



Association for Truth in Pet Food  
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## The Failed Pet Food Regulatory System in the United States



Walk into any pet store across the United States and you'll witness pet owners carefully scanning pet food labels with worried looks on their faces. They wonder...**which one is safe?**

Unfortunately, U.S. pet owners are provided with no assurances. They are at the mercy of a broken pet food regulatory system that fails to enforce law and fails to provide pet owners pertinent information to understand what they are feeding their pet(s).

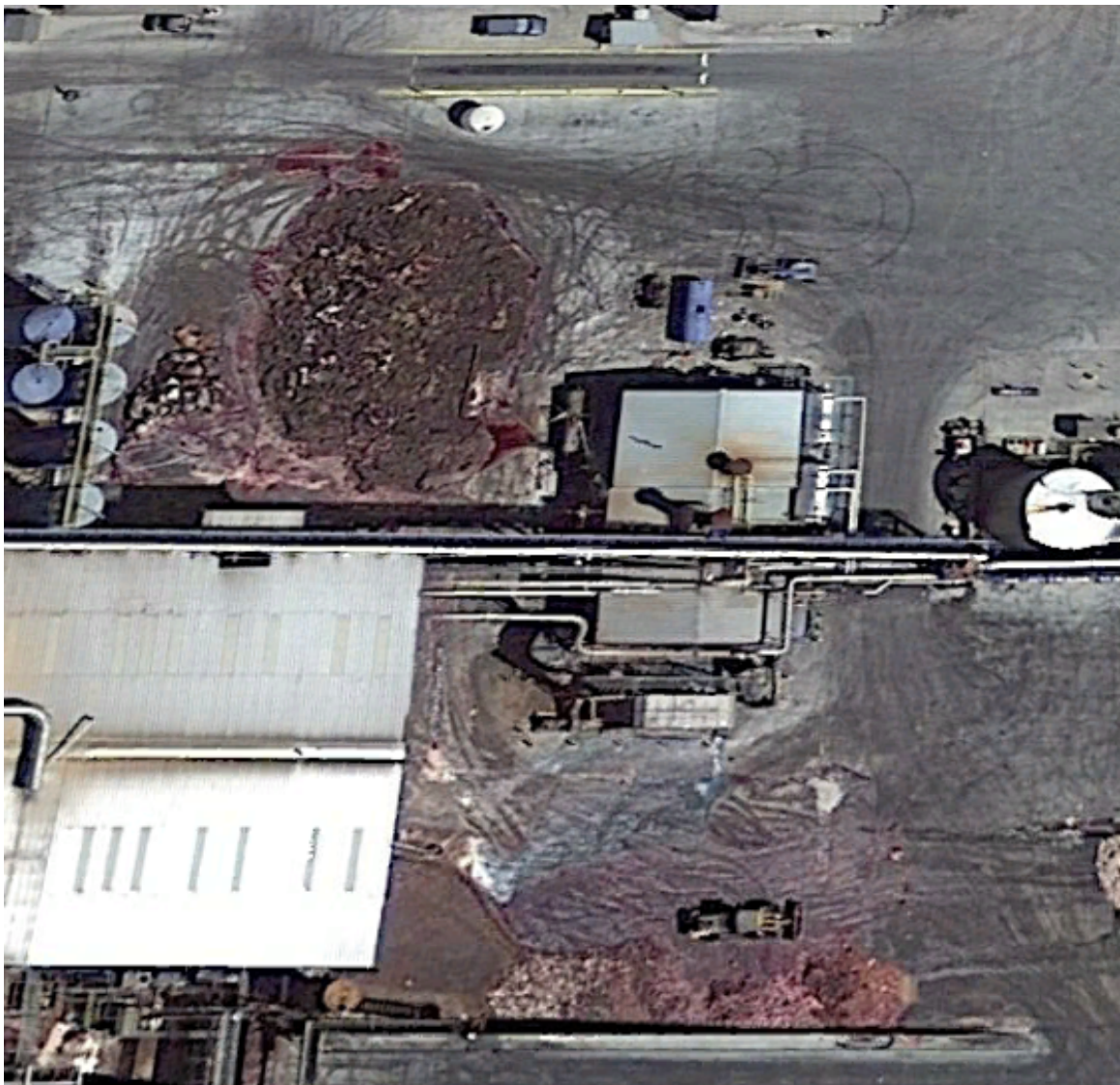
The current system of regulation of pet food must be promptly repaired.

## Lawlessness

Perhaps the most significant concern in pet food today is the confirmation the FDA Center for Veterinary Medicine (CVM) allows pet food ingredients to violate federal law.

In April of 2019, the [FDA CVM stated](#): “we do not believe that the use of diseased animals or animals that died otherwise than by slaughter to make animal food poses a safety concern and we intend to continue to exercise enforcement discretion.”

To example the inferior (and illegal) quality of the pet food ingredients allowed by FDA’s enforcement discretion, we provide the following images obtained through Google Earth. These images evidence a small sample of U.S. rendering facilities, processors designed to heat treat potentially dangerous material with the intent of making it ‘safe’ to put back into the supply chain. Among these materials are animals euthanized with pentobarbital.



