

Copper Claim Workgroup: **Final Report to the Pet Food Committee**

Background

The Copper in Dog Foods Expert Panel final report to AAFCO's Pet Food Committee (PFC), dated August 1, 2022, recommended PFC consider and further explore establishing the criteria for commercial dog food products to bear a 'Low Copper' claim within Model Regulation PF10 Descriptive Terms. Although the Expert Panel concluded there was insufficient scientific evidence to support establishment of a maximum copper amount in dog food, some panel members proposed this addition to the Model Regulations in recognition of the concern many dog owners and veterinarians have about the copper content in commercial dog foods. The Expert Panel did not have time to discuss the proposal at length before the final report was submitted to PFC, so at the Annual Meeting on August 1, 2023, PFC created the Copper Claim Workgroup and charged it with considering this proposal and the recommended language for the regulation. The workgroup met on September 27, October 27, and November 30, 2023.

The members of the workgroup and their affiliations are:

Dr. Karen Donnelly – Workgroup Chair, FDA's Center for Veterinary Medicine
Ms. Holly Jewell – South Carolina Department of Agriculture
Ms. Kristen Green – University of Kentucky, Division of Regulatory Services
Dr. Leslie Hancock – Pet Food Institute, Hill's Pet Nutrition
Dr. Marcie Campion – American Feed Industry Association, Cargill
Dr. Cathy Alinovi – Next Generation Pet Food Manufacturers Association
Dr. Jean Hofve – Pet Welfare Alliance
Dr. Renee Streeter – American College of Veterinary Internal Medicine (ACVIM - Nutrition)
Dr. Dave Dzanis – ACVIM (Nutrition)
Dr. Bill Burkholder – AAFCO Lifetime Member
Dr. Dharati Szymanski – American Veterinary Medical Association

Proposed Regulation

The original language for the regulation proposed in the Expert Panel report was for a "low copper" claim. Multiple members of the workgroup expressed concern that such a claim might imply that the copper content of the food was less than the minimum requirement listed in the AAFCO Nutrient Profiles and thus be confused with veterinary therapeutic diets specially formulated for dogs predisposed to, or with existing, liver disease such as Copper Associated Hepatopathy (CAH). Because the claim is intended to apply only to dog foods that meet or exceed the AAFCO minimum copper concentration for the indicated life stage, members of the workgroup agreed that the claim be revised to "controlled copper" and the regulation prohibit use of "low copper" or other similar wording. The revised proposed regulation now under consideration is shown below.

Regulation PF 10. Descriptive Terms [...]

(d) Copper Terms

(1) A claim "low copper," "low in copper," or words of similar designation is not allowed.

(2) A dog food that bears on its label the claim "controlled copper" shall:

- A. Be substantiated as nutritionally adequate for one or more life stages in accordance with Regulation PF7; and
- B. Contain a maximum of no more than 15 mg copper/kg DM and no more than 3.75 mg copper/1000 kcal of metabolizable energy; and
- C. Bear on its label in the Guaranteed Analysis in accordance with Regulation PF4 a guarantee for the maximum amount of copper in the dog food.

Discussion

At the conclusion of the three meetings, members of the workgroup were asked to vote whether they recommend PFC seek to establish the voluntary “controlled copper” claim regulation as shown above. **Six members voted in favor and four members voted against it** (two members shared in one vote because they represent the same organization). Most members provided position statements to explain why they voted a certain way, and these are attached to this report in Appendices A - H. A summary of the arguments for and against establishment of a “controlled copper” claim is below.

Those who voted against the “controlled copper” claim regulation did so primarily because they felt the claim was not adequately supported by scientific evidence. The proposed maximum copper concentration allowed under the claim is somewhat arbitrary; members of the Expert Panel decided on that limit based on the measured copper content of over 1500 commercial dog foods between 2017 and 2021 (See Figures 1 and 2 in Attachment 2 of the Expert Panel final report). The members voting against adopting the regulation argued that the claim is false and misleading because there is no evidence that the copper content range specified in the regulation is beneficial to dogs, especially dogs that have, or are predisposed to, CAH. Although the claim is not intended to indicate the diet can be used to prevent or treat CAH, these members felt such intended use is nevertheless implied and could lead to dog owners choosing foods with this claim rather than seeking guidance from their veterinarian. In addition, they argued that the regulation demonizes an essential nutrient and is likely to cause dog owners to assume all copper in dog food is harmful. They are also concerned that pet food manufacturers’ attempts to adhere to the “controlled copper” range could lead to nutrient imbalances or other nutritional issues with the diet. Finally, these members felt that the regulation was unnecessary because companies currently have the option for making a copper claim if they have the appropriate information to substantiate it.

