



Final: 5/2/19 ver 5 (accepted)

Ingredient Definitions Committee Meeting 4/04/19 e-meeting Report and Minutes

Recommendations to the Board and Association membership:

When needed, new text is presented in the committee minutes, appendix A.

- 1) Publish the New Feed Term “**Slaughter**, a process of killing an animal for food or feed.”
- 2) Publish **T3.1 Suncured Alfalfa Meal, or Pellets, or Ground Alfalfa Hay** as a Tentative definition. Leave 3.1 in place.
- 3) Modify **33.17 Gamma-linolenic acid safflower oil** and publish as Official.
- 4) New Definition **T60.118 Ground Juniper** publish as Tentative
- 5) New Definition **57.168 Selenomethionine hydroxy analogue** publish as Official.
- 6) Modify **73.046 Silicon dioxide** and publish as Official

Board Action:

To be considered in May 2019

Association Action:

To be considered in August 2019

Committee actions not requiring Association votes:

- a) Proceed with proposing edits to vitamin table adding non-chemical names.
- b) Established True Limestone workgroup
- c)

Topics moved to the next meeting:

- i. New Feed term Bison
- ii. New Feed term __ (workgroup output here) ___ Buffalo
- iii. GRAS verification workgroup to provide an update
- iv. Non-Defined workgroup to provide update in August.



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IDC Meeting Minutes 4/4/19

Meeting called to Order 8:31 AM PDT

1. Roll call of Committee members, present:
Richard Ten Eyck, Kristen Green, Mika Alewynse, Erin Bubb, David Beard, Brett Boswell, Ken Bowers, Michelle Boyd (joined late), Bob Church, Stan Cook (joined late), Dave Dressler, James Embry(left early), Maggie Faba, George Ferguson, Jacob Fleig, Steve Gramlich, Brett Groves, Ali Kashani, Dan King, Mark LeBlanc, Rick Manthei, Melanie Marquez, Dave Phillips, Tom Phillips, Nathan Price, Laura Scott, ~~Shannon Jordan~~, Charlotte Conway, Kent Kitade (joined late), Jennifer Kormos,

A quorum was present (27/27 voting members). The meeting was recorded.
There were 188 people logged into the webinar including the committee members.

2. CFR Modification 33.17 **Gamma-Linolenic Acid Safflower Oil**--cats
<https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-03514.pdf>
Motion to modify 33.17 to add cats as an intended species and publish as Official.
Brett Boswell moves, Bob Church seconds, motion PASSED
3. **Official Definition to publish in OP 57.168 Selenomethionine Hydroxy Analogue** Jennifer Kormos moved to add 57.168 as an Official Definition. Tom Phillips seconded, Motion PASSED
4. **Official Definition to publish in OP 73.046 Silicon Dioxide**, CFR update
Richard Ten Eyck moved to publish modifications to 73.046 as Official. Jacob Fleig Seconded. Motion PASSED
5. **T60.118 Ground Juniper** Erin Bubb moved to Publish as Tentative. George Ferguson seconded. – Motion PASSED
Discussion included the evaluation of terpenes and the length of time the recommendation has been in front of the committee.
6. **(placeholder) 3.1 Suncured Alfalfa Meal, or Pellets or Ground Alfalfa Hay**
is the aerial portion of the alfalfa plant reasonably free of other crop plants, weeds, and mold, which has been dried by solar means, stored as bales or stacks and finely or coarsely ground. If it is chopped instead of ground it must be designated as “Suncured Chopped Alfalfa” or “Chopped Alfalfa Hay”. ~~If it is ground and dehydrated by thermal means it must be designated as “Dehydrated Suncured Alfalfa”.~~

Erin Bubb moves to publish T3.1 adding to the current 3.1 definition: ***“If the ingredient is further dehydrated by thermal means after being ground, it must be designated as ‘Dehydrated Suncured Alfalfa Meal, or Pellets’”***



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George Ferguson seconds. Motion PASSED after a lot of discussion and presentations from the alfalfa industry. J.P. Ray a Nebraska alfalfa producer provided a rebuttal to the proposed change. Ken Vaupel spoke in favor of the proposal. Presentations are in the Feed BIN Library / Ingredient Definitions/Investigator Recommendations and on the teamboard.