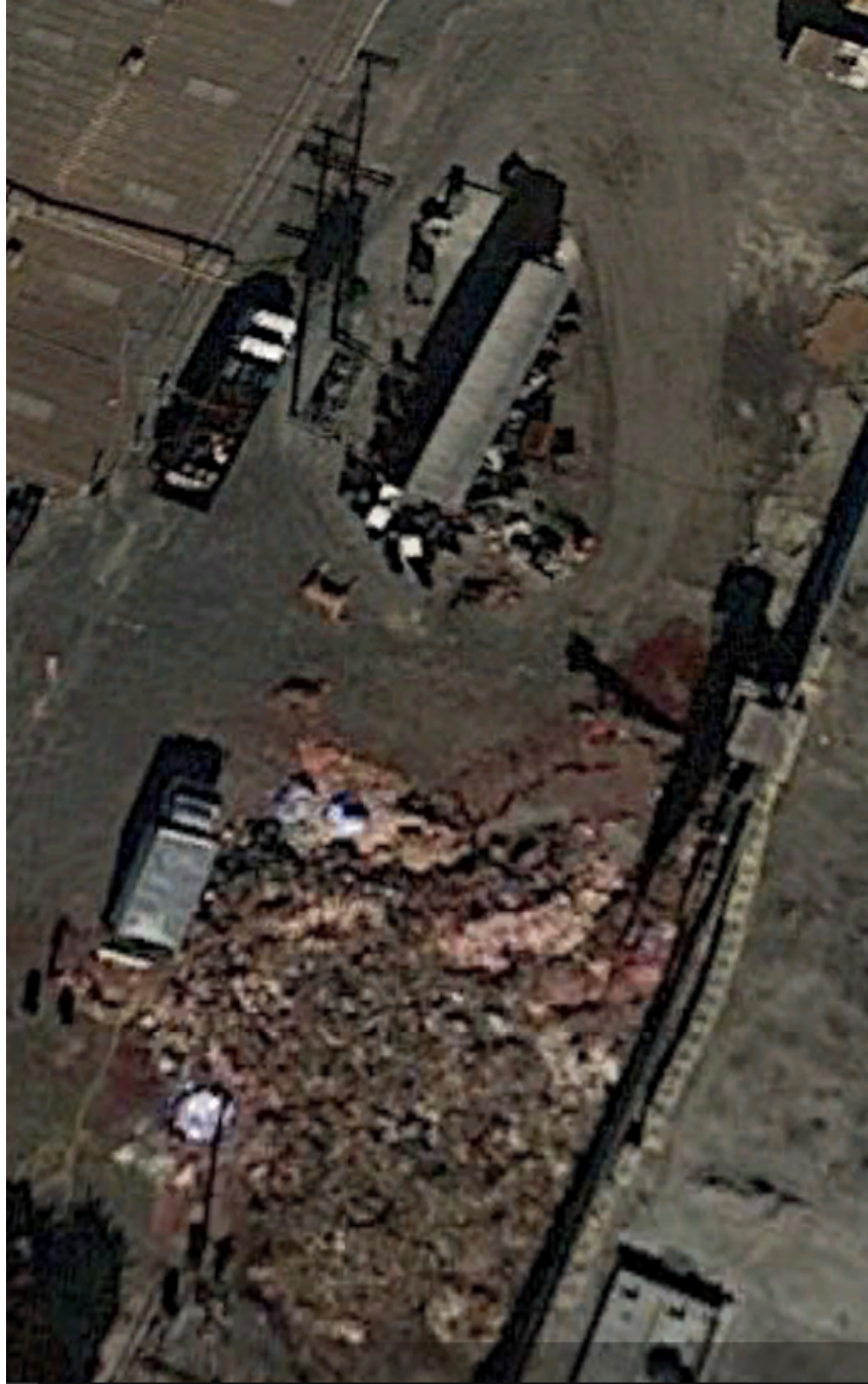
### **Darling Ingredients, California**

This image depicts materials destined for pet food production lines prior to processing (rendering).



This horrendous material is allowed by FDA to be labeled as 'food' with no warning or disclosure to the pet food consumer. The state of these facilities (bloody piles of animal parts, whole carcasses dumped on the ground) evidences a lack of concern of federal law, bacterial contamination and further decomposition of animal materials. Similar images were found at rendering facilities all across the U.S.

**West Coast Rendering  
California**



**Darling Ingredients  
Nebraska**







Valley Proteins, North Carolina



## **The FDA provided no evidence to validate the safety of these ingredients.**

In 2016 we filed a Freedom of Information Act request (Control Number: 2016-4226) with FDA asking the agency for scientific evidence confirming the safety of ingredients sourced from diseased/non-slaughtered animal materials. The FDA response to FOIA: *“After searching our files, we did not find the requested records.”* The agency provided no scientific evidence in the FOIA request to validate the safety of ingredients exemplified in the Google Earth images. The agency claims to be *“science based”* but failed to validate their industry standard/policy.

