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FDA/Center for Veterinary Medicine Survey #1, qualitative analyses for pentobarbital residue Dry dog food samples purchased in Laurel, MD, area, March - June 1998

KEY

Yes = confirmed for presence of pentobarbital No = failed to confirm for presence of pentobarbital No result = analyses failed quality assurance requirements

Rendered ingredients:

AD = animal digest
AF = animal fat
BBM = beef and bone meal
BT = beef tallow
MBM = meat and bone meal

NOTES

3-4 ppb = Estimated limit for confirming pentobarbital with highest confidence ppb = parts-per-billion pentobarbital, by weight (nanograms per gram) n = not given or not legible

Exhibit 31

Rendered	Confirmed for	Brand Name	Formulation Name	Lot Number
ingredients	the presence of			
(position in	pentobarbital?			
ingredient list)				
Beef Meal(1)	yes	Nutro	Premium	10:19 2AR7JJ
Beef Meal(1)	yes	Nutro	Premium	00:512BA7256259101069704
MBM(2) AF(6) AD(7)	yes	Ol'Roy	Krunchy Bites & Bones	V033
MBM(2) AF(5) AD(8)		Ol'Roy	Protein and Rice	V093
MBM(2) AF(5) AD(8)	yes	Ol'Roy	Protein and Rice	V071
MBM(2) AF(6) AD(9)	yes	Ol'Roy	High Performance with Chicken Protein and Rice	
MBM(2) AF(6) AD(9)	no result	Ol'Roy	High Performance with Chicken Protein and Rice	
MBM(2) AF(6) AD(7)	yes	Ol'Roy	Krunchy Bites & Bones	V153
MBM(2) AF(5)	yes	Trailblazer	Chunk Premium Quality	029813:30\A/2
MBM(2) AF(5)	yes	Trailblazer	Chunk Premium Quality	A5981315\A/R (?)
MBM(2) AF(5)	yes	Trailblazer	Bite Size Ration	A5889911A\A/1
MBM(2) AF(5)	yes	Trailblazer	Bite Size Ration	030800113\A/2
MBM(2) AF(4)	no	Pedigree	Mealtime	814EL0011E
MBM(2) AF(4)	no	Pedigree	Mealtime	816GL154D
MBM(2) AF(6)	no	Pedigree	Meaty Chunks with Rice and Vegetables	811FL0027E
MBM(2) AF(6)	no	Pedigree	Meaty Chunks with Rice and Vegetables	811FL2211E
MBM(2) AF(3)	yes	Dad's	Bite Size Meal	17:42
MBM(2) AF(3)	yes	Dad's	Bite Size Meal	7:12
MBM(2) AF(6)	yes	Weis Value	Chunky and Moist	Feb 0599x
MBM(2) AF(6)	yes	Weis Value	Puppy Food	99N132
BBM(2) AF(5)	no	Friskies	Come'n Get It	8104LP-61156
BBM(2) AF(6)	no	Friskies	Alpo	8015LP 60501
BBM(2) AF(6)	no	Friskies	Alpo	8096LP-60531
MBM(3) AF(5) AD(6)	yes	Super G	Chunk Style	V113
MBM(3) AD(5) AF(6)	no	Ol'Roy	Lean Formula	V013
MBM(3) AD(5) AF(6)	no	Ol'Roy	Lean Formula	V073
MBM(3) AF(5)	no result	Richfood	High Protein Dog Meal	1R04018
MBM(3) AF(5)	no	Richfood	High Protein Dog Meal	1R03308
MBM(3) AF(5) AD(6)	yes	Richfood	Chunk Style	1R0478
MBM(3) AF(5) AD(6)	yes	Richfood	Chunk Style	3R05088
MBM(3) AF(5)	no	Richfood	Gravy Style Dog Food	3R010598
MBM(3) AF(5)	yes	Richfood	Gravy Style Dog Food	3R06078
MBM(3) AF(5) Beef Dgst(7)	no	Super G	Gravy Style Dog Food	V013

