From:

Sent: Tuesday, February 13, 2024 4:47 PM

To: AAFCO

Subject: Fw: AAFCO Seeks Public Comments on Voluntary Copper Claim

CAUTION: This email originated from the internet.

Hello

Per your report below, I have a few comments. To say I am frustrated at some of the comments by the “NO” votes is an exaggeration because I am ANGRY. I don’t know how other to say it than all this boils down to is MONEY. The fact that some of these people are on the board of certain companies spells it all out in black in white to me. MONEY MONEY MONEY is all they care about.

I have been dealing with this copper for approximately 10 years now and have done some reading, especially items researched, studied and written by Dr. Sharon Center of Cornell University who I see is NOT on your list of “professionals” regarding this issue. She SHOULD BE!!!!!

First off, I have now lost 4 dogs to Copper Storage Disease. As I write this, I have a 5th dog that is at UC Davis having a liver biopsy done to see if she has it as well. That’s 5 dogs in less than 10 years. I’ve had my water checked and my water is NOT the issue. This is a HUGE problem.

The fact that your “professionals” refuse to believe this is a food related issue is just completely DUMBFOUNDING to me. Anyone can see that the type of copper was switched from Copper Oxide to Copper Sulfate approximately 20+ years ago. This problem did NOT exist like it does now until they switched the type of copper that is used in our kibble dog foods. It’s affecting all dogs now, not just Bedlington Terriers (genetic problem for them) like it was before. Even mixed breeds are popping up with Copper issues.

WAKE UP AND SMELL THE COFFEE!!!!!!

This has to stop because I personally am tired of losing dogs to this disease.

FIX IT NOW!!!!!

From:

Sent: Tuesday, February 13, 2024 3:28 PM

To: AAFCO

Subject: Copper killing our beloved dogs

CAUTION: This email originated from the internet.

Don’t you think that if dogs are sick or dying from Copper toxicities and Copper storage disease, and you are putting high quantities and maybe the wrong type of copper in their foods, you should take some responsibility and change the amount of and kind of copper you are putting on your food.

Dogs get a lot of copper from the environment, they don’t need huge amounts of copper in their food. Please take some responsibility and provide safe foods for all dogs.

How many dogs have to suffer a horrible death and how many families are heartbroken to lose their family members before you take notice. ????

I see a trend here, people are making their dogs food from home. Much safer.

From:

Sent: Tuesday, February 13, 2024 11:21 AM

To: AAFCO

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

To Whom it May Concern,

Serious concerns regarding the levels of copper in dog food and its effect on canine health have been raised for years, and establishing an upper limit for copper in dog food is long overdue. Copper is the mineral most likely to cause toxicity and is considered an accumulated poison; it accumulates in the liver, causing cell damage, and eventually, death. Excess intake of copper also decreases absorption of zinc and iron. Deficiency of such a micromineral is unlikely, and supplements shouldn't need to be added to properly balanced diets.

I fully support the endeavor to establish such a limit.

From:

Sent: Wednesday, February 14, 2024 8:00 AM

To: AAFCO

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

Dear AAFCO: my concern with using "copper controlled" is this implies pet food not stating this claim will be considered by the public as "uncontrolled". We have experienced this with labeling meat as containing no hormones as people believe if this claim is not stated, the product contains hormones.

Regards,

From:

Sent: Tuesday, February 13, 2024 12:42 PM

To: AAFCO

Subject: "Copper Claim Workgroup Comment"

CAUTION: This email originated from the internet.

To whom it may concern,

Upper end regulation should be withheld until such time as confirmation of the limits are known. There is no reason to impose limits based on speculation, since testing can confirm the absolute standard.

Best regards,

Bud Elmore

From:

Sent: Wednesday, February 14, 2024 7:09 PM

To: AAFCO

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

I am a consumer with 3 Labrador Retrievers:

4 Year Old Female with 2 ATP7B Mutations

2 year old female with 1 ATP7A and 1 ATP7B mutation

10 Year old Male with 1 ATP7A mutation

Until receiving the DNA results, I knew nothing about copper storage and had never looked for it in the analysis on dog food bags.

I am very disappointed that that this information is NOT REQUIRED on pet food bags, and that no maximum value is required.

Since finding the status of my double carrier girl, I have been careful to make sure I am feeding a food that is not high in copper. But why do I have to request that information from the manufacturers (many of them don't even answer, or simply say it is "withing the recommended range"?

Having a "Controlled Copper" designation is helpful, but only if manufacturers choose to do it.

It would be better and less complicated to simply REQUIRE listing copper content range on the bag along with the other nutrition data where consumers can easily find it. I understand there cannot be a definitive number, as variations are possible, but manufacturers should be aware that excess Copper is a concern, and we need to know those amounts.

In addition, manufacturers need to understand that there is no need to have excess copper in our dogs' food.

We are the advocates for our dogs. Please help us do that!

and the Fishdogs

From:

Sent: Thursday, February 15, 2024 9:41 AM

To: AAFCO

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

Workgroup,

The Greek philosopher Plato once said," A good decision is based on knowledge and not numbers." While I understand the reasoning behind trying to help consumers with a regulation that would allow the labeling of controlled amounts of copper in a pet food, I feel we do not have enough knowledge of the complete issue involving copper, at this point, to alter AAFCO regulations. We need more research on this subject that hopefully will provide more knowledge that then can provide a scientific approach to what may or may not be needed in terms of regulatory changes.

Sincerely,

Fromm Family Foods LLC.

From:

Sent: Tuesday, February 20, 2024 1:24 PM

To: AAFCO

Cc:

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

I would like to comment on the proposal for copper restriction and labeling of commercial dog foods. For background I have a Ph.D. in nutrition and have formulated pet foods for over 40 years so I feel qualified to

comment on this issue. The scientist in me recognizes the lack of hard data specifically showing high copper levels in commercial dog foods are causing liver disease in dogs. That said given what information we have seen recently and what we know about breed sensitivities to a variety of dietary nutrients including cooper and taurine, it would seem to be an extremely daunting task to find a single common maximum value for copper. There are currently 200 different dog breeds recognized by the AKC and then add to that all the mixed breed dogs kept as pets. Given the genetic diversity this population represents the time required to even begin to get a handle on this for the entire pet dog population would require decades and many millions of dollars. As such it seems like the proposed recommendation would be a reasonable step in the right direction given the primary mission should be to support the health of pets.

Having formulated thousands of dog food over the years I can assure you it would be relatively simple for an experienced formulator to keep copper for adult dogs at maintenance under 15 mg/kg, which is more than twice the AAFCO recommended value for maintenance (7.3 mg Cu/kg diet) and still above the AAFCO recommendation for all life stages (12.4 mg Cu/kg diet). This would be far less challenging to execute than the current AAFCO requirements for calcium for growing large breed puppies where the max of 1.8% is only 50% higher than the min (1.2%). The proposed values and labeling of such diets would be voluntary, would not provide a hardship to any carefully formulated diet and provides pet owners and veterinarians the information they need to make better decisions. Currently consumers or veterinarians must call the manufacturer to get dietary copper values and there is no way to validate those numbers. In contrast the proposal puts a reasonable upper limit and because it would appear on the package there would be enforcement of that upper limit by state AAFCO officials as they routinely sample and test commercial pet food sold at retail.

While I understand some companies will “market” this new value, in reality pet foods have been marketed for their nutrient content for at least the last 50 years. A good comparison is the currently allowed claim of low dietary magnesium for cat foods. While some cats may benefit from eating a diet low in magnesium, in reality dietary magnesium levels, within limits, are likely immaterial to the health of most cats if urine pH is properly controlled. For both magnesium and copper there is no risk of a deficiency since all complete pet food needs to meet the AAFCO nutrient profiles. Indeed, unlike trying to control dietary magnesium levels, controlling dietary copper levels is relatively simple since a large percentage (probably 30-60% depending on the ingredients used) of the copper in most commercial pet foods comes from the trace mineral premix.

As such I endorse the proposed values and labelling of commercial dog foods for “controlled copper” levels for those manufacturers that choose to participate.

Respectfully,

From:

Sent: Tuesday, February 20, 2024 7:17 PM

To: AAFCO

Cc:

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

2/20/24

RE: Copper Claim Workgroup Comment

Thank you for an opportunity to comment on the proposed AAFCO controlled copper diet claim. As veterinary specialists with more than 200 years of collective expertise and experience in the diagnosis and management of dogs with liver disease, we provide the following comments after viewing and discussing Dr Karen Donnelly’s Zoom presentation regarding “Copper Hepatopathy & Dietary Copper.

1. We welcome FDA’s acknowledgement of “increased awareness among dog owners, veterinarians, and pet food companies regarding concerns about copper concentrations in dog food.”.

2. We consider that establishing labelling regulations for a controlled copper diet is a first step in acknowledging the need for tighter control of dietary copper concentrations in dog food relevant to our observation of the increased incidence of Copper Associated Hepatopathy.

3. We encourage regulatory efforts and nomenclature that will clarify for consumers that dietary copper restriction to 15 mg/kg (0.375 mg/100 kCal) may not prevent Copper Associated Hepatopathy.

4. We suggest that copper concentrations declared in guaranteed analyses of the controlled copper diet label (and optimally in all dog foods) should be expressed in units that normalize copper intake to energy intake: i.e., mg/100kCal, rather than mg/kg.

5. We recommend that the total copper content in dog foods (including natural copper and premix additives) be declared in the guaranteed analyses on the product label allowing consumers to make informed decisions regarding the amount of copper fed to their dog. We acknowledge differences in bioavailability of various copper sources and the complex interactions influencing copper bioavailability among certain dietary ingredients.

As FDA and AAFCO committees move forward in considering the role of dietary exposure in dogs relevant to the increased prevalence of Copper Associated Hepatopathy, we recommend that one or more Veterinary Internal Medicine specialists with an expertise in hepatology who diagnose and care for affected dogs and personally interact with their owners be included.

From:

Sent: Wednesday, February 14, 2024 9:43 AM

To: AAFCO

Subject: “Copper Claim Workgroup Comment”

CAUTION: This email originated from the internet.

Dear workgroup members:

I have bred and trained Labrador Retrievers for years; I’m a judge in the Hunting Retriever Club and I actively compete my dogs in obedience, agility, and hunt tests.

I have an otherwise healthy Labrador Retriever bitch who was diagnosed with copper related hepatopathy in February of 2022. She was asymptomatic – it showed up on a routine blood test and was confirmed via liver biopsy.

Followed an extensive (and expensive!) course of treatment, including consultation on a low-copper diet with a veterinary nutritionist. She now has a personal chef (me!) and eats a home-cooked diet (rather expensive) with a frozen prescription diet (VERY expensive) as backup.

Her liver numbers have returned to normal, but it appears that this all could have been avoided with a reasonable upper limit in copper in commercial dog food. I have owned Labs for years, well before the elimination of the upper limit on copper, some from the same bloodlines as the affected dog, and none have ever developed CAH before.

I am not alone in this, as the attached article from Cornell Vet School shows.

PLEASE seriously consider formulation changes!

Yours very truly,

The looming concern about copper in dog food: Copper overload is quietly killing our dogs | Cornell University College of Veterinary Medicine (https://www.vet.cornell.edu/news/20220128/looming-concern-about-copper-dog-food-copper-overload-quietly-killing-our-dogs#:~:text=Your%20dog%27s%20dietary%20copper%20helps,copper%20in%20our%20dogs%27%20food.)

From:

Sent: Wednesday, February 21, 2024 7:01 AM

To:

Cc: AAFCO

Subject: RE: [External] RE: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

Sorry guys in my zeal to just get this submitted I simply made the edits that everyone sent me…read it over for clarity and send it.

Sorry for not making any last minute edits.

But got the job done.

--

From:

Sent: Wednesday, February 21, 2024 4:20 AM

To:

Cc:

Subject: Re: [External] RE: Copper Claim Workgroup Comment

Great I'll thanks! FRCVS is just fine!

Sent from my iPhone

> On 21 Feb 2024, at 04:36, wrote:
>
> Already submitted... was OK not being on it. Thanks everyone.....nice response.
>
> Get Outlook for Android
>
> ---
>
> From:
>
> Sent: Tuesday, February 20, 2024 8:41:37 PM
>
> To:
>
> Cc:

Subject: [External] RE: Copper Claim Workgroup Comment

Hi , looks great! A couple of minor edits: there is a missing end-quotation mark at the end of the first paragraph and an extra period at the end of the sentence for 1. Also, is listed twice (once on the same line as). Lastly, I think wanted his name on the letter too.

Thanks for leading the way on this!

**Please note that I have a new Email Address:

**The Ethos email address has been decommissioned. Please update your address book and send all future emails to . Thank you!

From:

Sent: Tuesday, February 20, 2024 5:17 PM

To:

Cc:

Subject: Copper Claim Workgroup Comment

2/20/24

RE: Copper Claim Workgroup Comment

Thank you for an opportunity to comment on the proposed AAFCO controlled copper diet claim. As veterinary specialists with more than 200 years of collective expertise and experience in the diagnosis and management of dogs with liver disease, we provide the following comments after viewing and discussing Dr Karen Donnelly's Zoom presentation regarding "Copper Hepatopathy & Dietary Copper.

1. We welcome FDA's acknowledgement of "increased awareness among dog owners, veterinarians, and pet food companies regarding concerns about copper concentrations in dog food.".

2. We consider that establishing labelling regulations for a controlled copper diet is a first step in acknowledging the need for tighter control of dietary copper concentrations in dog food relevant to our observation of the increased incidence of Copper Associated Hepatopathy.