## **Confirmed violations of federal laws.**

Federal law ([Federal Food Drug and Cosmetic Act](#)) defines food as *“(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.”* Pet ‘food’ is included within this legal definition of food; *“or other animals.”*

The [Federal Food Drug and Cosmetic Act](#) defines an adulterated food as: (in part) *“(3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter.”*

The previous images of rendering facilities evidence the FDA CVM ignores repeated violations of part (3), (4), and (5) of the FD&C Act *“Adulterated Food”*, knowingly allowing adulterated materials into interstate commerce.

Other violations of federal law include the Food Safety Modernization Act *“[Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals](#)”*. The above images evidence failures of suppliers preventing decomposition of ingredients.

## **Consumers request FDA to end illegal ingredients.**

In October of 2016, pet owners submitted to FDA [Citizen Petition FDA-2016-P-3578](#) requesting the CVM to prevent *“diseased animals”* and *“animals that have died other than by slaughter”* to be processed into pet foods with no warning or disclosure to pet owners.

In April of 2019, the FDA responded:

**“we do not believe that the use of diseased animals or animals that died otherwise than by slaughter to make animal food poses a safety concern and we intend to continue to exercise enforcement discretion.”**

The Citizen Petition submitted by pet food consumers cited the following from the Federal Food Drug and Cosmetic Act (Subchapter IV Food, Sec. Definitions and Standards for Food):

“Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label.”

This federal law brings up two concerns of existing pet food regulations.

1. FDA CVM has not established definitions for pet food ingredients. All pet food ingredient definitions, labeling requirements, and nutritional requirements are owned, copyright protected, and sold by the Association of American Feed Control Officials.
2. FDA CVM and has not established any standard of quality for pet food ingredients.

Pet food ingredients having legal definitions significantly different than the same ingredients in human food could easily be considered “*optional ingredients*”. Federal law clearly explains that optional ingredients should be named on labels. However these pet food optional ingredients – including those exemplified in the images presented on pages 2 - 5 of this document – are not designated on pet food labels, preventing honesty and fair dealing in the interest of consumers.

Citizen Petition FDA-2016-P-3578 asked FDA to require disclosure of optional ingredients allowed in pet food (through FDA CVM enforcement discretion), the agency refused our request stating they did not believe transparency of pet food ingredient quality “*would help consumers to know specifically how pet food differs from human food.*”

Pet owners tried again, filing a Petition for Reconsideration evidencing the illegal nature of pet food ingredients sourced from condemned animal material, the confirmed human health risk of these illegal waste ingredients, and the significant consumer demand for transparency to quality of ingredients in their pet’s food. The FDA CVM again told consumers no, they would not enforce federal law. The agency’s response to the reconsideration request stated enforcement of law in pet food was not in the interest of justice; “***we further conclude that granting the Petition for Reconsideration would not be in the public interest and in the interest of justice.***”

There is no means for a pet owner to determine if a pet food contains ingredients sourced from diseased animals or animals that have died other than by slaughter. Ingredients sourced from euthanized (non-slaughtered or diseased) animals have been discovered in all price ranges of pet foods and numerous styles of pet foods; from economy priced to premium priced, including canned, kibble, and raw pet products.

### **USDA opinion varies dramatically from FDA opinion.**

While it is FDA CVM’s belief - without scientific evidence – that this material is safe for pets to consume, sister agency the United States Department of Agriculture disagrees. From a [2003 USDA document](#) on animal carcass disposal, this federal agency clearly acknowledges the risk to pet health from the illegal ingredients allowed in pet foods by FDA enforcement discretion.

“Because raw materials in an advanced stage of decay result in poor-quality end products, carcasses should be processed as soon as possible; if storage prior to rendering is necessary, carcasses should be refrigerated or otherwise preserved to retard decay. The cooking step of the rendering process kills most bacteria, but does not eliminate endotoxins produced by some bacteria during the decay of carcass tissue. These toxins can cause disease, and pet food manufacturers do not test their products for endotoxins.”

### **Human health risk ignored.**

An August 2020 study from [Purdue University](#) found that **1 in 10 Americans have eaten a pet food**. When we alerted FDA of this human health risk study the agency responded (bold added for emphasis):

*“Pet food and pet treats are labeled for pet consumption not human consumption. As we explained in our response to your Citizen Petition [FDA-2016-P-3578] “...as long as hazards are controlled, and the animal food is not otherwise adulterated, we do not believe that the use of diseased animals or animals that died otherwise than by slaughter to make animal food poses a safety concern...” [FDA Response, p. 5]. In addition, **we do not intend to require labeling specifically related to ingredients derived from animals that died other than by slaughter.**”*

While we understand this dangerous material needs to be properly disposed of, to dispose of it in a pet product that is labeled as “food” without disclosure to the consumer could (should) be considered a criminal offense. The pet food and rendering industries are directly permitted to commit and profit from this crime by FDA CVM and partner regulatory agencies, to dispose of adulterated material by returning it to the supply chain - marketed as a whole food product and not the product of recycling materials or the product of materials deemed unfit for consumption.