The members who voted in favor of the regulation did so because they felt if certain dog foods bore the “controlled copper” claim, it would make it easier for dog owners and veterinarians who are concerned about the copper content of dog foods to find foods that contain less copper than the typical amounts found in other, non-therapeutic commercial dog foods. They pointed out that the copper content of diets making the “controlled” claim would be above the minimum requirement for the indicated life stage, and as it is with any type of food, it is the manufacturer’s responsibility to ensure the food is complete and balanced. Thus, there should be no more safety concerns for dog foods bearing this claim than there would be for any others. They also acknowledged that although companies could make a copper claim without the regulation in place, defining the amount of copper that meets a “controlled copper” claim assigns a uniform meaning to the claim, which in turn creates a level playing field by which such foods can be regulated among the states. This is akin to what AAFCO has done with other descriptive terms such as “light” and “low fat”. Finally, they argued that foods making the claim would not be permitted to also make claims or imply that the diets will prevent or treat CAH, so the concerns that owners will be misled by the claim into making medical decisions for their dogs instead of consulting their veterinarians are overblown.

Conclusion

By a slim majority, the workgroup recommends PFC establish the regulation for a “controlled copper” claim on dog foods as shown above. It is within AAFCO’s mission to provide clarity to consumers, promote consistency in the marketplace, and support animal health, all of which is accomplished with this regulation. There are very strong opinions on both sides of this issue, so I encourage PFC members to also read the attached statements. All workgroup members agree that more research about the effects of dietary copper on dogs’ health is needed, but in the meantime, PFC needs to decide if the proposed regulation is an appropriate and acceptable step towards addressing the issue. Most of the workgroup believes that it is.

Respectfully,

Karen L. Donnelly, DVM, MS
Chair, AAFCO Pet Food Committee Copper Claim Workgroup
FDA/CVM

List of Appendices:

A – PFI Statement

B – AFIA Statement

C – ACVIM (Nutrition) Statement

D – AVMA Statement

E – NGPFMA Statement

F – Bill Burkholder Statement

G – Kristen Green Statement

H – Pet Welfare Alliance Statement

In the interest of pet health, consumer trust and regulatory integrity, PFI cannot support the creation of specific nutrient claims for a disease where there isn't evidence-based science. We support the majority opinion of the AAFCO expert panel which stated that "no maximum amount of copper should be set for complete diets for dogs **until objective scientific data is available to establish such a maximum.**" The upper limit of copper being proposed for a "controlled copper," AAFCO-approved label claim is required to be above the minimum allowable copper in dog diets, so it remains unclear what is being "controlled."

Consumer data from an independent survey shows that should this claim be allowed, a significant cohort of consumers would look for dog food with no or low copper even though they did not have an understanding of the role of dietary copper in complete and balanced foods or own a dog with known copper associated liver disease (CALD). The data show that consumers will interpret this as an implied drug claim without understanding its impact to animal health (available upon request). Copper is an essential trace mineral and it functions interactively with other trace minerals like zinc and manganese, something consumers may not understand as a proportion of consumers stated they wanted a food with no copper.

Dogs that are truly suffering from CALD should be under the care of a veterinarian, which might include being fed diets with the therapeutically lower copper levels in a diet that is carefully balanced with other dietary minerals and their forms, including zinc, magnesium, and iron in their salt forms as these have been shown to be part of successful therapeutic programs. CALD can only be diagnosed through histologic analysis of a liver biopsy sample and quantitative assessment of hepatic copper concentrations. The diagnosis and treatment of CALD is complex, and requires veterinary expertise.

The proposed "controlled copper" food may actually run the risk of stopping a consumer from consulting with their veterinarian. In addition, taking an arbitrary action conveys to researchers, veterinarians, and pet parents this is a solution to CALD, and may prevent the pursuit of additional research and scientific evidence as it conveys the assumption that the proposed controlled levels of dietary copper will have a known positive impact on pet health, which is unfounded.

Furthermore, in healthy dogs no study has demonstrated that feeding higher levels of copper to dogs without genetic mutation and/or concurrent hepatic disease leads to CALD. The misperception that there is a causal link between dietary copper and disease in healthy dogs is driving the consumer disinformation behind these proposed regulations. If AAFCO chooses to move forward with this type of claim based on a subset of consumer sentiment about an essential nutrient, does this mean that every time anyone raises an issue of an essential nutrient then a claim needs to be put into the marketplace? We strongly feel that any claim needs to be scientifically sound and not misleading to consumers.

We propose a moratorium on any regulatory changes until additional research is completed to address the scientific knowledge gaps related to CAH and dietary copper. This would not be the first time that a moratorium on a claim would be instituted by the AAFCO Pet Food Committee.

Established in 1958, PFI is the trade association and the voice of U.S. cat and dog food manufacturers. Our members account for the vast majority of the dog and cat food made in the United States, with more than \$50 billion in domestic annual dog and cat food and treats sales and annual exports of more than \$2.4 billion. PFI membership also includes companies that supply ingredients, equipment and services to dog and cat food makers. We are all proud to be feeding over 186 million dogs and cats in U.S. households.