3. We encourage regulatory efforts and nomenclature that will clarify for consumers that dietary copper restriction to 15 mg/kg (0.375 mg/100 kCal) may not prevent Copper Associated Hepatopathy.

4. We suggest that copper concentrations declared in guaranteed analyses of the controlled copper diet label (and optimally in all dog foods) should be expressed in units that normalize copper intake to energy intake: i.e., mg/100kCal, rather than mg/kg.

5. We recommend that the total copper content in dog foods (including natural copper and premix additives) be declared in the guaranteed analyses on the product label allowing consumers to make informed decisions regarding the amount of copper fed to their dog. We acknowledge differences in bioavailability of various copper sources and the complex interactions influencing copper bioavailability among certain dietary ingredients.

As FDA and AAFCO committees move forward in considering the role of dietary exposure in dogs relevant to the increased prevalence of Copper Associated Hepatopathy, we recommend that one or more Veterinary Internal Medicine specialists with an expertise in hepatology who diagnose and care for affected dogs and personally interact with their owners be included.

From:

Sent: Wednesday, February 21, 2024 9:41 AM

To: AAFCO

Subject: Copper Clain Workgroup Comment

CAUTION: This email originated from the internet.

Please require dog food manufacturers to list the copper content on the packaging. The level of copper in food is should not be in excess of the minimum daily requirements as excessive levels of copper can cause disease in dogs with a predisposition for copper storage disease, and possibly even those without a genetic predisposition. Thank you.

From:

Sent: Wednesday, February 21, 2024 8:11 AM

To: AAFCO

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

I support setting a cap on copper in dog food and the right for consumers to have easily understandable labeling for the copper in dog foods.

From:

Sent: Wednesday, February 21, 2024 8:50 AM

To: AAFCO

Cc:

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

PLEASE move forward with the Controlled Copper proposal! Even if AAFCO does not set an overall cap for all dog foods, just having the transparency of some foods to use the claim would greatly help the owners of the thousands of genetically predisposed dogs to research and compare foods on a level playing field.

Death by slow liver failure due to CAH is painful, and the proposal has the potential to help predisposed Breeds lower their risk of acquiring the disease. Please help US help THEM!

ADAMAScanine pro.com

From:

Sent: Wednesday, February 21, 2024 2:22 PM

To: AAFCO

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

Hello,

I support dog food being able to have a Controlled Copper claim. As a consumer, I do not see any downsides to having this regulation. Manufacturers who wish to meet the maximum 15mg/kg of copper in their food can use this language and other manufacturers don't have to change anything. This only benefits consumers because we'll be more easily able to identify the foods we want to feed.

I have a pet Doberman and know this breed is predisposed to copper associated hepatopathy. I am very concerned about copper levels in dog food and it is difficult to get this information even when directly contacting food manufacturers. Having manufacturers be able to say Controlled Copper on dog foods will make selecting dog food a lot easier for me and others in similar situations.

Regards,

From:

Sent: Wednesday, February 21, 2024 2:23 PM

To: AAFCO

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

To who it may concern,

I am writing today to show my support in declaring a "controlled copper" claim on dog food.

My beloved poodle Bindi currently is on medication for gall bladder gunk/sludge which more than likely has resulted in her high liver enzymes & liver damage related to a copper storage issue.

Thankfully at the moment she is not unwell & even though we did not pursue surgical diagnosis of a copper storage hepatopathy we have decided to feed her a low copper diet to try to lessen the stress placed on her liver & the damage done.

Imagine my frustration when trying to find out the copper levels added in to dog food.

I understand that it is hard to give a "final" amount as naturally amounts will vary with ingredients added & that they can vary season by season but even being able to find out the copper amount added to the food in their "vitamin & mineral mix" can be difficult.

That's not even mentioning treats that have a "vitamin & mineral mix" added to them!

Please, we ask for transparency in this matter as everyone is trying to do the best by their beloved companions & no one needs to be in the place that we find ourselves in when we realise that we've inadvertently been poisoning our dogs by trying to feed them well.

Here is the face of one of the afflicted.

May I present Bindi

Regards

Jodie

From:

Sent: Thursday, February 22, 2024 4:34 AM

To: AAFCO

Subject: Copper content in commercial dog food

CAUTION: This email originated from the internet.

I strongly encourage that the governmental agency that regulates ingredients in dog food follow the recommendations by the specialists who know best in the American College of Veterinary Nutritionists about changing the copper content in commercial dog foods. This is very important because many dogs are getting a life threatening liver disease secondary to copper accumulation in the liver (Copper Hepatopathy). Please listen to the experts!!!

Thank you.

From:

Sent: Wednesday, February 21, 2024 9:35 PM

To: AAFCO

Cc:

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

To: Copper Claim Workgroup Members

I write in support of the proposed "Controlled Copper" claim that would indicate that the dog food is nutritionally adequate for one or more life stages in accordance with AAFCO's *Model Regulations for Pet Food and Specialty Pet Food*; 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 bear a Guaranteed Analysis on its label in accordance with the model regulation guarantee for the maximum amount of copper in the dog food."

I have direct experience with the danger of high levels of copper in commercially prepared dog food, and want both minimum and maximum copper levels displayed in the guaranteed analysis on dog food labels.

In December, 2021, my Moon (female beagle, born May 2017, spayed at 13 months) had a dental and our vet removed a couple of follicular cysts. He prefers to do, and I always ask for, pre-anesthesia bloodwork before any procedures with my dogs. She had an elevated liver enzyme value which can be caused in the moment

by many things ranging from she ate something weird to really bad stuff. She was totally asymptomatic and he sent me home with SAM-e and we drew blood again in 3 weeks just before Moon and I left for winter agility camp in Florida. He called while I was in Florida at camp and was concerned because the liver value had gone up relatively sharply. He had already consulted with a specialist before calling me to make sure he had the best info and the right questions. We spent an hour on the phone going through everything that I fed (food and treats) for the previous 6 months — he was most concerned about the potential for her retaining copper (which some dogs do when the concentration in their food is too high) which can ultimately cause significant liver damage, but since she was asymptomatic, did not want to jump into a liver biopsy right off the bat since that is highly invasive. Scary sh#t, folks. I had switched one of the foods in my dogs' food rotation during the fall, and we agreed that might be it, so we did an n=1 experiment by simplifying her diet back to one dry food that she'd been on since leaving puppy food behind, continuing the SAM-e (which took us almost 3 weeks to get in February, 2022) and testing again in several weeks. I switched Lili and Dancer back to the original food rotation at the same time. When we got home from camp, I did some online research and telephone call research with all the foods and supplements we used and learned that the food I had added in early fall, 2021, was high (148 mg/kg dry matter) in minimum copper concentration while everything else (food, treats, and supplements) was well within bounds (4-16 mg/kg). I shared that with our vet - he added my research to her file, and said he was very encouraged by that info.

We went about 10 weeks with the simplified diet and SAM-e and me watching her closely and praying a lot. The blood draw we did in mid-April, 2022, showed an over normal liver values, but just barely, and way way way down from where it was in January, 2022. I am so thankful. So we were on the right track, I got our vet's ok to go back to our original food rotation (from before I made the change in fall, 2021), and checked again in 6 months.

Moon's values have been normal since about 6 months after I made the change to drop the (unbeknownst to me) food with the high copper levels and she is doing great. I'm convinced that my vet, his caring, and his attention to the emerging literature on high, unregulated copper content in dog food, saved her life.

, Moon & Lili

From:

Sent: Friday, February 23, 2024 5:28 PM

To: AAFCO

Subject: Copper claim workgroup comment

CAUTION: This email originated from the internet.

To Whom it Concerns:

I am writing in support of regulating the addition of vitamins and minerals specifically copper into dog food. While it is good there is a minimum standard I believe there should also be a maximum standard as well. As you are aware excessive amounts of copper and other trace minerals can have a detrimental effect on dogs. As a long time owner of Doberman Pinschers, a breed predisposed to copper storage disease, I am in FULL SUPPORT of having dog food manufactures guarantee and state in the nutrition facts the maximum amount of copper in the food, so that I as a consumer can make fully informed choices on which product I choose to support and feed to my dogs.

Thank you for your consideration,

From:

Sent: Tuesday, February 27, 2024 7:09 PM

To: AAFCO

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

To The Association of American Feed Control Officials

I am a veterinary internist and a breeder of Labrador Retrievers. I would like to support the establishment of controlled copper claims for dog foods. I agree that establishing labelling regulations for a controlled copper diet is a first step in acknowledging the need for tighter control of dietary copper concentrations in dog food relevant to the observation of the increased incidence of Copper Associated Hepatopathy.

I also encourage regulatory efforts and nomenclature that will clarify for consumers that dietary copper restriction to 15 mg/kg (0.375 mg/100 kCal) may not prevent Copper Associated Hepatopathy.

I agree that copper concentrations declared in guaranteed analyses of the controlled copper diet label (and optimally in all dog foods) should be expressed in units that normalize copper intake to energy intake: i.e., mg/100kCal, rather than mg/kg.

I agree that the total copper content in dog foods (including natural copper and premix additives) be declared in the guaranteed analyses on the product label allowing consumers to make informed decisions regarding the amount of copper fed to their dog. I acknowledge differences in bioavailability of various copper sources and the complex interactions influencing copper bioavailability among certain dietary ingredients.

From:

Sent: Wednesday, February 28, 2024 2:25 PM

To: AAFCO

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

I am grateful for this opportunity to provide feedback and contribute to the discussion surrounding the potential 'controlled copper' claim for dog food.

I'd like to introduce myself as a passionate advocate for pet health and an active member of the pet care community. I am reaching out to you with a unique perspective on this issue close to my heart. My experiences as both a dedicated pet owner and various roles within the pet care industry have equipped me with valuable insights into the challenges faced by our companions.

I am writing to share my personal journey with you – one that includes navigating the complexities of copper-associated hepatopathy (CuAH) in dogs. Despite not having a breed predisposed to this condition, my dog faced this challenging diagnosis, sparking my dedication to understanding and addressing CuAH in pets beyond the typical "at-risk breeds".

I am in favour for adding the proposed language for a "Controlled Copper" claim.

Every measure taken to regulate copper intake holds significance. Considering the challenges associated with CuAH in dogs, including its insidious onset, lethal chronicity, and the emotional and financial toll it takes on pet owners, like myself, such a claim could offer a means of managing copper intake in the general population of dogs. I do, however, advocate for much more decisive and demanding action to be continued by AAFCO to address this pressing issue effectively.

While I understand and value the scientific process and the importance of evidence-based practices, I share the sentiment that there exists a substantial body of evidence provided by the Copper Hepatopathy Working Group, which consists of diplomats of Board-certification in veterinary internal medicine, veterinary pathology, veterinary nutrition, and veterinary sports medicine and rehabilitation. It is disheartening to witness AAFCO's dismissive stance towards legitimate concerns regarding copper-associated hepatopathy. That, "AAFCO believes the recommendations for copper in commercial dog food are appropriate, until scientific data shows otherwise," – but this was not a unanimous decision.

By integrating this claim into dog food labeling, pet owners can make informed decisions to optimize the health of their beloved companions. This transparent labeling approach fosters a proactive stance in safeguarding the health and well-being of dogs. Moreover, it provides pet owners with peace of mind, knowing they are taking concrete steps to be vigilant in their pet's care. Copper concentrations of canine diets can be highly variable, averaging between 20-30 mg/kg DM, but have been known to go as high as approximately 140 mg/kg DM. Pet

owners actively are seeking information from manufacturers regarding the copper content in their pet's food, a task that can require significant time and effort, and sometimes, with no answers at all. The concerned pet owner would have a clearer and more transparent means of understanding and managing their pet's copper intake with the potential implementation of a "controlled copper" claim on dog food labeling.

However, it's crucial to recognize that this claim represents just one aspect of addressing the broader issue of copper-related health concerns in dogs. It should serve as a catalyst for further initiatives aimed at tackling the root causes and implementing comprehensive strategies to mitigate the impact of copper-associated diseases.

Clinical signs of hepatopathies are often non-specific, which can complicate and delay a proper diagnosis and treatment. In 2017, faced with an arduous eight-month journey to uncover a diagnosis for my own dog, Riggs, an Old English Sheepdog, I navigated the complexities of his health challenges— copper associated hepatopathy (CuAH). Since then, I am still deeply committed to advocating for those affected by CuAH, offering the support and resources that were once lacking for individuals like us facing this challenge. The community I've established continues to expand, underscoring the ongoing significance of this issue. It is now well recognized that the surge in CuAH cases transcends traditional breed boundaries. Mixed breed dogs and those often referred to as "designer" dogs, combining various breeds, have emerged as highly susceptible to CuAH as well, as the diversity of my members demonstrate.

Confronted with a myriad of responses ranging from uncertainty to disheartening indifference, I persevered in advocating for Riggs, grappling with the emotional toll of navigating an intricate medical landscape for my beloved dog. The challenges encountered during this journey became a catalyst for my pursuit of knowledge and expertise in the realm of veterinary health.

Canine associated hepatopathy is and continues to be recognized with increasing frequency, while the growing studies and the work by the Copper Hepatopathy Working Group are demonstrating it is possible that copper plays a role due to several industry changes, which gives answers to those with an unknown etiology.

Now, our story, once unique and rare, is not just an isolated case but rather, a part of a growing recognition of CuAH. As their work accumulates, shedding light on the role of copper in this condition, our journey has become a shared narrative, offering insights and answers to those who grapple with the same diagnosis.

Where once we faced invisibility, there is now a resounding call for recognition and change.