## Failure After Failure

After the 2007 pet food recall – the deadliest pet food recall in history - the Office of Inspector General (OIG) investigated the FDA’s handling of recall procedures. The OIG final report stated FDA’s “*lax adherence to its recall guidance and internal procedures and the inadequacy of some of those procedures, limited FDA’s ability to ensure that contaminated pet food was promptly removed from retailers’ shelves.*” In 2007, the FDA failed the public, and an untold number of pets died due to that recall failure.

We provide the following examples of pet food investigations evidencing the FDA CVM continues to perform incomplete recall investigations, and continues to fail pet owners.

### **Mars Petcare 2017**

Obtained through Freedom of Information Act request, in July 2017 we learned that FDA performed a follow up inspection at a Mars Petcare plant in Columbus, Ohio following a recall issued by this pet food facility months earlier. The FDA follow up inspection report stated:

#### “Inspectional Observations

1. Failure to inspect, segregate, or otherwise handle raw materials and ingredients used in manufacturing under conditions that will protect the animal food against contamination and minimize deterioration.
2. Failure to take effective measures to exclude pests from your plant and protect against contamination of animal food by pests (Discussion Item from 10/27/2016 EI).”

The 2017 inspection report included multiple pages of a “*Pest Sighting Log*” maintained by the pet food manufacturer. One page of this pest sighting log noted “*Millions of Roaches*” in the pet food plant.

The FDA stated in the inspection report: “*The failure to take adequate measure to exclude and prevent pests from the manufacturing and related areas of the firm poses a significant public health safety concern while also being a regulatory violation.*”



The FDA inspection report clearly noted this pet food manufacturer failed to protect the pet food from contamination, failed to minimize deterioration of ingredients, failed to prevent the infestation of millions of roaches on production lines, and these failures “*poses a significant public health safety concern*” – however, the FDA CVM did not issue a Warning Letter to this manufacturer and did not require the company to recall contaminated pet foods. All violations of food safety law were ignored by FDA CVM.

### **Hill’s Pet Food 2019**

On [January 31, 2019](#), Hill’s Pet Food recalled brands of canned pet food for excess vitamin D resulting in many pet illnesses and deaths. It is FDA CVM’s responsibility to properly perform a trace forward and trace backward investigation to ensure all contaminated pet food is removed from store shelves. *Trace forward* is to investigate where the contaminated pet foods went – such as to distributors and retailers. *Trace backward* is required to find the original source of the adulteration (such as an adulterated ingredient), and determine which lots of pet food contain the adulterated ingredient, then further investigate the supplier to determine if other pet food manufacturers received the adulterated ingredient.

[Two months after](#) the initial Hill’s recall was announced, 31 additional lots of dog foods were added to the recall. This second recall for the same cause of the original recall - delayed for 2 months - is evidence the FDA CVM repeated their 2007 recall failure, failing to properly trace all adulterated pet foods manufactured by Hill’s. Hundreds, perhaps thousands of dogs suffered serious illness or death due to this failed investigation.

### **Smucker’s Big Heart Brands 2019.**

In [December 2019](#), the J. M. Smucker Big Heart Brands pet food manufacturer announced a recall of Special Kitty canned cat food. Concernedly, the FDA issued recall press release did not disclose the cause for the recalled pet food, citing “*health concerns potentially associated with ingredients believed to not meet the Company’s quality and safety standards.*” To allow a recall announcement to exclude the cause is a serious failure to pet owners. Without veterinarians being able to identify the cause of cat illnesses, sick pets could not be properly treated. Several months later, we discovered via the [FDA Enforcement Reports](#) database that the Special Kitty cat foods were recalled “*due to excessive level of choline chloride in product.*”

In [July of 2020](#), the same manufacturer – Smucker’s Big Heart Brands - announced another canned cat food recall for the same cause; Natural Balance canned cat food was recalled for “*elevated levels of choline chloride*”. A second recall linked to the identical excess ingredient and manufactured at the same time as the initial recalled products shows once again that FDA failed to properly trace the adulterant. This failure to remove contaminated pet foods from store shelves lasted twenty-nine weeks, resulting in an untold number of preventable pet illnesses and deaths.

### **Euthanized animals in pet food 2017 thru 2018.**

Between February 3, 2017 and February 14, 2018 more than 91 million pounds of canned dog foods were recalled because they contained the drug used to euthanize animals (pentobarbital). If the recalled cans were laid end to end, the pet food would stretch from Key West, Florida to Los Angeles, California to FDA headquarters in Washington D.C.

What is astonishing about these recalls is that the pentobarbital contamination was discovered by the actions of a single pet owner and a television station journalist, not FDA safety testing of pet food. The initial recall was due to the actions of a pet owner in Washington (State) whose dog died from the pet food. This pet owner made the decision to have a necropsy performed on her dog, discovering pentobarbital in the dog food within the pet's stomach. Those lab results were provided to regulatory and a recall followed. After learning of the recall, WJLA television journalist Lisa Fletcher randomly tested 62 cans of dog food. The journalist found pentobarbital in nine cans of Gravy Train dog food. Her results were provided to FDA which resulted in more recalls.