December 7, 2023

Karen Donnelly, DVM
Chair, AAFCO Copper Working Group
Via email

Dear Dr. Donnelly,

The American Feed Industry Association (AFIA) votes in opposition to establishment of a “Controlled Copper” claim within the Association of American Feed Control Officials (AAFCO) Model Regulation PF10 Descriptive Terms for the criteria for commercial dog food products. The prolonged discussion of this issue over more than two years through two working groups and an expert panel confirms the lack of consensus amongst companion animal nutritionists for this proposed claim. Furthermore, if manufacturers choose to market dog food based on copper content, then the current AAFCO model regulations for pet food clearly spell out the steps for them to take. There is no merit in developing an AAFCO-sanctioned claim regarding copper content in canine diets.

The AFIA does not support the creation of guidelines for nutrient content that are not founded on evidence-based science. Guidelines for pet food-related claims that are scientifically proven to address issues, such as obesity, appropriately exist in the AAFCO *Official Publication*. For example, low magnesium claims are supported through numerous peer reviewed trials confirming the efficacy. Development of these label claims requires mineral balance, safety, and efficacy studies to support premarket approval through the Food and Drug Administration Center for Veterinary Medicine. This proposal on copper would not require such equivalent scientific rigor.

Creating an AAFCO-sanctioned marketing claim regarding copper content in dog food based on an arbitrary value (as confirmed by Dr. Bill Burkholder) of 15 mg Cu/kg dry matter to address consumers’ desires rather than animal well-being is ill-advised. Labels marketing ingredients based solely on current consumer interest, without a foundation in science but bearing AAFCO-approved guidelines, will add to the confusion that already exists in choosing appropriate food for pets. The upper limit of copper being proposed for a “controlled copper,” AAFCO-approved label claim is required to be above the minimum allowable copper in dog diets, so it remains unclear what is being “controlled.”

Our Industry. Our Passion. Our Voice.

The AFIA strongly advises against AAFCO developing a “controlled copper” label claim built on a spate of publicity, which is founded on weak science about a possible nutritional component to a disease with a known genetic linkage in dogs. Developing an AAFCO-approved “controlled copper” marketing claim is a hasty step by regulators lacking clear research and scientific evidence of an association between the source or amount of dietary copper and the incidence of copper-associated hepatopathy (CAH).

In 2020 the Veterinary Information Network (VIN) updated their information on CAH. It reported that considerable progress had been made through genetics and breeding to reduce the incidence of the disease in Bedlington Terriers. Since genetics has been shown to be a root cause in this disease, why not spend time determining if this is also the root cause in the few other impacted breeds? Only a minor percentage of the total dog population is impacted, so why not focus mitigation and education efforts strategically, rather than targeting all healthy dogs. This would also minimize the impact of any unintended consequences with diets bearing this claim, since adequate mineral research has not been done to show that there are not any other consequences in healthy dogs.

Dogs that are truly suffering from CAH should be under the care of a veterinarian, which may include being fed diets with therapeutic amounts of copper. The disease can only be diagnosed through histologic analysis of a liver biopsy sample and quantitative assessment of hepatic copper concentrations. Unlike pet obesity, which an owner can easily self-diagnose, the diagnosis and treatment of CAH is complex, requires veterinary expertise and is not clearly linked to diet.

As of December 7, 2023, neither the American Veterinary Medicine Association (AVMA) nor the American College of Veterinary Internal Medicine (ACVIM) have reached a consensus regarding development of a controlled copper claim for canine diets. AAFCO should carefully weigh this when considering development of a “controlled copper” claim for canine diets.

For these reasons, the AFIA remains strongly opposed and votes no to the development of a ‘Controlled Copper Claim’ within the Association of American Feed Control Officials Model Regulation PF10 Descriptive Terms for the criteria for commercial dog food products.

Sincerely,
American Feed Industry Association

Appendix C

ACVIM (Nutrition) Liaison's Update December 15, 2023

Renee Streeter DVM, DACVIM (Nutrition)
David A. Dzanis DVM, PhD, DACVIM (Nutrition)

The American College of Veterinary Nutrition, which for many years has offered its scientific expertise to AAFCO on matters pertaining to the nutrition and feeding of animals, has now reorganized to become one of a number of specialties within the American College of Veterinary Internal Medicine (ACVIM). The focus of the organization, however, has not changed, i.e., the prevention and management of disease in animals through dietary intervention. Members ("Diplomates") of the Nutrition Specialty ["ACVIM (Nutrition)"] are Board Certified Veterinary Nutritionists® by virtue of their extensive training, rigorous examination and demonstrated expertise in the field, and serve as experienced leaders in clinical practice, academia, and industry. ACVIM (Nutrition) is comprised of over 100 Diplomates who are uniquely qualified to assess the merits of the proposal before AAFCO and offer their opinions.

