before next IDC session to address concerns.

## Session 2:

August 3, 2021 3:30PM – 5:00PM Eastern

Discussion continued on table 90.27 with 23 of 24 members present virtually. Falina Hutchinson joined the committee. Kent Kitade was absent.

Tom Phillips presented a revised **table 90.27** version 08/02/2021. After discussion and a couple edits the motion passed unanimously.

11) (session 2) Dave Edwards, CVM provided an update on ingredient definition review performance. New staff are onboard and getting up to speed. CVM completed 41 of 45 (91%) AAFCO feed ingredient definition reviews on time so far in fiscal year 2021.

12) Common Food Index subcommittee report– Richard Ten Eyck, Dave Phillips. Non-defined workgroup is working on procedures. The guideline on CFI went through the MBRC and was accepted by Association membership this week. The guideline will be placed in chapter 5, but not as an SUIP. Users should view the CFI as an enhancement to the ODI tool. The CFI procedures need to come back to IDC and then go to strategic affairs for incorporation into the procedures manual.

13) ( moved to end of session 2 agenda) MSBC Workgroup Report -Austin Therrell, This expert panel met 5 times and formulated a couple recommendations. The workgroup felt that MSBC was safe and suitable for use as a source of vitamin K activity in the food for all animals. Austin moved to accept the workgroup report, Jacob Fleig seconded. PFI provided the workgroup a literature search on vitamin K and Nestle Purina provided feeding data. This information is proprietary in nature and was not shared with IDC. Charlotte Conway, FDA/CVM noted that she was a member of the workgroup but reiterated that CVM has consistently stated that additional

data is needed to expand intended uses in the ingredient definition of MSBC. Laura Scott, CFIA indicated their approval of MSBC would not cover pet food. *Motion to accept the report passed unanimously with CVM abstaining.*

The Chair thanks the committee for the time spent working out a path forward on this topic. It was difficult to get all stakeholders onto the same page using small groups. Discussion continues on day 3.

14) Report from workgroup reviewing animal proteins - Stan Cook The workgroup has been meeting monthly. No work products were presented. Some discussion covered whether an expert panel is needed to better describe materials used for pet food and changes in processing over the last several decades. They will have another update for IDC in January.

15) ~~**Review use of finished feed vs complete feed in chapter 6 of the OP – CVM (10 min)~~ pushed to October

Session 3:

August 5, 2021 11:30AM – 12:30PM Eastern

Video stored at: https://aafco.mocaworks.com/viewer/?eID=1955665

The third session was called to order shortly after 11:30AM Eastern. Kimberly Truett, WA joined as a new IDC member. 21 / 25 members were present. Members Absent: George Ferguson, Brett Groves, Mark LeBlanc, and Kelli Younker

Agenda Item 13 was carried forward to session 3:

After some questions on MSBC and discussion about the expert workgroup report. Tom Phillips offered language for a definition. "**T90.XX Menadione Sodium Bisulfite Complex** is the water-soluble, crystalline complex of menadione and sodium bisulfite. Menadione Sodium Bisulfite Complex provides a source of Vitamin K activity in animal feed. The compound may be safely used for animal feed in accordance with good manufacturing and feeding practices. The vitamin may also be listed as Vitamin $K_3$ (Menadione Sodium Bisulfite Complex)."

Two recommendations were made by the MSBC expert working group. Their first recommendation was broken into two actions. Their second recommendation was not taken up by the committee.

**MSBC Action 1.)** AAFCO publish a guideline in chapter 5 (need draft language from work group) that provides consensus that Menadione Sodium Bisulfite Complex (MSBC) be used as a safe and suitable source of Vitamin K activity in the food for all animals in the United States in accordance with good manufacturing and feeding practices. Motion: Erin Bubb 2nd: Laura Scott Motion Passes, FDA abstain *Richard is crafting draft language.*

**MSBC Action** 2.) That AAFCO pursue defining additional intended uses of **Menadione Sodium Bisulfite Complex** in chapter 6. Motion: Stan Cook 2nd: Dave Dressler motion passes unanimously

Discussion was held on the workgroup's second recommendation for the committee to review the PFI white paper. Concerns surrounded use of a confidential information in committee work. There was interest in a redacted version of the document. No motion came forward from the committee.