I support a claim that will in any way contribute to lower copper levels, as this could potentially alleviate the burden of copper-associated hepatopathy in dogs. A pivotal step in addressing the rising cases of CuAH in dogs is reexamining and determining copper intake in dogs. This is a change that can and should be made, as it is already known we are exceeding the tolerated intake with data that supports copper delivery in base diets is adequate. I hope you continue to advocate for the well-being of our canine companions and push for advancements in pet nutrition standards regarding a copper maximum intake.

When faced with a diagnosis of copper-associated hepatopathy, it becomes evident that copper is ubiquitous – it's in everything. This realization is not an exaggeration; rather, it stems from the profound presence of copper as an element abundantly found in the environment, present in soil, water, and various foods consumed by both humans and animals. Its natural occurrence in the environment ensures that there is no shortage of intake opportunities. Given its ubiquitous presence in the environment and multiple intake sources, there is no shortage of copper intake for individuals, including dogs.

This is a lifelong disease that demands continuous management, encompassing a comprehensive approach. This includes regular veterinary monitoring to track the progression of the condition, specialized diets (which are very limited) tailored to mitigate copper accumulation, and the administration of medications and supplements designed to support liver health. The multifaceted costs associated with CuAH not only extend to financial expenses (which in pet insurance, cost us over $20,000 with thousands more in costs that weren't covered) but also encompass the emotional toll on pets, pet owners – and the veterinary team, highlighting the importance of a dedicated and supportive care approach for the well-being of affected pets throughout their lifetime.

Once your dog is diagnosed with copper storage disease, I can assure you, the unrest never ends, even after they've passed, echoing the perpetual worry and heartfelt concern for your pet's and your future pet's well-being. Copper-associated hepatopathy can be hard to diagnose, distressing to treat, but it is possible to prevent. Anything that can be done to mitigate this disease's impact is invaluable, and the potential implementation of a "controlled copper" claim on dog food labeling represents a significant step forward in this regard. Let us continue to advocate for the well-being of our companions.

Thank you for bringing attention to this significant issue. I am grateful for your efforts in raising awareness and advocating for the challenges posed by copper-associated hepatopathy in dogs. Together, we can make a difference in addressing and mitigating the impact of this condition on dogs.

Warm regards,

Soul Dog Synergy

https://souldogsynergy.com/preventing-the-pitfalls-copper-associated-hepatopathy-in-dogs/

References

Center, S. A., Richter, K. P., Twedt, D. C., Wakshlag, J. J., Watson, P. J., & Webster, C. R. L. (2021). Is it time to reconsider current guidelines for copper content in commercial dog foods? Journal of the American Veterinary Medical Association, 258(4), 357-364. Retrieved from https://doi.org/10.2460/javma.258.4.357

Copper in Dog Foods Expert Panel Final Report with Recommendations to the Pet Food Committee. Retrieved from https://www.aafco.org/wp-content/uploads/2023/01/Copper_in_Dog_Foods_Expert_Panel_Report_to_the_PFCkv2136684-2136685.pdf

Expert Panel Upholds AAFCO Guidelines for Copper Concentrations in Foods for Normal Dogs. Retrieved from https://www.aafco.org/news/expert-panel-upholds-aafco-guidelines-for-copper-concentrations-in-foods-for-normal-dogs/

Food and Drug Administration. (2021, October 4). FDA Virtual Listening Session on the Oversight of Pet Food - Center Slides for FDA SA Center Copper Canine Dog Food [PowerPoint slides]. Retrieved from https://www.regulations.gov/document/FDA-2021-N-0859-0040

Strickland, J. M., Buchweitz, J. P., Smedley, R. C., Olstad, K. J., Schultz, R. S., Oliver, N. B., & Langlois, D. K. (2018). Hepatic copper concentrations in 546 dogs (1982-2015). Journal of Veterinary Internal Medicine, 32(6), 1943-1950. https://doi.org/10.1111/jvim.15308

Response from AAFCO to JAVMA Viewpoint Article of February 15, 2021. Retrieved from https://www.aafco.org/wp-content/uploads/2023/03/Response-from-AAFCO-to-JAVMA-Viewpoint-Article-of-February-15-2021.pdf

Webster, C. R. L., Center, S. A., Cullen, J. M., Penninck, D. G., Richter, K. P., Twedt, D. C., & Watson, P. J. (2019). ACVIM consensus statement on the diagnosis and treatment of chronic hepatitis in dogs. Journal of Veterinary Internal Medicine, 33(3), 1173-1200. https://doi.org/10.1111/jvim.15467

From:

Sent: Sunday, February 25, 2024 8:00 PM

To: AAFCO

Cc:

Subject: Copper Claim Workgroup

CAUTION: This email originated from the internet.

I strongly support the Copper Claim Workgroup recommendation.

I watch animals closely, particularly dogs. I see dogs frequently eating grass. I also mow an 80-tree fruit tree orchard. When I remove mower blades to sharpen them, the dogs really enjoy licking the green/chlorophyll from the back of the blades—I turn the blades over, so the dogs do not cut their tongues. They will go back to the blades and lick, whenever I go over to the shed. I think they are satisfying a need, one that is exasperated by most dogs today being indoors most of the time and not having access to the outdoors and chlorophyll. To me, dogs not having access to chlorophyll is not in their long-term best interest. An upper limit might or might not be advisable.

I also think that the dosage of vitamin D should be increased with such a high percent of dogs indoors and not receiving vitamin D from being in the sunshine.

Thanks.

Pet’s Best Life, LLC

From:

Sent: Wednesday, February 28, 2024 2:58 PM

To: AAFCO

Subject: Copper Storage Disease

CAUTION: This email originated from the internet.

My name is

My dog Skyler who is 4 years old is suffering from CSD due to the dog food he was eating. Since he was diagnosed almost two years ago it has been a very costly ($10,000) illness to work with. I researched as much as I could and was shocked to find out how. Little regulation takes place when it comes to pet food. Skyler now has to be on a medication for the rest of his life. His life has been basically cut in half. Life expectancy for CSD is only 3-7 years. He also has to stay on a prescribed food that is very costly. I am begging you to please stop allowing so much copper in dog food. It is a terrible thing to use as a filler. As devoted pet owners we need better regulations on our pets foods. Thank you for taking the time to read this.

Sincerely

and Skyler

From:

Sent: Wednesday, February 28, 2024 4:46 PM

To: AAFCO <aafco@aafco.org>

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

Hello, My name is and I live in Massachusetts. My 7 year old yellow Labrador retriever, Rennie, was diagnosed with Copper Associated Hepatopathy in November 2022 after she had a liver biopsy. Her liver enzymes had been rising slowly over a little more than a year. We began seeing a Vet Internal medicine specialist in October 2022. We began feeding her Royal Canine prescription low copper dog food in November 2022 and began feeding her a vet board certified nutritionist homemade diet two weeks ago to try to reduce the copper even more. We fed Rennie Wellness chicken grain free puppy food for the first year, Wellness chicken adult grain free dog food for a year and then our Vet asked us not to feed a grain free diet due to dogs having heart issues eating grain free commercial dog foods. We then get her Open Farm white fish for a year and a half and Wellness chicken and rice dog food (not grain free) for two years. Rennie has had to be on a lot of medications the past 15 months and has very often not felt well because of the medication. She has chronic hepatitis and is now on Azathioprine, penecilimine, vitamin B-6, vitamin E and Denamarin. She has had to have blood work every month and now every two weeks for two months since she began the Azathioprine. She has been very negatively affected by her illness and it has affected her quality of life. We also have emotionally and financially been negatively affected. I put in something with the FDA telling them. I would like there to be limits on the amount of copper that can be put in dog foods. I would have thought there would already have been. Thank you for all you do to provide safety to consumers.

Thank you,

From:

Sent: Thursday, February 29, 2024 10:43 AM

To: AAFCO

Cc:

Subject: FW: Reminder to Submit | AAFCO Seeks Public Comments on Voluntary Copper Claim

Importance: High

CAUTION: This email originated from the internet.

Good morning,

Would it be possible to provide TCR with the URL where public comments are posted and available?

We would like to provide a link for our readers.

If comments are not yet online, would it be possible to provide us with a zip file or some type of file that would allow us to read the comments?

Thanks in advance,

From:

Sent: Wednesday, February 28, 2024 10:07 PM

To: AAFCO

Subject: Copper Storage Disease

CAUTION: This email originated from the internet.

I have a 5yro Miniature Aussie. I fed him what I thought was quality dog food. It was not until several abnormal blood tests, ultrasounds, and a liver Biopsy did I learn my baby Biscuit was being poisoned by unnatural forms of copper. We attempted to treat him last year with a drug to bind to the chelated copper that was added to his food. The drug used to try to help his liver heal did not work but instead caused him to have anorexia, depression, nausea, and he was lethargic. We were not able to continue the treatment as he wouldn't eat. That was March 2023 he is now on a copper free diet but his numbers continue to rise as his liver cannot get rid of the chelated copper that he was fed for the first 4 years of his life. It is a shame that that was added to dog food when it was not needed. As a dog owner I thought that if I spent more money on high quality food my dogs would have a good quality life. My dog now continues to take an antidepressant every day and a stimulant to help him eat just his regular copper free food. He has not been the same and it is my hope that he will be able to live his life in a relatively comfortable and pain free state. However, he may not live the full life that he would have lived had he not been exposed to chelated copper in his dog food. Please consider this as I am one of many dog parents that have experienced this situation and the diminished quality and longevity of their dog's life.

From:

Sent: Wednesday, February 28, 2024 6:34 PM

To: AAFCO

Subject: Copper Content

CAUTION: This email originated from the internet.

To Whom It May Concern,

I am writing to you as it relates to the minimum required amount of copper in dog foods, and the egregious amounts that are used in many commercial foods. Quite simply, copper is killing dogs at an expedited rate, and it is abhorrent that this is allowed to continue as a means of maximizing profits by including unhealthy additions to food. Dogs are humans best friends, and you have absolutely no soul, empathy, or humanity if you allow this to continue - the sufferings of loving dog owners, dog owners who are good, honest, and caring people, is yours to own.

Respectfully,

From:

Sent: Wednesday, February 28, 2024 4:53 PM

To: AAFCO

Cc:

Subject: Copper claim workgroup comment

CAUTION: This email originated from the internet.

As someone who had a 3 year old English Cocker Spaniel die within a month of diagnosis of end stage liver disease & copper levels 3 out of 5, I request you max out the amount of copper and type of copper in dog food.

The daily recommended amount of copper required by a dog is 7mg/kg of food served. Purina Pro Plan sensitive skin and stomach salmon and rice has 15mg. The copper is also chelated copper which is not good for dogs.

I have NEVER lost a dog in my life aged 3.

I think you also need to make pet food manufacturers state on their packaging the type and amount of the minerals but specifically copper.

I now only feed my other dogs home made food because I don't trust the pet food industry anymore.

regards

From:

Sent: Thursday, February 29, 2024 11:42 AM

To: AAFCO

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

I appreciate the opportunity to comment on these proposed regulations. My comments are based on my expertise, experience, and insights of over 34 years in the petfood industry and formal animal nutrition training.

After review of data provided, I do not support creation of AAFCO creating a 'low copper claim' as proposed for dog foods.

My objections are as follows:

A) The upper limit of the controlled copper claim of no more than 15 mg/kg DM (3.75 mg copper/1000 kcal of metabolizable energy) is arbitrary. The use of an upper limit implies that copper values above 15 mg/kg DM may be detrimental to dogs, however there is insufficient data to support this assertion for setting this value as an upper limit.

B) Consumer confusion could result from a misunderstanding of the meaning of the upper copper limit of the claim. Dogs with known copper storage conditions require dietary copper intakes lower than this proposed maximum but dog owners may think a food with this low copper claim is indicated for their dog's copper storage condition based on the claim. Further, dog owners may select a product with this low copper claim but their dog may have an undiagnosed liver condition, be unaware that their dog has genes that predispose their dog to copper storage disease, or have other health conditions where a copper intake lower than this maximum is indicated. This proposed controlled copper claim, opens dog food makers using this claim, to individual and class action lawsuits and litigation. In a scenario where a dog owner confused abut the claims, purchases a food with this claim, and their dog has an adverse health event linked to copper intake potentially have grounds for legal action. These legal actions may also incorporate AAFCO members or member state regulatory officials because a decision to define a controlled copper claim with maximum value was approved by the AAFCO organization or committee.

C) Dog food makers can already use a 'controlled copper claim' on their products and determine a minimum and maximum label guarantee. The dog food maker has the burden to determine what levels of minimum and maximum copper are appropriate for their dog food product's intended use and therefore accept risks of using such a claim and risks of misinterpretation and consumer confusion. There is no value for AAFCO to arbitrarily define a maximum copper level under the guise of protecting pet health when the working committee has made public that there is a lack of data supporting an upper limit for the health of dogs. The proposed action by AAFCO is very different than what FEDIAF did in setting a maximum copper level based on environmental concerns and FEDIAF has been clear the maximum is not linked to pet health. As mentioned, establishing an arbitrary maximum copper under the guise of protecting dog health opens AAFCO up to lawsuits from petfood makers alleging unfair regulation and oversight focused on certain types of dog foods or certain brands that have higher copper levels than proposed maximum and favoring other brands and types of dog foods with lower copper levels.

My recommendation is: 1) AAFCO should not adopt the 'low copper claim' as proposed, and 2) AAFCO must continue to monitor this topic, and if additional, high-quality scientific data becomes available, then AAFCO should revisit this topic.