3	Confirmed for the	Brand	Formulation	Lot
	presence of			
(position in ingredient	pentobarbital?	Name	Name	Number
list)				
(-) (-)	no	Super G	Gravy Style Dog Food	V093
Dgst(7)				
	yes	Super G	Chunk Style	V003
	yes	Super G	Chunk Style	V113
	yes	Pet Essentials	Chunk Style	0-0046-L9
	yes	Pet Essentials	Chunk Style	D-1106-L9
MBM(3) AF(5)	yes		Krunchy Kibble	3R
	yes	America's Choice		R
MBM(3) AF(5) AD(6)	yes	Weis Value	Crunchy Dog Food	99N052
MBM(3) AF(5) Beef Dgst(7)	yes	Weis Value	Gravy Style Dog Food	N092
MBM(3) AF(7) AD(8)	ves	Weis Value	High Protein Dog Food	N072
	ves	Ol'Roy	Meaty Chunks and Gravy	K5 0825
	no	Ol'Roy	Meaty Chunks and Gravy	V90051
		Ken-L Ration	Gravy Train Beef, Liver and Bacon	W20351
	yes		Flavor	
BBM(3) AF(4) AD(5)	yes	Ken-L Ration	Gravy Train Beef, Liver and Bacon Flavor	W31203
BBM(3) AF(6)	no	Purina	Mainstay	U2326-L8
BBM(3) AF(6)	no	Purina	Mainstay	U1529-L6
BBM(3) BT(4)	no result	Purina	Dog Chow	E1837-L2
BBM(3) AF(6)	no	Friskies	Come'n Get It	8082L9-62159
BBM(3) AF(4)	yes	Ken-L Ration	Gravy Train	W12123
BBM(3) AF(4)	yes	Ken-L Ration	Gravy Train	W11525
BBM(3) BT(4)	no	Purina	Little Bites	U0502L4
BBM(3) BT(4)	no	Purina	Little Bites	U1201-L4
BBM(3) AF(5) AD(9)	no	Heinz	Kibbles 'n Bits Jerky	L70600
BBM(3) AF(5) AD(9)	yes	Heinz	Kibbles 'n Bits Jerky	L2 228
BBM(3) AF(5) AD(9)	no	Heinz	Kibbles 'n Bits 'n Bits 'n Bits	L200:38
BBM(3) AF(5) AD(9)	no	Heinz	Kibbles 'n Bits 'n Bits 'n Bits	L7 0448
MBM(4) AF(6)	yes	Weis Value	Kibbles Variety Mix	Mar 0999z
MBM(4)	yes	Kibble Select	Premium Dog Food	11P
MBM(4)	yes	Kibble Select	Premium Dog Food	1238
	no	Fieldmaster	Fieldmaster	C1334-L3
	no	Fieldmaster	Fieldmaster	U2108-L5
	no	Purina	High Pro	U1829L6
	no	Purina	High Pro	U1749-L6
	no	Purina	Grrravy	U1643-L7
	no	Purina	Grrravy	U1059-L6

Rendered ingredients		Brand Name	Formulation Name	Lot Number
(position in ingredient				
list)	pentobarbital?			
BBM(4) AF(6) AD(7)	yes	Heinz	Kibbles 'n Bits Puppy	L1-0343
BBM(4) BT(7) Dried AD	no	Purina	Dog Chow Senior	U2055L3
(10)				
BBM(4) BT(7) Dried AD	no	Purina	Dog Chow Senior	U0303L4
(10)				
BT(4) BBM(10)	no	Purina	Kibbles and Cheezy Chews	N-0113-L10-E
BT(4) BBM(10)	no	Purina	Kibbles and Cheezy Chews	N-19-58-L11-W
MBM(5) AF(7)	yes	Champ Chunx	Bite Size Dog Food	H20054
BBM(5) AF(6)	no	Purina	Kibbles and Chunks	N-20-37-L10-E
BBM(5) AF(6)	no	Purina	Kibbles and Chunks	I-21-10-L10-E
BBM(5) BT(6)	no	Purina	Butcher's Blend	N1224-L20
BBM(5) BT(6)	no	Purina	Butcher's Blend	N-1723-L20
BBM(5) AD(8)	no	Heinz	Kibbles 'n Bits Lean	L30906
BBM(5) AD(8)	yes	Heinz	Kibbles 'n Bits Lean	L2 1156
BT(5)	no	Purina	Dog Chow	U1239-L2
BT(5)	no	ProPlan	Beef and Rice Adult	U2053-L2
BT(5)	yes	ProPlan	Beef and Rice Adult	U0131 L2
BBM(6) BT(7)	no	Purina	Fit & Trim	U0557L3
BBM(6) BT(7)	no	Purina	Fit & Trim	U2133-L4
BT(6)	yes	ProPlan	Beef and Rice Puppy	E0601-L3
BT(6)	yes	ProPlan	Beef and Rice Puppy	E0359 L2
MBM(7) AF(9)	no	Ol'Roy	Dinner Rounds Soft Dry Dog Food	8D30PB1
MBM(7) AF(8)	yes	Reward	Dinner Rounds Dog Food	8C19PA1
MBM(7) AF(8)	no	Reward	Dinner Rounds Dog Food	8D23PB1