A statement was proposed and voted on by ACVIM (Nutrition). In this statement the reasoning to support the statement and the reasons why others oppose the sentiment were outlined and we recommended language for the OP which was as follows:

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The results of the vote demonstrated a definite majority within ACVIM (Nutrition) to be in favor of the statement and proposed regulatory language. However, we decided that despite this majority vote, we are not ready to provide a consensus statement at this time. There are 2 reasons:

- 1) This vote, although largely in favor of the statement, did not constitute an overwhelming consensus for such a contentious and emotionally charged issue (61% voted for use of the statement). Some of our no votes came from colleagues that don't think any action should be taken on this issue at all, while others came from Diplomates that don't think this goes nearly far enough.
- 2) Although the statement as proposed attempted to provide a compromise between various factions within the College, strong opinions were expressed by the ACVIM executive leadership that the document – which would be ACVIM branded – was too dismissive of legitimate concerns among ACVIM SAIM (Small Animal Internal Medicine) colleagues who are adamant that there is ample evidence that a copper maximum for all dog foods is essential to protect animals consuming these products. So, before an official statement were to go out under the ACVIM banner, it would have to be amended

to make all viewpoints very clear, particularly that there are numerous ACVIM Diplomates that will stand in vehement disagreement with the current proposal, and rather be in favor of much more decisive and demanding action by AAFCO.

In summary: The majority vote within ACVIM (Nutrition) supports the regulatory criteria for a "controlled copper" claim as provided above. However, given the polarized views on the topic within the College as a whole, a formal consensus statement cannot be provided at this time.

Appendix D - Position of the American Veterinary Medical Association

AVMA does not support regulatory action to allow an over-the-counter dog food product to have a label claim pertaining to copper, because the AVMA believes decisions to feed a reduced-copper (or other component-adjusted diet) should be made in consultation with a veterinarian. We are concerned that it will not be possible to provide adequate instructions on the label of an over-the-counter diet that will enable clients to safely determine whether such a diet is right for their dog in the absence of a conversation with their veterinarian. We also believe we need additional data regarding what amount of copper is necessary to avoid deficiencies and toxicosis in dogs prone to copper storage disease, as compared to healthy dogs who are not affected by such conditions, before such a label can be responsibly applied.

Position Statement Regarding Copper Claims in Pet Food from Next Generation Pet Food Manufacturers Association

Summary

Growing concern in the veterinary community regarding copper levels in pet foods has led to questions regarding proper inclusion levels in commercial pet food. As pet food is pet owners' primary input into their pets' lives, it's logical to question if dietary copper levels could (or should) be restricted in certain situations for certain dogs.

Incontrovertible evidence to restrict dietary copper levels has not yet been proven in the peer-reviewed literature. However, data is easily obtained to demonstrate consumer interest. As the trade association representing fresh pet food manufacturers, Next Gen Pet Food Manufacturers Association convened a scientific committee of veterinarians, pet food formulators, laboratory analysts and consumer advocates to evaluate the need to restrict copper levels in pet food.

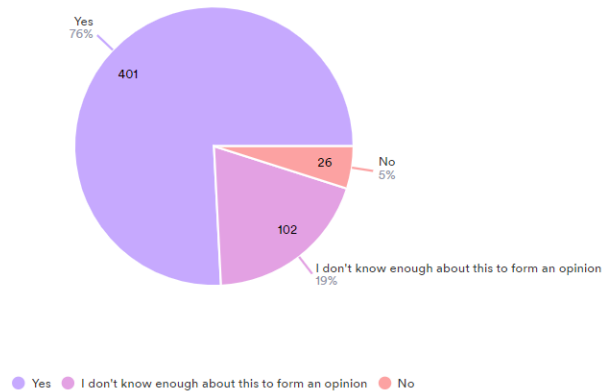
We surveyed over 500 pet owners, veterinarians and nutritionists, we tested local retail grocery store beef liver for copper levels, our nutritionists formulated DIY recipes based on this liver to evaluate copper levels, we tested conventionally available kibble pet food and we performed *in vivo* hair analysis in more than 230 dogs. Results demonstrate: 1. Interest exists by all consumer groups that industry restrict copper in some pet foods; 2. Wide variation exists in copper and associated minerals (iron and zinc) in not only conventional food, but retail raw ingredients, thus DIY recipes, and in the pets as well. Therefore, this is a very important topic.

Survey Data

To determine the knowledge level of our consumers, we conducted a survey of pet owners, veterinarians and diet formulators who work in the fresh food industry. The survey generated 529 responses. 76% of those surveyed believe copper levels in pet food should be restricted to fall between 1 and 2 times the AAFCO minimum.

Would a voluntary maximum level of copper, labeled as "low copper", be of benefit to veterinarians and/or pet owners?

