JUSTFOODFORDOGS WHITEPAPER

An Evidence-Based Analysis of the Dog Food Industry in the USA

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About the Authors

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Dr. John Tegzes is a board certified veterinary toxicologist and professor at the College of Veterinary Medicine of Western University of Health Sciences in Pomona, CA. After graduating from the School of Veterinary Medicine at the University of Pennsylvania, he pursued specialty training in clinical toxicology at UC Davis and became a specialist in the study of toxins and their effect on pets. His interest in nutrition stems directly from his specialty, as reputable pet food companies should consult with toxicologists regularly to ensure adequate testing and compliance. Dr. Tegzes also co-authored the groundbreaking research featured in this report.

Oscar E. Chavez, BVetMed MRCVS MBA

Dr. Chavez graduated from the Royal Veterinary College in London, and later joined the faculty of Animal and Veterinary Sciences at California State Polytechnic University, Pomona, where he was director of the four year AVMA program in veterinary technology and conducted the world’s first at-home feeding trials and research on whole food canine nutrition. He has been researching, analyzing, formulating, and testing whole food canine diets for four years. While he remains an adjunct faculty and professor of clinical nutrition, his current full time role is Chief Medical Officer at JustFoodForDogs LLC.

Collaborating Researchers

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Dr. Sandelin is professor and Chair of the Animal and Veterinary Sciences Department at California State Polytechnic University, Pomona. He leads a research team including distinguished faculty from Cal Poly Pomona and Western University Health Sciences school of veterinary medicine, and is primarily responsible for submitting original research to journals for publication.

Lee Allen Pettey PhD

Dr. Pettey is an animal nutritionist and faculty at California State Polytechnic University, Pomona. He co-authored the research conducted using JustFoodForDogs diets and is also responsible for the official formatting and preparation of the research manuscript for official peer-review.
July 4, 2014

Division of Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket ID: FDA-2013-N-0013
Agency: Food and Drug Administration (FDA)
Parent Agency: Department of Health and Human Services (HHS)

Dear U.S. Food and Drug Administration:

This letter is in response to the FDA’s current consideration of proposed rule §1.904 as it applies to the Sanitary Food Transportation Act of 2005 (2005 SFTA) and the FDA Food Safety Modernization Act (FSMA). We caution the FDA of any further differentiation between standards for the production of food and animal food, especially as it relates to our pet population. A proposed exemption for animal food standards already exists in Docket No. FDA-2013-N-1425 and RIN 0910-AG63 (Focused Mitigation Strategies To Protect Food Against Intentional Adulteration). Recently the FDA has concluded that animal food is not at a high risk for intentional contamination and has therefore exempted animal food from the same regulations to prevent adulteration as human food. In drafting this rule (§1.904) it is important that no further differentiation or exemptions be made between animal food and food as it relates to sanitary transport.

Contamination or adulteration of pet food has been confirmed repeatedly through testing. The global recalls of 2007 exposed a criminal intent to adulterate food and the toxin almost became widespread in our own food chain in 2008, as it did in China. Recently, in April 2014, a Hong Kong consumer agency found alarming levels of a carcinogenic mycotoxin Aflatoxin B1, as well as melamine and cyuranic acid, the adulterants at fault in the 2007 recalls, in top USA brand pet foods that were shipped to Hong Kong. Contamination of pet feed in the USA manufacturing process is not yet controlled; mycotoxins in particular are affected by handling and transport.

JustFoodForDogs LLC is a small company that makes food for dogs. We were founded with one simple goal: to improve the quality of life of as many dogs as possible through whole balanced nutrition. Given the known shortcomings of the current pet feed system, we make our food using only ingredients inspected and approved by the USDA for human consumption, all of which are stored, handled, and transported to us by our USDA registered suppliers. We cook the food in our kitchens in small batches and formulate it scientifically to meet dogs’ nutritional needs. We vacuum seal and freeze the diets fresh with no chemical preservatives. We do all of this, because we believe it is the only way to prevent exposure to the contamination and adulteration found in the standard commercial pet feed system. We produce excellent, nutritious meals and pet parents, vets, and veterinary specialists have confirmed excellent results. In addition, recent initial research at local universities has shown significant differences in blood parameters that may be used as a measure of health from dogs eating our food.
We have also built a team of scientists, including a board certified veterinary toxicologist, and a PhD in animal nutrition. As support for our assessment, we offer our whitepaper, published July 1, 2014 and authored by this team, for review and consideration relevant to this issue. As evidenced in our report, cited with peer-reviewed literature, contamination is still rampant in the feed industry and we believe the sanitary transportation of feed ingredients can play a critical role. Under the current proposal in Docket No. FDA-2013-N-1425 and RIN 0910-AG63, the FDA will have little authority to regulate intentional adulteration in animal food; therefore it is required that all other possible forms of contamination are tightly regulated.

It is unclear as to why the contaminants listed in our whitepaper have been consistently found in pet feed ingredients over the last 20 years and why this remains a threat today. However, it is conclusive evidence of the effects of having different standards for animal and human foods as it relates to our pets’ health. Furthermore, if the same rules are developed to reduce contamination for animal and human food, but those rules are intentionally ignored in the pet food industry, does that constitute the intentional adulteration of pet food? If so, how will the FDA act under this rule vs. the proposed rule as it relates to adulteration? Adulteration of any kind is a crime and should be definitively controlled in all cases. Exemptions in standards against adulteration for animal food should not be made; it is akin to allowing criminal behavior in the production of pet feed.

