## Regulation PF4. Intended Use Statement and Nutritional Adequacy Claims

## **Question/Comment:**

**PF4.** Reg PF4 Title

PF4.

Word Statement needs to be added - Intended Use Statement

**PF4.** Regulation PF4. Intended Use Statement and Nutritional Adequacy Claims (add the word "statement").

**PF4.** In PF 4, it clearly lays out the intended use but does not clearly identify the Nutritional Adequacy Claim. It sometimes uses the verbiage 'intended use claims', there needs to be clarity between intended use and nutritional adequacy claims.

#### **Response:**

Several people indicated the regulation change to "Intended Use Statement and Nutritional Adequacy Claims". This will be added.

#### **Question/Comment:**

As a general comment, there was a little confusion about how the different life stages need to be added to the statement. The way that they are worded or organized within the text of the regulation could be clearer. If there is a way to make it easier to follow, we recommend that be given some thought.

#### Response:

Multiple options were considered and the work group believes the draft text was most appropriate.

#### **Question/Comment:**

PF4(a) Remove "on the principal display panel of a pet food or specialty pet food label," it's redundant and should appear in section PF4(a)(2)

## Response:

More clarity as to where it should be is in PF4(a)(2).

## **Question/Comment:**

PF4 - question - since these are all listed in quotation marks, it implies that it must be verbatim despite that not being stated. I think some companies would like to be able to say: "Complete Small Breed Adult Dog Food" or "Complete Large Breed Adult Dog Food" when they have size distinctions within their product line. Or something like: Complete Food for Senior Dogs (seniors are adults obviously). Would this be allowed?

remove "in accordance with the qualified/unqualified claims in PF4(b). The phrase seems to allow purpose statements and intended uses to be called a "claim." This makes the realm of claims more confusing. For example, it would allow a statement like "Complete Perfect Dog Food."

## **Response:**

No, this would not be allowed. These are meant to be verbatim.

## **Question/Comment:**

**PF4(a)(1)(A)** Need to remove "in accordance with unqualified claims in Reg. PF4(b)

PF4(a)(1)

This cannot be removed because it would allow claims without required qualifiers.

### **Question/Comment:**

"All Life Stages" means gestation/lactation, growth, and adult maintenance life stages. How does this apply to non-mammal specialty pets (ie. Birds, lizards, etc.) who do not gestate/lactate. Can their daily food still be labeled as for all life stages?

#### **Response:**

We appreciate the commenters point and have undertaken steps to revise the definition of "All life stages".

#### **Question/Comment:**

Would suggest "un/qualified claims" have a definition as its I don't believe its common lingo or knowledge to pet food business owners.

## **Response:**

The term is further defined and qualified in the regulation in PF4(a)(1)(B).

#### **Question/Comment:**

So, we'll be allowed to make claims such as "Perfect for Growing Hamsters" or "100% Nutrition for Adult Birds"?

## **Response:**

If there is no NRC then you have to use PF4a1g. Daily {Species} Food

### **Question/Comment:**

#### PF4(a)(1)(B)

add "pet" so it states "For pet food products intended...."? Or is it assumed by the end of the statement ....size of a pet or specialty pet in accordance with....?

## **Response:**

We believe the statement as written is clear.

#### **Question/Comment:**

remove "in accordance with the qualified/unqualified claims in PF4(c) Seems to allow purpose statements and intended uses to be called a "claim." This makes the realm of claims more confusing. See above.

## Response:

This cannot be removed because it would allow claims without reqired qualifiers. To make this clearer, We have changed claim to statement in the title of this section and also in the language section

#### PF4(a)(1)(B)(i)

Reg PF 4 (a) (1) B. i and ii

What about pet food that are for two life stages, growth and maintenance, growth and lactation? These sections need to be edited to include "one or more" of the statements. ie., "complete food for adult dogs and puppies", "complete food for lactating cats and kittens."

Reg PF4 (a) (1) B i and ii

Is it permissible for a brand to preface that "Complete" with Premium? ie., Premium Complete Food for Dogs?

## **Response:**

The language in pf4 (a) (1) (B) (i) and (ii) will be changed to include one or more of the following life stages to address this concern. No marketing claims can be added to the statement. Marketing claims may appear elsewhere on the lableing.

#### **Question/Comment:**

PF4(a)(1)B(i)(aa) There's potentially a point of confusion where it's stated "Puppies < 70 lbs as an adult," or "Dogs except puppies > 70 lbs as an adult]" at the bottom of page 4. Obviously, the statements refer to large dogs which is clarified at the bottom of page 9. Does the "large dogs" quantifier need to be moved up earlier in the document?

> PF4a1Bica and da - I think this could be confusing to the consumer. I would suggest something like: Small & Medium Breed Puppies (< 70# as an adult) and Large Breed Puppies (> 70# as an adult) or Dogs except Large Breed Puppies (> 70 lbs as an adult). Some people struggle with the < and > symbols so it seems more clarity should be provided. This could also be done by writing out the words, but I know space considerations are likely at hand here.

PF4 is a bit confusing – it looks like "Dog" includes all puppies but large breed, there is an option for "puppy (< 70 lbs as an adult" and puppy". So, this would seem that large breed puppies only fall under "puppy"? It seems more logical to make a designation for large breed puppies, rather than making all the options but "puppy" exempt large breed puppies! I think pet owners and veterinarians are used to looking specifically for foods appropriate for large breeds, not assuming a food is appropriate unless it says that it isn't.

## **Response:**

This format was tested by consumer survey and >80% understood what it meant and found it useful. Furthermore there will be outreach will be done to educate consumers of these changes.

## **Question/Comment:**

What about other life stages such as gestation/lactation here and in ii.? I know it's not usually called out here but rather separate feeding directions. However, it is not called out/clear in that section either.

## **Response:**

The language in pf4 (a) (1) (B) (i) and (ii) will be changed to include one or more of the following life stages to address this concern. No marketing claims can be added to the statement. Marketing claims may appear elsewhere on the lableing.

Are Complete, Adult, and Growing the ONLY terms allowed for specialty pet products, in particular?

As an example, ornamental fish diets are typically referred to as "Staple" or "Color" foods. Juvenile or larval fish are considered "Fry" foods.

Therefore, we should not be limited to only statements listed here and below.

Or, what if a product has more than one life stage? How is this addressed?