Survey #2, quantitative analyses for pentobarbital residue Dry dog food samples purchased in Laurel, MD, area, December 2000

KEY

QUANTITATIVE ANALYSES

ppb = parts-per-billion pentobarbital, by weight (nanograms per gram) --- = not found above 1 ppb limit of detection a = found in 1-2 ppb range, but not accurately measurable

QUALITATIVE ANALYSES

yes = confirmed for presence of pentobarbital no = failed to confirm for presence of pentobarbital blank = not analyzed by qualitative method

Rendered ingredients:

AD = animal digest AF = animal fat BBM = beef and bone meal BT = beef tallow MBM = meat and bone meal

NOTES

1 ppb = Lowest concentration for detecting pentobarbital with some confidence 2 ppb = Lowest concentration for measuring pentobarbital accurately 3-4 ppb = Estimated limit for confirming pentobarbital with highest confidence n = not given or not legible

Rendered ingredients (position in	Measured (ppb)	Confirmed for presence of pentobarbital?	Brand Name	Formulation Name	Lot Number
ingredient list)					
MBM(2) AF(5) BBM(6) AD(8)	10.0	yes	Old Roy	Puppy Formula, Beef Flavor	0407003
MBM(2) AF(5) AD(8)			Old Roy	Premium Chicken and Rice	0409002
MBM(2) AF(5) AD(8)	32.0	yes	Old Roy	Puppy Formula, Chicken and Rice	0415002
MBM(2) AF(5) AD(8)	а	no	Richfood	Dog Food Chunk Style	50 09:50 1
MBM(2) AF(6) AD(9)	а		Old Roy	High Performance Chicken and Rice	0417002
MBM(2) AF(5)			Pedigree	Meaty Chunks Mealtime	046DT0117C
MBM(2) AF(5) AD(7)	а		Safeway	High Protein	0650 EA
MBM(2) AF(6) AD(9)	3.9	yes	Richfood	High Protein Dog Meal	50 22:34 1
MBM(2) AF(6)			Pedigree	MealTime Large Crunchy Bites	935CK0906E
MBM(2) AF(8) AD(9)	а	no	Safeway	Puppy food	EB2206
MBM(2) AF(6) AD(9)	15.0	yes	Weis	Total High Energy Chicken and Rice	?17 09:23 2
BBM(2) AF(5) MBM(7)			Friskies	Come and Get itBeef, Chicken, Liver	0269LP70610
BBM(2) BT(6) AD(8)			American Fare	Bites and Bones	C1800 L1
MBM(3) AD(5) AF(6)	3.9	yes	Old Roy	Lean Formula	0409003
MBM(3) AD(4) AF(5)			Old Roy	Meaty Chunks and Gravy	V80333
MBM(3) AF(5) AD(7)			Safeway	Tasty Nuggets	EB 22:00
MBM(3) AF(5) Beef Digest(7)	4.5	yes	Super G	Gravy Style Dog Food	n
MBM(3) AF(5) AD(6)	16.4	yes	Super G	Chunk Style Dog Food	0415003
BBM(3) AF(4) AD(5)			Heinz	KenL Ration Gravy Train Beef Liver and Bacon	W3 0819
BBM(3) AF(5) AD(9)	а		Heinz	Kibbles N Bits Original, Chicken and Beef	L72111
BBM(3) AF(6) AD(8)	25.1	yes	Heinz	Kibbles and Bits Beefy Bits	L22027
BBM(3) BT(4)			Purina	Dog Chow Little Bites	C 0202 L2
AF(3)			Hills	Science Diet Senior, 7+, small bites	K02350044
AF(3)	8.4	yes	Dad's	Bite Size Meal Chicken and	n