### **Pervasive pentobarbital problem ignored.**

FDA CVM Director Dr. Steven Solomon admitted to industry in October 2018 that pentobarbital in pet food is a "*pervasive problem*". Obtained through Freedom of Information Act request, below is a direct quote of Dr. Solomon's presentation to industry:

"Most of us probably think that pentobarbital comes from a couple of bad actors that use a euthanized animal when they know they aren't really supposed to. New evidence is showing that it may be a much more pervasive problem throughout the animal food supply than originally thought, and we have reason to believe rendered products can be a source for pentobarbital, if not controlled."

If FDA was properly monitoring the industry and its ingredient suppliers, such contaminated product would not have had the opportunity to reach production lines, let alone store shelves.

### **Warning ignored.**

The FDA issued a [Warning Letter to Valley Proteins](#) – a pet food ingredient rendering facility as exemplified in images on pages 2 - 5 of this document – in November 2019 citing "*the presence of pentobarbital*" in ingredients produced by the company. The FDA Warning Letter stated: "*On February 11, 2019; April 3, 2019; April 16, 2019; and April 22, 2019, FDA inquired whether you planned to recall the animal food product contaminated with pentobarbital. You stated you did not plan to do so and did not provide FDA with requested information regarding the amount of potentially affected product that was distributed by your firm before you learned of the positive FDA test result.*"

Even though this pet food ingredient supplier directly refused multiple FDA requests to recall adulterated ingredients (2/11, 4/3, 4/26 and 4/22/2019), the FDA did not take any further action against the company. No recall was issued, no pet food consumer was alerted their pet's food could contain a euthanized animal.

The FDA Warning Letter also provided a concerning opinion from Valley Proteins: "*Your written response to Form FDA 483 failed to adequately address this problem. In the response, you assert that pentobarbital is an "unavoidable contaminant not known to present a health hazard"*".

Valley Proteins made a shockingly false statement to FDA (pentobarbital is not known to present a health hazard) and failed to address the pentobarbital problem, but the agency took no further action against the ingredient supplier or the rendering industry in general. The FDA CVM took no further action to prevent pentobarbital euthanized animals from being processed into pet food ingredients even after one of the largest U.S. suppliers informed the agency pentobarbital is considered an "*unavoidable contaminant*."

## **Deadly aflatoxin contaminated pet foods.**

In four months' time – September 3, 2020 through December 30, 2020 – 60 million pounds of cat and dog foods were recalled due to elevated levels of aflatoxin. As of the publication of this document, the FDA reports “*more than 110 dogs have died*” linked to these recalls. A little over 1 million pounds of the recalled pet foods were the result of regulatory random testing. The remaining 58+ millions of pounds of adulterated pet foods were recalled only after pet illnesses and deaths were reported to the agency. This cause of recall and pet deaths, elevated levels of aflatoxin, is completely preventable through proper monitoring of ingredients and inexpensive testing.

The [FDA assures pet owners](#) that existing law (Food Safety Modernization Act Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals) prevents these types of pet food recalls.

“The part 507 regulation requires many animal food manufacturers, including pet food manufacturers, to have a food safety plan in place before they begin producing animal food. The food safety plan must include an analysis of hazards for each type of animal food the manufacturer produces to identify known or reasonably foreseeable hazards and to determine if those hazards require the manufacturer to implement risk-based preventive controls to significantly minimize or prevent the hazards. A manufacturer also must validate that its preventive controls will be adequate against each hazard.”

As evidenced by more than 110 pet deaths and 60 million pounds of pet food recalled, existing Preventive Controls established by FDA are failing pet owners.

## **Reconditioned recalled pet food.**

With no disclosure to pet owners, the FDA allows pet food manufacturers to “*recondition*” recalled pet foods and re-sell the products back to consumers. All of the serious recalls mentioned within this section could have been provided this reconditioning opportunity by FDA, yet no pet food consumer is ever warned their pet’s food could be manufactured with reconditioned recalled products.

Unfair and deceptive trade laws make it illegal to put used/recycled parts in a computer without disclosing it to consumers, however no such consideration is given to consumers of pet food.

## **The failures of partner agencies.**

Unfortunately for U.S. pet owners, FDA’s failures are not the only obstacles we face in the search for safe pet food. Regulatory partners of FDA Center for Veterinary Medicine fail pet owners as well.

FDA CVM’s partnership with the private organization Association of American Feed Control Officials (AAFCO) prevents public access to nutritional requirements of pet foods, labeling requirements, and ingredient definitions. Besides FDA employees participating in AAFCO meetings facilitating the organization to profit from the work of public employees, FDA also provides funding to AAFCO for their participation in the Animal Feed Regulatory Program Standards. Since 2016, FDA has provided AAFCO with almost \$300,000.00.



