Model Bills and Regulations Committee Report 2019 AAFCO Annual Meeting August 5, 2019 – Louisville, Kentucky

Committee Recommendations:

The Model Bills and Regulations Committee recommends the following revisions be made to the Model Bills and Regulations, and that the AAFCO Board of Directors review the proposed revisions for future consideration by the Association membership.

- 1. Delete Regulation PF3(e) from the Model Regulations for Pet Food and Specialty Pet Food as indicated in Attachment D.
- **2.** Revise Regulation PF4(g) within the Model Regulations for Pet Food and Specialty Pet Food as indicated in Attachment E.
- **3.** Revise Regulation 3(a)(4)(XII)(c) within the Model Regulations Under the Model Bill as indicated in Attachment E.

Board Recommendations:

Association Actions:

Committee Report and Minutes:

Model Bills and Regulations Committee Chairman Doug Lueders called the meeting to order at 1:00 p.m. on Aug. 5, 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), Robert Geiger (Indiana), Kristen Green (Kentucky), Ben Jones (Texas), Eric Nelson (FDA), 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 (NGPFMA), 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 January 21, 2019 committee meeting conducted in Savannah, Georgia were previously approved on March 27, posted on the AAFCO website and Feed BIN, and were included in the 2019 AAFCO Annual Meeting Committee Reports.

SUIP Working Group Report

Robert Geiger moved to accept for discussion recommendations previously made by the Statements for Uniform Interpretation and Policy (SUIP) workgroup that had been tabled by the committee during its Savannah meeting.

Ben Jones seconded the motion. The committee approved.

Old Business

1. Tabled (postponed) from Savannah - Recommendations for SUIP #3 (Attachment A)

The committee considered proposed recommendations to SUIP #3 – Trade or Proprietary Names as indicated in Attachment A.

Richard Ten Eyck moved to postpone action on the recommendation until the updated Guide for New Ingredient Submissions is considered by the AAFCO membership. Ken Bowers seconded the motion. The committee approved.

2. Tabled (postponed) from Savannah - Recommendations for SUIP #17 (Attachment B)

The committee considered proposed recommendations to SUIP #17 – Carriers as indicated in Attachment B.

Ken Bowers moved to postpone action on the recommendation until the Model Bills and Regulations Committee considers the proposed Regulation 6(h) language. Scott Ziehr seconded the motion. The committee approved.

3. Proposed Revision to Model Bill Section 7 - Adulteration (Attachment C)

The committee considered proposed revisions to Model Bill Section 7 – Adulteration as indicated in Attachment C.

Robert Geiger moved to postpone action on the proposed revision until the committee's next meeting. Ken Bowers seconded the motion. The committee approved.

New Business

The committee proceeded to consider new business.

1. Deletion of PF3(e) - Brand and Product Names (Attachment D)

The committee considered the proposed deletion of PF3(e) from the Model Regulations for Pet Food and Specialty Pet Food as indicated in Attachment D.

Ken Bowers moved to delete PF3(e). Kristen Green seconded the motion. The committee approved.

2. Proposed Revision to Model Regulations for Pet Food and Specialty Pet Food PF4(g) - Expression of Guarantees (Attachment E)

The committee considered the proposed revision of PF4(g) from the Model Regulations for Pet Food and Specialty Pet Food as indicated in Attachment E.

Scott Ziehr moved to accept the proposed revision. Ken Bowers seconded the motion. The committee approved.

3. Proposed Revision to Model Regulations 3(a)(4)(XII)(c) - Expression of Guarantees (Attachment E)

The committee considered the proposed revision of Model Regulations 3(a)(4)(XII)(c) as indicated in Appendix E.

Ken Bowers moved to accept the proposed revision. Robert Geiger seconded the motion. The committee approved.

Assignments for Midyear Meeting

Concern was expressed by Leah Wilkinson, AFIA, that revisions to Model Regulation 4(g) – Expression of Guarantees for microbials approved by the AAFCO membership during the Annual Meeting Association Business Session could cause the industry to incur significant relabeling costs.

In response, Chairman Lueders directed the following individuals to further evaluate the issue and report findings to the committee during the 2020 AAFCO Midyear Meeting: Jan Campbell, Emily Helmes, Leah Wilkinson, Angele Thompson, Scott Ziehr, and an FDA representative to-be-determined (Padma Pillai).