As Americans we love our pets, they are voiceless members of our American family because they cannot comment on policy. Like children, our pets rely on our protection and loyalty to ensure they are not poisoned by the food they eat. Likewise, our American pets give their pet parents years of unconditional love, and help provide our citizens many benefits, including healthier and longer lives, reduced stress, reduced depression, reduced heart rates, and an increased will to live longer and fight disease. These medical benefits have been confirmed repeatedly through pet therapy research.

American citizens have enjoyed years of freedom and protection from our government; a fact we proudly celebrate today, July 4, 2014. On this day, JustFoodForDogs requests that our four-legged citizens and family members also be celebrated and protected through the development of the Food Safety Modernization Act, as was the original spirit of the FDA Amendments Act 2007 (title X).

Mahatma Gandhi once said, “The greatness of a nation and its moral progress can be judged by the way its animals are treated.” Please do not include any further exemptions for animal food standards in regulation. Please help us protect all our beloved citizens both human and four-legged in this great nation.

Sincerely,

Oscar E. Chavez, BVetMed MRCVS
Chief Medical Officer – JustFoodForDogs

Shawn Buckley
CEO/Founder – JustFoodForDogs
Introduction

Should we be rethinking how we feed our dogs?

The past six to eight years have been exceedingly dynamic in the pet food industry; they have included major recalls, the discovery of toxic contaminants in dry pet food, recurrent bacterial contamination, human illnesses from handling pet food, and other concerns. An example is the FDA’s unprecedented recent release of a video offering consumers guidance on how to “safely handle” pet food and treats in the home. In response to consumer demands for higher standards, the Food and Drug Administration (FDA) is considering further regulating established practices within the pet food industry, calling the current structure worrisome. At the same time some organizations associated with the pet food industry assert that the status quo is adequate and safe. Recently, pet food from various American brands that was imported into Hong Kong from the USA was found to have alarming levels of carcinogenic aflatoxin B1 and the toxic adulterant melamine, the same one responsible for the global recalls of 2007.

As an industry, are we victims of our own early progress - trapped in an outdated paradigm that we have created and from which breaking connections would be very difficult?

A well known example of this trap is that of countries stifled by early progress in communications that are “leapfrogged” by countries moving directly from having no telephones at all to having advanced cellular technology, bypassing copper wire, and its limitations altogether. It would appear the multi-national food companies that dominate the pet food industry are quite tied to the notion of feeding pets the by-products of our own food production. They may, in fact, cling to it even as an emerging methodology proves promising, perhaps at the expense of the health of our pets. Many of these companies employ veterinarians and specialists who are unable to see past their frame of reference, standing by the “quality” of the products their companies produce in the face of the pages of evidence presented in this report. The question is will pet parents, and possibly the FDA, have the will to force changes? At the moment it would appear they do.

The information in this report is intended to provide a broad, objective, and evidence based outlook at the current structure of the pet food industry, its possible impact on pets’ health, pet owner demands, available feeding modalities, and novel research on the use of feed grade vs. USDA inspected, approved, and certified ingredients in pet food.

Current situation: FDA Amendments Act of 2007

The Food & Drug Administration Amendments Act of 2007 (FDAAA) calls for the FDA to establish new feed ingredient standards, which will ultimately be used in pet food. The FDA feels “the AAFCO process ultimately falls short” and that “the majority of ingredients that are included in the AAFCO ‘official publication’ are neither approved food additives nor are they generally recognized as safe (GRAS).”

The AFIA has recently published a one-page call to action recruiting ally organizations in hopes of avoiding an FDA legislative solution, citing current feed standards have been “safely used for years.”

At the same time, consumer demands within the pet food industry are changing, pet food sales are increasing and companies are remaining highly profitable, with most of the growth among premium boutique kibble brands claiming to have health advantages over their traditional counterparts. Some pet owners and veterinarians are increasingly seeking feeding options that are alternative to kibble or cans for various reasons, citing anecdotal benefits, but there remains an unresolved debate among veterinarians, veterinary nutritionists, food scientists, and the public surrounding the potential benefits and dangers of novel feeding modalities for pets. The variety of options available, lack of objective research and information, as well as conflicting opinions among consumers and veterinary professionals have made it difficult for pet owners to make educated choices on nutrition. Despite an apparent lack of scientific investigation in alternative modalities of feeding, the popularity of these foods has continued to increase.

Resources


Current feeding modalities

While there are overlaps among today’s methods of feeding, mainstream commercial feeding modalities that currently exist in pet nutrition can be broken up into the following broad categories:

Complete and balanced, standard commercial processed pet food that is made with feed grade (animal grade) ingredients not fit for human consumption, but deemed suitable for pets. They include extruded dry and canned feed, and the currently popular grain-free (low carb) diets.

Complete and balanced, fresh prepared commercial whole pet foods using USDA certified meats and ingredients fit for human consumption that have been scientifically balanced for pets. These may include homemade pet diets and recipes if they are properly formulated and balanced.

Raw commercial or homemade diets. Commercial versions are primarily formulated with feed grade (animal grade) meats and animal parts usually rejected from the production of food for people and deemed not fit for human consumption.