7. Vitamin common names A, C, E – Tom, concept is in the BIN, need text. Tom Phillips moved to pursue edits to table 90.25. Richard Ten Eyck seconded, Motion Passed

Extensive discussion on label format for vitamins, not all states allowing parenthetical add-ons to the common or usual name. Proposal should only address vitamins used in pet and specialty pet. Committee was most comfortable with a common name followed by a parenthetical of the source. E.g. “Vitamin B2(Riboflavin)”

PFI, Richard Ten Eyck, Consumer group TBD, will help with edits.

8. Revise feed term **Stabilized** (process) – Ali Ali moved to revise the feed term “Stabilized” Jacob Fleig Seconds, Came from the SUIP workgroup. Committee had several questions and would like to see it go back to the SUIP workgroup for fine tuning. motion FAILED

Charlotte will help Ali to fine tune language.

9. New feed term Bison – Brett NOT Considered in this session. Workgroup will be hearing from Brett. Should be ready in August.

10. New feed term ____ (work group output here) ____ Buffalo -Brett NOT Considered in this session. Workgroup will be hearing from Brett. Should be ready in August.

11. New feed term “treat” – Ali Ali Kashani moved to publish a new feed term “Treat”. Brett Groves seconded. Fair amount of discussion. Occasional feeding may be preferred language. Some debate on species covered as well as inclusion of complete and balanced wording. Motion FAILED

12. Feed term slaughter or workgroup update – Ali Ali moved to publish a new feed term “**Slaughter**, a process of killing an animal for food or feed.” Jacob Fleig seconded. Requested a year ago to help clarify its use in several animal products definitions. Good deal of discussion. Bob Church proposed removing the word “humanely” as too subjective. Motion and second revised to remove “humanely.”



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Would this require inspection? No. Brett Groves called for the question. Vote by Roll call was 13 AYE, 10 NAY motion PASSED

13. **Hemp Update** (5 min) Bob Church Not much new, still waiting on industry to provide safety and efficacy data. Sue Hays will be updating the AAFCO white paper on hemp. Generally information is current. Leah suggested adding what the Farm Bill did and did not do to animal food hemp status. CVM is talking to people assembling Data to support a definition. FDA holding a public meeting on 5/31/19 on cannabis.
14. **Limestone workgroup update** – Jennifer Kormos Proposal received from industry for additional limestone definition and some modifications. Need BIN project set up. “True Limestone” Workgroup formed, Jennifer Kormos, Lead; AFIA; Diego Paiva (CVM);
15. GRAS verification workgroup update - Richard
 - a) Goal is established, workgroup needs to meet in next 6 weeks.
16. Volunteers to review “Is this Animal Food” Flowchart (for web) – Richard
Volunteers: Cathy Allinovi, AFIA, Dave Edwards, Angele Thompson
17. CVM item one (placeholder) (may move up agenda) (Juniper)
18. Confusing pet food name workgroup report (placeholder) Brett Boswell Workgroup is being re-energized. Brett is looking for others to join.
19. Status on high profile ingredients (placeholder) – Richard / CVM NONE to discuss
20. Discussion of common human foods in pet food (placeholder)- George Ferguson. Melanie Marquez (incoming Human Food By-Products investigator) discussed Vegetable Pomace (not defined) seeking a definition. Industry may be using Food Processing Waste in the interim, but need to satisfy the safety assessment requirements.

Milk Products investigator was seeking clarification on human food and Discussion of GRAS notices being separated between Animal Food and Human Food. Each would need a separate Independent Conclusion of GRAS because they are different intended use.