#### Response:

We appreciate the commenters point and have undertaken steps to revise the definition of "All life stages". We are revising the definition of all life stages to include stages for specialty pet.

#### **Question/Comment:**

**PF4(a)(1)B(i)(ca)** Ib with no plural and no period. These may be confusing statements to consumer.

Written different ways. Should the parenthesis be in the statement or not? Should be consistent.

Should parentheses be on B.i.ca and da above as well?

#### Response:

PF4(a)(1)B(i)(da) Ib with no plural and no period.

These may be confusing statements to consumer.

Written different ways. Should the parenthesis be in the statement or not? Should be consistent.

needs a bracket removed

## **Question/Comment:**

## PF4(a)(1)(D)

The intention was to consistently use the word Treat as opposed to Snack. However, this does not preclude the use of the word snack elsewhere on the package, correct?

## **Response:**

You are correct you may use the word snack elsewhere on the package.

## **Question/Comment:**

Can additional descriptive words be added to, for example, DOG TREATS, to state "PREMIUM DOG TREATS" or similar narrative? Can the same be used for Complete Foods above?

## Response:

You are correct you may use the word snack elsewhere on the package. No, but it can be used elsewhere on the label.

#### PF4(a)(1)(F)

The intended use of some products is as a mixer, others are intended as a topper, to be poured over the top, not mixed in. We request the option to use Food Mixer or Food Topper.

"Food Mixer" means a pet food or specialty pet food product that is intended to accompany or contribute to a complete diet but is not generally intended to be a complete diet. Please provide flexibility to include other terms such as "topper."

A 'mixer' is not a product that 'accompanies' a pet food product. These are products that are 'mixed into' or 'mixed-in' to pet food. Typically, if a product is accompanied by something, it is referred to as a topper or other similar term. These are all food supplements (i.e., not a complete and balanced diet) so it is unclear why a specific, separate term is required for a food 'mixer'.

## Response:

After much consideration by the workgroup Food Mixer was the best option for all these types of products.

#### **Question/Comment:**

#### PF4(a)(2)

We think that readers of the document would benefit from additional clarification or a reference in relation to net quantity formatting since it now is the standard for the size of the intended use statement. The size of the net quantity is not defined in this document, so it should be listed, or a reference made to where this size is located and in what regulation it is found. This addition will avoid potential confusion, especially with other countries who may have different requirements for formatting net weight in their packaging regulations.

One concern within the nutritional adequacy section is the requirements for the statement type and background colour being the same as the net quantity. In some cases, it will be challenging to do this without drastically changing the package design. We suggest that this requirement be made a little more flexible, with the actual intent as the requirement. Something like, "the statement needs to be legible and type contrasting against the background colour for easy reading," or something similar that outlines the intent more clearly without forcing companies to a rigid type and background colour.

need transition language for A and B below.

## Response:

The language will reference 16 CFR 500.21 The workgroup discussed this thoroughly and decided on the chosen requirements for consistency.

## **Question/Comment:**

## PF4(a)(2)(A)

This requirement for placement/prominence is more detailed than for human food. This requirement could be streamlined if AAFCO just used the human food language.

## **Response:**

It was paraphrased from the human food to fit the intentions of the formatting expectations.

## **Question/Comment:**

Appear within the bottom 30 percent of the area of the label pane in lines generally... Replace with principal display panel.

Thus this means that it can appear anywhere on the PDP?

The language will be updated to principle display panel to be consistent.

#### **Question/Comment:**

#### PF4(a)(2)(B)

Can a reference be made as to where these size requirements for net quantity can be found since it is required that they are at least as large as the net quantity?

#### **Response:**

The language will be updated to reference (16 CFR 500.21)

## **Question/Comment:**

Why would an intended use statement be 'at least as large as' the statement of net quantity? Shouldn't it be larger so that the customer can readily spot the intended use of the product? Placement of the package in the bottom 30% of the label along with the net quantity could be problematic especially if the requirement for the intended use statement is for the same color, style, and background color.

## **Response:**

The language will be updated to reference (16 CFR 500.21) The workgroup discussed this thoroughly and decided on the chosen requirements for consistency.

#### **Question/Comment:**

#### PF4(a)(2)(C)

This requirement for placement/prominence is more detailed than for human food. This requirement could be streamlined if AAFCO just used the human food language.

## **Response:**

It was paraphrased from the human food to fit the intentions of the formatting expectations.

## **Question/Comment:**

Requirement for color of the species statement to match net weight on PDP will cause significant changes to some treat labels and may confuse consumers.

## **Response:**

The workgroup discussed this thoroughly and decided on the chosen requirements for consistency.

## **Question/Comment:**

## PF4(a)(2)(D)

This is exactly what the NIST regulations state for Free Area

Reiterating that the intended use and net quantity statements will be confusing to the customer and likely 'get lost' in the label.

We assume that the intended use statement can be separated from the net quantity statement by 'at least a space equal to the height of the letter "N"' but it has to remain in the lower 30% of the label panel, be the same color/type, etc., correct?

The workgroup discussed this thoroughly and decided on the chosen requirements for consistency. Yes it shoul be the same color.

#### **Question/Comment:**

"printed label informaiton" We assume this includes graphics? Or other text, pictures, etc.?

#### **Response:**

Yes, your assumptions are correct.

#### **Question/Comment:**

# **PF4(a)(4)** Will an example of the graphics be included in the final rule- for nutrition facts box? We highly recommend graphic examples be included in the final rule for reference.

## Response:

Yes, guidance for the nutrition facts box will be provided.

#### **Question/Comment:**

## **PF4(b)** See above, similar concerns for specialty pet foods.

### Response:

Yes, guidance for the nutrition facts box will be provided.

#### **Question/Comment:**

"perfect" should not be allowed to be used as it implies that there is some objective metric all pet foods are measured against and may provide negative connotation when the otherwise balanced profile (AAFCO-compliant) does not perform to the expectation of the consumer.

Never understood how a claim such as 'perfect' is allowable for any type of food.

## **Response:**

Perfect' in this context must meet 'complete and balanced' standards.

## **Question/Comment:**

## **PF4(b)(3)(c)** the expectation of nutritional adequacy is not in line with the term "perfect."

## **Response:**

Perfect' in this context must meet 'complete and balanced' standards.