Adjournment

Chairman 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 2:00 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 Attachments for August 5, 2019 Meeting

Attachment A – Proposed Revision to Statements for Uniform Interpretation and Policy (SUIP) #3

The SUIP Working Group 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.

Attachment B – Proposed Revision to Statements for Uniform Interpretation and Policy (SUIP) #17

The SUIP Working Group recommends adding Regulation 6(h) language regarding *Carriers* (as below) to Regulation 6 of the Model Regulations Under 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)].

Attachment C – Proposed Revision to Model Bill Section 7. Adulteration (new language bold and underscored)

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 <u>human or animal</u> 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 <u>human or animal</u> health; or

Attachment D – Proposed Revision to Model Regulations for Pet Food and Specialty Pet Food PF3(e)

Background:

PF3(e) has been in the AAFCO OP since the 70s or 80s. Subsequently, many changes have been made to PF(3), including the addition of the "with" regulation and further refinement of the flavor and other regulations in this section. In the 90's there was a complete rework of the regulations although the working group was told not to change the intent of the regulations. The workgroup at that time was not sure of the intent of PF3(e), so they left it in the PF Regulations.

It appears that PF3(e) was meant as a catch all but has outlived its usefulness. Regulators and industry have yet to identify a situation under which it might be valid to use today.

Pet Food Committee Recommendation: Remove PF3(e)

- (e) The product name of the pet food or specialty pet food shall not be derived from one or more ingredients unless all ingredients are included in the name, except as specified by Regulation PF3 (b) or (c); provided that the name of an ingredient or combination of ingredients may be used as a part of the product name if:
 - (1) The ingredient or combination of ingredients is present in sufficient quantity to impart a distinctive characteristic to the product or is present in amounts which have a material bearing upon the price of the product or upon acceptance of the product by the purchaser thereof; or
 - (2) It does not constitute a representation that the ingredient or combination of ingredients is present to the exclusion of other ingredients.

Attachment E – Proposed Revisions to Model Regulations for Pet Food and Specialty Pet Food PF4(g) and Model Regulation 3(a)(4)(XII)(c)

Background:

"Guarantees for crude protein, crude fat, **and** [emphasis added] crude fiber are not required when the pet food or specialty pet food is intended for purposes other than to furnish these substances or they are of minor significance relative to the primary purpose of the product, such as a mineral or vitamin supplement."

There is an opinion that PF4(g) should not be interpreted as an all or none requirement for an exclusion for the three guarantees. Rather PF4(g) should allow for exclusion of one, two, or all three of the guarantees according to whether the product is not intended to, and in fact does not, provide significant amounts of one or more of the three nutrients. Examples, a fat/fatty acid supplement composed of triglycerides for dogs does not provide much, if any, protein or crude fiber, so guarantees for protein and crude fiber should be allowed to be excluded from the guaranteed analysis on that product's label. Another example would be a fiber supplement for, say, specialty pets like rabbits or guinea pigs that is made from wheat stalks. The product would not be intended to, and would not, provide much crude fat or crude protein, and in my opinion should not be required to make guarantees for anything other than crude fiber and moisture.

So, there are two possibilities here:

- 1. The regulation was poorly written and needs to be amended if my interpretation of its intent is correct; or,
- 2. The regulation was intended to be an all or none exemption from the requirement for crude protein, crude fat AND crude fiber guarantees.

A proposal in typical AAFCO editing format (deleted text struck through, new text bold and underscored) for clarifying PF4(g) is:

Pet Food Committee Recommendation: PF4(g) CLARIFICATION - Regulation PF4 (g) Guarantees for crude protein, crude fat, and or crude fiber are not required when the pet food or specialty pet food is intended for purposes other than to furnish <u>one or</u> **more of** these substances or they <u>one or more</u> are of minor significance relative to the primary purpose of the product, such as a mineral or vitamin supplement.

Model Bills and Regulations Committee Recommendation: Regulation 3(a)(4)(XII)(c) CLARIFICATION - Regulation 3(a)(4)(XII)(c) Guarantees for crude protein, crude fat, and or crude fiber are not required when the commercial feed is intended for purposes other than to furnish <u>one or more of</u> these substances or they <u>one or more</u> are of minor significance relative to the primary purpose of the product, such as drug premixes, mineral or vitamin supplements, and molasses.