Standard commercial pet foods

The commercial pet food industry, as it exists today, is largely consolidated and consists primarily of extruded, processed dry food and processed canned food, formulated from feed grade ingredients. Grain-free and low carbohydrate kibbles and cans are a subcategory of this group. Feed grade ingredients mean that they cannot be used for human consumption, as they have not been deemed safe for people. Mars Petcare Inc. ($16.7 billion revenue, 2012) and Nestle Purina Petcare ($16.2 billion revenue, 2012) dominate the pet feed market. They manufacture the majority of commercial pet feeds sold in the USA and exported globally:¹

Mars Petcare Inc.®
Nestle Purina Petcare®
Procter and Gamble®
(recently acquired by Mars Petcare Inc.)
Colgate Palmolive®
Del Monte®
(now Big Heart Pet Brands)

Del Monte sold its pet food operations in February 2014 to a subsidiary of itself (Del Monte Pacific) and then changed the name of the pet food operations to Big Heart Pet Brands.²³ Corporate name changes are very uncommon for successful, long-established, profitable companies. In business, the strategic decision to change your name is not taken lightly, and is usually reserved as a last resort - for example in the midst of a public relations crisis, or similar recovery effort. Perhaps the best and most recent example of this was in January 2003 when Phillip Morris announced that it would change the name of its tobacco operations to Altria Group, and keep running its consumer food group as Kraft Foods.

According to USA Today, “the move was immediately criticized.” The article cited comments that the name change was “a PR maneuver meant to distance the corporation’s image from its deadly business practices.”⁴

Resources

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Additionally, on April 9, 2014, it was announced that Procter and Gamble, a well-known consumer foods company, would be selling its pet food division to Mars Petcare for $2.9 billion.

Despite the various brand names and illusion of variety, the above five companies supply the overwhelming majority of the commercial pet feed (kibbles and canned) sold in the USA. In addition, most of these companies share a few suppliers and therefore almost all the kibble and cans made in the USA are made from essentially the same feed ingredients, as was evident in the global recall of 2007. The cause of the recalls was sourced to a single large supplier of feed ingredients to the industry: Menu Foods. The recall affected over 180 brands of commercial pet food and killed thousands of pets. The cause was determined to be linked to feed adulterated with melamine, an industrial chemical that will register as protein in tests, but is actually a chemical used to make plastic consumer goods and is also known to cause renal failure and urinary crystals in pets.

For this reason among others, many veterinary nutritionists agree that all kibble diets made from larger manufacturers are essentially formulated the same. They warn that higher prices between these brands do not always equate to higher quality, and that some commercial pet feeds claiming to be premium may actually only be premium in price.

The notion that all commercial kibbled and canned diets are essentially the same seems to be supported by a recent high profile lawsuit (and similar complaints) filed against a smaller but very popular player in the industry, Blue.

The FDA established action levels for food animals but admits that these levels may not always be appropriate for pets, since pets are not used for food animals. The FDA stated in a document dated April 21, 2008,

“Feed” ingredients are raw materials that most commercial pet food companies use to make their food, but that would not be allowed in food intended for human consumption. They are not considered safe to eat by humans. Despite the term pet “food,” feed is not food, since “feed can include ‘material from diseased animals’ or ‘contamination by filth’ or ‘contamination by industrial chemicals.’”

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“There appears to be little or no difference between ingredients intended for use in pet foods and those intended for use in other animal foods and feeds. Therefore, the agency believes the most appropriate course of action is to develop ingredient standards and definitions and processing standards for all animal feeds, including pet food.”

Food animals are not expected to live 15-20 years, and usually the goal in feeding food production animals is to convert them to slaughter weight as efficiently and quickly as possible. As such, allowances in feed may include levels of contaminants that are deleterious long term.

Currently, pet food manufacturers can voluntarily create a HACCP plan to routinely screen their foods for toxins. If they have an established HACCP plan, the FDA will enforce the standards that the company establishes for itself. If they do not have a HACCP plan, however, there is little or no enforcement.

Recently, some large pet food companies have boasted a more responsible approach and claim to have implemented adequate testing through a HACCP plan. As part of the research for this report, two of the largest manufacturers were contacted and were asked to provide the details of the mycotoxin assay used for testing and the levels deemed allowable in their plants. Various representatives of both companies responded similarly: the details are “proprietary.” Apparently, they

**Feed vs food ingredients**

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**Resources**


are not obligated to (or may be unwilling to) disclose the details of their quality control plan to the public, and may simply respond to any inquiries with the excuse that the information is proprietary (electronic mail correspondence on file at JustFoodForDogs LLC). Proprietary usually means "company secrets," and the vets and nutritionists employed by the companies may not even know this information.

In addition, pet feed manufacturers should also be monitoring for the presence of melamine in their ingredients. To date, the FDA has not mandated melamine testing as a minimum requirement in animal feeds. Feed by-product ingredients, as defined by AAFCO, can also be another concern. Feed by-products often come from rendered animal carcasses or body parts. Feed by-products are not intended for human consumption, and by their nature may come from diseased, contaminated, or otherwise condemned food animals. While the rendering process is meant to decontaminate the feed ingredient from most pathogens, they may not always be completely decontaminated. Some veterinary nutritionists, who may represent some of these companies in one way or another, argue that animal by-products have been irrationally demonized by the public and through the marketing of brands that have pledged not to use them. They tend to make this point in an effort to discredit any smaller brands that claim to exclude by-products from their formulations. These nutritionists make the claim that heart, liver, kidney, and tripe are all common by-products consumed by people, thus there is no reason to be put off by them when using them in pet feed. While it is true that humans do consume chicken liver, beef liver, beef heart, tripe, etc., the point made by these veterinarians is flawed because the quality of production is high for these items when they are meant for human consumption; they go through a rigorous USDA process of certification that includes high standards of slaughter, handling, transport, and storing. Feed grade by-products and rendered by-products for use in pet feed and as defined by AAFCO on the other hand, are not safe for human consumption and therefore should not be used in pet food.