## **Question/Comment:**

**PF4(c)** objection to the use of the term "perfect" based on the same argument as b, above.

objection to use of the term "intended use." The juxtaposition of the claim and qualifications seems inconsistent with what is required in PF4(b). As written, this would allow a statement like "100% nutritious for kittens" but not allow "100% nutritious."

PF4(c) is intended to be more limited than PF4(b).

#### **Question/Comment:**

**PF4(d)** is the reference to

is the reference to PF5(a)(3)(G) correct? I don't see a PF5(a)(3)(G).

## Response:

This will be addressed when formatted.

#### **Question/Comment:**

does the scientific substantiation need to be made public, or made available upon request?

## **Response:**

The intent is available upon request.

#### **Question/Comment:**

**PF4(g)(1)(c)** What happens when someone cannot find a specialty pet nutrient requirement for National Research Council such as finches, parakeets?

## **Response:**

A complete and balanced statement is not allowed but there is an option for it to be a 'daily food'.

#### **Question/Comment:**

PF4(h)(2)

PF4(f)

PF4(h)(2) The statement of comparison shall be preceded by a statement that the product meets the AAFCO-recognized profile: however, the statement that the product meets the AAFCO-recognized nutrient profile is not required provided that the nutritional adequacy statement as per Regulation PF4(b)(1) or PF4(c)(2)(A) appears elsewhere on the product label; This is referring to Nutritional Adequacy Statement when PF4 only refers to Nutritional Adequacy Claims, unless Statement and Claim are synonymous, in which case that should be clarified in the definitions. Replace PF4(b)(1) PF4(b). The (1) is only one of several options that can be used to support an optional unqualified intended use claim. Replace PF4(c)(2)(A) with: PF4(c). The (2)(A) refers to one small part of the overall optional allowance to make a qualified intended use claim, if you go back to the (c) level it covers all the options/requirements.

## **Response:**

Several people indicated the regulation change to "Intended Use Statement and Nutritional Adequacy Claims". This will be added.

## Question/Comment:

PF4(h)(3)

Do the Nutritional Facts panel percentages (min and max) need to match the guarantees against the AAFCO profile since this can be calculated? Would the claims be otherwise misleading if they do not corroborate each other?

## **Response:**

Yes, the claims would otherwise mis-leading if the claims do not corroborate each other.

## Regulation PF5. Pet and Specialty Pet Nutrition Facts

#### **Question/Comment:**

Currently, AAFCO publishes a table of permitted analytical variance for nutrients in the guaranteed analysis. We understand that authorities will continue to focus on variation of nutrients expressed as a percentage, and that the expressions of nutrients per household measure are simply calculations that are not subject to a test of variability. This needs to be clearly outlined.

#### Response:

You are correct the regulatory action would be applied to analytical results of the nutrients and not the calculated values.

#### **Question/Comment:**

Still have concerns on requiring dietary fiber when no lab is routinely analyzing for it. In Indiana, we do not have the instrumentation to analyze. Indiana laws and rules do not adopted Model regulations. Indiana's feed rule will still have crude fiber as a requirement.

#### Response:

We recognize this will require a change to state regulations, labs will need to employ the method to analyze dietary fiber. This is one of the costs of modernization.

#### **Question/Comment:**

What will the tolerance be on the carbohydrate maximum?

## Response:

It is understood that the carbohydrate value is the result of a calculation, protein, fat, dietary fiber, moisture are values that will be tested by regulators.

#### **Question/Comment:**

• States that the background must be white or a neutral color for the Pet Nutrition Facts Box. Manufacturers desire to use boxes which include 2-3 colors.

## **Response:**

The box will be one color.

## **Question/Comment:**

question - would the gusset be considered a "prominent place"? Some brands have ingredients, GA, etc in the gusset currently.

## Response:

The side gussets would be one of the appropriate location for the facts box.

## **Question/Comment:**

In the first line of this section, it says that the pet nutrition facts shall be displayed in a 'prominent place'. This is extremely vague and subjective and could lead to different people interpreting 'prominent' differently. We suggest that this be made a littler clearer as to where the facts table should be displayed, or not displayed.

PF5(b)

'Prominent' was used to allow flexibility to acknowledge different package size and shape.

#### **Question/Comment:**

For clarity, could "mixers), but not necessarily on the principle display panel." be replaced with mixers), on the information panel.

## **Response:**

Our intent was to assure the intended use of the product to appear both in the fact box and on the principal display panel.

## **Question/Comment:**

line 2-it should be made clear if a product is for further manufacture of pet food, then nutritional statements are not required.

## **Response:**

An ingredient going into pet food is not required to meet the rules of a complete food for pets. When labeling ingredients for pet food the Model feed regulations would apply.

## **Question/Comment:**

PF5(b)(1)

PF5 – requiring nutrient guarantees to be on a [familiar household unit] is a HORRIBLE idea! It will get pet owners comparing the amounts of nutrients between diets that may have very different calorie amounts per [familiar household unit]. You can't compare the amount of any nutrient in a cup of a food that is 450 kcal/cup to the amount in a product that is 325 kcal per cup, but that is what the proposed new labels will encourage people to do. This works okay for human Nutrition Facts because it's all based on a set serving size and 2000 kcal per day for everyone. But, we know that the "serving size" will vary dramatically from pet to pet. Putting things on a volume or unit basis will be much worse than the current system on a %/100g basis!!!! Every DACVIM (Nutrition) I know agrees strongly that this is an opportunity to put everything on a calorie basis (per 100 or 1000 kcal) and it is LUDICRIOUS to not take the opportunity here to "do it correctly" so it is easy to compare one food to another and to the Nutrition Profiles.

"Feeding unit" needs to be consistent across all pet foods to be of any use (the variable serving size is a huge issue with human foods as well). For pet foods, this should either be per 100 or 1000 kcals. The number of grams could be included as well but allowing each company to define its "feeding unit" will make the already confusing situation much, much worse.

While we commend AAFCO for moving away from the current Guaranteed Analysis system, we are concerned that listing nutrients per familiar household unit is not helpful for the average pet owner. If considering dry foods that are measured in cups, the volume of any particular diet that fits into a standard measuring cup will vary based on kibble density and shape. If an owner is concerned about the protein content of a particular diet, for example, they are less able to make direct comparisons between dry food products with the per household unit system than they can with the current Guaranteed Analysis system. The same can be said for high moisture products, which are available in various types and sizes of containers. In the above example, the average pet owner will think that Diet A contains more protein than Diet B based on the gram per household unit requirement. When converted to a Calorie basis, however, the protein content in Diet B is actually 57% higher compared to Diet A.