16) Discussions on changing established common or usual names: (pushed to the next meeting)

   a. topic 1(Corn Gluten Meal):– Dan King (20min)

b. topic 2 (Bagasse)- Mark LeBlanc (10 min)
c. Workgroup report on sunsetting (withdrawing) procedures for common or usual names in the OP. – (need a new lead) (10 min)

17) ICG workgroup report – Richard Ten Eyck (Pushed to the next meeting)

18) Update on the ingredient submission workshop modules – Meagan Davis (update was given in Education and Training earlier in the week)

19) Online training modules for ingredient requests. – Sue Hays, E.D. attempted to run but the LMS froze after about 2 minutes. Need to play it again in October. Discussion continued on timing of the release and pricing.

20) Adjourned approximately 1:13 PM EST

## Announcements

A. Next Meetings: October 19, 2021 Noon Eastern
B. New Investigators:
C. **Stale Ingredients:** The following are being removed from consideration as definition requests. Please submit a new request if still desired.
    a.

D. Parking Lot topics:
    a. Facilitate a round table discussion on the use of hemp in animal food.
    b. Establish a feed term for “Finished Feed” and “Total Ration.”
    c. NANP Subcommittee report –have not met -Ashley Shaw /Casey/Al
    d. ODI Subcommittee report – working on getting ODI changes table in front of OP –Jacob, Kelly
    e. **FROM PFC (draft):** *Vitamin common names for pet food should be addressed by IDC independent of the PFLM project. Information from the qualitative consumer research should be provided to the IDC. Work of the IDC common vitamin name workgroup should be quantitively consumer panel tested preferably at the same time as the PFLM changes.*
    f. Remove calcium Lignin Sulfonate from ODI.

g. Human Grade feed term edits accepted by IDC in January 2021 are being held until the human grade guidelines are passed out of model bill committee.
h. Review use of finished feed vs complete feed in chapter 6 of the OP – CVM (10 min) (feed term?)
i. Bring tentative definitions up for review to move to official.
j. Set up MSBC guideline editing workgroup.
k. Establish plan and timelines for defining MSBC.
l. Discussions on changing established common or usual names:
m. Review use of finished feed vs complete feed in chapter 6 of the OP
n. Update on Ingredient submission modules
o. Announce access of Ingredient Definition Process learning modules.

Minutes approved 9/16/21 with the following members not voting: George Ferguson, Kent Kitade, Mika Alewynse, Stan Cook, James Embry, Dave Phillips, Tom Phillips, Kelli Younker, Cory Skier and Falina Hutchinson.

## Appendix A for IDC 8/2/21 -8/5/21 minutes

**T12.8 Barley Protein Concentrate** is the dried protein fraction of barley prepared by enzymatic hydrolysis of starch, beta glucans, and fiber. The ingredient is prepared from barley that is dehulled or of a hulless variety. It must not contain less than 60% crude protein on a dry matter basis. The finished ingredient should not contain more than 10% moisture. It is to be used in the feed of fish as a source of protein.(proposed 2022)

**T33.29(A) 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, finfish feed, **and adult dog food**, 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, xxx; amended xxx)

Add to 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) |
|---|---|---|---|---|---|---|---|
| 36 Part 1 (PDF – 1023 pages) Part 2 (PDF – 1023 pages) | Veramaris USA LLC | Marine microalgae oil from Schizochytrium sp. | Marine Microalgae Oil | To be used as a source of long chain polyunsaturated fatty acids (PUFAs), docoahexanoic acid (DHA) and eicosapentaenoic acid (EPA) in canned and dry/extruded dog foods | dogs | 1/2/20 | FDA has no questions. (PDF - 4 pages) |

| 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) |
|---|---|---|---|---|---|---|---|
| 37 Part 1 (PDF - 400 pages) Part 2 (PDF - 585 pages) | Veramaris USA LLC | Marine microalgae oil from Schizochytrium sp. | Marine Microalgae Oil | To be used as a source of long chain polyunsaturated fatty acids (PUFAs), docoahexanoic acid (DHA) and eicosapentaenoic acid (EPA) in canned and dry/extruded cat foods | cats | 6/29/20 | FDA has no questions. (PDF - 4 pages) |