USDA inspected, approved, and certified ingredients undergo the highest quality control and food production in the USA, which ensure stricter testing for the toxins regularly found in the lower quality feed standard. The inspection and approval program is considered the most advanced and the strictest process of food production in the world. It is also important to note, however, that not all human foods are necessarily safe for dogs and cats, and for this reason recipes and formulations should only be considered when they come from a source with expertise and knowledge in animal nutrition. For instance, both grapes and raisins are toxic to dogs, as well as a number of other common food products and sweeteners commonly used in human diets.

**FDA action levels**

The FDA establishes "action levels," which are recommendations on maximum allowable toxin contamination for food and feed. Action levels do not ensure compliance; instead they "represent limits at or above which FDA will take legal action to remove products from the market." Many of the action levels established are intended to protect people in the human food chain and pets are ill defined, existing in this grey area, as they are neither food production animals or people. Additional allowances of contamination with toxins may be established for pet feed ingredients compared to food fit for humans through loop holes established in the FDA's official Compliance Policy:

**Compliance Policy CPG Sec. 675.100 Diversion of Contaminated Food for Animal Use** states “FDA does not object to the diversion of contaminated food for animal feed adulterated with rodent, roach, or bird excreta.”

**Compliance Policy CPG Sec. 675.200 Diversion of Adulterated Food to Acceptable Animal Feed Use** states, “The [FDA] will consider the requests for diversion of food considered adulterated for human use in all situations where the diverted food will be acceptable for its intended animal food use. Such situations may include:

a. Pesticide contamination in excess of the permitted tolerance or action level.
b. Pesticide contamination where the pesticide involved is unapproved for use on a food or feed commodity.

c. Contamination by industrial chemicals.

d. Contamination by natural toxicants.

e. Contamination by filth.

f. Microbiological contamination.

g. Over tolerance or unpermitted drug residues.

Compliance Policy “CPG Sec. 690.300 Canned Pet Food” states “Pet food consisting of material from diseased animals or animals which have died otherwise than by slaughter, which is in violation of 402(a)(5) will not ordinarily be actionable, if it is not otherwise in violation of the law. It will be considered fit for animal consumption.”

The above statements specifically empower pet feed manufacturers to make pet “food” using “material from diseased animals” or ingredients that include “contamination by filth” or “contamination by industrial chemicals” in their formulations without threat of action or without being “in violation of the law.” In contrast, none of these allowances are made in the production of food intended for human consumption.

JustFoodForDogs uses no feed ingredients in any of our meals; as such we are proudly introducing a “No Feed Grade Ingredients” statement on our labels. We only use food ingredients certified by the USDA and/or FDA approved for human consumption. We recommend you look for this statement, or a similar wording, on any pet food you consider purchasing:

Melamine

Melamine, the industrial chemical responsible for the kidney failure observed during the 2007 global recalls and credited for the same problem in the Chinese human food chain in 2008,¹ is still not a mandated quality control test for pet food manufacturers. The consequence of which was evident in April 2014 when a Hong Kong consumer protection group found traces of melamine in pet food imported from the USA.²

Melamine testing is, however, now required by the USDA in processed foods approved for human consumption, due to the extensive scientific evidence that exists proving that it is toxic:

In 2008, The Journal of the American Veterinary Medical Association confirmed that 70 pets died of renal disease due to necrosis (dying) of the kidneys linked to melamine-tainted food during the recall.³

Also in 2008, a study published in the Journal of Veterinary Pathology analyzed kidney samples from a dead Parson Russell Terrier, a dead Burmese Mountain Dog, and a dead mixed breed dog suspected to have died from contaminated food. They confirmed the deaths were linked to illnesses caused by melamine from commercial pet food.⁴

The Journal of Toxicological Sciences also published a paper in 2008 citing a conclusive link between melamine contaminated feed ingredients and the outbreak of renal toxicity during the recall.⁵

Resources


In 2009, *The Journal of Interdisciplinary Toxicology* described two examples where melamine was found in two feed (animal grade) products, and took it one step further to warn of possible human food contamination.\(^1\)

In 2010, *The Journal of Medical Toxicology* looked at 278 pets that died during the outbreak, confirmed the connection, and found that those that were weak or debilitated (sick or aging pets) were the most vulnerable.\(^2\)

Another 2010 study in the *Journal of Veterinary Medical Science* analyzed the death of two young dogs in Treviso, Italy. The study concluded these dogs died from a similar cause as those who died during the 2007 recall – melamine toxicity from pet food.\(^3\)

**Ongoing concerns of melamine contamination and testing**

The 2014 Hong Kong consumer tests demonstrated that concerns about melamine in pet food remain unresolved. The Hong Kong story put into question the premium quality of once highly regarded USA imported pet feed and American brands.\(^4\)

The threat of the melamine entering the food chain has been a concern for some time, thus food approved for human consumption by the USDA now requires testing for melamine.