In our view, a pet owner should be able to make direct comparisons between different diets without needing to complete mathematical calculations first. Because one cannot directly compare Guaranteed Analysis values across all diets regardless of moisture content, we agree with AAFCO that another labeling method is needed. As opposed to the proposed per household unit method, however, we recommend using a standardized Calorie level, similar to the Nutrition Facts system in use for human foods. To be easily applicable to animals of different sizes, we recommend a 100 Calorie standard. In this system, each nutrient is listed per 100 Calories, as seen in the example table above. Since every diet, regardless of moisture content, container volume, kibble density, kibble shape, etc. will all be listed per 100 Calories, the consumer is finally able to pick up different diets and easily compare these values across different products.

We have a similar critique with using a household unit to display the Calories from protein, fat, and carbohydrate. It is standard practice to list these values as percentages, again allowing for direct comparison across all forms of pet food. Maintenance of this standard percentage system will continue to maintain simplicity for the average pet owner.

"unit of familiar household unit" is redundant.

The first unit can be deleted and just leave "The familiar household unit "

## PF5(b)(1)

Remove the first occurrence of "unit," as written it does not make sense. Is there an explanatory statement to be used before the grams/unit to state its purpose? It is not a serving size.

- Not having a consistent unit may lead to consumer confusion. A unit could be a cup, ½ cup or ¼ cup. This could be confusing for some consumers that are not paying attention to the units. They could erroneously compare two different labels, one that is calculated per ¼ cup and one that is calculated per ½ cup. Same issues for specialty pet on p 10
- In stating that the Pet Nutrition Facts has to include familiar household unit and weight in grams, does this need to be the same unit and measurement for the feeding guideline?

PF5(c)(1)

Not having a consistent unit may lead to consumer confusion. A unit could be a cup, ½ cup or ¼ cup. This could be confusing for some consumers that are not paying attention to the units. They could erroneously compare two different labels, one that is calculated per ¼ cup and one that is calculated per ½ cup.

## **Response:**

The word 'whole' is being inserted in front of "Unit of Famililar household unit". It should be a whole household unit and not be divided to a half cup. Because available label space is limited, compromises needed to be made as to the how nutrient content information could be expressed in the PNFB. Yes, expression in terms of calorie content is very useful when comparing the nutritional merits of complete dog or cat foods, with the presumption that the animal eats enough of that one food to meet its daily caloric need. However, the requirement for a PNFB on the label equally applies to treats, mixers and food supplements. Because the animal typically consumes smaller amounts of these types of foods in conjunction with the complete food, expression in terms of calories does not adequately reveal to the purchaser how much of each nutrient is being provided by each food component relative to the total diet. Also, expression in terms of household units directly relates to the feeding directions, which makes determination of daily nutrient intake for a given animal an easier concept for the purchaser to grasp. For those DACVIM (Nutrition) folks who wish to educate clients and general practitioners on the merits of comparing products in terms of calorie content, the information needed to derive those values is in the PNFB.

#### **Question/Comment:**

"Pet Nutrition Facts" Also, is there a font/panel size requirement? Can lines of text be wrapped to fit in confined spaces? Can the Pet Nutrition Facts box be added to the bottom of a box or bag? Is that considered 'a prominent place'?

## **Response:**

There is not a font/panel size requirement. Must be prominent, yes lines of text may be wrapped as long as clear, readable and understandable. No the bottom of a box or bag is not a prominent location for the box, so therefore, not appropriate to place the box there.

## **Question/Comment:**

"in a prominent place" Can this be better defined? 'a prominent place' is vague

## Response:

Prominent' was used to allow flexibility to acknowledge different package size and shape. Definition of 'prominent' applies to something commanding notice by standing out from its surroundings or background (Merriam Webster).

"set off" This means to start a journey or cause someone to start doing something. Do you mean to state "The information shall be placed in a box ..." or positioned, or situated, or arranged, etc.?

Can it be restated to say "The information shall be placed in a box using black or one-color type hairlines, printed on a white or other neutral contrasting background to be clearly visible under the heading "Pet Nutrition Facts." It must be centered in the top row of the box and at least twice the size of all other text in the box."...

That said, why the requirement for black or one-color type and white or other neutral contrasting background? This could essentially change the way we brand our products. Is there a way to add some flexibility into these requirements?

#### Response:

'Set off' is consistent with the human food rule. The requirment for prominence should provide the consumer understanding. The option for it allowing color other than black and white was to provide flexibility.

### **Question/Comment:**

Household or common unit of measure? We should provide examples or define. Here and throughout.

## **Response:**

Examples are provided in PF5(a)(1)

#### **Question/Comment:**

Not sure why we consistently state to use a 'centered' line because if the information is in a box, the line should go from the left to the right side. Do we mean 'parallel'? or 'complete, parallel lines'? this is why is critical to include examples of what these sections should look like. Same comment here and throughout.

## **Response:**

This current draft language is consistent with the human food rule. Yes, guidance for the nutrition facts box will be provided.

## **Question/Comment:**

"the next line of text" But no minimum size requirement?

## **Response:**

There is no minimum size requirement.

## **Question/Comment:**

## PF5(b)(2)(A)(i)

This section should include "ME" somewhere in the text in order to match the regulation dictation math. Perhaps include a statement to indicate the caloric calculation is to provide information on the caloric density of the product per familiar household unit

## **Response:**

ME is not required on the label, but is the unit of measure in PF9.

#### PF5(b)(2)(B)

- Calories or Kilocalories?
- Calorie content statement must have the number of calories contributed by protein, fat and carbohydrate? Or is the "from" portion optional? If required, why? Seems this should be optional.

#### Response:

We decided to allow the use of calories, similar to human food and familiar to the average purchaser. We decided caloric distribution is valuable information.

#### **Question/Comment:**

Human food removed calories from fat on their nutrition panel, why are we adding these additional requirements to Pet Food labeling? Awkward wording. Consider: Below the calorie content statement, "from" should be indented followed by the Protein, Fat and Carbohydrate to reflect that it is a component of the total calories.

• The formatting requirements for this section are unclear. Is this intended to give flexibility in format? For example, it is all supposed to be on one line or it can be split out into columns similar to the nutrient guarantees? • Can it be clearer that the "(calculated)" refers to Protein, Fat and Carbohydrates and not just Carbohydrates.