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21. Topic from Gallery: When will Oat Fiber be Official? Discussed process modify vs. new definition. Investigator and CVM are getting questions on the current definition and not clear on what resolution will be. This clouds when the investigator may recommend a change to Official.

Meeting Adjourned 11:12AM PDT

Minutes accepted 5/2/19 with 17/26 members voting affirmative. These committee members did not vote: Kristen Green, Michelle Boyd, Stan Cook, James Embry, Ali Kashani, Mark Leblanc, Melanie Marquez and Laura Scott.

Helvetica 12 B I U To: Kristen M Green ▾ Michelle Boyd ▾ Stan Cook ▾ James A. Embry ▾ ALI Kashani ▾ Mark LeBlanc ▾ Melanie Marquez ▾ Richard C Teneyck ▾ Laura Scott ▾



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APPENDIX A to IDC 4/4/19 Minutes

T3.1 Suncured Alfalfa Meal, or Pellets, or Ground Alfalfa Hay is the aerial portion of the alfalfa plant, reasonably free of other crop plants, weeds, and mold, which has been dried by solar means, stored as bales or stacks, and finely or coarsely ground. If it is chopped instead of ground, it must be designated as “Suncured Chopped Alfalfa” or “Chopped Alfalfa Hay”. **If the ingredient is further dehydrated by thermal means after being ground, it must be designated as “Dehydrated Suncured Alfalfa Meal, or Pellets”**(proposed xxxx)

33.17 Gamma-linolenic acid safflower oil- The food additive, gamma-linolenic acid safflower oil, may be safely used in animal food as a source of gamma-linolenic acid and other omega-6 fatty acids in accordance with the following conditions:

(a) The additive is the oil obtained from whole seeds and/or partially dehulled seeds of a *Carthamus tinctorius* L. safflower Centennial variety genetically engineered to express the delta-6-desaturase gene from *Saprolegnia diclina* Humphrey. The 453 amino acid, delta-6-desaturase enzyme converts the fatty acid linoleic acid to gamma-linolenic acid (all-cis-6,9,12-octadecatrienoic acid) during seed development.

(1) The additive obtained from the seeds of the genetically engineered safflower Centennial variety may be blended with oil obtained from seeds of non-engineered oleic acid safflower varieties in order to meet the specifications required for the additive or the blend in paragraph (a)(2) of this section.

(2) The additive or a safflower oil blend containing the additive for use in animal food meets the following specifications:

(i) Crude fat content of the additive or the safflower oil blend is not less than 99.5 percent.

(ii) Gamma-linolenic acid content is between 350 and 450 milligrams (mg) gamma-linolenic acid per gram of the additive or the safflower oil blend.

(iii) Total content of stearidonic acid and cis, cis-6,9-octadecadienoic acid in the additive or the safflower oil blend must not exceed a total of 0.3 percent.

(b) Addition of the additive, or the safflower oil blend, to complete dry adult maintenance dog food must meet the following:

(1) Addition of the additive or the safflower oil blend cannot provide more than 36 mg gamma-linolenic acid per kilogram body weight of the dog per day in more than 86 mg of the additive or the safflower oil blend. This maximum addition rate of the additive, or the safflower oil blend, is 0.3 percent of a complete dry adult maintenance dog food containing 3,600 kilocalories of metabolizable energy per kilogram of food as-fed.

(2) Adjustments must be made for differing concentrations of gamma-linolenic acid and for dog food formulas of different caloric density and/or that are fed to specific weights, breeds, or dogs of different activity levels to meet the requirements of this paragraph.



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(c) Addition of the additive, or the safflower oil blend, to complete dry adult maintenance cat food must meet the following:

(1) Addition of the additive or the safflower oil blend cannot provide more than 33 mg gamma-linolenic acid per kilogram body weight of the cat per day in more than 79 mg of the additive or the safflower oil blend. This maximum addition rate of the additive, or the safflower oil blend, is 0.5 percent of a complete dry adult maintenance cat food containing 4,000 kilocalories of metabolizable energy per kilogram of food as-fed.