The most famous publication addressing the incident of melamine toxicity in humans is a 2009 study in the *Journal of the American Society of Nephrology* that essentially “discovered” melamine as a potential hazard for humans from human cases in China.\(^5\)

In 2009, a Canadian study published in the journal *Paediatrics and Child Health* expressed concerns of exposure of Canadian children to melamine in processed baby foods.\(^6\) Also in 2009, the *Journal of Environmental Health Perspectives* published a concern about melamine in processed human foods, including infant formula.\(^8\)

In 2009, the above studies prompted the FDA to establish maximum residue limits (MRL) and mandatory melamine testing in human foods, but not pet foods.\(^9\)

In 2010, the *Journal of Medical Toxicology* outlined an outbreak in infants, and cited a similar kidney disease process as the one linked to the melamine recalls in pets. The study also asserted that the FDA has established melamine testing in foods certified for human consumption.\(^10\)

A similar concern was published in the same year in a review written in the *Journal of Emerging Health Threats*.\(^11\)

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Feasibility of melamine testing in feed ingredients used for pet food

According to published studies, testing for melamine in pet feed is straightforward and inexpensive.\(^1\)\(^2\)\(^3\)\(^4\)

There are various methods of testing, and many of them have been developed to be quick and accurate. Some larger companies claim they already perform voluntary testing; however there is no official government oversight or regulation unless they voluntarily incorporate the details of the testing into their HACCP plans. Most manufacturers prefer to keep testing voluntary and avoid including melamine testing into their HACCP plan.

Salmonella and other bacteria

In addition to chemical toxins, there are bacteria that sometimes get into pet foods. *Salmonella*, *Campylobacter*, *E. coli*, and *Clostridium* are important bacteria that have been associated with commercial pet feeds. Dried kibbled pet feeds are at higher risk for *Salmonella* contamination. While the animals eating the food may not become sick with salmonellosis, they can shed the infectious organisms into their home environments, potentially exposing and infecting the people with whom they live. A playful lick from a puppy could cause illness in a child. Children and the elderly are at greater risk for harmful consequences from *Salmonella* infection.

The FDA has recently released a safety video focusing on bacterial contamination and other toxins in dry kibble.\(^5\)

The video references the case of a specific commercial pet food plant that was also the subject of a March 2014 study published in the *Journal of the American Veterinary Medical Association*, which details how at least 53 known human illnesses were linked to commercial pet foods made at this plant in 2012.\(^6\) A class action lawsuit linked to this outbreak was recently settled.\(^7\) Both the FDA and American Veterinary Medical Association (AVMA) have consistently warned about the threat of *Salmonella, E. coli*, and *Campylobacter* in commercial pet feeds, particularly in raw commercial diets.\(^8\)\(^9\)

Carcinogens and other toxins

Some research suggests that some carcinogens that are tightly controlled and regulated in food produced for human consumption may not be as well controlled in feed used for pet food. In 2003, a study published in *Mutation Research* hypothesized that there is a connection between chemicals found in commercial pet food and cancer in animals that eat these foods.\(^10\) In addition, various smaller threats have been identified in stored commercial dry pet food including molds and storage mites. It is thought these may be the source of some allergic reactions and skin lesions in dogs.\(^11\) Aflatoxin B1, the contaminant found in the recent April 2014 Hong Kong report, is a known carcinogen.

Resources

**Mycotoxins**

The risk of mycotoxin contamination in grains was first realized in the 1960s when 100,000 turkeys intended for human consumption died from an unknown cause from "turkey x disease"; it was later established the toxin was aflatoxin.¹ Mycotoxins are unavoidable contaminants of grains and crops, but since their discovery have been effectively controlled in the human food industry through careful testing, storage, and transport. In contrast, less care in testing, storage, and transport is thought to be part of the reason that mycotoxins are more prevalent in finished processed pet feeds made with feed grade grains. Pet food companies are trusted to control these toxins and to keep them below sub-lethal levels but there are few legally defined processes to ensure they are meeting these expectations and virtually no government enforcement.

Mycotoxins (or their exclusion) may be one of the reasons behind the anecdotal benefits reported in Grain Free pet foods.

As early as 1993, concerns of toxins in feed (animal grade) ingredients were referenced. At that time, it was reported that the FDA would continue to monitor the issue.²

In 1997, the journal of Food Additives and Contaminants reported a specific concern regarding mycotoxins in pet food, when it was established that low levels of them could be found in feed grade ingredients.³

A study published in the Journal of Food Protection in 2001 cited concerns regarding the identification of various fungi (the source of mycotoxins) in commercial pet foods imported from Argentina and warned about the “risk for animal health.”⁴

A 2006 study published in the Journal of Agricultural and Food Chemistry looked at mycotoxins in pet feed around the world and concluded that contamination can lead to chronic effects on the health of pets.⁵

In 2007, the International Journal of Food Microbiology published a study that stated “mycotoxin contamination in pet food poses a serious health threat to pets,” and listed them: aflatoxins, ochratoxins, trichothecenes, zearalenone, fumonisins and fusaric acid; all of which have been found in feed ingredients for pets and are linked to acute toxicity and chronic health problems.⁶

A 2008 study published in the Journal of Animal Physiology and Animal Nutrition found high levels of mycotoxins in the raw ingredients used for pet food in Brazil.⁷

A 2010 study in the Journal of Mycotoxin Research tested 26 commercial dog foods for a variety of mycotoxins and found sub-lethal levels that were concerning; it was determined that long-term exposure to them could pose chronic health risks.⁸

A 2012 study published in the Journal of Toxins found concerning levels of multiple mycotoxins in European manufactured pet food despite some regulatory oversight through the EU.⁹

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Aflatoxin is a secondary metabolite of a mold that sometimes infects grains, corn is a common grain affected by aflatoxin; it is one of many mycotoxins but it is currently the one that is the greatest focus of the pet feed industry and one where some action levels have been set. Two molds, Aspergillus flavus and Aspergillus parasiticus produce aflatoxin. These molds can infect corn while it’s growing as well as while it is in storage after being harvested. Even after any visible evidence is gone, the aflatoxin may still be present in grain; therefore, manufacturers often screen for aflatoxin before using corn in feed. Unfortunately, in a big shipment of corn, aflatoxin will exist hidden in “hot pockets” and may not be easily found; testing can sometimes miss it.

