Model Bills and Regulations Committee Report
2018 AAFCO Annual Meeting
July 30, 2018 – Anaheim, California

Committee Recommendations:

1. The Model Bills and Regulations Committee recommends the following language be added to the Model Regulations for Pet Food and Specialty Pet Food Under the Model Bill as PF2(a)(8) and current PF2(a)(8) be changed to PF2(a)(9), and that the AAFCO Board of Directors review the proposed revisions for future consideration by the Association membership.

   PF2(a)(8): A statement of calorie content if required under PF9; and …

Board Recommendations:

Association Actions:

Committee Report and Minutes (July 30, 2018):

Model Bills and Regulations Committee Chairman Doug Lueders called the meeting to order at 1:30 p.m. on July 30, 2018. 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), Erin Bubb (Pennsylvania), Bill Burkholder (FDA), George Ferguson (North Carolina), Robert Geiger (Indiana), Ben Jones (Texas), 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).

Minutes from Previous Committee Meetings

Chairman Lueders noted that minutes from the January 22, 2018 committee meeting conducted in Anaheim were previously approved, posted on the AAFCO website and Feed BIN, and were included in the 2018 Annual Meeting's General Session packet.

Old Business

1. **Labeling of Mineral and Vitamin Units Work Group Report:** Mr. Ziehr, chair of the work group established to evaluate uniformity associated with labeling of mineral and vitamin units, as well as label unit nomenclature used throughout the

Model Bills and Regulations, provided recommendations as indicated in Attachment A.

Chairman Lueders accepted the work group's report and advised the committee the work group's recommendations would be further considered at 2019 AAFCO Midyear Meeting. He thanked members for their service and then disbanded the work group.

2. **Statements for Uniform Interpretation and Policy (SUIP) Work Group Report:** The SUIP Work Group was established by Chairman Lueders during the 2018 AAFCO Midyear Meeting to consider whether SUIPs should have a defined path to incorporation into the Model Bills or Regulations or eventually be deleted. Members of the work group are Padma Pillai (FDA), Liz Beckman (Feed Labeling Committee), Steve Younker (AFIA), Austin Therrell (Feed and Feed Ingredient Manufacturing Committee), Emily Helmes (ETA), Angele Thompson (PFI) and Cathy Alinovi (NGPFMA). Chairman Lueders reported that Cathy Alinovi graciously volunteered to chair the work group. Discussions are still on-going and it is anticipated the work group will present recommendations at the 2019 AAFCO Midyear Meeting.

New Business

The committee proceeded to consider new business.

1. **SUIP Proposal for Generally Recognized as Safe (GRAS) Self-Conclusions**

Chairman Lueders presented for discussion language that had come to the MBRC via the BOD's GRAS Policy work group. The presented language was not the official position of that work group but rather language that the work group felt needed additional vetting by the MBRC to see if it had traction to become an AAFCO position statement or SUIP.

The proposed SUIP language would apply to animal food ingredients subject to Generally Recognized as Safe (GRAS) self-conclusions:

> **Proposed SUIP:** To ensure safety and efficacy of animal food ingredients, AAFCO members are encouraged to forward GRAS self-conclusions received for a new ingredient or an intended use not listed for an ingredient in the current OP to the AAFCO Ingredient Definitions Committee. The IDC will file a GRAS notice to FDA and ask FDA if they have any questions about the GRAS self-conclusion. The Notice to FDA and responses from FDA will be recorded in the IDC minutes.

In response to the proposal, Emily Helmes (ETA) delivered the statement indicated in Attachment B. In addition, comments made by other industry

advisers pertaining to the proposed SUIP generally aligned with the views expressed by Ms. Helmes.

No action was taken by the committee on the proposed SUIP. Chairman Lueders stated that he would seek input from the AAFCO Board of Directors on the proposed SUIP before asking for further committee discussion.

2. PF2(a)(8) – Statement of calorie content if required under PF9

The committee considered the recommendation from the Pet Food Committee to add the following language as PF2(a)(8) within the Model Regulations for Pet Food and Specialty Pet Food Under the Model Bill and to change current PF2(a)(8) to PF2(a)(9):

> **Proposed PF2(a)(8):** A statement of calorie content if required under PF9; and…

Ms. Bubb moved that proposed PF2(a)(8) be added to the Model Regulations for Pet Food and Specialty Pet Food Under the Model Bill and current PF2(a)(8) be changed to PF2(a)(9), and that the AAFCO Board of Directors review the proposed revisions for future consideration by the Association membership.

The motion was seconded by Mr. Bowers. The committee approved the motion by a voice vote.

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
Attachments for July 30, 2018 Meeting

Attachment A

Labeling of Mineral and Vitamin Units
Work Group Recommendations

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 species in order of predominance, and shall be stated and conform to the following:

   (1) Colony forming units per gram (CFU/g) consistent with the directions for use; or

   (2) Colony forming units per pound (CFU/lb.) consistent with the directions for use; or

   (3) 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 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.

Attachment B

Statement Delivered by Emily Helmes, Enzyme Technical Association, at July 30, 2018 AAFCO Model Bills and Regulations Committee Meeting in Response to SUIP Proposal on GRAS Self-conclusions

Proposed SUIP: To ensure safety and efficacy of animal food ingredients, AAFCO members are encouraged to forward GRAS self-conclusions received for a new ingredient or an intended use not listed for an ingredient in the current OP to the AAFCO Ingredient Definitions Committee. The IDC will file a GRAS notice to FDA and ask FDA if they have any questions about the GRAS self-conclusion. The Notice to FDA and responses from FDA will be recorded in the IDC minutes.

Statement: The Enzyme Technical Association (ETA) opposes this proposed SUIP (Statement of Uniform Interpretation and Policy) for the following reasons:

(1) ETA, AFIA, and other industry members are participating in the AAFCO GRAS Workgroup efforts to develop an AAFCO GRAS Verification Process (update report to be given at tomorrow's IDC meeting), and this SUIP would likely conflict with the recommendations from that WG.

(2) A GRAS notice cannot be submitted by the AAFCO IDC without a signed statement and certification from an AAFCO representative as required in accordance with the GRAS Notice Final Rule 21 CFR § 570.225. Unless the IDC self-concludes the GRAS status of the ingredient that is the subject of the self-conclusion, it will be unable to meet the signed statement and certification requirement; hence the submission from the IDC would be considered incomplete by FDA without this information and would not be evaluated. Therefore, because the proposal does not include plans for the IDC to self-conclude the ingredient submissions as GRAS, the proposal is not viable under the GRAS regulatory requirements.

As a result, we recommend that MBRC not vote on this new SUIP and that it await the WG recommendation to AAFCO IDC, expected by the midyear AAFCO meeting, January 2019.