(2) Adjustments must be made for differing concentrations of gamma-linolenic acid and for cat food formulas of different caloric density and/or that are fed to specific weights, breeds, or cats of different activity levels to meet the requirements of this paragraph.

(d) To assure safe use of the additive, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling of the additive shall bear the following:

(1) The name of the additive, gamma-linolenic acid safflower oil, or GLA safflower oil;

(2) A guarantee for the minimum content of gamma-linolenic acid; and

(3) Adequate directions for use such that the finished animal food complies with the provisions of paragraphs (b) and (c) of this section.

(Proposed XXXXX) 21 CFR 573.492

57.168 Selenomethionine hydroxy analogue

Selenomethionine hydroxy analogue [R,S-2-hydroxy-4-methylselenobutanoic acid (CAS 873660-49-2)] is manufactured by the reaction of elemental selenium with methyl lithium 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.

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

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

(ii) Cadmium, not more than 1 ppm;

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

(iv) Mercury, not more than 1 ppm.

(2) Selenium, as selenomethionine hydroxy analogue, is added to complete feed for chickens, turkeys, and swine at a level not to exceed 0.3 ppm.

(3) 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:

(i) The name, selenomethionine hydroxy analogue;

(ii) 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;



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- (iii) Minimum guarantee for selenomethionine hydroxy analogue content of not less than 5.2 percent;
- (iv) 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
- (v) An expiration date not to exceed 1 year from the date of manufacture.
- (4) 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.
- (5) 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.
- (6) 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."

(Proposed XXXX) 21 CFR 573.920

T60.118 Ground Juniper is a roughage consisting of the entire aerial portion of the juniper plant (trunk, bark, branches, leaves, and berries), obtained only from *Juniperus pinchotii* and/or *Juniperus ashei*. Any plant part below ground level is excluded to avoid contamination with soil and/or rocks. It is ground to pass a screen no larger than 5/8 inches (15.875 mm). The ingredient must be guaranteed for crude protein and acid detergent fiber. Ground juniper is to be fed as a dietary roughage for cattle, sheep, or goats in accordance with good feeding practices. (proposed xxxx)

73.046 Silicon dioxide

The food additive silicon dioxide may be safely used in animal feed in accordance with the following conditions:

- (a) The food additive is manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect.
- (b) It is used or intended for use in feed components as an anticaking agent, and/or grinding aid, as follows:

Feed component	Limitations (percent)
BHT (butylated hydroxytoluene)	2
Methionine hydroxy analog and its calcium salts	1
Piperazine, piperazine salts	0.8
Sodium propionate	1
Urea	1



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Vitamins ^a	3
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(c) It is used in feed as an anticaking agent in an amount not to exceed that reasonably required to accomplish its intended effect and in no case in an amount to exceed 2 percent by weight of the finished feed.

d) It is used or intended for use in feed components, as a carrier as follows:

Feed component	Limitations (percent)
Flavors	50
Selenomethionine hydroxy analogue	95

e) To assure safe use of the additive, silicon dioxide is to be used in an amount not to exceed that reasonably required to accomplish its intended effect, and silicon dioxide from all sources cannot exceed 2 percent by weight of the complete feed.

21 CFR 573.940 (Proposed 1964, Adopted 1965, Amended 2008, Adopted 2010, Amended 2018, **Amended xxxx**)

^aSilicon dioxide may be mixed with Vitamin E at levels up to 50%, to produce Vitamin E Supplement for addition to animal feed. Where silicon dioxide is used as a dispersant and/or flow agent to assist with uniform and consistent distribution of the vitamin E supplements in animal feed, silicon dioxide should be declared on the ingredient list of the vitamin E supplement.