Sincerely,

From:

Sent: Thursday, February 29, 2024 12:01 PM

To: AAFCO ; AAFCO PFC

Subject: Controlled Copper Model Regulation

CAUTION: This email originated from the internet.

Dear AAFCO,

As a state animal food regulator and , I support the proposed Regulation PF10. Descriptive Terms… (d) Copper Terms, and the standardization of “Controlled Copper”.

The Copper Workgroup developed model regulation that standardizes what controlled copper in dog food means. As stated by members of the workgroup, “This standard provides a level playing field for the industry, it frees the regulatory officials from extensive review and questioning of the manufacturer for what is meant by the claim.”

Marketing claims are most useful when the claim is standardized and establishes supportive evidence with labeling guarantees. Defining the use of the descriptive term, “controlled copper”, with requirements to be nutritionally adequate for one or more life stages, contain an established maximum for copper when using this claim, and to bear in the guaranteed analysis a guarantee for the maximum amount of copper in the dog food is fully appropriate.

Let’s not rely on a state-by-state approach to interpreting low copper claims on dog food. The pet food industry is seeking uniformity with product labeling. AAFCO promotes uniformity and a level playing field.

Thank you,

PA Department of Agriculture

From: AAFCO PFC

Sent: Thursday, February 29, 2024 4:39 PM

To:

Subject: RE: Copper Claim Workgroup Comment

Hi and ,

Next week , and and I will meet to discuss the comments received. We do plan to post all comments received and will know next week what that will look like.

Regards,

From: r

Sent: Thursday, February 29, 2024 1:36 PM

To: AAFCO PFC;

Subject: FW: Copper Claim Workgroup Comment

PFC – are you posting these somewhere?

From:

Sent: Thursday, February 29, 2024 1:36 PM

To: AAFCO <aafco@aafco.org>

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

Dear ,

Please find two documents attached for posting to the copper library of resources within the AAFCO pet food committee folder.

Thank you.

February 29, 2024

AAFCO

Copper Claim Workgroup

RE: AAFCO Seeks Public Comments on Voluntary Copper Claim

On behalf of the American Veterinary Medical Association (AVMA) and our more than 105,000 member veterinarians we thank you for the opportunity to provide comments on the proposed voluntary “Controlled Copper” Claim. The AVMA supports the efforts of the AAFCO to guide state, federal and international feed regulators with respect to label standards, while supporting the health and safety of animals and people.

The AVMA does not support allowing manufacturers of an over-the-counter dog food product to attach a “Controlled Copper” label claim, because the AVMA believes decisions to feed a reduced-copper (or other food component-adjusted diet) should be made in consultation with their veterinarian. We are concerned that it will not be possible to provide adequate label instructions on 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 (minimum) and toxicosis (maximum) 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.

We are not aware of studies demonstrating the proposed limit for the “Controlled Copper” claim of a maximum of no more than 15 mg copper/kg DM and no more than 3.75 mg copper/1000 kcal of metabolizable energy prevent copper accumulation in dogs with a propensity for copper storage disease. Such a claim may mislead both owners of dogs with a propensity for copper storage disease, as well as owners of healthy dogs, that there is a prevention benefit to feeding such a diet when one may not exist for their dog.

In closing, we support the AAFCO in its efforts to assure consumers that labels on pet food products are truthful and not misleading, and we thank the AAFCO for the opportunity to provide comments regarding the proposed voluntary “Controlled Copper” claim. For questions regarding the AVMA’s comments, please contact

Sincerely,

AAFCO Members, Pet Food Committee and other stakeholders,

Pet food makers working through the Pet Food Institute (PFI) have been engaged in the discussion of copper levels in dog food prior to the formation of AAFCO's copper expert panel. These discussions have focused consistently on nutritional science and the welfare of dogs.

Industry engagement, the JAVMA opinion article, the formation of an expert panel, the additional AAFCO copper working group and the FDA public meeting have brought a renewed level of attention to the issue of Copper Associated Hepatopathy (CAH). This engagement and awareness demonstrates continuous improvement, which we believe was the intent of the authors of the JAVMA opinion piece.

Products made by PFI members provide sole source nutrition to an overwhelming majority of the dogs living in U.S. households. As the industry that designs and creates these products, we believe that supporting a controlled copper claim is the wrong direction at this time due to the strong potential of harm to dogs and the misconceptions that consumers will draw from this claim.

More scientific research on this topic is needed and regulators, both AAFCO and the FDA, need to work with the veterinary community to take a regulatory approach under their own control rather than abdicating the responsibility to consumers and industry. AAFCO's first action was to form an expert panel to examine the potential of a problem. This was a sound approach. That panel determined that not enough science currently exists to make changes to the nutrient profiles and any change would be arbitrary. AAFCO and the Pet Food Committee need to listen to that recommendation and focus on a scientific solution instead of an easy regulatory stopgap.

We include a number of points and resources below – please note that most of our comments mirror those of the expert panel.

Could a controlled copper regulation do more harm than good?

- Contrary to the statement in the working group conclusion, this claim does not support animal health, but in fact could do the opposite.

- PFI counts numerous board-certified nutritionists and veterinarians among its members. There is a consensus opinion among them that if this well-intentioned regulation gets ahead of science, it could be potentially harmful to pets.

- Sufficient research data is not available that the proposed controlled copper claim will protect health; any protective benefit is merely a hypothesis.

- No study has demonstrated that feeding high levels of copper to dogs leads to copper associated liver disease in dogs without known genetic mutations and/or concurrent hepatic illness.

- The working group was in full agreement that the draft claim guidance utilizes an arbitrary maximum. This action conveys to researchers, veterinarians, and pet parents that purchasing this product will prevent disease and will ultimately stall the pursuit of needed scientific evidence to identify the true causes and factors that result in CAH.

- AAFCO is a science-based organization that claims to help keep food safe for pets and provides protection to consumers; will approval of this regulation, against the recommendations of the Expert Panel lead to additional regulations on other nutrients because of anecdotal evidence or consumer questions?

- As the proposed regulation PF10 (d)(1) is currently worded, "A claim of "low copper", "low in copper", or words of similar designation is not allowed." This would stop the sale of therapeutic foods, defined as "Veterinary Diets" that are intended to be used under veterinary guidance. Therapeutic foods are specially formulated for the nutritional management of pets with specific conditions including those that require LOW copper. Stopping the sale of therapeutic diets would undoubtedly be harmful to those animals that truly need a veterinarian directed low copper diet.

- CAH is a disease with an unknown true incidence and a genetic involvement that is not fully elucidated. This claim is clearly intended as an implied drug claim with the acknowledgement from those involved that the purpose of the regulation is to address a presumed health benefit without the science to support the regulation. The intent for the claim is to prevent a perceived disease condition.

- There will be pet parents with animals at risk for CAH that will purchase this product and not seek veterinary care/oversight when it is most needed. These claims will lead pet owners to self- diagnose and self-treat their pets. Science-based regulations are established to ensure pet health. Setting regulations instead to appease pet owners regarding nutrient levels negates the knowledge and expertise of the NRC and the AAFCO expert nutrition subcommittee in making decisions in dietary copper recommended allowances.

- Self-diagnosis and self-treatment of sick pets will result in animal distress as has been documented in other veterinary diet experiences. Considering the establishment of a controlled nutrient claim, a recent survey documented that consumer perception believes it imparts a health need or benefit as demonstrated in Admundson et.al., 2024. Additionally, one organization has shown examples where a diet specifically formulated with below-AAFCO- minimum nutrient levels intended to support health in a specific disease was perceived incorrectly by pet owners who then fed a retail diet marketed with similar 'controlled' nutrient claims. Many pet owners by-passed their veterinarians and stopped feeding the veterinary diet as well as needed medications.

- Focusing on a single essential nutrient paves the path for imbalances among nutrient ratios that may have serious consequences for animal health.

- Would support for a controlled level claim negate how all other controlled claims are defined? We must be cautious in setting an unintended precedent. Regulators should consider the rigors in establishing nutrient tolerances when deciding to approve a claim conveying a nutrient limit.

- It is dangerous to put regulations forward that imply prevention of a disease (especially one with a known genetic component). If pets then develop copper storage disease while on a 'controlled copper diet' would this create liability for the pet food company and regulators that created the perception these are therapeutic and preventive?

It was a unanimous consensus of both the Expert Panel and the Working Group that more research is needed.

- The true prevalence of copper associated liver disease has not been determined, so the argument that there is an increased incidence should not be based subjectively on anecdotal experience.

- More data is necessary to determine if copper accumulation in the canine liver is problematic. A lot has changed in caring for dogs, feeding habits, and diagnostics regarding liver disease. This is leading to increased focus but not definitive answers.

- Inbreeding and genetic drivers may be a part of the explanation. The mutations in genes that are involved in copper excretion are just now being discovered. A genetic predisposition, hepatitis, and/or cholestasis, causing defects in handling copper excretion, makes dogs intolerant for high dietary levels of copper, and those dogs may benefit from copper-restricted diets.

- No reliable data to support the need for an arbitrary controlled copper level, which is inherently a drug claim, has been provided. Studies on copper content of liver biopsies referenced in the 2021 JAVMA viewpoint article and the Feb 8, 2024, FDA webinar have several limitations, including the lack of a healthy control group. The control group in one study was a group of patients that underwent liver biopsies, from which no necro-inflammatory lesions were found. Reasons for taking the biopsies were not mentioned nor was a dietary history available. The reasons for the 2 "eras" (1982-1988 and 2009-2015) are not well defined. In the Strickland et al 2018 article (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10787350/#CIT0029) cited as evidence of increasing copper levels, the authors point out that clinical relevance of the observed increases in hepatic copper concentrations remains elusive. Dietary histories of the study dogs were not available.

- An analysis of 16 years of hepatic data in dogs fed a wide range of commercial diets showed that liver copper concentrations decreased from 2006 through 2011, increased in 2012, decreased in 2013 and peaked in 2016 and have been decreasing ever since.

- Genetic informed breeding programs have effectively reduced the incidence of disease in the Bedlington Terrier. Is there a known non-genetic, diet associated liver disease co-hort? More research is needed to answer this.

It is inevitable that this claim will create consumer confusion.

- Rather than creating clarity for consumers, this claim will create confusion. Consumer data shows that pet parents will follow a claim even without understanding its impact to animal health and that this statement would be interpreted as an implied drug claim by a significant share of consumers.

- A consumer survey on this claim showed that a significant number of consumers will perceive less copper as better, regardless of the state of their pet. Responses showed that after hearing about a controlled copper diet some level of consumers wanted a dog food with zero copper. This was demonstrated on the FDA Grand Rounds- Copper in Dog Food: A Case Study in Reconciling Nutritional & Regulatory Science webinar when this exact question was asked in the chat.

- By AAFCO supporting this claim, it will create a market situation where some companies may be pressured into supplying these products in order to have a complete portfolio and meet consumer demand, yet these products are confusing to consumers and potentially harmful to pets.

- Both AAFCO and the FDA were uncomfortable changing the nutrient profiles, this is not a solution to the problem.

Proposed Interim Solution

Given the high degree of controversy about the request, and the consensus that more research is needed, PFI members request a moratorium while supporting efforts to pursue collaborative research to produce data to study the incidence of disease and what controlled limits support normal hepatic copper in healthy dogs.

There have been several articles published since this discussion began, a few are listed here and should be reviewed by members of the Pet Food Committee.

AAFCO reaffirms guidelines on copper levels in dog food.

Scott Nolan, AVMA News, April 17, 2023

https://www.avma.org/news/aafco-reaffirms-guideline-copper-levels-dog-food

The Association of American Feed Control Officials (AAFCO) reaffirmed its guidelines for copper concentration in commercial dog foods after an expert panel concluded there is currently a lack of definitive evidence linking copper-associated hepatitis in dogs and the copper content in dog foods. “At this time AAFCO does not see the need to restrict the use of other sources of (copper) in dog foods beyond any restrictions already imposed in their definitions or approvals,” AAFCO CEO Austin

Therrell wrote in March. “Until such time as science definitively shows additional controls or restrictions are needed, AAFCO feels that recommendations for (copper) concentration in foods for normal dogs are appropriately and sufficiently regulated at present.”

“Arbitrarily setting some value as a maximum for copper implies that diets containing less than, or equal to, the maximum are safe for dogs and that diets containing more than the maximum amount are unsafe, with neither condition having been demonstrated to be true,” the panel wrote.”

The art of establishing mineral tolerances of dogs

Abstract of article submitted to JAS

George C. Fahey, Jr., Marcie Campion, George Collings, Renan Donadelli, Leah Lambrakis, Matthew Panasevich, J. C. Peters, James Templeman, Leslie Hancock.

Dogs and cats are living longer and healthier lives through the scientific development of nutritional information. This information has allowed the building of many new types of foods, treats and supplements that promote life, health, and enjoyment by your pet. There are several organizations that have provided helpful reviews of nutritional data through scientific councils that help build safe and healthy criteria for all food products. These are available for those who want to know more about pet nutrition.

For many nutrients, there is a large database of information to help build products. Nutrients that are called macro or micro minerals (e.g., sodium, potassium, zinc, copper, etc.) often have more limited information.

More recently strong opinions about pet health have been shared and robustly communicated without adequate scientific research to support the hypotheses. This has led to misinformation, many concerns and fear.

To safeguard the health of companion animals and provide assistance to the regulatory framework regarding nutritional welfare of dogs and cats, scientific panels have come together frequently from industry, government, and academia to review, approve, and challenge nutritional guidelines. This overview provides the reader context into the rigor needed to establish safe mineral tolerances for dogs.