Representatives of pet feed manufacturers will say that contamination with aflatoxin is unavoidable, and that actions levels set by the FDA for aflatoxin are the same for food and feed: 20 ppb (parts per billion). While it is true that aflatoxin contamination is unavoidable, proper testing, storage, and transport is well defined in the production of USDA/FDA ingredients approved for human consumption, but not as well enforced for pet feed. FDA action levels for aflatoxin in feed grade ingredients for food animals, depending on the species and use, can range from 20 ppb to 300 ppb. By comparison, the FDA action levels for foods intended for human consumption are maxed out to 20 ppb.

Aflatoxin is a carcinogen in both humans and animals. It also is known to cause liver disease in dogs; therefore it should be avoided in pet foods. Even at levels under the maximum allowable 20 ppb, chronic exposure to aflatoxins can be a health concern. Pet feed manufacturers that include corn in their formulations should routinely test both the corn used in the feed as well as the feed as fed for total aflatoxin concentration. They should also test for a separate aflatoxin metabolite called aflatoxin B1, the contaminant found in the Hong Kong 2014 testing. Unfortunately, there is not much oversight or enforcement in this regard within the industry.

It is important to note that there are about a hundred known mycotoxins, and thousands more are expected, but have yet to be identified. The trichothecene mycotoxins are sometimes found in grains ranging from barley and wheat to oats and corn, and testing protocols for it in pet feeds are not well defined. The trichothecenes are immunosuppressive and can have harmful effects with repeat exposures. A different fungus called Fusarium spp produces these mycotoxins.

Grain-free and low carbohydrate

Some of the perceived adverse health effects resulting from the chronic ingestion of the above mycotoxins and contaminants may be partly to blame for the demonization of grains in pet food. Many newer, independent brands became successful overnight by simply marketing their formulation as “Grain Free” or “Gluten Free.” Some commercial kibble and can companies claim carbohydrates to be unnecessary “fillers” and have trademarked new marketing labels, such as “biologically appropriate to,” claiming dogs must be fed like their wolf counterparts. There is no documented literature to support that pets do nutritionally better on grain free or low carb diets, and in fact research published in Nature suggests that dogs have evolved away from a starch-rich diet. The researchers went on to hypothesize that dogs adapted to process carbohydrates in their nutrition as part of their domestication process, similar to how they changed their behavior patterns to more closely match human body language. The authors surmise that in fact, these differences are what make dogs distinct from wolves. Nevertheless, there is anecdotal evidence reported by pet parents and some veterinarians that pets fed a grain free kibble vs a standard kibble may receive some benefits.

It is important to remember that it is the mycotoxins and melamine that are toxic and not grains. It is possible that the anecdotal benefits reported by pet parents are related to the exclusion of mycotoxins found in feed grade grains, and not specifically grains. Grains can be nutritious additions to a pet food formulation as they provide calories as carbohydrates, which have a nutritional value of 3.0 to 4.0 kcals (calories) of energy per gram. Dogs and cats can only get their calories from three nutrients: fat, protein, or carbohydrates; grains help balance the diet so that less metabolizable energy must be obtained from fat and protein alone. Without carbohydrates or grains as an option for balancing some diets, some pets could become overweight or acquire pancreatitis from high fat diets, or may develop urinary crystals, stones, or other problems from high protein diets.

Resources

While this will not always happen, and many pets may thrive on low carb diets, others will not and carbohydrates must remain an integral element of veterinary nutrition. One basic example is the need to create a formulation with a moderate protein restriction and/or low fat for a dog or cat with renal insufficiency and pancreatitis. This formulation becomes very difficult to achieve without carbohydrates.

Mycotoxins and contaminants are more adequately controlled in grains and crops used for human consumption. Thus, the elimination of grains altogether from pet food formulations is not necessary if the grains being used come from a high quality USDA and FDA inspected and approved source and are fit for human consumption.

In fact, the use of some high quality carbohydrates and grains as a balance of calories is still likely to be the best long-term approach to general nutrition, especially in dogs.

Current challenges to the progress of the FDAAA of 2007

For all the reasons presented here, the FDA has been working on stricter rules for the pet food industry since the recall;¹ progress, however, has been slow. According to a recent market report, the global pet food ingredient (feed) industry is worth over $34 billion dollars.² Nevertheless, the FDA has deemed that many currently approved ingredients in commercial pet food are not “GRAS” (generally recognized as safe),³ and they are currently completing an analysis on the ingredients allowed in pet food. The FDA’s assessment that feed definitions are inadequate is being challenged by the American Feed Industry Association (AFIA). The AFIA, and some other associated groups connected to the pet food industry are currently lobbying Congress, the FDA, and other pet industry organizations in the hopes of avoiding any new laws on the issue.⁴