I	I	I	I	Rice	I
BT(3)	11.6	ves	PetGold	Master Diet Puppy Formulation	11:17 FA
MBM(4) AF(6)		,,,,	Safeway	Small Bites	00:14 EC
MBM(4) AF(6)			Weis	Total Pet Kibbles	n
MBM(4)			Dad's	Kibble Select	n
BBM(4) AF(6) AD(7)	2.8	no	Heinz	Kibbles and Bits Puppy	L70222
BBM(4) BT(6)			Fieldmaster	Adult	C2258L4
BBM(4) BT(5)			Purina	Puppy chow, Beef Flavor	C0559 L1
BBM(4) BT(6)			Purina	Kibbles and Chunks Beef	C234 L1
BBW(+) BT(0)			l' d'illa	Flavor	0204 21
AF(4)			Neura	Special Diet Formulation 300	SM017311:37
Rendered ingredients (position in ingredient list)	Measured (ppb)	Confirmed for presence of pentobarbital?	Brand Name	Formulation Name	Lot Number
AF(4)			Nature's Recipe	Easy to Digest	NT B 18:41
AF(4)			Friskies	Alpo Lamb Meal Rice and Barley	0237UA20635
AF(4)			Pedigree	Mealtime with Lamb and Rice	045C50933C
AF(4)			Hills	Science Diet Large Breed Adult	K07360152
AF(4) MBM(5) AD(6)			Heinz	KenL Ration Choice Blend	W4 1947
BT(4)			PetGold	Master Diet Adult Formulation	EA 09:25
MBM(5) AF(6)			American Fare	High Protein	C0935 L6
BBM(5) BT(7) AD(8)			Purina	Dog Chow Senior 7+	C 2159 L2
BBM(5) BT(6) AD(8)			American Fare	Adult Formulation	n
BBM(5) BT(7) AD(8)			Purina	One Beef and Rice	C 0405 L2
BBM(5) BT(6)			Purina	Butchers Blend	N 0751 L20
AF(5)			Hills	Science Diet Large Breed Canine, Puppies	142K51737
AF(5)			Safeway	Lamb Meal and Rice	EB1556
AF(5)	а		Neura	Special Diet Formulation 200	SM002714:27
BT(5) AD(9)			ProPlan	Beef and Rice, Adult Formulation	V0621L2
BT(5) BBM(6)			Safeway	Kibbles and Munchy Chews	F061414
BT(5) BBM(6)			American Fare	Kibbles and Munchy Morsels	C1931 L2
MBM(6) AF (7)			Heinz	Reward Dinner Rounds	P1 1238
AF(6) BBM(8)			Friskies	Alpo Complete Puppy	0007UA22125
AF(6)			Nature's Recipe	Lifestages Senior Lamb and Rice	V80449
AF(6)			Hills	Science Diet Sensitive Stomach	K12251603
AF(6)			Hills	Science Diet Sensitive Skin	K15350650
AF(6)			Pedigree	Puppy	0420S1702C
BT(6) AD(8)			American Fare	Puppy Formulation	D 0756 L8
BT(7)			Safeway	Select Adult Dog Formulation (Nutra Balance)	E2200L3
BT(7)			Maxximum Nutrition	Lamb and Rice Formula	n
Meat Meal(7)			Flavorite	Kibbles Dog Food	3104269

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U.S. Food and Drug Administration



CENTER FOR VETERINARY MEDICINE

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Food and Drug Administration/Center for Veterinary Medicine Report on the risk from pentobarbital in dog food

The low levels of exposure to sodium pentobarbital (pentobarbital) that dogs might receive through food is unlikely to cause them any adverse health effects, Food and Drug Administration scientists concluded after conducting a risk assessment.

During the 1990s, FDA's Center for Veterinary Medicine (CVM) received reports from veterinarians that pentobarbital, an anesthetizing agent used for dogs and other animals, seemed to be losing its effectiveness in dogs. Based on these reports, CVM officials decided to investigate a plausible theory that the dogs were exposed to pentobarbital through dog food, and that this exposure was making them less responsive to pentobarbital when it was used as a drug.

The investigation consisted of two parts. First, CVM had to determine if dog food could contain residues of the drug. Second, if residues were found, the Center had to determine what risk, if any, the residues posed to dogs.

In conjunction with this investigation, the Center wanted to determine if pet food contained rendered remains of dogs and cats.

How pentobarbital can get into dog food

Because in addition to producing anesthesia, pentobarbital is routinely used to euthanize animals, the most likely way it could get into dog food would be in rendered animal products.

Rendered products come from a process that converts animal tissues to feed ingredients. Pentobarbital seems to be able to survive the rendering process. If animals are euthanized with pentobarbital and subsequently_rendered, pentobarbital could be present in the rendered feed ingredients.

In order to determine if pentobarbital residues were present in animal feeds, CVM developed a sophisticated process to detect and quantify minute levels – down to 2 parts per billion of pentobarbital in dry dog food. To confirm that the methods they developed worked properly, CVM scientists used the methods to analyze dry commercial dog foods purchased from retail outlets near to their Laurel, MD, laboratories. The scientists purchased dog food as part of two surveys, one in 1998 and the second in 2000. They found some samples contained pentobarbital (see the attached tables).