16 years of canine hepatic copper concentrations within normal reference ranges in dogs fed a broad range of commercial diets

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10787350/pdf/txad147.pdf

An in press JAVMA abstract: We are alerting the JAVMA editor that we are sharing this excerpt from the abstract.

Amundson et al have a study publication in final prepublication (JAVMA), that examined the effects of age, sex, breed, liver histopathology, and year of death/sample collection on liver copper concentrations in dogs fed various commercial dog foods throughout their lives. Analysis of year of death showed that liver copper concentrations decreased from 2006 through 2011, increased in 2012, decreased in 2013 and peaked in 2016, decreasing thereafter. Mean copper concentration of abnormal liver histopathology samples was lower than mean copper concentrations of normal liver histopathology samples. Age (12.95 ± 2.67) and sex had no effect on liver copper concentrations. Liver copper concentrations varied significantly with breed and year of death; however, average liver copper concentrations of each year are within normal reference ranges. This was a retrospective study of dogs fed a wide variety of commercial foods and serves as a controlled baseline of hepatic copper levels.

Prospective and controlled studies are needed to further understand what factors influence canine hepatic copper concentrations.

Dog and cat owners have minimal awareness of copper's function in pet food and certain claims create negative bias

Madison D. Amundson, BS; Laura A. Motsinger, PhD; Leslie Hancock, DVM

An in press JAVMA articleThe Association of American Feed Control Officials (AAFCO) recommends a copper minimum, but not a maximum concentration in pet foods which, in turn, has raised concerns about the potential for copper toxicity in dogs and cats. AAFCO convened a panel of nutrition experts who were investigating the matter and found insufficient evidence to suggest a maximum. However, an option was proposed to consider establishing a standard for low or controlled copper diets. This survey investigated pet owner awareness of dietary copper in pet food. A blinded panel invited 2877 pet owners to participate in the survey and was completed by 252 dog and cat owners. Results reported 78% having very little (n=47) or no (n=149) knowledge about the role of dietary copper in pet food and, about half of respondents reported being "uncertain" about a "low, moderate, or controlled copper" statement. Consequently, 19% of owners claimed that their purchasing decisions would be strongly influenced by a similar statement, but 47% said they may be impacted; totaling 66% seeding a negative bias. Of all participants, 56 owners reported that they would buy a controlled copper food for various reasons including, but not limited to, safety and health purposes, quality concerns, nutritional awareness, and general beliefs. Conversely, 34 owners reported that they would not buy a controlled copper food due to unfamiliarity and desire for more knowledge around the role of dietary copper.

Overall, 28% of owners feel there are benefits to a controlled copper food, while 57% are unsure if there is an advantage or disadvantage but would consider it. These insights suggest that certain claims prompt dog and cat owners to desire additional education around the role of dietary copper, and potentially other nutrients, in pet food and raise concerns with the role of claims and negative nutrition bias.

Copper metabolism and its implications for canine nutrition

Laura A Amundson, Brent N Kirn, Erik J Swensson, Allison A Millican, George C Fahey Transl Anim Sci, . 2024 Jan 3:8:txad147. doi: 10.1093/tas/txad147. eCollection 2024. https://pubmed.ncbi.nlm.nih.gov/38221962/n

Canine copper nutrition has received increased attention due to recent reports of apparent copper- associated hepatitis in the USA and European Union. In order to properly address the need to modify the U.S. National Research Council and Association of American Feed Control Officials canine copper recommendations that will have implications for all dogs, it is important to understand the complexities of copper metabolism, confounding variables affecting copper status, and the available research on this topic in dogs. Recent trends in consumer preference for dog diets, supplements, and functional treats introduce another layer of complexity, as most ingredients used in these formulations provide vastly different proportions of essential nutrients, thus resulting in great variation in nutrient profiles available to the animal. Given its vital role in many physiological processes, it is important that both nutritional deficiencies and toxicities be avoided. There are important nutrient interactions that need to be accounted for. Zinc, iron, molybdate, and sulfur are all known to antagonize the amount of bioavailable copper. Zinc is a potent inducer of MT production that will preferentially bind and sequester Cu+ and, thus, increase the risk of a zinc-induced copper deficiency, regardless of dietary copper concentration. High dietary iron can cause copper-deficient anemia via disturbances in copper utilization after it has been absorbed (Ha et al., 2017 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10787350/#CIT0015). Concomitant

increase in iron and copper concentrations was observed and compared among dogs with varying degrees of liver lesions (Schultheiss et al., 2002 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10787350/#CIT0027) and underlines the possibility of other mineral contributions to hepatic pathologies. Although there are few data about the interaction of copper and lead, Gori et al. (2021 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10787350/#CIT0013) observed increased liver lead concentrations in dogs with liver copper concentrations above 400 ppm (dry weight basis). Similar to the iron and copper relationship mentioned earlier, there is not sufficient evidence to determine causation versus correlation, but these results emphasize the need for further investigation of the overall nutrient status of dogs suffering from CAH. Therefore, it is imperative that veterinarians, nutritionists, and pet food manufacturers collaborate with the shared goal of providing dog food options that supply the essential nutrients at adequate concentrations to support an active and healthy life.

Is copper-associated hepatopathy the new DCM?

Stephanie Clark, S. McCauley and B Quest. Pet Food Processing, January 2024

https://www.petfoodprocessing.net/articles/17850-is-copper-associated-hepatopathy-the-new-dcm

Authors are all board certified nutritionists.

The push to scrutinize copper mirrors the methodology that sparked the controversy around DCM, namely a reliance on anecdotal observations and retrospective case studies with significant limitations that should not be used to draw sweeping conclusions. Regardless of comments from the opinion article in JAVMA, the actual incidence rate of copper-associated hepatopathy is still unknown. When pet owners are faced with situations where the science is unclear but scary headlines are abundant, they don't know who to trust and don't have enough information to make an informed decision. In 2016 there were concerns in the veterinary community that copper was insufficient in pet foods. There needs to be sound scientific research with control groups and sufficient animals.

COMMD1 Exemplifies the Power of Inbred Dogs to Dissect Genetic Causes of Rare Copper-Related Disorders

Ronald Jan Corbee and Louis C. Penning

Animals **2021**, 11(3), 601; https://doi.org/10.3390/ani11030601

Copper storage disorders are considered rare diseases. Although the European Union (EU) and the United States have different definitions of rare diseases (EU, not more than 50 per 100,000; US less than 200,000 patients in the US, recalculated as around 86 per 100,000), it is clear that for each individual rare disease, no large patient cohort exists.

Sincerely,

Pet Food Institute

From: Dave Dzanis

Sent: Thursday, February 29, 2024 6:28 PM

To: AAFCO

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

Dear Pet Food Committee Members:

The opportunity for me to personally comment on this topic is greatly appreciated. In that vein, I respectfully ask the Committee Members to consider my thoughts in this matter as published in the January 2024 issue of Petfood Industry magazine. A digital version of the article may be found at the link below. Importantly, please note that the entitled "*How can AAFCO help address emerging pet food health issues surrounding copper?*" reflects my personal views only and should not be construed to be the official position of any organization nor to be an opinion necessarily shared by any other groups or individuals.

https://www.petfoodindustry-digital.com/petfoodindustry/library/item/january_2024/4164115/?oly_enc_id=5801D8468478C9Y

I would also strongly recommend that Committee Members read and consider the position statement by of Kentucky as included in the Copper Claim Working Group's final report. She makes a very well thought out and convincing argument for acceptance of the proposed amendments as seen from the regulator's perspective.

Thank you for your time and consideration in this matter,

From:

Sent: Thursday, February 29, 2024 6:40 PM

To: AAFCO

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

Hello AAFCO:

We respectfully are submitting comments about the proposed controlled copper claim.

Position of the Academy of Veterinary Nutrition Technicians

Academy of Veterinary Nutrition Technicians (AVNT) does not support regulatory action to allow an over-the-counter dog food product to have a label claim pertaining to copper, because the AVNT 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.

About the Academy of Veterinary Nutrition Technicians (AVNT)

The mission of the Academy of Veterinary Nutrition Technicians (AVNT) is to advance the area of and promote excellence in the discipline of veterinary nutrition. The AVNT provides a process by which veterinary technicians may become certified as a Veterinary Technician Specialist (VTS) in the field of nutrition thereby increasing the competence of those practicing in the field of veterinary nutrition. The AVNT mission is to enhance the skills and knowledge of veterinary nutrition technicians and promote technicians as integral members of the veterinary nutrition team.

--

Best regards,

From:

Sent: Friday, March 1, 2024 11:06 AM

To: AAFCO

Subject: Copper Storage Disease and AAFCO standard for copper

CAUTION: This email originated from the internet.

Your website would not sent this message, so I am sending it to you by email.

I have now spent thousands and thousands of dollars on my Labrador Retriever because of copper storage disease. He is 10, and not expected to live to 11. The rise in ALT was caught early. His biopsy was done ear-

ly. He went on the one dog food out there for CSD, The Scoop, now Voyager. No improvement. He has been on all the meds. Now I cook for him because dog food has become so unreliable, and what there is, didn't help. Canine nutritionists are also unreliable, since the kinds of studies both the industry and nutritionists rely on are so flawed. Who feeds their children one meal, formulated for $200, after a consultation for $500, 2 or 3 times a day, because some nutritional experts claim it is "complete and balanced"? A second meal plan costs another $200. This defies common sense. The industry has gone mad. For a while, grain-free was the thing, then there was a rise in DCM; or super-high protein; or raw. I blame AAFCO. The added vitamins and minerals added to insure a minimum amount in AAFCO-compliant dog foods don't even take into account those naturally present in the ingredients--the actual "food" in the dog food. Since you don't know what the maximum allowable copper should be, why do you allow a minimum copper amount to be calculated based on formulations of copper that radically increase its absorption, sending the amount of copper metabolized by the dogs from the food as well as the supplements up to a level that causes liver disease? Personally I will never again pay any attention to AAFCO standards since so much is based on what you do not know rather than what you can show by solid studies, which apparently means you can set standards based on guesswork, or on small, distinguishable observation studies--extrapolating to senior males from growing puppies and lactating females. And believe me, I've read all I can find. A 10 year old lab does not need the copper a lactating female needs, and may have been storing excess copper for most of his adult life. Even for a lactating female, how much chelated copper does she need? Do you actually know? I'm mad and I'm done.

From:

Sent: Friday, March 1, 2024 9:44 AM

To: AAFCO

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

Dear AAFCO Copper Working Group,

AAFCO should not be creating a 'low' or 'controlled' copper claim.

First, there is no evidence within the scientific literature to support this claim in pets (dogs or cats). This has long been a requirement for a first step in changing rules and/or regulations. Peer-reviewed data should be generated to establish causality, versus a possible correlation, between types of copper used in canine diets and potential for copper hepatopathy. An opinion article written by veterinarians at a veterinary school—who typically see a subset of specialized cases—does not establish causality, it identifies a small number of dogs who may have other factors causing copper imbalances.

Second, because this isn't based in a clear scientific basis, this request calls into question whether a 'low' or 'controlled' copper claim is necessary to advance the health and best interest of dogs. As with all concerns for nutrition, the best interest and health of ALL dogs is what we must be concerned with when making changes to an AAFCO minimum or maximum. When the nutritional needs of a few are being considered over the needs of the many, we are doing the species as a whole a disservice—particularly when the entire micronutrient balance is not being considered. Specialized care for the few would be the correct answer, in this case, and is available through prescription diets provided under the guidance of a veterinarian.

Third, by allowing industry as a whole to make a 'low' or 'controlled' copper claim as it is currently proposed, we are removing necessary veterinary advice from pet health situations. Allowing a 'low' or 'controlled' copper claim removes a tool from a veterinarian's hands when a dog truly needs a low copper food. This becomes a drug claim, one which directly impacts pet health by means of food outside of a structure/function claim, and can be taken out of context by pet owners. Veterinary or prescription diets for dogs with copper processing disorders typically fall within the range that AAFCO's working group has suggested (15 ppm copper). Allowing companies without FDA review for drug claims to make this claim removes the veterinary oversight necessary to maintain health, and can cause an imbalance in other micronutrients that are impacted by copper's use within the body.

Fourth, the handling of this issue has been poorly managed all around. AAFCO has set up at least three different panels for the review of this topic, which seems to the casual observer as though AAFCO is fishing for an answer. When the first two expert panels did not return the answer that was desired—with sound, scientific cause, a new panel was convened after a misconstrued statement was brought forward (the need for a low

copper claim was to be explored, there was no need established to make a claim). This type of behavior leads to distrust in the AAFCO system, and can lead to recognized experts declining to participate in further discussions when their knowledge is truly needed for future issues.

The average consumer does not understand the role copper plays in their dog's health, as evidenced by the Next Generation Pet Food Manufacturers Association data; the average consumer would choose a diet without copper. As with human nutrition, we have failed to educate our consumers—they do not understand the role of different nutrients in helping their pets live longer, healthier lives. Instead of providing nutrition education and advocating for veterinary consultation when needed for specialized nutritional needs, AAFCO will be furthering this error by allowing a controlled copper claim.

Best regards,

From:

Sent: Friday, March 1, 2024 3:12 PM

To: AAFCO

Cc:

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

Dear Pet Food Committee – Copper Claim Workgroup,

I hope this email finds you well. On behalf of BSM Partners', please find attached our comments regarding the proposed controlled copper claim. If you have any questions or require further information, please do not hesitate to reach out.

Thank you for your time.