### Response:

We decided caloric distribution is valuable information.

#### **Question/Comment:**

#### PF5(b)(3)

Using minimums/maximums makes these worthless. They need to be in typical or average analysis to be of any use to pet owners and veterinarians

## Response:

The states accept guarantees within an analytical variance, this is consistent with the table in the AAFCO publication.

## **Question/Comment:**

Concentration?

Are there any regulatory allowances for calculated values?

## Response:

The word 'concentration' is intended to help the reader understand the math to convert from guarantee to amount per familiar household unit. No, calculation it is calculated from the other labeled components that are subject to regulatory variation.

## **Question/Comment:**

PF5(b)(3)(A)(i-iv) Manufacturers will need clarity on the regulatory allowances for a calculated value (ie., Total Carbohydrate). Will the guaranteed amount will be the test value for regulatory monitoring? If the per household measure will be used, how will AV's be defined? Will these be based on Mins/Maxes that are not listed on the label?

## Response:

No, calculation it is calculated from the other labeled components that are subject to regulatory variation.

#### PF5(b)(3)A, iii

AAFCO members - manufacturers will need clarity on the regulatory allowances for a calculated value (ie., Total Carbohydrate).

Please confirm if the guaranteed amount will be the test value for regulatory monitoring. If the per household measure will be used, AVs will need to be defined.

#### **Response:**

No, calculation it is calculated from the other labeled components that are subject to regulatory variation. Yes, the guaranteed amount is the value for regulatory monitoring.

## **Question/Comment:**

this should also include the deduction of fiber, no? I think most owners do not consider fiber to be part of carbohydrate (indenting the fiber line after is not clear enough), so if this is kept then it should be stipulated "Total Carbohydrate (includes fiber)" plus having the fiber line indented.

#### Response:

Total carbohydrate does not carve out fiber and is in-line with human food.

#### **Question/Comment:**

#### PF5(b)(3)A, iv

1. Section PF5 seems to indicate that the Total Dietary Fiber (TDF) assay will be used to quantify the fiber content of the food rather than the Crude Fiber (CF) assay. Do we understand that correctly?

We hope this is the case as the CF assay is a very notorious assay known for its under-recovery and variability in accounting for the fiber content of foodstuffs.

2. Third, in reviewing Section PF9 we see that the fiber level of a food will continue to be measured by the CF assay for the purpose of calculating the modified Atwater ME (energy content) of the food. If our understanding of this is correct, what is the reason for not using TDF to determine the fiber content of the food? Is it possible that the energy content is more accurately predicted when using the CF assay rather than the TDF assay?

## **Response:**

- 1. Yes
- 2. The reason for using total dietary fiber is that is provides a more complete and accurate indication of the fiber in the product rather than does crude fiber. This is true, crude fiber still required for calorie calculation and not aware of an alternative formula that has been validated against feeding trials similar to the modified Atwater formula.

## **Question/Comment:**

is the "total dietary fiber" methodology prescribed elsewhere? Ditto for starch and sugars.

## Response:

AOAC method 991.43.

### PF5(b)(3)(A)(vi)

Dietary fiber needs to be defined. Is it crude fiber? How is fiber to be tested? We need to understand the definition to comply.

#### Response:

AOAC method 991.43.

#### **Question/Comment:**

**PF5(b)(3)(A)(vii)** Should these include the Min or Max designation?

### **Response:**

Yes, more guidance will be available.

## **Question/Comment:**

## PF5(b)(3)(B)

1. Please prohibit ash from being included in the guaranteed analysis (or anywhere on the label)

## **Response:**

Ash has historical relevance and we decided not to prohibit it.

#### **Question/Comment:**

Just to clarify: is the requirement to list this as Ash (Max) on the tag? If so, we recommend writing it similar to line vi. above: When listed, ash shall be guaranteed as "Ash (max)" as a percentage and shall immediately follow moisture.

## **Response:**

The work group will edit this.

## **Question/Comment:**

## PF5(b)(3)(C)

Recommend rewriting just the first sentence of this area to be clearer about the (max) call out. "When listed, dietary starch and sugars shall be guaranteed as "Dietary Starch (max)" and "Sugars (max)."

## **Response:**

The work group will edit this.

## **Question/Comment:**

PF5(b)(3)(D)(ii)(a This is already covered in section PF5 (a)(3)

a)

ba)

## Response:

Guidance will be provided that will address this.

## **Question/Comment:**

**PF5(b)(3)(D)(ii)(** should add "in the same size type as the guarantees"

## **Response:**

This is already covered in section PF5 (a).

PF5(b)(3)(D)(ii)( These three sections are confusing. Section ba. and E. seem contradictory in their requirement for hairline vs bold line immediately after the last ba)-PF5(b)(3)(E) guarantee. Please clarify which it should be. Please clarify the order- which comes first, the \* not recognized or the Nutritional Adequacy statement? They are both supposed to come immediately below the guarantees.

#### Response:

Guidance will be available.

#### **Ouestion/Comment:**

#### PF5(b)(3)(E)

is this out of place? Seems this should be mentioned before regulation about disclaimer "\*not recognized..."

## Response:

No, guidance will be available.

#### **Question/Comment:**

## PF5(b)(3)(F)

We suggest that there should be a statement added after the guarantees in F that says - Except when a dog or cat food is described as a treat, food mixer or food supplement.

#### **Response:**

Under the new rules all treats, mixers and supplement will include the nutritional adquacy statement which may be for intermittent or supplemental feeding only.

## **Question/Comment:**

"bold line" We didn't use 'centered' line here; we believe all 'centered' terms should be removed

## Response:

These rules aligned with those for human food. Guidance will be available. This is not referenced in 'F' because 'E' defines where the line will be.

## **Question/Comment:**

## PF5(b)(3)(F)(iii)

Is this the language to be used with a treat? If so, listing 'Supplemental feeding' is very confusing as this is defining Food Supplement as very different from a treat. Recommend: adjusting it to: "This product is intended for [intermittent, supplemental or limited] feeding only" (and keep the rest of the statement).

## Response:

Yes. Supplement and supplmental have different meanings. Consistent language will be helpful to the consumer.