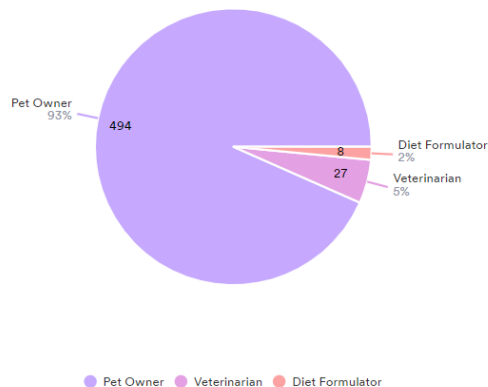
529 Responses



Eight respondents were veterinarians and also diet formulators. Five of these formulate balanced diets for DIY pet owners, 3 for manufacturers or rescue groups. 27 respondents were veterinarians who recommend the use of fresh food diets to their clients. 494 respondents were pet owners who feed fresh food diets to their dogs.

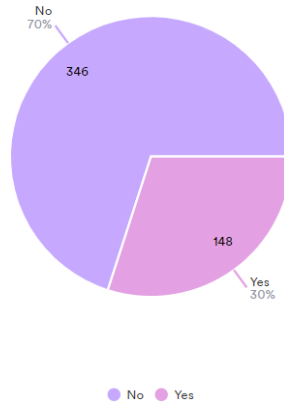
Are you a:

529 Responses

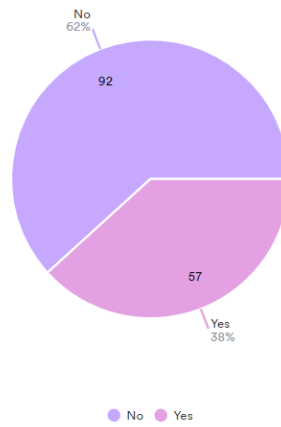


148 (30%) pet owners had a dog with diagnosed liver disease. 57 (38%) of these had a liver biopsy conducted. (Biopsy data was not collected so as to avoid cumbersome collection of data.)

Do you have/have you ever had a dog with liver disease?
494 Responses- 35 Empty



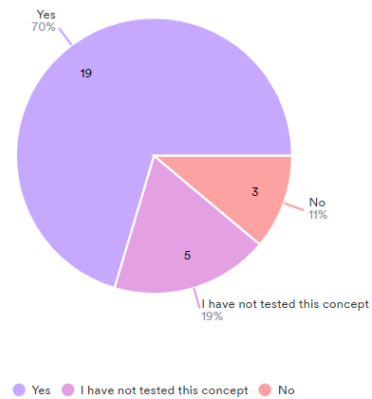
Was a biopsy taken to diagnose liver disease?
149 Responses- 380 Empty



Of 27 veterinarians surveyed, 19 (70%) find copper plays a role in liver disease, 5 (19%) do not have enough information and 3 (11%) do not find a connection between dietary copper and liver disease.

Do you find copper plays a role in liver disease in your patients?

27 Responses- 502 Empty



Overall, those surveyed do have an interest in pet foods labelled for restricted copper levels.

Analysis of Retail Liver

To determine if copper concentration variation is a problem only in formulated pet food or also in DIY diets, we conducted laboratory analysis of 3 conventionally available grocery store liver products from the meat section. The samples included low-cost conventional beef liver (sample 1), mid-range priced conventional beef (2), and pasture-fed beef (3). The results revealed high variation in copper levels; conventionally raised meat far exceeds recommended levels where the grass-fed product had far less copper load. Iron and Zinc levels were also variable.

Brand	Copper	Iron	Zinc	Fe/Cu	Zn/Cu
1	103	12.8	13.1	0.12	0.13
2	42.1	16.2	13.5	0.38	0.32
3	1.5	14.7	16.7	9.8	11.1

Table 1. Mineral Analysis for 3 Retail Liver Products (all data reported in mg/100g)

Mineral Levels in Balanced Home-Prepared Diets Using Retail Beef Liver

Using the above-mentioned measured copper levels, our veterinary nutritionists formulated a balanced diet for adult dogs using these liver products and evaluated for copper/mineral levels. Dietary inclusion level of 10% liver reveal the copper levels in the diet range from extremely high to normal, corresponding to source of the liver.

All dietary ingredients were held constant, except for different livers. The data demonstrate massive variability dependent on the source of the liver. Not only is copper concentration in pet food critical, it's also critical in livestock feed; that is beyond the scope of this discussion. Although it's clear that livestock feed is impacting the mineral concentrations in the raw beef liver.