--

March 1, 2024

Subject: Concerns Regarding the Approval of Controlled Copper Claim for Pet Food

Dear Pet Food Committee – Copper Claim Workgroup:

We believe that copper requirements and claims should be based on sufficiently powered, prospective research; therefore, we are writing to express our concerns against approving the use of a controlled copper claim specifically designated for use in pet food production. Our concerns are primarily two-fold. Firstly, we believe that the controlled copper language will lead to meaningful amounts of consumer-level confusion and perhaps unnecessary fear as even experts are divided over the appropriate levels of copper. Second, and most importantly, there is a clear lack of scientific consensus regarding necessary levels of copper supplementation and the likelihood is that if this regulation moves forward, copper supplementation will decline and this could, in turn, cause more harm to dogs that may have needs above the currently recommended thresholds. Third, there are already provisions in the model regulations that give guidance for a nutrient claim. In sum, we are strongly against this proposed recommendation until appropriate prospective research on copper needs can be conducted, assessed, and incorporated into updated nutritional guidance.

We recognize the confusion and concern among pet owners regarding the nutritional adequacy and safety of commercial pet food products. The lack of clear guidelines and conflicting information on copper supplementation only adds to this uncertainty. As advocates for both pets and their owners, we are committed to addressing these concerns through transparent communication, education, and advocacy for evidence-based nutritional standards.

In addition to our ongoing literature review, we intend to conduct an incidence study of copper storage disease in companion animals. This study aims to assess the prevalence and severity of copper-related health issues in pets, providing valuable insights into the incidence of copper-related diseases that have claimed to be on the rise. We will also be conducting a consumer insight survey to assess if pet owners are concerned about copper. Based on the Copper Claim Workgroup: Final Report to the Pet Food Committee's Appendix E, a consumer insight study with pet owners, veterinarians, and nutritionists, questions regarding more regulation and less around copper. By examining real-world data and case studies, we hope to better understand the impact of varying copper levels on animal health and well-being.

The proposed "Controlled Copper" claim is unnecessary to be defined and codified under PF10 as the workgroup itself references PF7(a)(2) as the underlying methodology for substantiating claims of nutritional adequacy, which is currently enacted, and already requires substantiation of the claim through approved protocols.

Moreover, as the Association of American Feed Control Officials (AAFCO) states, "If there is not a maximum on a nutrient it does not mean that nutrient is safe at any concentration. Instead, it reflects that there is a lack of information in dogs and cats on toxic concentrations of those nutrients…By setting an arbitrary maximum it may prove worse than having no maximum at all." (pages 162-163, AAFCO, 2024). Currently, there are no evidence-based data to suggest that the minimum total dietary copper recommendations provided by the National Research

Council (NRC) and AAFCO are insufficient to meet basic physiological needs, let alone a maximum of copper. To add to the confusion and dangers of setting arbitrary minimums, controls, and maximums without data has been seen in the past. It has already been demonstrated that pet parents react quickly causing disruption and volatility in the pet food supply chain when changes occur without proper scientific substantiation. Furthermore, we wish to draw attention to the changes in copper guidelines outlined by the AAFCO in their previous publications.

In 1991, AAFCO established the first dog food nutrient profiles based on the 1974 NRC requirements (Council, 1974). Copper content was established at a minimum of 7.3 mg/kg dry matter basis, or 2.1 mg/1,000 kcals, and a maximum was based on swine data at 250 mg/kg dry matter basis (Council, 1980). In 1997, AAFCO recommended that copper supplementation should be limited to copper sulfates or chelates, which have a higher bioavailability than oxides, despite no evidence suggesting copper deficiencies. In 2007, the AAFCO increased the minimum copper requirement for growth and reproduction from 7.3 mg/kg DM (2.1 mg/1,000 kcals) to 12.4 mg/kg DM (3.1 mg/1,000 kcals). Additionally, the copper maximum was removed from the previous 250 mg/kg DM basis to having no maximum due to insufficient data in dogs (AAFCO, 2007). This was increased based on multiple studies conducted in puppies and during gestation and lactation that are referenced in the National Research Council's 2007 *Nutrient Requirements of Dogs and Cats* (Council, 2007).

A recent study (Center et al., 2021) raises speculation that the potential increase in copper-associated hepatopathy could coincide with AAFCO's recommendation to stop the usage of copper oxide due to its low bioavailability (Amundson et al., 2024). Copper sufficiency cannot be evaluated based on copper concentration alone, but one must consider other nutrients such as zinc and iron that can directly affect copper's bioavailability (Amundson et al., 2024). These changes highlight the ongoing discussions and uncertainties surrounding copper requirements in pet food formulations. While AAFCO serves as a critical regulatory body in setting standards for pet food ingredients, the evolving nature of nutritional science underscores the need for continued research and scrutiny in this area.

There is speculation that copper levels are increasing in dog food over time; however, based on this summary (Table 1) of peer-reviewed articles that have evaluated copper content in dry dog food.

Table 1: Means and range (mg/kg DM) of past studies assessing copper in dry dog food.

	Dry Dog Foods		
Reference	n	Mean (mg/kg DM)	Range (mg/kg DM)
Fieten et al., 2012	32	17.8	7.6 - 23.6
Kelly et al., 2013	18	12.0	7.7 - 18.0
Gagne et al., 2013[1]	45	17.6	9.2 - 36.0
Mielczarek & Szydlowski, 2017[2]	12	32.9	14.5 - 51.8
Paulelli et al., 2018	62	15.8	14.7 - 17.0

Pereira et al., 2018	20	22.8	11.0 - 47.0
Kepinska-Pacelik et al., 2023	41	17.3	8.8 - 29.3
Overall	230	19.5	7.6 - 51.8

[1]Levels were calculated based on copper averages in milk (0.34 mg/100g) (Kienzle, 1988; Anderson et al., 1991).

[2]This study stated that 6 puppy/growth formulated diets and 6 adult maintenances were selected.

Given the complexity and significance of these issues, we believe that further research and collaboration are essential to inform evidence-based decision-making regarding the approval of controlled copper claims for pet food production. By conducting comprehensive, controlled, and prospective studies and engaging with stakeholders and other institutions. BSM Partners will work collaboratively with other institutions to work towards establishing clear guidelines that prioritize animal health, consumer safety, and responsible pet nutrition through sufficiently powered, prospective research. Considering these concerns and our commitment to further research, we urge the regulatory body to reconsider the approval of the controlled copper claim for pet food production until sufficient research has been established.

Thank you for considering our perspective on this important issue. We look forward to collaborating with you and other stakeholders to address these concerns and ensure the safety and quality of pet food products.

Sincerely, BSM Partners

References

AAFCO. 2007. *Official Publication*: Association of American Feed Control Officials Inc.

AAFCO. 2024. *Official Publication*: Association of American Feed Control Officials Inc. Pages 162-163.

Amundson LA, Kirn BN, Swensson EJ, Millican AA, Fahey GC. 2024. Copper metabolism and its implications for canine nutrition. *Transl. Anim. Sci.* 3;8:txad147. doi: 10.1093/tas/txad147.

Anderson, RS, Carlos, GM, Robinson, IP, Booles, D, Burger, IH, Whyte, AL. 1991. Zinc, copper, iron and calcium concentrations in bitch milk. *J. Nutr.* 121(11 Suppl):S81-2. doi:10.1093/jn/121.suppl_11.S81.

Center, SA, Richter KP, Twedt DC, Wakshlag JJ, Watson PJ, Webster CRL. 2021.Is it time to reconsider current guidelines for copper content in commercial dog foods? *J. Am. Vet. Med. Assoc.* 258:357–364. doi:10.2460/javma.258.4.357

Dirksen, K, & Fieten H. 2017. Canine copper-associated hepatitis. *Vet. Clin. North Am. Small Anim. Pract.* 47:631–644. doi:10.1016/j.cvsm.2016.11.011

Fieten H, Hooijer-Nouwens BD, Biourge VC, Leegwater PAJ, Watson AL, Van den Ingh TSGAM, Rothuizen J. 2012. Association of dietary copper and zinc levels with hepatic copper and zinc concentration in Labrador Retrievers. *J. Vet. Intern. Med.* 26:1274-1280.

Gagné JW, Wakshlag JJ, Center SA, Rutzke MA, Glahn RP. 2013. Evaluation of calcium, phosphorus, and selected trace mineral status in commercially available dry foods formulated for dogs. *J. Am. Vet. Med. Assoc.* 243:658-666.

Johnston, AN, Center SA, McDonough SP, Warner KL. 2009. Influence of biopsy specimen size, tissue fixation, and assay variation on copper, iron, and zinc concentrations in canine livers. *Am. J. Vet. Res.* 70:1502–1511. doi:10.2460/ajvr.70.12.1502

Kelly DG, White SD, Weir RD. 2013. Elemental composition of dog foods using nitric acid and simulated gastric digestions. *Food Chem. Toxicol.* 55:568-577.

Kępińska-Pacelik, J., Biel, W., Witkowicz, R. et al.2023. Mineral and heavy metal content in dry dog foods with different main animal components. *Sci. Rep.* 13(6082). doi: 10.1038/s41598-023-33224-w

Kienzle, E. 1988. Trace element requirements of dogs. *Anim. Nutr.* 16:153:212.

Mielczarek, M, Szydlowski, K. 2017. The heavy metal content in commercial dog foods. West Pomeranian University of Technology. *Pisc. Zootech.* 332(41)1:29-36. doi:1 0.21005/AAPZ2017.41.1.04

National Research Council. 1974. *Nutrient Requirements of Dogs*. Washington, DC: The National Academies Press. doi:10.17226/20184.

National Research Council. 1980. *Mineral Tolerance of Domestic Animals*. Washington, DC: The National Academies Press. doi:10.17226/25.

National Research Council. 2006. *Nutrient Requirements of Dogs and Cats*. Washington, DC: The National Academies Press. doi:10.17226/10668.

Paulelli ACC, Martins Jr AC, Silva de Paula E, Souza JMO, Carneiro MFH, Júnior FB, Batista BL. 2018. Risk assessment of 22 chemical elements in dry and canned pet foods. *J. Consumer Protection Food Safety*. doi:10.1007/s00003-018-1178-5.

Pereira AM, Pinto E, Matos E, Castanheira F, Almeida AA, Baptista C, Segundo MA, Da Fonseca AM, Cabrita AR. 2018. Mineral composition of dog foods: impact on nutrition and potential toxicity. *J. Agric. Food Chem.* doi:10.1021/acs.jafc.8b02552

From:

Sent: Friday, March 1, 2024 10:56 AM

To: AAFCO

Subject: Comment on voluntary 'controlled copper" claim

CAUTION: This email originated from the internet.

To whom it may concern,

As a Board Certified Veterinary Nutritionist, I would like to share my comment regarding the voluntary 'controlled copper' claim for dog foods.

I **do not support** the use of 'controlled copper" voluntary claim on dog foods and the vote of the Copper Claim Workgroup for the following reasons:

1. The true prevalence of copper associated liver disease has not been determined, so the argument that there is an increased incidence in the pet dog population is currently based subjectively on people's own clinical experience in a small subgroup of dogs.

2. While the dietary copper levels of diets for dogs with liver disease should be low, it does not mean that all dog foods should have restricted copper levels. This claim should be reserved for therapeutic diets that are used under veterinarian's supervision, not wellness diets.

3. The 'controlled copper' claim will limit access of therapeutic dog foods to veterinarians and pet owners to support dogs with true liver diseases.

4. This claim will empower pet owners to self-diagnose and treat dogs.

5. The rationale for setting a maximum of 15 ppm is not sufficiently scientifically substantiated.

Thank you for the opportunity to share my opinion on this matter.

Kind regards,

--

From: AAFCO

Sent: Friday, March 1, 2024 2:12 PM

To: AAFCO

Subject: AAFCO "Copper in dog food"

CAUTION: This email originated from the internet.

From:

Subject: Copper in dog food

Message Body:

why isn't there a maximum level for copper in dog food. Excessive copper is killing our dogs . Not even counting the amount of chemicals they put into the dog's food that they don't have the list.

Thank you for your time and help.

--

This e-mail was sent from a contact form on AAFCO (https://www.aafco.org)

Response of AFIA to the AAFCO Copper Claim Workgroup: Final Report to the Pet Food Committee

March 1, 2024

The American Feed Industry Association thanks the Association of American Feed Control Officials for the opportunity to participate in the Copper Claim Workgroup convened during the fall of 2023. We submit these additional comments on the final report of the workgroup and request the AAFCO pet food committee consider an edit to the proposed regulation, ***if the regulation is adopted by the committee for consideration by the AAFCO board.***

The AFIA opposes the premise of the creation of a controlled copper claim for dogs as presented in the final report of the AAFCO Copper Claim Workgroup. The current elevated public awareness of Copper Associated Hepatopathy (CAH) brought about by the opinion piece in the Journal of the American Veterinary Medicine Association, the FDA grand rounds on copper in dog food and articles in the popular press have brought a heightened level of attention to the issue. The Expert Panel convened by AAFCO in 2022 determined that changes to the AAFCO nutrient profiles for copper in canine diets would be arbitrary as there is no published research linking the presence of dietary copper to the incidence of CAH in dogs without a genetic pre- disposition to the disease. This sentiment was repeated by Dr. William Burkholder, a member of both the Expert Panel and the Work Group in his comments during the 2024 mid-year AAFCO meeting held in Chattanooga, Tenn., when he stated that any proposed changes to the AAFCO regulations should be based on sound science. As there is no confirmed scientific link between the dietary source or amount of copper in canine diets and CAH there is no evidence to support the creation of this claim.