## **Question/Comment:**

#### PF5(c)

There should be clear guidance on the use of calorie content for specialty pet. States have said it is prohibited on specialty pet and the AAFCO pet/specialty guide says calories are not sanctioned on specialty pet. Can a statement of calorie content appear on a specialty pet label who has a recognized nutritional profile?

## Response:

No.

"in a prominent place" Needs to be better defined as could be interpreted differently than states

## **Response:**

Prominent' was used to allow flexibility to acknowledge different package size and shape.

## **Question/Comment:**

"twice the size" At least twice the size; can't be larger?

## Response:

Exactly twice the size.

## **Question/Comment:**

PF5(c)(2)(A)(i-iv) It is assumed that any nutrient max will follow its corresponding min.

## Response:

Yes, when both minimum and maximums are stated.

#### PF5(c)(2)(A)(iv)

A guarantee for total dietary fiber is problematic for specialty pets because:

1. There are no set requirements for "total dietary fiber" according to the NRC (1995, 1994, 2011) in common specialty pet species including mice, rats, guinea pigs, hamsters, gerbils, commercial poultry, freshwater fish, marine fish and shrimp.

2. Information on total dietary fiber of feedstuffs is limited and variable. The most reliable and complete datasets are only available for insoluble fibers (NDF, ADF).

Without reliable data on soluble fiber, a guarantee for "total dietary fiber" will be meaningless given the high level of uncertainty needed to be accounted for when setting the guarantee. Historically there has been little interest in soluble fiber associated with animal diets – the interest in soluble fiber has been primarily focused on human health. Therefore, soluble fiber levels may be available for common ingredients in the human food chain but there is limited information for feedstuffs. The NRC does not include soluble fiber in feed compendium tables and the USDA's National Animal Nutrition Program (NANP) is lacking data on soluble fiber levels for numerous ingredients including oats (IFN 4-03-309), alfalfa hay (IFN 1-00-078), millet (IFN 4-03-098), oat groats (IFN 4-03-332), rye (IFN 4-04-047), rice (IFN 4-03-932) – sample size is 2, brewer's yeast (IFN 7-05-527), and corn gluten meal (IFN 5-02-900). Information we do have on common animal diet ingredients is quite variable. For example, the NANP reports a 21.56% and 175.28% coefficient of variation for soluble fiber levels for corn and wheat, respectively. Crude fiber is helpful to ensure that a product has not been diluted but doesn't provide information about the quality of the diet. If the goal for including a new fiber guarantee is to provide meaningful information to the end users, we recommend providing a guarantee for neutral detergent fiber (NDF) and/or acid detergent fiber (ADF). Both values represent types of insoluble fiber. Insoluble fiber plays an important role in ruminant and pseudoruminant (rabbit) diets. There is abundant research on insoluble fiber levels in feedstuffs with NDF and ADF levels including NRC feed compendium tables and for most feedstuffs in the NANP. A complete diet that supports proper digestion and animal health can be formulated using NDF and ADF levels for specialty pets and agricultural species. A guarantee for NDF and/or ADF would be more meaningful than total dietary fiber for specialty pets.

## Response:

Information on dietary fiber of feedsuffs Is limited and all the same issues exist for dog and cat foods to assure consistency across pet foods they should be the same.

## **Question/Comment:**

## PF5(c)(2)(B)

Just to clarify: is the requirement to list this as Ash (Max) on the tag? If so we recommend writing it similar to line vi. above: When listed, ash shall be guaranteed as "Ash (max)" as a percentage and shall immediately follow moisture.

## **Response:**

Guidance document will explain.

## **Question/Comment:**

## PF5(c)(2)(C)

Please add guidance for guaranteeing Dietary Starch and Sugars for specialty pets. W recommend mirroring the pet section and using item C.

Guidance document will explain.

## **Question/Comment:**

#### PF5(c)(2)(C)(iii)

- is this needed since there are no AAFCO recognized nutrient profiles for specialty pets?
- if this paragraph remains, should add "in the same size type as the guarantees"

## **Response:**

We believe its need to provide order for these GA's.

Size requirement is stated in (c).

### **Question/Comment:**

## PF5(c)(2)(C)(iii)( ba)

The disclaimer shall appear immediately after the last such guaranteed amounts. No such disclaimer shall be appear unless an AAFCO-recognized nutrient profile is available for the specific species of specialty pet.

#### Response:

The work group will edit this.

### **Question/Comment:**

The disclaimer shall appear immediately after the last such guaranteed amounts. No such disclaimer shall be appear unless an AAFCO-recognized nutrient profile is available for the specific species of specialty pet.

## **Response:**

The work group will edit this.

## **Question/Comment:**

## PF5(c)(2)(D)

is this out of place? Seems this should be mentioned before regulation about disclaimer "\*not recognized...

## Response:

No, guidance will be available.

## **Question/Comment:**

## PF5(c)(2)(E)

is this needed since there are no AAFCO recognized nutrient profiles for specialty pets?

How will this work for Specialty Pet feeds that don't have a recognized Nutrient Profile and are called a daily food per the definition? Utilizing iii. from this section will be confusing to consumers since it sounds like it shouldn't be fed everyday. Please either rewrite iii or provide another option that allows for daily feeding when there is no recognized nutrient profile.

## Response:

The work group will edit this.

## **Question/Comment:**

#### PF5(d)

"food supplement" Not a food mixer? Assuming we keep this term

PF5(d) only applies to supplements, 'Mixer' follows regular rule, because of the ability to declare the amount/unit and alter guarantees.

#### Question/Comment:

#### PF5(d)(1)

"For a food supplement" Again, what about food mixers? They will also be a source of nutrients

## Response:

PF5(d) only applies to supplements, 'Mixer' follows regular rule, because of the ability to declare the amount/unit and alter guarantees.

#### **Question/Comment:**

#### PF5(d)(2)

"food supplement" Again, food mixers apply or not?

### **Response:**

PF5(d) only applies to supplements, 'Mixer' follows regular rule, because of the ability to declare the amount/unit and alter guarantees.

#### **Question/Comment:**

## PF5(d)(1)(C)(i)

Based the first paragraph for this Food Supplement section "a pet food or specialty pet food which is formulated as and represented to be a food supplement shall include all of the information required in PF5(a) or PF5(b) except" those two sections cover the requirement to have hairline separators between all GA's so it's not needed here.

## Response:

Because of the complexity of the requirements of building the Facts Box, stating exactly where lines are needed is to provide clarity.