In addition, the veterinary nutrition academic system is not currently structured to objectively investigate the health impact of extruded, processed pet foods and their manufacture on our pets. Two large companies make up over 60% of the $50 billion market and dominate the pet food industry; they have become very profitable making pet “foods” using feed ingredients. These same large companies fund and support virtually every veterinary nutrition residency specialty in US veterinary schools and abroad. Waltham⁵ (Royal Canin⁶/Mars) and Hills Pet Nutrition Inc.⁷ (Colgate Palmolive), support many nutritional education programs in veterinary schools around the world, sometimes even in the same school.⁵⁶ Nestle Purina Petcare also provides funding for residencies.⁷ Despite the pages of evidence presented here, as well as the recent comments about AAFCO feed definitions by the FDA to the contrary, the overall message of the American College of Veterinary Nutrition (ACVN) is that pet foods made with feed ingredients are generally safe.⁸ In a document posted as an official statement on the recalls, the ACVN assures the public that only 1% of food on the market was implicated. They go on to imply that any parties questioning the ingredients used in commercial pet food are engaging in “wild speculation about the safety and wholesomeness of commercial pet foods in general” and are promoting “mistrust of both the industry and government oversight of the industry.” The ACVN ascertains that those questioning the current system may be using the events of the 2007 recall to “advance their own causes or agendas,”⁹ and they do not express any intention to research the matter. They also cite the “long history of the industry’s provisions of safe and nutritious products to the consumer” and sponsor a column in the Journal of the American Veterinary Medical Association titled Timely Topics in Nutrition that consistently warns against alternate modalities of feeding pets. It would seem the perception of the ACVN on the safety of commercially manufactured pet feeds is in direct contrast to the perception of pet parents and some veterinarians.

Resources

Another organization focusing on animal and veterinary nutrition is the American Academy of Veterinary Nutrition (AAVN), which works in collaboration with the ACVN. The current vice president of the organization is also an employee of Royal Canin/Mars. Over the last year, electronic discussions among this group questioning the safety of commercial pet foods made with feed ingredients have not been well received and have led to repeated requests by the executive committee to change the subject matter of the discussions (electronic communications on file JustFoodForDogs LLC). It would seem this organization, as a whole, is also currently unwilling to review the situation objectively.

If the very organizations specializing in veterinary nutrition are seemingly unwilling to, or do not find the need to, investigate recurrent concerns on the mass production of commercial, extruded diets made with feed ingredients, then to whom do veterinarians, pet parents, and other professionals go with their concerns?

The research usually presented by diplomats of the ACVN has consistently attempted to discredit any feeding modalities that are not traditional extruded kibble and cans made with feed ingredients, claiming it is still the safest way to feed our pets, and offering few reputable options as alternatives. They consistently cite a lack of evidence to support other feeding modalities including the use of higher quality ingredients, such as USDA certified meats and fresh whole foods approved for human consumption.

To date, the academic and political structure described above may have limited objective investigation into alternative feeding modalities for pets and limited research on the use of fresh, whole ingredients (fit for human consumption) in pet food. However, the growth of small, independent companies wanting to evaluate the merits of these diets is now fueling new investigations.

In a ground breaking study, independent university research completed on all five JustFoodForDogs daily diets found measurable differences in blood parameters on dogs fed whole food diets made with USDA certified meats and ingredients approved for human consumption over kibble. Dogs eating JFFD experienced a boost in immune function, also found significantly higher digestibility scores for raw whole food diets when compared to kibble, and in the study investigating feeding modalities in domestic cats also found significantly higher digestibility scores for raw whole food diets when compared to kibble. In the same study they found there was no significant difference in digestibility when comparing between the feeding of the raw whole food ingredients and the same ingredients after they were lightly cooked to 71°C (160°F).

Raw feed diets usually include a combination of uncooked meat from animals, fish, or poultry, however there is no mandated assurance of the quality or grade of the meat. When commercially manufactured, these diets are not usually produced using meats that are USDA certified and approved for humans, which means they could include rejected carcasses or medicated animals. This meat could include “4D meat” which is defined as meat derived from dying, diseased, disabled and dead livestock that has been deemed unfit for human consumption.

Resources

Some manufacturers will hide the fact their meat is not fit for humans and say “USA meat” or “meat from a USDA facility.” This wording is misleading as only “USDA certified” meats has any legal meaning.

Ingredients usually include flesh (muscle), internal organs, blended body parts and bones. They may also include untreated milk, or uncooked eggs. Despite their popularity among the public, veterinary nutritionists consistently warn against the risks of raw diets, some of the concerns are summarized here:

**Complete and balanced**

While many who feed raw diets report achieving a complete and balanced meal consistently, studies have revealed important concerns about the potential for nutritional imbalances when raw diets are not consistently formulated properly.  

**Contamination with pathogens**

Raw meat can be contaminated with a variety of pathogens that can harm both animals and humans. As stated, most meat used in commercially produced raw diets are not USDA certified, inspected, and approved; thus they may acquire increased bacterial contamination from the hide, feathers, slaughter, evisceration, or during processing and packing. Salmonella spp and E. coli are of particular concern.

**Possible GI injury**

Given the inclusion of raw animal parts, raw diets may contain bones and bone fragments. These should be limited or avoided as they have been implicated in hazards to the pets that eat them, including: tooth fractures, injury and perforation of the esophagus, stomach, small intestine, or colon.

While the above risks have been documented, users of raw diets report many anecdotal benefits that they claim outweigh some of the risks. One explanation for these benefits may be the higher digestibility of raw compared to extruded diets.

There may be some benefits to feeding raw diets over standard commercial kibble or cans, however a high level of expertise and knowledge is required and there are some risks. For this reason we cannot recommend raw feeding as a mainstream form of pet nutrition. If you choose a raw diet for your pet, it is essential that you use only commercial preparations made with USDA certified meats and ingredients intended for human consumption and careful food handling practices. We recommend only considering preparations that have passed AAFCO feeding trials. It should be noted that even meat certified by the USDA is not intended to be consumed raw; it is assumed that a small amount of contamination may be acquired during handling and transport and as such it is intended to be destroyed during light cooking.