Marketing claims, such as "aids in a healthy urinary tract, require individual companies to conduct research proving that their over-the-counter diet can in fact help maintain urinary tract health. This substantiation of the claim is necessary to achieve approval of the claim and is available to any regulator upon request. The proposed copper claim has no such scientific rigor attached to it. If this claim is to be allowed, it should be reviewed by the FDA, like pet food claims for urinary tract health. This claim is not just a dietary claim, it is an implied drug claim and therefore, should not be in the purview of AAFCO.

Regulators assert the copper claim is necessary to "level the playing field" in the marketplace but we would argue this is not true. If a company wants to make this claim, then they should have to defend it either through animal research or a literature search to the FDA like other claims such as urinary tract health. Based on data presented in the second meeting of the work group by Dr. Leslie Hancock-Monroe, this claim will be misleading to consumers and may have unintended health consequences to dogs which require therapeutic diets containing copper below the AAFCO allowed limits for copper.

As currently written, the proposed language to create a controlled copper marketing claim would exclude products from the marketplace that are proven to assist dogs with veterinary diagnosed copper issues by providing diets below the AAFCO required lower limits. As drafted the regulation will <u>allow</u> pet foods with no therapeutic benefit to enter the market with a misleading marketing claim but without the rigor of scientific review by the FDA. The proposed regulation will <u>remove</u> products from the market that are scientifically formulated to help dogs who have undergone a veterinary diagnosis of CAH. The first goal of AFIA pet food manufacturing members is to support the health and safety of the animals they feed. ***If the AAFCO pet food committee votes to***

adopt the regulation it must first edit the regulation before approval and consideration by the AAFCO board to allow therapeutic diets which can actually benefit dogs to remain on the market.

If the AAFCO pet food committee votes to adopt the revised proposed regulation we suggest the following changes be made:

Regulation PF 10. Descriptive Terms […]

(d) Copper Terms

(1) A claim "low copper," "low in copper," or words of similar designation is ~~not allowed~~ allowed when the copper content of the diet is below the AAFCO minimum.

Thank you for your consideration of our points.

Sincerely,

December 20, 2023

, AAFCO Pet Food Committee Co-chair
, AAFCO Pet Food Committee Co-chair
, AAFCO President
, AAFCO Executive Director

Dear ,

The American Feed Industry Association and Pet Food Institute are dismayed and concerned by the decision of the working group, convened by the Pet Food Committee of the Association of American Feed Control Officials (AAFCO) and charged with exploration of establishing within the Model Regulation PF10 Descriptive Terms for the criteria for commercial dog food products, a 'Low Copper' claim. The vote of 6 for the development of a controlled copper claim and 4 in opposition of the measure clearly indicates disparity among the working group members. Furthermore, the vote is not in alignment with the findings in the report of the AAFCO expert panel comprised of subject matter experts on companion animal nutrition.

We strongly urge the AAFCO Pet Food Committee to reject the development of controlled copper claim. 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.

We do 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*. In their report, the AAFCO expert panel stated:

"… arbitrarily setting some value as a maximum for copper implies that diets containing less than, or equal to, the maximum are safe for dogs and that diets containing more than the maximum amount are unsafe, with neither condition having been demonstrated to be true."

We support the majority opinion of the 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." This statement also holds for an AAFCO sanctioned marketing claim for "controlled copper."

Creating an AAFCO-sanctioned marketing claim regarding copper content in dog food based on an arbitrary value of 15 mg Cu/kg dry matter to address consumers' desires rather than animal wellbeing 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." We strongly advise 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 known genetic linkage in dogs. Developing an AAFCO approved "controlled copper" marketing claim is a hasty step 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).

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. Without any changes to current AAFCO model regulations, companies that choose to include marketing statements about copper content in pet food are free to do so if the food meets the AAFCO minimum requirement for copper and the claim is truthful and not misleading. If consumers are interested in the amount of copper in their dogs' diets, then manufacturers can include the information on labels using existing regulatory pathways.

We request a time to meet with the AAFCO board to discuss our position on this issue ahead of the annual meeting in January. Additionally, we request sufficient time on the pet food committee agenda to fully present our position on the working group decision.

Thank you for your consideration of our requests.

American Feed Industry Association Pet Food Institute

February 29, 2024

Michigan State University Veterinary Diagnostic Laboratory

4125 Beaumont Rd.

Lansing, MI 48910

RE: Copper Claim Workgroup Comment

Thank you for the opportunity to comment on the proposed AAFCO controlled copper diet claim. As veterinary laboratory pathologists and toxicologists from the Michigan State University Veterinary Diagnostic Laboratory (MSU VDL), with more than 200 years of collective experience and expertise in the pathologic and toxicologic diagnosis of dogs with liver disease, we would like to add our names in support of the letter recently sent by a group of veterinary internists. We agree with and fully support the following recommendations made by that group.

1. We welcome FDA's acknowledgement that there is an "increased awareness among dog owners, veterinarians, and pet food companies regarding concerns about copper concentrations in dog food."

2. We consider establishing labelling regulations for a controlled copper diet is a first step in acknowledging the need for tighter control of dietary copper concentrations in dog food relevant to our observation of the increased incidence of Copper-Associated Hepatopathy.

3. We encourage regulatory efforts and nomenclature that will indicate that dietary copper restriction to 15 mg/kg (0.375 mg/100 kCal) may not prevent Copper-Associated Hepatopathy in dogs.

4. We suggest that the copper concentrations declared in guaranteed analyses of the controlled copper diet label (and optimally in all dog foods) should be expressed in units that normalize copper intake to energy intake: i.e., mg/100kCal, rather than mg/kg.

5. We recommend that the total copper content in dog foods (including natural copper and premix additives) be declared in the guaranteed analyses on the product label allowing consumers to make informed decisions regarding the amount of copper fed to their dog. We acknowledge differences in bioavailability of

various copper sources and the complex interactions influencing copper bioavailability among certain dietary ingredients.

6. As FDA and AAFCO committees move forward in considering the role of dietary exposure in dogs relevant to the increased prevalence of Copper- Associated Hepatopathy, we recommend that one or more of each a Veterinary Internist, Pathologist and Toxicologist with an expertise in hepatic pathology and toxicology that routinely diagnose dogs with Copper- Associated Hepatopathy be included.

As veterinary pathologists, since 1997 we have seen a clear and concerning increase in the number of dogs with Copper-Associated Hepatopathy based on liver biopsy and necropsy sample submissions with combined histopathology and mineral analysis. This diagnosis is made on a weekly basis at our laboratory with an estimated greater than four fold increase in diagnosis compared to prior to 1997. **The staggering increase in the diagnosis of Copper-Associated Hepatopathy is a very real and alarming trend. These dogs represent a wide range of purebred and mixed breed dogs, including many, if not most of which, are no longer the breeds believed to be of increased risk.** Our study (Strickland JM *et al.* J Vet Intern Med. 2018 Nov;32(6) and another study [Johnston AN, et al. J Am Vet Med Assoc. 2013 Feb 1;242(3)] have both unequivocally demonstrated this observation to be true. Each study looked at two cohorts of dogs, one from prior to 1997 and one from post 1997. The Johnston et al. study only included Labrador Retrievers but the Strickland et al. paper included all breeds of dogs that were submitted to the MSU VDL during those time periods. The latter states that "44.3% of all dogs [Predisposed breed (PB) and Non-predisposed breed (NPB) dogs] with hepatitis had hepatic copper concentrations [Cu]H > 1000 µg/g in recent years whereas only 16.7% of dogs with hepatitis had $[Cu]_H$ > 1000 µg/g in the historical period." "In time period 2009–2015, median $[Cu]_H$ were 101 µg/g and 313 µg/g greater than median $[Cu]_H$ in time period 1982– 1988 for NPB and PB dogs, respectively (P < .001 for both comparisons). The proportion of dogs with $[CU]_H$ > 300 µg/g increased in NPB (28% to 49%) and PB dogs (48% to 71%) during these periods (P = .002 for both comparisons). Median $[Cu]_H$ in dogs with hepatitis **increased 3-fold over time in both NPB (P = .004) and PB populations** (P < .001)." Several other peer-reviewed studies have been published alerting the community to this rising rate of Copper-Associated Hepatopathy as well.

"Beginning in the 1970s, the Association of American Feed Control Officials (AAFCO) nutrient profiles, which were based on National Research Council recommendations, required a minimum amount of copper in pet dog food. Many of these trace mineral requirements were **extrapolated from non- species-specific data.** The published AAFCO profiles in 1997 required the use of copper sulfates or chelates in these premixes which were far more bioavailable than the previously utilized copper oxide. **This was done despite there being no evidence to suggest clinical copper deficiency was a problem at the time. The nutrient profiles published in 2015 have increased copper requirements for growing and lactating dogs, and maximum thresholds have been removed for all dogs.** Since the original minimum requirements were established in the 1970s, it has been common practice in the commercial pet food industry to formulate mineral premixes to meet or exceed minimum requirements. These premixes are often added to the food without consideration for the copper already present in the ingredients." (Strickland et al.)

The changes made in 1997 were made based on a small study in 1993 conducted in purpose-bred beagles (Czarnecki-Maulden G, Rudnick R, Chausow D. Copper bioavailability and requirement in the dog: comparison of copper oxide and copper sulfate (abstract). *FASEB J* 1993; 7:A305); **this study was never published in peer-reviewed form. The claim that dogs prior to 1997 were at risk of copper deficiency is unfounded.** Moreover, at the MSU VDL, we searched the pathology database for cases of canine copper deficiency from 1975 to 2000 and found **ZERO cases of copper deficiency.**

We strongly urge the FDA and AAFCO committees to adopt the recommendations listed above.

Sincerely,

From:

Sent: Saturday, March 2, 2024 12:38 AM

To: AAFCO

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

Greetings AAFCO workgroup members,

As an individual veterinary nutritionist, I would like to provide a comment on the proposed “controlled copper” claim. As a nutrition specialist and veterinarian, I support evidence-based practices whenever possible. Approving a voluntary low/controlled copper claim when there is no evidence that it is necessary or beneficial is NOT in the best interest of pets.

1. Presumably, the goal of such a claim is to help correct/prevent/address a problem. However, the actual problem has not yet been identified. The perception that there has been an increased incidence of copper-associated hepatopathy is not actually supported by evidence. This alone makes any attempt to limit an essential nutrient unnecessary.

2. If future research shows increasing incidence of copper accumulation in the liver of dogs, and that this is associated with disease, additional research will be needed to identify a cause. Currently, there is no evidence that liver disease is caused by the copper content of commercial diets. The only true cause of copper hepatopathy identified to date is a genetic disease identified in one breed of dog (Bedlington Terrier). If other causes of primary copper hepatopathy exist, these have yet to be discovered, and they may or may not be treated by dietary copper restriction alone.

3. For those patients that truly require a limited copper diet to help manage liver disease (with primary or secondary copper accumulation), the level of copper in the proposed “controlled copper” diet will most likely be too high. The presence of diets labeled as “controlled copper” and therapeutic restricted copper diets in the market will only confuse pet owners and veterinarians, and increase the likelihood that patients with true liver disease are inappropriately treated. In other words, there is no evidence that feeding a food with a “controlled copper” claim will benefit any dog. However, it is likely that a “controlled copper” wellness food, which is not sufficiently restricted in copper for pets with liver disease, will confuse owners and veterinarians, and be detrimental to dogs with true copper-associated hepatopathy. The risks to sick pets outweigh the perceived/unsupported “benefits” to healthy pets. The only beneficiaries of a “controlled copper” claim will be the commercial companies that choose to use this as a marketing tool and coerce pet owners into believing an essential nutrient is harmful (without any real evidence to that effect).

4. Further research into copper requirements of dogs (and cats) is warranted. Identifying a safe upper limit for the essential nutrient copper in healthy dogs should remain a primary goal. However, arbitrarily selecting a cutoff and creating a “controlled copper” claim is not a solution to the lack of evidence for a safe maximum level. If the voluntary claim is adopted, even in the short-term, it could hinder further research on this topic by creating the perception that the suggested “problem” has been “fixed”.

AAFCO’s support of a “controlled copper” claim would be irresponsible. It suggests that AAFCO is not a science-based advisory body, but rather bends to the pressure of industry marketers and opinionated/vocal veterinary experts who present their opinion as fact. It adds confusion to an already confusing landscape of pet foods, and blurs the lines between wellness and therapeutic products. It limits the ability of veterinarians to successfully recommend specially formulated and scientifically tested therapeutic foods that have been shown to help sick pets, while doing nothing to improve the lives of healthy pets.

I urge AAFCO to look at the science, and keep the best interest of pets (and pet owners) in mind. There is clearly no scientific support for a “controlled copper”, low copper, or even maximum copper level in commercial dog food at this time.

Thank you for your attention to this letter, and your dedicated work on this important issue.

Sincerely,

From:

Sent: Saturday, March 2, 2024 2:11 AM

To: AAFCO

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

I strongly urge the FDA and AAFCO committees to adopt the recommendations listed below.

1. I welcome FDA's acknowledgement that there is an "increased awareness among dog owners, veterinarians, and pet food companies regarding concerns about copper concentrations in dog food."

2. I consider establishing labelling regulations for a controlled copper diet is a first step in acknowledging the need for tighter control of dietary copper concentrations in dog food relevant to our observation of the increased incidence of Copper-Associated Hepatopathy.

3. I encourage regulatory efforts and nomenclature that will indicate that dietary copper restriction to 15 mg/kg (0.375 mg/100 kCal) may not prevent Copper-Associated Hepatopathy in dogs.

4. I suggest that the copper concentrations declared in guaranteed analyses of the controlled copper diet label (and optimally in all dog foods) should be expressed in units that normalize copper intake to energy intake: i.e., mg/100kCal, rather than mg/kg.