## **Question/Comment:**

## PF5(d)(1)(C)(ii)

should add "in the same size type as the guarantees"

## Response:

This text is not needed, because it is stated in PF5(a) and (b).

## **Question/Comment:**

#### PF5(f)

In an era in which pets with an overweight and obese body condition are more common than pets with an ideal body condition, it is imperative that owners are able to easily identify the Calorie content of the items they are providing by mouth. In our experience, it is common practice for an owner to be administering multiple supplements to their pets, including vitamin and mineral products. Many of these products contain flavoring components that may not be related to the primary purpose of the product, yet still are able to impart a Caloric content. When several of the supplements are used, especially in smaller animals, the total Caloric intake can be in excess of what the pet owner perceives, therefore contributing an unexpected Caloric load. We recommend requiring Calorie content to be listed on all products in which any of the ingredients, whether related to the primary purpose of the product or not, may contribute Calories.

## **Response:**

Calorie statement is required on all dog and cat foods including food supplements/mixers. Draft model regulation will be edited to remove 'Calories' from language.

This is confusing considering Calories on Specialty Pet are currently prohibited.

#### Response:

Calorie statement is required on all dog and cat foods including food supplements/mixers. Draft model regulation will be edited to remove 'Calories' from language.

#### **Question/Comment:**

PF5(g)

One concern that we have raised in all previous comments that PFAC submitted, that has yet to be dealt with appropriately is that the proposed nutrition facts tables will not fit on very small packages, particularly now that there are minimum type height requirements. We see some accommodation for small packages of < 40 square inches that will be helpful, but we do not understand why AAFCO will not consider allowing similar provisions for very small packages (for example, less than 12 square inches of total surface area) that are currently in place for human food sold in the United States. FDA recently updated their rules for Nutrition Facts Labeling for human food and retained the exemption for small packages (< 12 square inches of total surface area) that do not bear claims. For these exempted small packages, a telephone number can be provided, to enable consumers to call and obtain nutrition facts in a type height no smaller than 6 point or all upper-case type of 1/16 inches minimum height. 21 CFR § 101.9 (j) 13 (i). If there are no claims on the package, we think that legibility is more helpful to the consumer, provided that they can ultimately get the information that they require. Other potential ways of alleviating space problems on very small packages could include exempting some of the requirements, such as the calories for each macronutrient, and potentially allowing more short forms, such as are allowed in human food for packages with a total surface area of < 40 square inches. We believe that a solution for small packages is critical, and that the problem will be further exacerbated in countries or regions where labeling in multiple languages is required or expected by consumers.

## Response:

We appreciate the commenters point and have undertaken steps to revise.

## **Question/Comment:**

For the small packaging in linear format, is there a slash or a parenthetical? The mock up we provided had the per household measure first and the guaranteed value in parenthesis. This format was accepted by the working group, but it appears the language was not updated fully. It will be impossible to fit the additional required information on some small packages at the min type height required. Recommend to have an exemption in line with human food regulations for very small packages (<12 square inches): exemption for very small packages (< 12 square inches) that do not bear claims.

For these exempted small packages, a telephone number be provided, in place of the pet nutrition facts. The Phone number (and/or web address) will enable consumers to call and obtain nutrition facts in a type height no smaller than type of 1/16 inches minimum height. Adapted from: 21 CFR § 101.9 (j) 13 (i)

Guidance with an example Facts Box will be provided.

### **Question/Comment:**

Pet Nutrition Box

We would suggest that an actual Pet Nutrition Facts example goes here and that language in Reg PF5 says see the formatting example at the end of Regulation 5. Alternatively it could go after PF12 and be referenced there.

The Pet Nutrition Facts example should have a header that says "Formatting Guide for Reference only"

## **Response:**

Guidance with an example Facts Box will be provided.

## **Question/Comment:**

We are concerned we will not be able to fit all the required information onto some of our small packages.

Very small packages will be an issue regardless that it can be placed a linear format. Exceptions should be included for some of these requirements as they are cumbersome.

## **Response:**

Guidance with an example Facts Box will be provided.

## **Question/Comment:**

## PF5(g)(3)

"shall be sufficiently large so as to be conspicuous" Vague

## Response:

Language is meant to be flexible but specifics are also provided in the small package table. Consipicuous standing out so as to be clearly visible attracting notice or attention (Oxford).

## **Question/Comment:**

## PF5(g)(4)

suggest adding "forward slash" before the symbol in the following?

(4) The guaranteed amount shall appear immediately before the amount "per [familiar household unit]" for each nutrient with each value separated by a forward slash "/" with units clearly identified

## **Response:**

The work group will edit this.

## Regulation PF6. Ingredients

#### **Question/Comment:**

## PF6(a)(1) Some states don't allow this

## Some states don't allow this. Adding it here creates confusion.

#### **Response:**

States will have a basis to accept once in the model regulation.

#### **Question/Comment:**

Replace "microorganisms" with "ingredients that include genus and species." This would allow for ingredients like yucca schidigera to be included.

#### Response:

The work group agrees with comments and has inserted the suggested language in the proposed model regulation.

#### **Question/Comment:**

# **PF6(a)(2)** This language coupled with vitamin table 90.27 introduces a double parenthetical, we suggest the first parentheses after vitamins becomes a bracket for ease of reading, clarity and grammar.

## **Response:**

The work group discussed and believes that parenthetical is more flexible.

#### **Question/Comment:**

## **PF6(a)(3)** suggest adding green highlighted and striking through yellow highlighted below

(3) Ingredients shall be listed and identified by the name established by in AAFCO ingredient definition, except any ingredient for which no AAFCO ingredient definition name exists shall be identified by the common or usual name;

## Response:

The work group agrees with comments and has inserted the suggested language in the proposed model regulation.

## Question/Comment:

## PF6(a)(4) What does 'if necessary' mean?

We believe it allows for a standard ingredient to list a parentheses or not. Some ingredients Title 9 or 21 may have a requirement.

## **Response:**

Regulations require that foods that have a standard of identity list individual ingredients parenthetically such as "yogurt (ingredients on yogurt label)" or "peanut butter (ingredients on peanut butter label)".

## Question/Comment:

What does "if necessary" mean in this context?

## **Response:**

In the yogurt example above, if there are additional ingredients then it is necessary to list ingredients parenthetically.

"As provided in the regulation" Can an example be listed here?

#### Response:

For example see regulation Title 21 CFR 131.200 for yogurt.

