Model Bills and Regulations Committee Report 2019 AAFCO Midyear Meeting January 21, 2019 – Savannah, Georgia

Committee Recommendations:

- The Model Bills and Regulations Committee recommends that the following revisions be made to the Statements for Uniform Interpretation and Policy (SUIP) of Chapter 5 in the AAFCO *Official Publication*, and that the AAFCO Board of Directors review the proposed revisions for future consideration by the Association membership.
 - a. Add the following preamble to the SUIP section of the AAFCO *Official Publication*:

This section includes Statements for Uniform Interpretation and Policy (SUIP) of the AAFCO Model Bills and Regulations. In general, AAFCO SUIPs do not establish legally enforceable responsibilities. Instead, these SUIPs describe AAFCO's current thinking on a topic and should be viewed only as recommendations, in the absence of specific regulatory or statutory requirements. There are many pathways for statements to be published in Chapter 5, one of which is by recommendation from the AAFCO Model Bills and Regulations Committee to the AAFCO Board of Directors as a means of further clarification and interpretation. These statements should be reviewed every two years on odd number years at the AAFCO Mid-Year Meeting by a subgroup of the Model Bills and Regulations Committee to determine relevancy and applicability, then deleted or moved to the appropriate section of the Official Publication when such actions are warranted.

- b. Delete SUIP 10 Brand Names
- c. Move SUIP 15 Raw Leather Residue to Regulation 10 Adulterant of the Model Regulations under the Model Bill by adding the following language:

10(a)(6) Raw leather residue from tanning or leather manufacturing.

Delete SUIP 15 if Regulation 10(a)(6) is approved by the AAFCO membership.

d. The Model Bill and Regulations Committee accepts the SUIP Workgroup recommendation to add Regulation 8(b) language to the Model Regulations under the Model Bill (as indicated below) based on SUIP 19 regarding Feeding or Use Directions for Feeds Containing High Levels of Non-Protein Sources of Nitrogen and moving current Regulation 8(b) and (c) items to Regulation 8(c) and (d) respectively.

8(b) Feeding or use directions for those feeds in which more than 50% of the protein content is derived from non-protein nitrogen sources should include

recommendations as to providing adequate supplies of drinking water, sources of energy, forages being fed, minerals, adaptation ("warm-up") periods and stress conditions when necessary.

Delete SUIP 19 if new Regulation 8(b) is approved by the AAFCO membership.

- 2. The Model Bills and Regulations Committee recommends Regulation 4 Expression of Guarantees of the Model Regulations Under the Model Bill be revised as indicated in Attachment B, and that the AAFCO Board of Directors review the proposed revisions for future consideration by the Association membership.
- 3. The Model Bills and Regulations Committee recommends Regulation PF4 Expression of Guarantees of the Model Regulations for Pet Food and Specialty Pet Food Under the Model Bill be revised as indicated in Attachment C, and that the AAFCO Board of Directors review the proposed revisions for future consideration by the Association membership.
- 4. The Model Bills and Regulations Committee recommends Regulation PF9 Statements of Calorie Content of the Model Regulations for Pet Food and Specialty Pet Food Under the Model Bill be revised as indicated in Attachment C, and that the AAFCO Board of Directors review the proposed revisions for future consideration by the Association membership.

Board Recommendations:

Association Actions:

Committee Report and Minutes:

Model Bills and Regulations Committee Chairman Doug Lueders called the meeting to order at 1:30 p.m. on Jan. 21, 2019. He welcomed committee members, industry advisers and guests who were present, and reviewed the agenda.

In addition to Chairman Lueders, committee members participating in the meeting were: Ken Bowers (Kansas), George Ferguson (North Carolina), Robert Geiger (Indiana), Kristen Green (Kentucky), Richard Ten Eyck (Oregon), and Scott Ziehr (Colorado).

Industry advisers participating were: Meghan Dicks and Steve Younker (AFIA), David Dzanis (APPA/ACVN), Emily Helmes (ETA), Catherine Alinovi (Next Generation Pet Food Manufacturers Association), Jan Campbell and David Fairfield (NGFA), and Angele Thompson and Pat Tovey (PFI).

AAFCO Executive Director Sue Hayes also participated in the meeting.

Minutes from Previous Committee Meeting

Chairman Lueders noted that minutes from the July 30, 2018 committee meeting conducted in Fort Lauderdale were previously approved, posted on the AAFCO website and Feed BIN, and were included in the 2019 AAFCO Midyear Meeting Committee Reports.

SUIP Working Group Report

The committee considered recommendations made by the Statements for Uniform Interpretation and Policy (SUIP) Work Group that had been established during the 2018 AAFCO Midyear Meeting to evaluate whether SUIPs listed on pages 233-235 of Chapter 5 in the 2019 AAFCO *Official Publication* should have a defined path to incorporation into the Model Bills or Regulations or eventually be deleted.