Brand	Copper	Iron	Zinc	Fe/Cu	Zinc/Cu
1	92.9	62.7	113.6	0.7	1.2
2	41.1	65.6	113.9	1.6	2.8
3	6.6	64.3	116.6	9.7	17.7
AAFCO minimum	1.83	10	20	5.5	10.9

Table 2. Fresh Food, Home Prepared, Veterinary Diet Balanced to AAFCO Minimums Using Retail Liver Products (all data reported in mg/1000kcal) for 20-pound sedentary, adult dog

Comparison of Mineral Levels in Retail, Conventional Kibble Products

An evaluation of 5 conventional pet foods (adult, all life stage, kibble, nationally available) to determine mineral variation in actual copper levels in commonly available, nationally recognized brands of kibble. We found that not only were the copper levels quite a bit higher than the AAFCO minimums in all brands, but we also found Fe/Cu and Zn/Cu ratios to have very wide variation (implying iron and zinc concentrations are quite broad as well).

Nutrient	AAFCO min	Brand 1	Brand 2	Brand 3	Brand 4	Brand 5
Copper (Cu)	1.83 mg/1000kcal	18.0	16.5	14.0	31.5	24.5
Iron (Fe)	10 mg/1000 kcal	224	281	365	1200	301
Zinc (Zn)	20 mg/1000 kcal	257	242	190	170	170
Zn/Cu	10.9	14.3	14.7	13.6	5.4	6.9
Fe/Cu	5.5	12.4	17.0	26.1	38.1	12.3

Table 3. Laboratory Analysis of Mineral Concentrations in 5 Nationally Available Commercially Prepared Diets

Hair Mineral Analysis of Pet Dogs

And finally, hair analysis of 232 dogs was conducted to measure body copper levels, as well as evaluate the body concentrations and ratios of zinc to copper and iron to copper as found *in vivo* in dogs.

Dogs were stratified based on diet formulation (+/- formulated by a veterinarian or nutritionist) and whether synthetic nutrients were added to the diet. Data were compared to copper levels, as well as other minerals, and their ratios.

Of significance, in those dogs with high levels of copper deposits (>1.8 mg) there was no difference between diets with and without addition of synthetic nutrients ($p= 0.17$), but formulated diets had much higher probability of having high copper levels than non-formulated diets ($p= 0.028$); and formulated diets had a relative risk 2.33 times more likely to have high copper levels than non-formulated diets (90% CI). The implication being that professional nutritional formulation does not protect against high copper levels.

Again, the evidence is that the variation is tremendous. Most diets strategies present wide variation.

Summary statements

It is clear from our surveys that not only veterinarians, but pet owners share a concern about copper levels in pet food.

There is both a need and public interest, in certain circumstances, to limit dietary copper levels. By no means do we expect every manufacturer to jump on the limited copper claim band wagon; for the grand majority of animals, it may not be necessary to restrict copper. But why should we limit market availability simply because only a percentage of the marketplace needs copper restriction? This would be like forbidding labeling of “diet” foods because only a percentage of the population is obese.

Limited copper levels in pet food benefits the consumer, benefits pets, and provides certain manufacturers niche differentiation. Furthermore, a limited copper claims allows for pet foods to be regulated equally.

From a manufacturing perspective, we encourage diversity in the pet food marketplace. A limited, or moderate, copper claim is neither a requirement, nor something that every manufacturer will embrace. But for those who wish to enter the niche market, a moderated copper claim provides the mechanism.

Finally, from the perspective of consumer transparency, we feel the more information that is shared with the public the better. Ultimately, it is the consumer’s decision which product to buy. For some consumers, they will want increased information regarding copper content in their pet food. For other consumers, this will be a non-issue. But it’s clear from the survey that a percentage of the marketplace absolutely does want to know what is the copper level in their pet food. Therefore, the industry should provide that information in a regulated, manageable way.

For the Science Committee, NGPFMA
27 November 2023

Appendix F – Statement from Dr. Bill Burkholder, DVM, PhD, DACVIM (Nutrition)

The model regulation (MR) accomplishes a number of things. First, the MR informs interested consumers about the copper content in diets where the manufacturer is attempting to lessen the concentration of copper in the diet to something close to the dietary recommended allowance. Second, it establishes what the maximum copper concentration in the diet can be if the manufacturer wishes to make a claim that the copper concentration is “controlled.” The MR establishes the adjective used in the claim to be “controlled” and prevents the use of an adjective that has no established maximum and that is misleading when used because of lack of scientific definition for what “low” copper is for dogs. Thus, it standardizes what controlled copper in dog diets means. This standard provides a level playing field for the industry and frees the regulatory officials from extensive review and questioning of the manufacturer for what is meant by the claim. It also establishes what supportive evidence for the claim must be on the label, namely the maximum copper guarantee. Although the case has been made that the regulatory structure already exists for making such a claim, without the above elements the claim would not be standardized and the same claim on different products could refer to substantially different concentrations of copper among the products making the claim.

The argument has been advanced that it is not known if the maximum amount of copper allowed by the MR for claiming controlled copper will help dogs predisposed to copper associated hepatotoxicity (CAH) and thus the claim could be misleading. The MR does not seek to establish what copper concentrations should be in therapeutic diets for CAH. When judged with respect to the concentrations of copper found in approximately 1500 samples of commercial dog foods over five years, the claim is not misleading and is truthful.