Of greater significance, through the Animal Feed Regulatory Program Standards (AFRPS) program, the FDA has provided 23 states with more than \$52 million since 2011 to implement the AFRPS. The funding provided by FDA is contingent on states updating state laws to match federal laws, training for regulatory staff, and updated laboratory procedures.

AFRPS member states and federal funding received:

[Alabama Department of Agriculture](#) – \$299,780.00  
[California State Department of Food & Agriculture](#) – \$2,250,000.00  
[Colorado Dept of Agriculture](#) – \$2,307,330.00  
[Connecticut Dept of Agriculture](#) – \$1,891,673.00  
[Florida Department of Agriculture](#) – \$3,135,392.00  
[Georgia Department of Agriculture](#) – \$2,250,000.00  
[Illinois Department of Agriculture](#) – \$589,162.00  
[Iowa Department of Agriculture](#) – \$3,150,000.00  
[Kansas Department of Agriculture](#) – \$2,250,000.00  
[University of Kentucky Division of Regulatory Services](#) – \$2,400,000.00  
[Louisiana Department of Agriculture & Forestry](#) – \$2,591,327.00  
[Michigan State Department of Agriculture](#) – \$1,350,000.00  
[Minnesota Department of Agriculture](#) – \$2,325,000.00  
[Missouri Department of Agriculture](#) – \$3,063,115.00  
[New Jersey Department of Agriculture](#) – \$3,024,848.00  
[New Mexico Department of Agriculture](#) – \$3,150,000.00  
[Nebraska Department of Agriculture](#) – \$2,277,000.00  
[North Carolina Department of Agriculture & Consumer Services](#) – \$2,362,500.00  
[Pennsylvania State Department of Agriculture](#) – \$2,933,672.00  
[South Carolina Department of Agriculture](#) – \$1,904,760.00  
[Tennessee State Department of Agriculture](#) – \$2,249,577.00  
[Office of the Texas State Chemist](#) – \$2,362,500.00  
[Washington State Department of Agriculture](#) – \$2,362,500.00

Despite significant funding to these twenty-three states, there is evidence state regulatory authorities do not enforce law and do not follow procedures in a similar manner to FDA's selective enforcement of law suggesting a significant misappropriation of federal funding.

Rendering facilities that process condemned animal material (exemplified in images on pages 2 - 5) operate in most of these 23 states and rendered ingredients are sold in interstate commerce in all 23 states. All commercial feed/pet food laws within the 23 states define an adulterated feed/pet food as (in part) a product that contains a diseased animal or animal that has died other than by slaughter. Allowing rendering facilities to sell ingredients sourced from diseased animals and/or animals that have died other than by slaughter within their state and allowing pet foods containing these ingredients to be sold with their state evidences each AFRPS participating member ignores state and federal pet food/animal feed laws.

All 23 states that FDA provides funding to through AFRPS participate in AAFCO. All of these states adopt "by reference" the AAFCO copyright protected pet food regulations, nutritional requirements, labeling requirements, and legal definitions. Adopting state laws 'by reference' prevents the public and regulated individuals from accessing these laws. The partner regulatory authorities that FDA has provided more than \$52 million to, collectively prevent pet owners and veterinarians from access to the legal requirements of the products they purchase and recommend. Further, the pet food industry itself is forced to purchase the regulations they are regulated by.

## Lack of Transparency

FDA CVM continues to enter into a Memorandum of Understanding with AAFCO; [MOU 225-07-7001](#) provides the Association of American Feed Control Officials (AAFCO) complete ownership of pet food labeling requirements, nutritional requirements of complete and balanced pet food, and all legal definitions of pet food/animal feed ingredients.

Pet food labeling requirements, nutritional requirements, and all legal definitions of pet food ingredients are copyright protected by AAFCO and sold at a cost of \$120.00 per year.

FDA employees participate in AAFCO meetings, sending numerous individuals to two AAFCO meetings a year; 147 FDA representatives attended the January 2021 AAFCO meeting. Federal (and state) employees assist in writing the legal requirements of pet food while allowing AAFCO ownership of them. As well, a representative of FDA (Dr. Dave Edwards) sits on the AAFCO Board of Directors. Due to MOU 225-07-7001, pet owners and veterinarians have no public access to pet food nutritional requirements, labeling requirements and legal definitions of ingredients.

### **Why is this such a significant concern for pet owners and veterinarians?**

Every ingredient in pet food has a unique legal definition that varies significantly from the same ingredient in human food. As example, human food chicken is required to be USDA inspected and passed, and all laws and legal definitions regarding human food chicken are public information. To the contrary, the AAFCO legal definition of pet food chicken allows all of the following to be labeled as “*Real Chicken*”: USDA inspected and passed chicken, USDA inspected and condemned chicken, non-inspected chicken, chicken bones, chicken skin, a combination of chicken skin and bones with no meat, and or a powdered chicken product re-hydrated prior to pet food manufacturing (without disclosure on the label). Pet owners are provided with no clarification if their pet’s food contains edible chicken, inedible condemned chicken, bones, skin or powdered chicken.