Members of the SUIP Work Group are Catherine Alinovi, chair (NGPFMA), Lizette Beckman (Feed Labeling Committee), Emily Bulian Helmes (ETA), Padma Pillai (FDA), Austin Therrell (Feed and Feed Ingredient Manufacturing Committee), Angele Thompson (PFI) and Steve Younker (AFIA).

The SUIP Work Group recommendations and committee actions are indicated in Attachment A.

Old Business

1. Proposed Revisions to Regulation 4 – Expression of Guarantees

The committee considered proposed revisions to Regulation 4 – Expression of Guarantees of the Model Regulations Under the Model Bill as indicated in Attachment B.

Ken Bowers moved that the proposed revisions to Regulation 4 be accepted and that the AAFCO Board of Directors review the proposed revisions for future consideration by the Association membership.

Scott Ziehr seconded the motion. The committee approved the motion.

New Business

The committee proceeded to consider new business.

1. Proposed Revisions to PF4 – Expression of Guarantees

The committee considered proposed revisions to Regulation PF4 of the Model Regulations for Pet Food and Specialty Pet Food Under the Model Bill as indicated in Attachment C.

Kristen Green moved that the proposed revisions to Regulation PF4 be accepted and that the AAFCO Board of Directors review the proposed revisions for future consideration by the Association membership.

Robert Geiger seconded the motion. The committee approved the motion.

2. Proposed Revisions to PF9 – Statements of Calorie Content

The committee considered proposed revisions to Regulation PF9 of the Model Regulations for Pet Food and Specialty Pet Food Under the Model Bill as indicated in Attachment C.

Kristen Green moved that the proposed revisions to Regulation PF9 be accepted and that the AAFCO Board of Directors review the proposed revisions for future consideration by the Association membership.

Robert Geiger seconded the motion. The committee approved the motion.

3. Proposed Revisions to Section 7. Adulteration.

The committee considered the proposed revisions to Section 7 – Adulteration of the Model Bill as indicated in Attachment D. The committee tabled action on the proposed revisions in order to get input from FDA. The MBRC will consider the language again at the committee's next meeting.

Adjournment

Mr. Lueders asked whether there was any other business to be considered by the committee. Given that none was identified, the committee meeting was adjourned at 2:30 p.m.

On behalf of the Model Bills and Regulations Committee, I respectfully submit this report and request acceptance of the report and recommendations by the AAFCO Board of Directors and the Association membership.

Model Bills and Regulations Committee Attachment for January 21, 2019 Meeting

Attachment A

Statements for Uniform Interpretation and Policy (SUIP) Working Group Report to the Model Bill and Regulations Committee

The SUIP Working Group makes the following recommendations to the MBRC:

1. Recommends adding the following preamble – giving purpose and process to the SUIP section, as well as a timeline for periodic review of these policy statements.

Introduction/Preamble

This section includes Statements for Uniform Interpretation and Policy (SUIP) of the AAFCO Model Bills and Regulations. In general, AAFCO SUIPs do not establish legally enforceable responsibilities. Instead, these SUIPs describe AAFCO's current thinking on a topic and should be viewed only as recommendations, in the absence of specific regulatory or statutory requirements. There are many pathways for

statements to be published in Chapter 5, one of which is by recommendation from the AAFCO Model Bills and Regulations Committee to the AAFCO Board of Directors as a means of further clarification and interpretation. These statements should be reviewed every two years on odd number years at the AAFCO Mid-Year Meeting by a subgroup of the Model Bills and Regulations Committee to determine relevancy and applicability, then deleted or moved to the appropriate section of the Official Publication when such actions are warranted.

Committee Action:

Moved to Accept: Ken Bowers Seconded: Robert Geiger

Motion: Passed

2. Recommends separating active statements from deleted statements, keeping each part in chronological sequence. This provides for historical information while making the section easier to read.

Committee Action:

Moved to Accept: Kristen Green

Seconded: Ken Bowers

Motion: Passed (editorial change)

Recommends moving SUIP 3 - Trade or Proprietary names - to the deleted list. The
rationale is that AAFCO Ingredient Definitions Committee (IDC) has already
incorporated this language into the update to the Guide for New Ingredient
Submissions.

Committee Action: Recommendation tabled until the IDC acts upon update to the Guide for New Ingredient Submissions.

4. Recommends moving SUIP 10 – Brand names – to deleted list. From a legal perspective, a feed control officer is neither in a position to determine nor manage this issue.