Appendix G – Statement from Ms. Kristen Green, University of Kentucky, Division of Regulatory Services

I vote aye.

The rationale, from my standpoint, stems from the below points:

- There is consumer and vet interest in having this information available – therefore industry will respond with their own version of labeling claims/levels/data, etc. We will see varied approaches to this across firms and will start to see it presented more often on packaging. We should get ahead of this issue.
- While there is a route to have firms individually present data to states for review of claims – this relies on a state-by-state approach, which is EXACTLY what the industry is fighting against in all other categories right now. Individual presentation and ‘approval’ of data packages leads to massive inconsistency. And is a huge drain on state resources. And firms can still offer data packets to support their findings to support other Cu claims that they may want to make to differentiate themselves in the marketplace.
- An expert panel has already reviewed the available scientific data and suggested the regulation as reasonable. I much prefer that route to state-by-state interpretation.
- AAFCO exists to promote uniformity and a level playing field (along with health of course). This clearly achieves the first two.
- The max Cu level is higher than the minimum required by the profiles, so I am not concerned about safety. These levels could be followed now.
- I think that the argument that the public will not understand and will treat these claims as ‘vet advice’, etc. are overstated. Consumers aren’t stupid, and only those looking for the information will find it. And if they are already looking, they are already somewhat informed. I also don’t believe that offering this information on the labeling will make folks less likely to consult their veterinarian. They either already do or already don’t.
- The arguments that there are better ways to inform the public about Cu issues in dogs – or that additional research should be done re: levels and nutrient interactions – are both true. They are also both outside of AAFCO’s purview and not under our control. As additional data comes to light (if it does at all), this information should be considered in reviewing the language and levels that you attached.
- Finally, I don’t think that the level is perfectly scientifically based, nor is it the perfect time to implement. I DO think that this approach (for a voluntary claim) is reasonable, is a compromise and supports AAFCO’s mission of uniformity and transparency while promoting health.

Appendix H – Pet Welfare Alliance Statement

To: Dr. Karen Donnelly
Veterinary Medical Officer / Division of Animal Food Ingredients
Center for Veterinary Medicine
Office of Surveillance and Compliance
U.S. Food and Drug Administration
karen.donnely2@fda.hhs.gov

From: Jean Hofve, DVM
PO Box 273
Jamestown CO 80455
jeanhofvedvm@gmail.com
303-523-7888

Re: Copper Working Group Vote

Hi Karen,

I so appreciate being part of this workgroup!

I represent the Pet Welfare Alliance, a group of concerned pet parents whose views so often go unrecognized in these debates!

As you might have anticipated, I vote **yes** on adding the proposed language to PF10 in the OP:

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B. Contain a maximum of no more than 15 mg copper/kg DM and no more than 3.75 mg copper/1000 kcal of metabolizable energy; and

C. Bear on its label in the Guaranteed Analysis in accordance with Regulation PF4 a guarantee for the maximum amount of copper in the dog food.

I've now had a chance to go back over some of the history and research on this issue, and would like to make the following comments as a practicing veterinarian and as a representative of the Pet Welfare Alliance, a consumer advocacy group. Here are my comments. You are welcome to share them. Feel free to share them with the rest of the WG, or let me know if you want me to do that.

1. It was AAFCO that created the copper issue in the first place. Now that we are seeing the results of AAFCO's actions, it is logical that AAFCO should take steps to mitigate them. This is entirely appropriate for AAFCO, as one of its primary roles is consumer protection. From the 2023 AAFCO OP, page 6:

AAFCO Philosophy Regarding Feed Regulation

The most important aspect of feed regulation is to provide protection for the consumer as well as the regulated industry.

Successful marketing of a product typically includes claims of content and performance. It could be argued that a product which does not live up to its claims would soon drop from the marketplace because it would not sustain repeat sales. However, subtle deviations from label claims may not be readily apparent and may result in health or production losses before use of the offending product can be discontinued. Therefore, a means of monitoring feed products to verify label claims needs to be established. Feed regulations can fulfill this need if they are established to include provisions for evaluating products for nutrient content, efficacy and safety.

Consumers are concerned about what they are purchasing, and label disclosure can serve to inform them about product content. Armed with information about competing products, the consumer can make an informed purchase decision.