**Raw vs. Cooked Whole Food**

Research supports that there are benefits to real ingredients over extruded diets and there are documented risks in feeding extruded kibble diets, thus whole food diets are generally recommended over processed kibble. Since research shows there are no significant differences in digestibility between raw and cooked diets, whereas there may be some potential hazards, it is our recommendation that food for pets be formulated using lightly cooked, USDA certified, inspected and approved ingredients fit for human consumption, carefully prepared, de-boned, handled at minimum safe temperatures, and lightly cooked to avoid unwanted contamination.

**4D Raw Meat**

While officially considered “subject to regulatory action” if shipped across state lines in its raw form, the loopholes discussed allow 4D meat to be used in pet food without legal consequences. 4-D meat is particularly dangerous when used in raw feed.

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**Resources**


to salvagers for use as animal food. Meat from these carcasses is boned and the meat is packaged frozen without heat processing. The raw, frozen meat is shipped for use by pet food manufacturers. This meat may present a potential health hazard to the animals that consume it and to the people who handle it."

Important considerations in choosing a pet food company

Given the reasons outlined in this report, the lack of government oversight, and undefined testing requirements, raw ingredient quality should be the primary consideration when choosing a pet food diet. Brands that use whole food ingredients intended for human consumption are the safest. Human foods are held to higher standards for mycotoxins and other potential contaminants; whereas foods for pets made with feed ingredients are in a gray area with respect to contaminant testing.

"It is recommended that pet parents look only for foods that are formulated using whole food ingredients certified by either the USDA or FDA for human consumption.

However, ingredient quality is not the only consideration when choosing a diet. Pet parents should inquire whether the company has performed feeding trials on its diets and whether they employ veterinarians as core members of the pet food team. Veterinarians should be available for questions and be integrally involved in diet formulation, analysis, and testing, and not just serve as spokespeople. An experienced veterinarian in quality control measures, preferably a board certified veterinary toxicologist, should also be part of the team. The veterinarian team should include an adequate support staff of licensed veterinary technicians and should be responsible for designing and overseeing safety testing of ingredients and finished products (as fed), and be able to conduct quality control programs, and to design, conduct, and interpret feeding trials of their products. Diets should be produced and manufactured locally in high quality modern facilities, and no aspect of the production process should be outsourced overseas. Production plants or facilities should be open to the public, transparent, and available for visits at any time. The company should provide full typical analyses on all diets, including detailed nutritional information as well as a basic caloric breakdown.

Whitepaper conclusion

The only legally protected, federally inspected, enforced, and well-defined quality controlled process for food production in the United States is the USDA certification, inspection, and approval program established under the FDA. For this reason, the only way to ensure adequate quality control is to feed pets only food that has been made with USDA certified meats and ingredients fit for human consumption and scientifically balanced for their needs. There are documented benefits of whole foods in health and nutrition\(^1\) and the 2010 USDA Dietary Guidelines for Americans recommends acquiring as much nutrition as possible from whole foods and not processed foods or supplementation.\(^2\)

Given the information presented in this report, it is our conclusion and position that the current structure of the pet food industry needs updating in order to meet the demands of pet parents for healthy nutrition for our pet population. While the details of such a program are outside the scope and reach of the authors, there is clearly a need for the federal government to establish increased oversight on the industry. Ingredient definitions should be amended, rules and regulations regarding testing should be strengthened, and higher ingredients standards for pet food should be set and enforced. It would be imprudent to conclude this report without offering at least a basic solution framework, offered below. We recommend an official, legally defined grading system be established for pet food so that pet parents can make their decisions based on legally defined merit, and not marketing claims.

A simple example of pet food (as fed) grade definitions is offered below:
I. **Grade A (As Fed) Pet Food** – Fresh, prepared, minimally processed pet food made with at least 95% of the ingredients inspected, approved, and/or certified by the USDA for human consumption. Formulations shall be nutritionally balanced and tested using AAFCO protocols to be nutritionally adequate for pets. This is the highest standard of nutrition available for pets.

II. **Grade B (As Fed) Pet Food** – Food for pets either made with less than 95% of the ingredients inspected, approved, and/or certified by the USDA for human consumption, or not yet tested using AAFCO feeding protocols, but expected to meet established nutritional profiles. Other criteria may be set, such as processing and production methods.

III. **Grade C (As Fed) Pet Feed** – Extruded and processed dry and canned pet feed, similar to how it exist today, but in compliance with yet to be established and improved feed ingredient definitions for pets. Pet feed would be deemed Grade C if it is made with 50% or more of the ingredients by dry weight from feed grade ingredients. It is the opinion of the authors that this quality of inexpensive pet feed is essential in order to maintain pet ownership and the human animal bond. However, this quality should be legally defined, disclosed, and properly labeled, and so that the consumer may make an educated and informed choice in their pet nutrition.

IV. **Grade D (As Fed) Pet Feed** – Until the system can be improved, the authors categorize any pet feeds made in the current structure, using currently defined AAFCO feed ingredients, as Grade D Pet Feed. It is recommended that until ingredient standards can be updated, these pet feeds include a disclaimer on the label, an example of which is provided below:

“The ingredients used to make this formulation may not be considered GRAS (Generally Recognized as Safe) by the FDA.”

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**Resources**


JustFood ForDogs.
It All Starts With Nutrition.

Newport Beach Location:
500 W. Coast Hwy., Newport Beach CA 92663

West Hollywood Location:
7870 Santa Monica Blvd., West Hollywood CA 90046

Sherman Oaks Location (Opening Summer 2014):
13900 Ventura Blvd., Sherman Oaks CA 91423