The same dramatic variances in quality can occur with every pet food ingredient, and consumers are not provided clarification to those ingredients as well.

### **Misleading labels unregulated.**

Pet food labels and websites frequently display images of choice cuts of poultry or meat when the product contains nothing similar to the quality portrayed (including ingredients exemplified in images on pages 2 - 5). No regulatory authority oversees these misleading marketing claims. Pet food labels and website are openly allowed to deceive consumers without concern to any enforcement action.

### **FOIA failures.**

The FDA CVM fails to provide consumers or consumer advocates Freedom of Information Act (FOIA) requested documents in a timely manner as required by federal law. In 2017, we filed a FOIA request with FDA CVM for the legal definitions of pet food ingredients (2017-10123). The FDA denied our request two years later stating the information requested was copyright protected. In September 2019 we filed an Appeal (9-0107-AA) based on the fact that the information requested was a shared work product of FDA and state government employees. We are still waiting on this appeal. In an email from FDA Appeals Officer Katherine Uhl dated 12/15/20 we were told “*I estimate your appeal will come to the top of the queue within 12-18 months.*” This means that a request for information submitted to FDA CVM in 2017 will not be provided until at least 2022.

## Broken Promises

In 2007, the U.S. experienced the deadliest pet food recall in history. More than 150 brands of pet food were recalled, thousands of pets died, thousands more suffered permanent kidney damage. Congress took swift action on behalf of U.S. pets implementing laws to prevent another deadly pet food disaster. [Ensuring the Safety of Pet Food](#) within the Food and Drug Administration Amendments Act passed in September 2007. Section 1002(a) of Ensuring the Safety of Pet Food required FDA to:

“Not later than 2 years after September 27, 2007, the Secretary of Health and Human Services..shall by regulation establish-

1. ingredient standards and definitions with respect to pet food;
2. processing standards for pet food; and
3. updated standards for the labeling of pet food that include nutritional and ingredient information.”.

Unfortunately for U.S. pet owners, FDA CVM failed to meet the September 27, 2009 deadline to implement these necessary pet food safety regulations. In 2010, Ensuring the Safety of Pet Food Section 1002(a) was not completed by FDA. In 2011, 2012, 2013, 2014, 2015, 2016, and in 2017 pet owners were not provided with any pet food safety regulation from FDA CVM as required by the Ensuring the Safety of Pet Food Section 1002(a) laws.

In January 2018, the [Federal Register](#) included “*an inventory of rulemaking actions under development throughout the Department*” Within this notice, under “*Food and Drug Administration – Completed Actions*” was “*Updated Standards for Labeling of Pet Food*”. The FDA published in the Federal Register they had “*completed*” the requirements of Ensuring the Safety of Pet Food, when in fact – they had not.

In late 2018, eleven years after the deadliest pet food recall in history, nine years after the deadline for FDA to implement the much-needed pet food safety regulations, months after the Federal Register stated “*Updated Standards for Labeling of Pet Food*” was “*Completed*” - [HR 5554](#), Animal Drug and Animal Generic Drug User Fee Amendments of 2018 was introduced and passed in Congress. The bill included an unrelated section eliminating the laws promised to pet owners in 2007; “*1) by striking paragraph (1); and (2) by redesignating paragraphs (2) and (3) as paragraphs (1) and (2), respectively.*” ‘Striking paragraph (1)’ was the deletion of pet food safety laws promised to pet owners in 2007 (quoted above).

Adding insult to injury to pet owners, FOIA acquired emails evidence the FDA CVM, AAFCO and an industry trade association (AFIA) were directly involved in submitting the language within HR 5554 bill that deleted Ensuring the Safety of Pet Food laws. FOIA acquired emails evidence FDA Dr. David Edwards, AAFCO Board of Directors Sue Hays, Stan Cook, Richard TenEyck, Bob Geiger, Ali Kashani, Ken Bowers, and AFIA representative Leah Wilkinson played a significant role in the legislative changes of HR 5554 that deleted the pet food safety laws promised to pet owners.

Today (2021) pet owners are left with no ingredient quality standards and no pertinent information on labels, just as they were in 2007.



## Inconsistency

In March 2021, the FDA published the notice "[Animal Food Labeling; Declaration of Certified and Non-Certified Color Additives](#)" in the Federal Register. This notice included the following concern from FDA for the need of pertinent information to be disclosed on pet food labels (bold added for emphasis):

“Our animal food labeling regulation at § 501.22(k) is consistent with the regulations requiring the declaration of color additives on human food labels. **The purpose of the labeling is to provide animal owners with information on the color additives used in animal food. Animal owners use the information to become knowledgeable about the foods they purchase for their animals.** Color additive information enables a consumer to comparison shop and to avoid substances to which their animals may be sensitive.”