Committee Action:

Moved to Accept: Ken Bowers Seconded: Kristen Green

Motion: Passed

5.	Recommends adding language to theensuring that the intent of SUIP 14 is included.	
	the deleted list if/when the newthe AAFCO membership. This item to be subm	
	(Process) Stabilized. When an ir been treated to improve stability, the expres	

"with improved stability" may appear following the ingredient in the statement of ingredients. (The process used is to be specified on the ingredient label.)

Committee Action:

Moved to Accept: Richard Ten Eyck

Seconded: Kristen Green

Motion: Passed

6. Recommends moving SUIP 15 – Raw leather residue from tanning or leather manufacturing – to the Adulterants [Model Bill, Regulation 10(a)(6)] list. Move SUIP 15 to the deleted SUIP list if/when Regulation 10(a)(6) is approved by the AAFCO membership.

10(a)(6) Raw leather residue from tanning or leather manufacturing.

Committee Action:

Moved to Accept: Ken Bowers Seconded: Kristen Green

Motion: Passed

7. Recommends adding Regulation 6(h) language regarding **Carriers** (as below) to Regulation 6 of the Model Bill. Move SUIP 17 – Carriers – to the deleted SUIP list if/when 6(h) is approved by the AAFCO membership.

6(h) Each carrier shall be listed in the ingredient statement on the label unless it meets the criteria for an incidental ingredient [21 CFR 501.100(a)(3)].

Committee Action: Recommendation tabled and to be considered during subsequent Model Bill and Regulations Committee meeting.

8. Recommends the Model Bill and Regulations Committee consider adding Regulation 8(b) language (as below) regarding Feeding or Use Directions for Feeds Containing High Levels of Non-Protein Sources of Nitrogen and moving current Regulation 8(b) and (c) items to Regulation 8(c) and (d) respectively.

Move SUIP 19 – Feeding or Use Directions for Feeds Containing High Levels of Non-Protein Sources of Nitrogen – to the deleted SUIP list if/when the new 8(b) is approved by the AAFCO membership.

8(b) Feeding or use directions for those feeds in which more than 50% of the protein content is derived from non-protein nitrogen sources should include recommendations as to providing adequate supplies of drinking water, sources of energy, forages being fed, minerals, adaptation ("warm-up") periods and stress conditions when necessary.

Committee Action:

Moved to Accept: George Ferguson

Seconded: Ken Bowers

Motion: Passed

9. Recommends adding the adoption date for SUIP 23 – Registration and Labeling of Silage Additive Products – to the language: (Adopted 1979). Additionally, in the first sentence of SUIP 23, where a reference to "Commercial Feed" wrongly cited as Section 3(d) of the Model Bill, and therefore the WG recommends this should be corrected to state Section 3(b).

Committee Action:

Moved to Accept: Kristen Green Seconded: George Ferguson Motion: Passed (editorial change)

10. Recommends moving SUIP 27 to the AAFCO Pet Food Committee for their consideration for inclusion in the Pet Food Regulation as a new PF12 (as below). Move SUIP 27 – Chews, Bones, and Toys for Pets and Specialty Pets – to the deleted list if/when PF12 is approved by the AAFCO membership.

Regulation PF12. Chews, Bones and Toys for Pets or Specialty Pets

Chews, bones and toys for pets or specialty pets are exempt from the requirements of state registration or licensing as long as the following are met:

- (a) Product labeling or advertising may not:
 - (1) Make claims that:

The product is intended for use as an animal food (such as any nutritional value ("digestible" or "high protein") or structure/function (? Provide example here):

- (2) Provide a:
 - (i) Guaranteed analysis: or
 - (ii) Calorie Statement
- (3) Contain the word 'treat' or 'snack'.
- (b) Product labeling or advertising may:
 - (1) Make dental claims by mechanical action;
 - (2) Contain animal food-acceptable flavors or color additives;
 - (3) Contain animal food-acceptable binders as long as the purpose is to hold the product together and at a "low inclusion rate" (to be defined).

Committee Action:

Moved to Accept: Robert Geiger

Seconded: Ken Bowers

Motion: Passed

11. Recommends to the MBRC that the working group be disbanded as the 2018-2019 mission has been completed.

Chairman Lueders did not disband workgroup due to pending actions required on recommendations. (SUIP #3 and SUIP #17)		