Dogs, cats not found in dog food

Because pentobarbital is used to euthanize dogs and cats at animal shelters, finding pentobarbital in rendered feed ingredients could suggest that the pets were rendered and used in pet food.

CVM scientists, as part of their investigation, developed a test to detect dog and cat DNA in the protein of the dog food. All samples from the most recent dog food survey (2000) that tested positive for pentobarbital, as well as a subset of samples that tested negative, were examined for the presence of remains derived from dogs or cats. The results demonstrated a complete absence of material that would have been derived from euthanized dogs or cats. The sensitivity of this method is 0.005% on a weight/weight basis; that is, the method can detect a minimum of 5 pounds of rendered remains in 50 tons of finished feed. Presently, it is assumed that the pentobarbital residues are entering pet foods from euthanized, rendered cattle or even horses.

Finding levels of pentobarbital residues in dog food

Upon finding pentobarbital residues in dog food, the researchers undertook an assessment of the risk dogs might face. Dogs were given known quantities of pentobarbital for eight weeks to determine if consumption of small amounts of pentobarbital resulted in any physiological changes that could indicate potential effects on health. In short, the scientists wanted to find the level of pentobarbital dogs could be exposed to that would show no biological effects. The most sensitive indicator that pentobarbital had an effect is an increase in the production of certain enzymes collectively called cytochrome P450.

Virtually all animals produce enzymes as a normal response to metabolize naturally occurring and man-made chemicals in their environment. Barbituates, such as pentobarbital, are especially efficient at causing the liver to produce these enzymes. In dogs, the most sensitive biological response to pentobarbital is an increase in the production of cytochrome

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P450 enzymes, which is why the scientists chose that as the best indicator of biological effect. If a low level of pentobarbital did not cause a dog to produce additional cytochrome P450 enzymes, then scientists could assume that the pentobarbital at that low level had no significant effect on the dog.

In CVM's study, experimental animals were each dosed orally with either 50, 150, or 500 micrograms pentobarbital/day for eight weeks. The results were compared with control animals, which were not exposed to pentobarbital.

Several significant pentobarbital-associated effects were identified in this study:

- 1. Dogs that received 150 and 500 micrograms pentobarbital once daily for eight weeks had statistically higher liver weights (relative to their bodyweights) than the animals in the control groups. Increased liver weights are associated with the increased production by the liver of cytochrome P450 enzymes;
- 2. An analysis showed that the activity of at least three liver enzymes was statistically greater than that of the controls at doses of approximately 200 micrograms pentobarbital per day or greater.

But researchers found no statistical differences in relative liver weight or liver enzyme activity between the group receiving 50 micrograms pentobarbital per day and the controls. Based on the data from this study, CVM scientists were able to determine that the no-observable-effect level – which is the highest dose at which no effects of treatment were found – for pentobarbital was 50 micrograms of pentobarbital per day.

Adverse health effects unlikely

For the purposes of CVM's assessment the scientists assumed that at most, dogs would be exposed to no more than 4 micrograms/kilogram body weight/day based on the highest level of pentobarbital found in the survey of dog foods. In reality, dogs are not likely to consume that much. The high number was based on the assumption that the smallest dogs would eat dog food containing the greatest amount of pentobarbital detected in the survey of commercial pet foods-- 32 parts per billion.

However, to get to the exposure level of 50 micrograms of pentobarbital per day, which is the highest level at which no biological response was seen, a dog would have to consume between 5 to 10 micrograms of pentobarbital per kilogram of body weight. But the most any dog would consume, based on the survey results, was 4 micrograms pentobarbital per kilogram of body weight per day.

It should be emphasized that induction of cytochrome P450 enzymes is a normal response to many substances that are naturally found in foods. It is not an indication of harm, but was selected as the most sensitive indicator to detect any biological effect due to pentobarbital.

Thus, the results of the assessment led CVM to conclude that it is highly unlikely a dog consuming dry dog food will experience any adverse effects from exposures to the low levels of pentobarbital found in CVM's dog food surveys.

Appendix

Development of a polymerase chain reactionbased method to identify species-specific components in dog food

Michael J. Myers, PhD; Dorothy E. Farrell, BS; David N. Heller, BS; Haile F. Yancy, PhD

Objectives—To determine whether there is a relationship between species-specific mitochondrial DNA (mtDNA), especially canine and feline mtDNA, and detectable amounts of pentobarbital in previously Caseahalvedvagi 231 samples. Document 258-4

Sample Population—31 dog food samples previously analyzed for pentobarbital (limit of detection, 1 µg/kg).