It is commendable that the FDA acknowledges the need for pet food labels to disclose pertinent information enabling a consumer to comparison shop and avoid certain ingredients. However, the inconsistency of what information the agency chooses to require or not require to be disclosed to consumers is concerning. Such as: the agency directly allows through selective enforcement pet food ingredients to violate federal laws, allowing diseased animals and animals that have died other than by slaughter to be processed as ingredients of pet food. The agency does NOT require this disclosure to be provided to consumers on pet food labels.

Because of this FDA decision (non-disclosure of inedible ingredients), consumers are not knowledgeable about the foods they purchase, are not allowed to properly comparison shop and/or are not allowed opportunity to avoid illegal substances in their pet's food.

The agency's selection process to what information is or is not required on pet food labels appears to be random, at the agency's discretion. Pet owners are currently provided no voice in what information FDA CVM decides to require or not require on pet food labels.

## Unresolved Investigations

There are concerning instances when FDA has alerted the public to a pet food investigation, but the agency has failed to publicly close the issue. FDA CVM investigations have abruptly stopped seemingly at the FDA's discretion, without disclosure to the public the status or resolve of the investigation.

### Jerky Treats

Beginning in 2007, the FDA began receiving reports of pet illness and death linked to jerky treats imported from China. By 2015 the agency had received reports of more than 6,200 pet illnesses and more than 1,100 pet deaths linked to these treats. For years the agency investigated the cause of pet illness and death linked to the treats, updating the public frequently. However, the updates ended with FDA's final public notice on May 16, 2016.

Dr. Steven Solomon, Director of FDA Center for Veterinary Medicine, stated in a keynote address at the August 2019 AAFCO meeting the jerky treat investigation was considered “resolved” by FDA. The FDA never explained to pet owners how the agency resolved their investigation, never provided pet owners with a cause for the thousands of pet illnesses and deaths linked to these treats.

## DCM

In July 2018, the FDA issued a public statement the agency was investigating a “*potential connection between diet and cases of canine heart disease.*” The agency stated they were “*alerting pet owners and veterinary professionals about reports of canine dilated cardiomyopathy (DCM) in dogs eating certain pet foods containing peas, lentils, other legume seeds, or potatoes as main ingredients.*” FDA issued their last update on this pet food issue almost two years ago, June 27, 2019.

In September 2020, Senators Kevin Cramer, James E. Risch, Mike Crapo, Steve Daines, John Hoeven, Roy Blunt, and Jon Tester sent a letter to FDA requesting the agency update the public to all existing science, including a request for the agency to provide the public information regarding recent science that opposes the suspicion (the agency previously alerted the public to) that grain-free pet foods are a potential cause of heart disease in dogs. Six months later – March 2021 – the FDA has not issued any other consumer update as the Senators requested and as the public deserves.

The FDA CVM’s failures to keep the public updated on investigations is a concerning disservice to pet owners.

## Conclusion

As concerning as the issues addressed in this document are, this is only a brief overview of the challenges millions of pet owners face daily in their pursuit of a safe, nutritious pet food.

Pet food in the U.S. is haphazardly regulated seemingly at the whim of regulatory authorities. Federal and state authorities intentionally allow law to be violated, intentionally allow the pet food industry to profit from recycled, illegal waste ingredients sold in interstate commerce with no disclosure on pet food labels. Consumers are prevented from access to regulations, prevented opportunity to participate in the regulatory process, and prevented from understanding what is included in their pet’s food. The FDA has continued to fail to properly investigate and remove from store shelves dangerous pet products. A complete overhaul of the current system of pet food regulation is necessary.

We believe all of the following updates are required:

1. Regulatory meetings must be open, providing any pet owner or any veterinarian free public access to participate.
2. All pet food rules, definitions, labeling requirements, and nutritional requirements must be published publicly on state and federal government websites with opportunity for public comment.
3. Federal and state laws must be fully enforced; pet food ingredients cannot be sourced from diseased animals or animals that died other than by slaughter or inedible waste processed by the rendering industry with no disclosure to consumers.
4. As was required in the Food and Drug Administration Amendments Act Ensuring the Safety of Pet Food, pet food ingredient definitions must include quality standards. All ingredient standards should become public information, open for public comment.
5. As was required in the Food and Drug Administration Amendments Act Ensuring the Safety of Pet Food, pet food labels must be updated providing pet owners full transparency to nutritional information and quality. Pet food labels must disclose the use of inedible ingredients. Pet owners (the largest stakeholder of pet food) and veterinarians must be provided a voice in the label update process.
6. Random audits must be performed on FDA and partner agencies that receive federal funding monitoring proper enforcement of law and proper adherence to procedure with pet food investigations. All audit reports must become public information; the public must be assured federal and state agencies are enforcing law, fully investigating dangerous products and promptly removing them from store shelves.

Sixty-seven percent of U.S. households, or about 85 million families, own a pet. American pet owners contribute significantly to the U.S. economy, spending \$95.7 billion on their pets in 2019. Pet owners deserve the same protection from adulteration, public access to laws/legal definitions, opportunity to provide comment, and the same informed labels as other FDA regulated products.