5. I recommend that the total copper content in dog foods (including natural copper and premix additives) be declared in the guaranteed analyses on the product label allowing consumers to make informed decisions regarding the amount of copper fed to their dog. I acknowledge differences in bioavailability of various copper sources and the complex interactions influencing copper bioavailability among certain dietary ingredients.

6. As FDA and AAFCO committees move forward in considering the role of dietary exposure in dogs relevant to the increased prevalence of Copper- Associated Hepatopathy, I recommend that one or more of each a Veterinary Internist, Pathologist and Toxicologist with an expertise in hepatic pathology and toxicology that routinely diagnose dogs with Copper- Associated Hepatopathy be included.

From:

Sent: Saturday, March 2, 2024 9:25 AM

To: AAFCO

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

Dear AAFCO members,

Please strongly consider the recommendations of the dedicated and knowledgeable members of the veterinary profession when voting on this issue. Copper- associated hepatopathy in dogs is an important disease process that has complex origins and needs many perspectives addressed for effective treatment and prevention. Please help us help dogs and their families live longer and healthier lives.

We strongly urge the FDA and AAFCO committees to adopt the recommendations listed below.

1. We welcome FDA's acknowledgement that there is an "increased awareness among dog owners, veterinarians, and pet food companies regarding concerns about copper concentrations in dog food."

2. We consider establishing labelling regulations for a controlled copper diet is a first step in acknowledging the need for tighter control of dietary copper concentrations in dog food relevant to our observation of the increased incidence of Copper-Associated Hepatopathy.

3. We encourage regulatory efforts and nomenclature that will indicate that dietary copper restriction to 15 mg/kg (0.375 mg/100 kCal) may not prevent Copper-Associated Hepatopathy in dogs.

4. We suggest that the copper concentrations declared in guaranteed analyses of the controlled copper diet label (and optimally in all dog foods) should be expressed in units that normalize copper intake to energy intake: i.e., mg/100kCal, rather than mg/kg.

5. We recommend that the total copper content in dog foods (including natural copper and premix additives) be declared in the guaranteed analyses on the product label allowing consumers to make informed decisions regarding the amount of copper fed to their dog. We acknowledge differences in bioavailability of various copper sources and the complex interactions influencing copper bioavailability among certain dietary ingredients.

6. As FDA and AAFCO committees move forward in considering the role of dietary exposure in dogs relevant to the increased prevalence of Copper- Associated Hepatopathy, we recommend that one or more of each a Veterinary Internist, Pathologist and Toxicologist with an expertise in hepatic pathology and toxicology that routinely diagnose dogs with Copper- Associated Hepatopathy be included.

From:

Sent: Friday, March 1, 2024 9:47 PM

To: AAFCO

Subject: [Possible spam] Copper Claim Work group Comment

CAUTION: This email originated from the internet.

We strongly urge the FDA and AAFCO committees to adopt the recommendations listed below.

1. We welcome FDA's acknowledgement that there is an "increased awareness among dog owners, veterinarians, and pet food companies regarding concerns about copper concentrations in dog food."

2. We consider establishing labelling regulations for a controlled copper diet is a first step in acknowledging the need for tighter control of dietary copper concentrations in dog food relevant to our observation of the increased incidence of Copper-Associated Hepatopathy.

3. We encourage regulatory efforts and nomenclature that will indicate that dietary copper restriction to 15 mg/kg (0.375 mg/100 kCal) may not prevent Copper-Associated Hepatopathy in dogs.

4. We suggest that the copper concentrations declared in guaranteed analyses of the controlled copper diet label (and optimally in all dog foods) should be expressed in units that normalize copper intake to energy intake: i.e., mg/100kCal, rather than mg/kg.

5. We recommend that the total copper content in dog foods (including natural copper and premix additives) be declared in the guaranteed analyses on the product label allowing consumers to make informed decisions regarding the amount of copper fed to their dog. We acknowledge differences in bioavailability of various copper sources and the complex interactions influencing copper bioavailability among certain dietary ingredients.

6. As FDA and AAFCO committees move forward in considering the role of dietary exposure in dogs relevant to the increased prevalence of Copper- Associated Hepatopathy, we recommend that one or more of each a Veterinary Internist, Pathologist and Toxicologist with an expertise in hepatic pathology and toxicology that routinely diagnose dogs with Copper- Associated Hepatopathy be included.

Sincerely,

March 21, 2024

Dear AAFCO,

The Pennsylvania Department of Agriculture, Bureau of Plant Industry, which manages commercial feed and pet animal food, supports the proposed Regulation PF10. Descriptive Terms… (d) Copper Terms, and the standardization of "Controlled Copper".

The AAFCO Copper Workgroup developed model regulation that standardizes what controlled copper in dog food means. As stated by members of the workgroup, "This standard provides a level playing field for the industry, it frees the regulatory officials from extensive review and questioning of the manufacturer for what is meant by the claim."

Marketing claims are most useful when the claim is standardized and establishes supportive evidence with labeling guarantees. Defining the use of the descriptive term, "controlled copper" with requirements to be nutritionally adequate for one or more life stages, contain an established maximum for copper when using this claim, and to bear in the guaranteed analysis a guarantee for the maximum amount of copper in the dog food is fully appropriate.

Reliance on a state-by-state approach to interpret low copper claims on dog food labels causes workload and economic issues for the states. In addition, the pet food industry is seeking uniformity with product labeling. AAFCO promotes uniformity across the nation and a level playing field.

Thank you,

Bureau of Plant Industry

PA Department of Agriculture

From:

Sent: Sunday, March 3, 2024 10:44 PM

To: AAFCO

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

We strongly urge the FDA and AAFCO committees to adopt the recommendations listed below.

1. We welcome FDA's acknowledgement that there is an "increased awareness among dog owners, veterinarians, and pet food companies regarding concerns about copper concentrations in dog food."

2. We consider establishing labelling regulations for a controlled copper diet is a first step in acknowledging the need for tighter control of dietary copper concentrations in dog food relevant to our observation of the increased incidence of Copper-Associated Hepatopathy.

3. We encourage regulatory efforts and nomenclature that will indicate that dietary copper restriction to 15 mg/kg (0.375 mg/100 kCal) may not prevent Copper-Associated Hepatopathy in dogs.

4. We suggest that the copper concentrations declared in guaranteed analyses of the controlled copper diet label (and optimally in all dog foods) should be expressed in units that normalize copper intake to energy intake: i.e., mg/100kCal, rather than mg/kg.

5. We recommend that the total copper content in dog foods (including natural copper and premix additives) be declared in the guaranteed analyses on the product label allowing consumers to make informed decisions regarding the amount of copper fed to their dog. We acknowledge differences in bioavailability of various copper sources and the complex interactions influencing copper bioavailability among certain dietary ingredients.

6. As FDA and AAFCO committees move forward in considering the role of dietary exposure in dogs relevant to the increased prevalence of Copper- Associated Hepatopathy, we recommend that one or more of each a Veterinary Internist, Pathologist and Toxicologist with an expertise in hepatic pathology and toxicology that routinely diagnose dogs with Copper- Associated Hepatopathy be included.

Clinical Assistant Professor | Department of Veterinary Pathology

College of Veterinary Medicine | Iowa State University

2714 Patterson Hall | 1800 Christensen Drive | Ames, IA 50011

From:

Sent: Saturday, March 2, 2024 3:16 PM

To: AAFCO

Subject: AAFCO Copper Claims

CAUTION: This email originated from the internet.

To The Association of American Feed Control Officials

I am a veterinary small animal internist, in private practice in California for over 25 years, and now a specialty consultant.

I would like to support the establishment of controlled copper claims for dog foods. I agree that establishing labelling regulations for a controlled copper diet is a first step in acknowledging the need for tighter control of dietary copper concentrations in dog food relevant to the observation of the increased incidence of Copper Associated Hepatopathy.

I also encourage regulatory efforts and nomenclature that will clarify for consumers that dietary copper restriction to 15 mg/kg (0.375 mg/100 kCal) may not prevent Copper Associated Hepatopathy.

I agree that copper concentrations declared in guaranteed analyses of the controlled copper diet label (and optimally in all dog foods) should be expressed in units that normalize copper intake to energy intake: i.e., mg/100kCal, rather than mg/kg.

I agree that the total copper content in dog foods (including natural copper and premix additives) be declared in the guaranteed analyses on the product label allowing consumers to make informed decisions regarding the amount of copper fed to their dog. I acknowledge differences in bioavailability of various copper sources and the complex interactions influencing copper bioavailability among certain dietary ingredients.

Thank you for your consideration,

Sincerely,

Idexx Reference Laboratories, Internal Medicine Consultant

From:

Sent: Monday, March 4, 2024 7:45 AM

To: AAFCO

Subject: Copper Claim Workgroup Comment

CAUTION: This email originated from the internet.

I am very concerned about the copper in food. Unfortunately, it is hard to get companies to listen when the standards are set to a dangerous level by your company.

Cornell has also published a report with this concern. Putting a conservative cap on the amount of copper, and ideally the type of copper, added to dog food will do no harm but will do a great good to all dogs sensitive to this disease.

Please revisit this issue, and set a upper limit less than 12 and switch to copper oxide. This is a real issue and needs to be addressed.

Thank you

From: AAFCO

Sent: Wednesday, March 6, 2024 2:01 PM

To: AAFCO

Subject: AAFCO “Copper In Dog Food”

CAUTION: This email originated from the internet.

From:

Subject: Copper In Dog Food

Message Body:

We need safe upper limits so dogs quit dying young of copper induced liver disease. My dog passed away at 5 after thousands in vet bills due to a toxic copper liver. Not a breed associated being genetically predisposed to copper problems. My friend lost her young 4 year old dog the same way. This has to be handled!! How can I get this resolved? Whoever keeps voting no on this based on not enough scientific evidence has blood on their hands!

This e-mail was sent from a contact form on AAFCO (https://www.aafco.org)

From:

Sent: Wednesday, March 27, 2024 5:48 PM

To: AAFCO

Subject: (Late) Copper Claim Comment

CAUTION: This email originated from the internet.

Hello, I know this is far past the date listed, but I just heard about this invite and wanted to contribute even if it goes nowhere.

March 6th of 2023, three days before AAFCO voted to uphold current copper regulations, my chow was diagnosed with terminal dietary-induced CAH. We had been getting her ultrasounds and tested since 2018, but the ultrasound didn't show scarring until it was too late. She passed away April 11th, just a few weeks after the diagnosis. As a consumer, I beg for more transparency to the public and more regulated copper. Please consider including my commentary if possible.

Thank you, .

ROYAL CANIN
a division of Mars Petcare

29 Feb 2024
AAFCO Pet Food Committee
PFC@aafco.org

Re: “Controlled Copper” proposed claim language

Dear Members of the AAFCO Pet Food Committee,

As it pertains to the copper claim working group’s report around model regulation for a “controlled copper” claim in commercial dog foods intended for healthy animals, we are aligned with the position of PFI and AFIA’s consensus statements in not supporting this claim. We believe regulations and regulatory definitions should be based on sound science, and because there is not data to support the range of copper for a diet to bear a “controlled copper” claim, we feel this proposed regulation is not responsible rulemaking.

However, if the proposal is seriously considered by the committee and passes, we need to raise a concern that we believe was inadvertently introduced and would directly impact veterinary/therapeutic diets. The working group states, “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).”

It is clear that the members of the working group acknowledge that there is a need for diets that have a Copper level lower than the AAFCO minimum for dogs. We agree that the proposal for complete and balanced diets using a “low copper” claim was inappropriate and agreed to the revision of “controlled copper” for complete and balanced diets was a more appropriate choice in descriptive terms.

However, the working group added to their recommendation that “… the regulation prohibit the use of “low copper” or other similar wording.” This poses a problematic conundrum for veterinary diets specially formulated for dogs predisposed to, or with existing, liver disease such as Copper Associated Hepatopathy (CAH) with a Cu level less than the AAFCO requirement.

PF10 (d) (1) prohibits a claim of “low copper” without qualification of the type of diet and (2) enables only a “controlled copper” claim when the product is complete and balanced and below 15 ppm.

The structure of this regulation enables a claim for a complete and balanced diet to refer to the copper content of the product which may or may not be helpful for the population of dogs who need a controlled copper content while it removes the ability

Simplified joint-stock company with a share capital of EUR 31,540,241.4
700 200 983 R.C.S Nîmes
Registered office : 650 Avenue de la Petite Camargue – 30470 Aimargues – FRANCE
APE Code 1092 Z – VAT n° : FR6170020083

Royal Canin USA, Inc.
500 Fountain Lakes Blvd.
Suite 100 St. Charles,
MO 63301
T : 636.926.1111
www.royalcanin.com/us

for a veterinary diet to accurately describe the amount of copper in the diet that is appropriate for the population of dogs who need a low copper content in their diet. Because the copper content is lower than the AAFCO minimum the controlled copper claim would not be available for a diet in this category.

If the Pet Food Committee wishes to move forward with a definition for a controlled copper claim, PF10 (d) (1) must be edited to not adversely affect the ability for a veterinary diet to accurately describe its copper content. Our recommendation would be to also define when a low copper claim would be allowed.
Change: A claim "low copper," "low in copper," or words of similar designation is not allowed.
To: A claim "low copper," "low in copper," or words of similar designation is allowed when the copper content of the diet is below the AAFCO minimum.

Thank you for your careful consideration,

Senior Regulatory Innovation & Portfolio Compliance Team Manager
Royal Canin North America