#### Question/Comment:

#### PF6(a)(5)

For purposes of pet food label modernization, we request removal of outdated examples: horsemeat or horsemeat by-products should be replaced with another example: venison or lamb.

#### Response:

The work group agrees with comments and has inserted venison in place of horse meat in the proposed model regulation.

#### **Question/Comment:**

Why are these caveats listed here instead of in chapter 6 with the definition of these ingredients?

#### Response:

These examples address specific concerns in pet food labeling and provide relevant clarification.

#### Question/Comment:

### PF6(a)(6)

If we declare the description of the fish used we are limiting the variety of ingredients that we can use in our products, and with the supply changes that the business have (globally) this could be a risk for the production process. Also in Latin America the product register process is very hard an change the description of fish used implies a new register process, that in some countries takes around one year, additional, requires changes in the packages.

### **Response:**

The regulation is intended to provide an accurate description of fish; the name of the ingredient shall be the acceptable market name or common name or it may still be called 'fish'.

#### Question/Comment:

It is PFI's recollection that the Working Group agreed upon example was "ocean white fish".

We recommend the use of that example.

## Response:

The new draft model regulations codifies common practices including allowing the common 'fisheries term' of white fish.

#### Question/Comment:

the term "whitefish" is problematic as some use it for one of many species (variable), and others use it for a specific species. Can you please require more specific use of fish terms for clarity?

## **Response:**

The new draft model regulations codifies common practices including allowing the common 'fisheries term' of white fish.

Is this only intended for non-defined fish items? If that is the case it needs to be more clear. Doesn't this caveat belong in chapter 6 with the ingredient definition of fish?

Does this mean that if you are using a blend of whitefish products, we will not have to list the individual fish names as the names appear in the FDA Seafood List?

There is a USDA definition for white fish. Can the USDA definitions for fish also be used or only the FDA Seafood List.

#### **Response:**

Animal foods are regulated by FDA, therefore, USDA definitions for fish would not be recognized. If using a blend, and the company can be document only white fish in the blend, 'white fish' is sufficient to be listed.

## **Question/Comment:**

"Seafood List" Again, can an example be provided?

## Response:

Reference the FDA Seafood List at:

https://www.cfsanappsexternal.fda.gov/scripts/fdcc/index.cfm?set=SeafoodList&sort=SLSN&order=ASC&startrow=1&type=basic&search=

#### Question/Comment:

## PF6(a)(7)

We are concerned about the last sentence and would like to recommend removal. "Sugar" whether it's used in the ingredient list or elsewhere on the package is associated with the ingredient (specifically sucrose from sugar cane or sugar beets) while "sugars" whether used in the Nutrition Facts or elsewhere on the package is to mean the nutrients mono and disaccharides (sucrose, glucose, fructose and others) as defined in the Official Feed Terms.

### Response:

Work group discussed that by removing the last sentence makes the regulation less clear with how the terms should be used.

#### Question/Comment:

#### PF6(e)

"the nature" Is a reference to 'quality' no longer allowed? It was previously allowed under PF5(d).

## **Response:**

The reference to quality was not previously allowed. The change to the draft model regs is to clarify that quality or grade of an ingredient is not allowed in the ingredient statement.

#### Question/Comment:

#### PF6(f)

This is slightly different than PF3 which only talks about the product name, but there is a lot of overlap. Is there a way to keep it all in one place and just make references as needed?

## Response:

PF3 provides the regulations for brand and product names, PF6 provides regulations pertaining to the ingredients if a percentage is referenced on the label.

## Regulation PF12. Handling and Storage Instructions

#### **Question/Comment:**

PF12(a)

Since the "Handling and Storage Instructions" are in quotes, does that preclude the replacement of "and" with "&" to save character spaces when possible.

## Response:

The heading "Handling and Storage Instructions" is required to be written as stated.

#### Question/Comment:

PF12(b)

No explanation was provided as to when the graphics would be used on a label. While some are easily understood, some are not. Such as the first graphic "Separate from human food". In what circumstances would this graphic be used on a pet food label? Are there additional regulations not included in this draft that would require this graphic to be used on a label? Are there additional regulations not included in this draft that require any of the graphics to be used on labels?

#### Response:

These are optional graphics to be used according to the product type. "Separate from human food" was designed to provide additional information and to be used if the manufacturer prefers. There are no other additional regulations that require graphics.

#### **Question/Comment:**

In a separate section or within the Handling and Storage section, please consider including some succinct food bowl hygiene guidelines. This information is quite important for pet caregivers ,especially when they have individuals 'at risk' (very young, very old, immunocompromised, etc) in the household or having access to the pets food/water bowls. This hygiene information is not recognized by the majority of pet caregivers.

## Response:

While important to the at home safety of use of the product, food bowl hygiene is outside the scope the of pet food labeling.

## **Question/Comment:**

what would be the use of "throw out when in doubt"?

## **Response:**

The statement is intended for consumer awareness, and for the manufacturer to decide when to use.

## **Question/Comment:**

Warning icons: Warnings for raw meat diets are needed to protect pets and public health (bacteria and antimicrobial resistance)

## Response:

The workgroup established voluntary language and graphics for pet foods manufactured without a kill step.

Picture and text will be required to be used together. If the intent is that we can use A, or A+B, but not B alone, then a statement to clarify graphics are not to be used in lieu of any language. It is important that High Resolution Vector files be available for these.

#### **Response:**

The work group agrees with your suggestions.

#### **Question/Comment:**

What about refrigerated products?

## Response:

The workgroup established voluntary language and graphics for pet foods manufactured without a kill step.

#### **Question/Comment:**

Can the color graphics below be changed to work with our own brand/packaging colors?

#### Response:

Graphics will be provided in high resolution files and colors are set as shown.

## **Question/Comment:**

It should be specified that the minimum graphic size refers to the border around the graphic.

## Response:

No, the border was not intended, the measurement is top of circle to bottom of language.

## **Question/Comment:**

Is the minimum graphic size for height or width? It is not clear as printed.

## **Response:**

No, the border was not intended, the measurement is top of circle to bottom of language.

## **Question/Comment:**

Reg PF2 (between (h) and (j) or after (a) we suggest a statement be added. "When handling statements are included they are to be used as stipulated in Regulation PF11."

## **Response:**

We appreciate the commenters point and have undertaken steps to revise.