Add a new table 90.27

## Table 90.27 Vitamin Ingredient Nomenclature for Labeling of Finished Pet Foods.

The names in the Label Listing column may be used to represent the vitamins in the right hand column in finished foods and treats for dogs and cats. This table is intended to aid in the labelling of pet foods and provide more familiar names for vitamins for consumers. This table is not intended to list all available vitamins for use in pet food. In all cases the ingredient definition should be reviewed to ensure that it is appropriate for the intended use.

| **Label Listing** | **AAFCO Ingredient Definition or 21 CFR listing** |
|---|---|
| Vitamin A (Vitamin A Acetate) | 90.25 Vitamin A Acetate |
| Vitamin A (Vitamin A Palmitate) | 90.25 Vitamin A Palmitate |
| Vitamin A (Vitamin A Propionate) | 90.25 Vitamin A Propionate |
| Vitamin $B_1$ (Thiamine Hydrochloride) | 90.25 Thiamine Hydrochloride |
| Vitamin $B_1$ (Thiamine Mononitrate) | 90.25 Thiamine Mononitrate |
| Vitamin $B_2$ (Riboflavin) | 90.25 Riboflavin |
| Vitamin $B_2$ (Riboflavin-5-phosphate) | 21 CFR 582.5697 Riboflavin-5-phosphate |
| Vitamin $B_3$ (Niacin) | 90.25 Niacin; nicotinic acid |
| Vitamin $B_3$ (Niacinamide) | 90.25 Niacinamide; nicotinamide |
| Choline (Choline Pantothenate) | 90.25 Choline Pantothenate |
| Choline (Choline Chloride) | 90.25 Choline Chloride |
| Choline (Choline Bitartrate) | 90.26 Choline Bitartrate |
| Vitamin $B_5$ ( Calcium Pantothenate) | 90.25 Calcium Pantothenate |
| Vitamin $B_5$ (Choline Pantothenate) | 90.25 Choline Pantothenate |
| Vitamin $B_5$ (D-Pantothenyl Alcohol) | 21 CFR 582.5580 D-Pantothenyl Alcohol |
| Vitamin $B_5$ (Sodium Pantothenate) | 21 CFR 582.5772 Sodium Pantothenate |
| Vitamin $B_6$ (Pyridoxine Hydrochloride) | 90.25 Pyridoxine Hydrochloride |
| Vitamin $B_7$ ( Biotin) | 90.25 Biotin |
| Vitamin $B_9$ (Folic Acid) | 90.25 Folic Acid |
| Vitamin C (Ascorbic Acid) | 90.25 Ascorbic Acid |
| Vitamin C (L-Ascorbyl-2-polyphosphate) | 90.25 L-Ascorbyl-2-polyphosphate |
| Vitamin C (Calcium Ascorbate)* | 90.25 Calcium Ascorbate |
| Vitamin C (Calcium L-Ascorbyl-2-Monophosphate) | 90.25 Calcium L-ascorbyl-2-monophosphate |
| Vitamin C (Erythorbic Acid) | 90.25 Erythorbic Acid (Iso ascorbic acid) |
| Vitamin $D_2$ (Ergocalciferol) | 21 CFR 582.5950 Vitamin $D_2$ |
| Vitamin $D_3$ (Cholecalciferol) | 21 CFR 582.5953 Vitamin $D_3$ |
| Vitamin E (α-Tocopherol Acetate) | 90.25 a-tocopherol acetate |
| Vitamin E (Tocopherols) | 90.25 Tocopherol (a-tocopherol) |

Notes: * Vitamin C activity in dry feeds of < 13% moisture only.