2. A single 1993 paper comparing copper oxide and copper sulfate suggested that copper oxide is not sufficiently bioavailable to be used as a copper source in pet foods. AAFCO relied on this one paper—which was not peer-reviewed, not replicated, and did not cite a single case of clinical deficiency in any dog anywhere—to change its 1997 Nutrient Profiles to require copper sulfates or chelates to be used as copper sources in pet food. [Czarnecki-Maulden et al. 1993]
3. The 2006 NRC Dog and Cat Nutrition Requirements failed to set a SUL due to insufficient data. In 2007, the AAFCO Canine Nutrition Expert Subcommittee—without any evidence that AAFCO’s published copper maximum was inappropriate—eliminated the maximum in its Nutrient Profiles.
4. The Expert Committee cited 23 papers, 11 of which were more than 10 years old. More recent papers show that the problem is bad and getting worse. Contrary to what was stated in one of our meetings, there have been numerous case reports of non-predisposed dogs developing CuAH/CAH. Additionally, several papers suggest that excessive copper in pet food is a broader issue than has yet been considered. (See References below.)
 - Excessive copper levels may be a contributing factor in idiopathic epilepsy [Rosendahl 2023].
 - There is evidence that increased copper levels may also be affecting cats [Yamkate et al. 2022] and ferrets [Richard et al. 2022].
5. Liver copper levels have risen ever since the change to copper sources in 1997. According to Strickland, et al. (2018), “While causation cannot be determined, the close temporal association of changes in [Cu]H with changes in AAFCO copper supplementation recommendations are concerning.” These changes are occurring both in pre-disposed and non-predisposed breeds.
6. These concerns are not limited to “a small group of veterinarians.” I was recently talking with a colleague who owns a small clinic in a suburb of Denver. I asked what she knew about copper in dogs. She had not read any of the articles about it so was unaware of the

controversy. However, she has had recently seen several cases of dogs with persistent, unexplained elevations of ALT that were subsequently diagnosed by a specialist with CuAH. If average veterinarians in average practices are seeing these cases, the problem is likely quite significant.

7. The ACVIM, with its 3,000 members, has expressed concern “that [t]here is strong case-based evidence that current dietary copper allowances for canine diets have caused increased hepatic copper concentrations in pet dogs of mixed or pure breed ancestry. This concern has been amply documented in peer-reviewed veterinary literature. While ACVIM has not reached a consensus on what action should be taken, has expressed a desire “to raise awareness to facilitate early diagnosis and treatment of canine CuAH.” That is precisely what the proposed change to the OP will accomplish.
8. The allegation that AAFCO is getting into marketing is frankly ridiculous. This is not a marketing issue; it is a safety issue. Previous examples include taurine, “lite/light/low calorie,” urine pH, etc. – all of which have profound implications for pet health.
9. The copper in mineral premixes is added on top of the natural copper content of ingredients. Many producers have moved away from “by-products” and use more livers and kidneys; these organs are particularly high in copper. This, of course, provides an even larger safety margin for “controlled copper” in dog foods.
10. In terms of liability, if there is such a possibility (which is really a stretch of the imagination), I would think there would also be liability for those who are actively fighting against this change. We are talking about a simple, easy-to-understand declaration for consumers concerned about their dogs, to help them make an appropriate choice. Opposition to this change goes directly against AAFCO’s primary mission, as shown above.
11. AAFCO regulators and industry representatives have been working very hard for years to implement the Pet Food Label Modernization (PFLM) project. Isn’t this issue exactly what PFLM is about? Giving consumers more information, more transparency, so they can make better choices?
12. Eventually the premix makers, manufacturers, feed formulation programs will come to the same conclusion: that they ought to reduce copper in their foods. They will quietly make changes in their recipes. But how many dogs will suffer over the next decade or two while that happens? Liver inflammation is painful. Ascites is painful. Losing a beloved pet is painful. How can we justify withholding this relevant information?
13. Of course, this issue needs more research. Scientific knowledge is expanded and refined every day. Nobody knows everything about pet nutritional needs, but we’re learning. And we have more than enough information now to make this simple change.

There really is no excuse for the vast overages of copper (and other minerals) in many pet foods. The current minimum copper for growth is 12.4 mg/kg DM, and for adult maintenance 7.3 mg/kg DM. Some foods have tested well over 10 times that level between 2015-2020, according to the Expert Committee report.

In one of our meetings, I mentioned that pet foods had routinely test at 300-400% of their minimum requirements. I was challenged on this. But tests of wet and dry dog and cat foods performed by the Kentucky Department of Agriculture in 1994-1995 showed that copper was at **300% or more** in well over 40% of dog foods. Note that this was while *copper oxide was still in*

use—clearly, ingredients alone were providing sufficient copper in the vast majority of foods. Less than 5% of products failed to meet 100% of the minimum requirement.

Food Tested	Cu > 300% of AAFCO min.
Dry adult dog foods	41.4%
Growth dry dog foods	58.8%
Canned adult dog foods	43.1%
Growth canned dog foods	48.3%

The same was true of other minerals like iron, zinc, and particularly manganese, which exceeded 450% of the AAFCO minimum in more than 90% of dog foods. I have seen no evidence that this habit of vastly over-supplementing minerals has changed since then. Are dogs now paying the price?

The proposed language is entirely justified, and supports AAFCO's mission of consumer protection. I believe it is a timely and necessary addition to the OP.

Thank you!

Sincerely,

Jean Hofve, DVM
Pet Welfare Alliance

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