Model Bills and Regulations Committee Attachment for January 21, 2019 Meeting

Attachment B

Labeling of Mineral and Vitamin Units Recommended edits

- 1. Model Regulations Under the Model Bill, Regulation 4: Expression of Guarantees Add: (c) (8) Products labeled with a quantity statement (e.g. tablets, capsules, granules, or liquid) may state vitamin guarantees in milligrams per unit (e.g. tablets, capsules, granules, or liquids) consistent with the quantity statement and directions for use.
- 2. Model Regulations Under the Model Bill, Regulation 4: Expression of Guarantees Revise (g) as follows:
 - (g) Guarantees for microorganisms shall be stated in colony forming units per gram (CFU/g) when directions are for using the product in grams, or in colony forming units per pound (CFU/lb.) when directions are for using the product in pounds. A parenthetical statement following the guarantee shall list each species in order of predominance.
 - (g) Guarantees for microorganisms shall list each <u>genus and</u> species in order of predominance, and shall be stated and conform to the following:
 - (1) Colony forming units per gram (CFU/g) or per pound (CFU/lb.) consistent with the directions for use; or
 - (2) Colony forming units per pound (CFU/lb.) consistent with the directions for use; or
 - (23) CFU per unit (e.g., tablets, capsules, granules or liquids) consistent with directions for use and the quantity statement or weight equivalent (e.g., 1 fl. oz. = 28 grams) for liquid products.
- 3. Model Regulations Under the Model Bill, Regulation 4: Expression of Guarantees Revise (h) as follows:
 - (h) Guarantees for enzymes shall be stated in units of enzymatic activity per unit weight or volume, consistent with label directions. The source organism for each type of enzymatic activity shall be specified, such as: Protease (*Bacillus subtilis*) 5.5 mg amino acids liberated/min./milligram. If two or more sources have the same type of activity, they shall be listed in order of predominance based on the amount of enzymatic activity provided.
 - (h) Guarantees for enzymes shall be stated and conform to the following:
 - (1) Units of enzymatic activity per unit weight or volume consistent with the directions for use; or
 - (2) Enzymatic activity per unit (e.g., tablets, capsules, granules, or liquids) consistent with the directions for use and the quantity statement or weight equivalent (e.g., 1 fl. oz. = 28 grams) for liquid products.

(3) The source organism for each type of enzymatic activity shall be specified, such as: protease (*Bacillus subtilis*) 5.5 mg amino acids liberated/min./milligram. If two or more sources have the same type of activity, they shall be listed in order of predominance based on the amount of enzymatic activity provided.

Model Bills and Regulations Committee Attachment for January 21, 2019 Meeting

Attachment C

Proposed Revision to PF4 – Expression of Guarantees

There has been some confusion about use of a heading in the Guaranteed Analysis. While most labels do use the words "Guaranteed Analysis" as the heading, some companies have expressed that the regulations do not clearly state the requirement for the heading. In order to clarify the need for the use of the heading, the following change to PF4(a) is being proposed:

Regulation PF4. Expression of Guarantees

- (a) The "Guaranteed Analysis" shall be listed <u>under the heading "Guaranteed</u> <u>Analysis"</u> in the following order and format unless otherwise specified in these Regulations:
 - (1) A pet food or specialty pet food label shall list the following required guarantees;
 - A. Minimum percentage of crude protein;
 - B. Minimum percentage of crude fat;
 - C. Maximum percentage of crude fat, if required by Regulation PF10;
 - D. Maximum percentage of crude fiber;
 - E. Maximum percentage of moisture; and
 - F. Additional guarantees shall follow moisture.....

Proposed Revision to PF9 - Statements of Calorie Content

There has been some confusion on the part of both regulators and industry about the requirement of "...in terms of metabolizable energy (ME)..." to be included in the calorie content statement. The energy of a food can be expressed in several ways: gross energy, digestible energy and metabolizable energy. The Model Pet Food & Specialty Pet Food Regulations state in PF9(a)(2) that the calorie content statement on pet food labels must be in terms of metabolizable energy. However, the wording in the regulation is not a clear enough communication of the requirement. The proposed language change is intended to clarify the regulation and lessen the confusion on the part of both the regulator and the regulated industry.

Regulation PF9. Statements of Calorie Content

- (a) The label of a dog or cat food, including snacks, treats, and supplements, shall bear a statement of calorie content and meet all of the following:
 - (1) The statement shall be separate and distinct from the "Guaranteed Analysis" and appear under the heading "Calorie Content";
 - (2) The statement shall be measured in terms of metabolizable energy (ME) on an "as fed" basis and must be expressed, including either the words 'metabolizable energy' or the abbreviation 'ME,' both as "kilocalories per kilogram" ("kcal/kg") of product, and as kilocalories per familiar household measure (e.g., cans or cups) or unit of product (e.g., treats or pieces); and
 - (3) The calorie content is determined by one of the following methods:

Model Bills and Regulations Committee Attachment for January 21, 2019 Meeting

Attachment D

Section 7. Adulteration

A commercial feed shall be deemed to be adulterated:

(a)

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such commercial feed shall not be considered adulterated under this subsection if the quantity of such substance in such commercial feed does not ordinarily render it injurious to health; or