## Edits not needing Association action:

**57.168 Selenomethionine Hydroxy Analogue**

[R,S-2-hydroxy-4-methylselenobutanoic acid (CAS 873660-49-2)] is manufactured by the reaction of elemental selenium with methyllithium to form a methylseleno salt, which is then reacted with R,S-2-hydroxybutyrolactone to form a salt of 2-hydroxy-4-methylselenobutanoic acid. After acidification and purification, the additive consists of not less than 39.5 percent total selenium by weight with a selenomethionine hydroxy analogue content of not less than 98 percent of total selenium. The total organic selenium content of the additive is not less than 99 percent of total selenium.

(a) The selenomethionine hydroxy analogue meets the following specifications:

(1) Arsenic, not more than 2 parts per million (ppm);

(2) Cadmium, not more than 1 ppm;

(3) Lead, not more than 1 ppm; and

(4) Mercury, not more than 1 ppm.

(b) Selenium, as selenomethionine hydroxy analogue, is added **to feed as follows:**

**(1) In complete feed for** chickens, turkeys, swine, **beef cattle, and dairy cattle** at a level not to exceed 0.3 ppm.

**(2) In feed supplements for limit feeding for beef cattle at a level not to exceed an intake of 3 milligrams per head per day.**

**(3) In salt-mineral mixtures for free-choice feeding for beef cattle up to 120 ppm in a mixture for free-choice feeding at a rate not to exceed an intake of 3 milligrams per head per day.**

(c) To ensure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling of selenomethionine hydroxy analogue in its packaged form shall contain:

(1) The name, selenomethionine hydroxy analogue;

(2) Minimum and maximum guarantees for a total selenium content of not less than 2.08 percent (weight/weight) and not more than 2.24 percent;

(3) Minimum guarantee for selenomethionine hydroxy analogue content of not less than 5.2 percent;

(4) The following statement, ``Storage Conditions: Selenomethionine hydroxy analogue must be stored in a closed package at temperatures not higher than 20°C (68°F)."; and

(5) An expiration date not to exceed 1 year from the date of manufacture.

(d) Selenomethionine hydroxy analogue, shall be incorporated into each ton of complete feed by adding no less than 1 pound of a premix containing no more than 272.4 milligrams of added selenium per pound.

(e) The premix manufacturer shall follow good manufacturing practices in the production of selenium premixes. Inventory, production, and distribution records must provide a complete and accurate history of product production. Production controls must assure

products to be what they are purported and labeled. Production controls shall include analysis sufficient to adequately monitor quality.
(f) The label or labeling of any selenium premix shall bear adequate directions and cautions for use including this statement: "Caution: Follow label directions. The addition to feed of higher levels of this premix containing selenium is not permitted."

21 CFR 573.920 (Adopted 2020, Amended 2022)

**87.20 Guanidinoacetic Acid.**
The food additive, guanidinoacetic acid, may be safely used in **poultry feeds** in accordance with the following prescribed conditions:

(a) The additive is manufactured by reacting glycine with cyanamide in an aqueous solution.

**(b) The additive is used or intended for use at levels not to exceed 0.12 percent of the complete feed:**

**(1) to spare arginine in broiler chicken and turkey feeds, or**

**(2) as a precursor of creatine in poultry feeds.**

(c) The additive consists of not less than 97 percent guanidinoacetic acid [N-(aminoiminomethyl)-glycine] (CAS 352-97-6) by weight.

(d) The additive meets the following specifications:

(1) Dicyandiamide not to exceed 0.5 percent;

(2) Cyanamide not to exceed 0.01 percent;

(3) Melamine not to exceed 15 parts per million (ppm);

(4) Sum of ammeline, ammelide, and cyanuric acid not to exceed 35 ppm; and

(5) Water not to exceed 1 percent.

(e) To assure safe use of the additive in addition to the other information required by the Federal Food, Drug, and Cosmetic Act:

(1) The label and labeling of the additive, any feed premix, and complete feed shall contain the name of the additive.

(2) The label and labeling of the additive and any feed premix shall also contain:

(i) A statement to indicate that the maximum use level of guanidinoacetic acid must not exceed 0.12 percent of the complete feed for **poultry**; and

(ii) Adequate directions for use.

21 CFR 573.496 (adopted 2018, amended 2022)