Procedure—Polymerase chain reaction (PCR) analysis was performed on dog food samples by use of PCR primers specific for either canine, feline, equine, bovine, porcine, ovine, or poultry mtDNA.

Results—PCR amplicons specific for feline or canine mtDNA at a 0.007% (70 μg/g [wt/wt basis]) or 0.0007% (7 μg/g) level, respectively, were not found in the 31 dog food samples. Most of the 31 dog food samples had a PCR amplicon on PCR analysis when a PCR primer set capable of simultaneously detecting mtDNA of cows, pigs, sheep, goats, deer, elk, and horses was used. Results of PCR analysis by use of primers specific for bovine, swine, sheep and goat, or horse mtDNA revealed amplicons specific for bovine or swine mtDNA only in 27 of the 31 samples. Analysis of the remaining 4 samples failed to yield amplicons for any mammalian mtDNA. Pentobarbital was detected in 2 of these 4 samples. Results of PCR analysis correlated with the stated ingredient list for most, but not all samples.

Conclusions and Clinical Relevance—Because canine and feline mtDNA were not found in a set of retail dog food samples, these results indicate that the source of pentobarbital in dog food is something other than proteins from rendered pet remains. (*Am J Vet Res* 2004;65:99–103)

Pentobarbital is a drug used to euthanatize unwanted animals as well as animals in situations of severe pain and suffering. In the past, some euthanatized animal carcasses were disposed of by rendering into products such as meat and bone meal, tallow, and other products. In 2 separate studies, several lots of commercial dog food were found to contain confirmable amounts of pentobarbital. 3.4

It has been presumed that pentobarbital was present in these dog food samples because euthanatized animals were included with other animal by-products used in preparing dog food. This presumption has been difficult to test because of the limitations of existing analytic methods.

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Address correspondence to Dr. Myers.

The purpose of the study reported here was to determine whether there is a relationship between species-specific mitochondrial DNA (mtDNA), especially canine and feline mtDNA, and pentobarbital in Entepedionsly and pentobarbital in developed a polymerase chain reaction (PCR)-based approach to identify species-specific products that might be present in dog food.

The current approach is a modification of the PCR-based method validated for detecting bovinederived materials in complete animal feed. The underlying principle of the method is the amplification of a specific mtDNA sequence by use of PCR primer pairs that permit species-specific amplification. The use of mtDNA sequences increases the number of targets available for amplification relative to genomic DNA, thereby increasing the sensitivity of the method. Accordingly, PCR primers specific for canine, equine, or feline mtDNA sequences were developed and used to test for the possible presence of rendered materials from these species in dog food. In addition, other species-specific PCR primers were used to assess the accuracy of the label claims by comparing the PCR assay results with the ingredient statements from the package label.

Materials and Methods

Dog food samples were obtained from retail outlets in the Baltimore-Washington DC area. These samples had been used previously in a study⁴ to determine whether the presence of pentobarbital could be confirmed and the amounts measured. These samples were purchased in December 2000. They were stored at room temperature (approx 23°C) until ground to a powder, then stored at 4°C until analyzed. The sample identification numbers used in this study do not correspond with the previously published table of results.⁶

The PCR primers were designed by use of a software program. The design of the PCR primers for canine, equine, and feline mtDNA used published sequences. To be a software program of the PCR primers for canine, equine, and feline mtDNA used published sequences.

The experimental procedure was previously described in detail.5,10 Briefly, a 0.5-g subsample of ground dog food was mixed with 4.5 mL of extraction buffer (5M guanidine thiocyanate; 0.02M EDTA, pH 8.0; 0.05M Trizma-HCL, pH 6.4; 1.3% Triton X-100) and allowed to incubate overnight (16 to 18 hours) at 60°C. The supernatant was placed in a new tube following centrifugation (4,200 X g) to remove undissolved material. Five hundred microliters of the clarified supernatant was mixed with 0.5 mL of extraction buffer and 0.04 mL of silica suspension. The silica was prepared according to Boom. 11 After a 10 minute incubation at room temperature the silica was precipitated by centrifugation $(13,000 \times g)$, then washed 3 times with wash buffer (extraction buffer minus EDTA and Triton X-100), 2 times with 70% ethanol, and once with acetone. Each wash step was accomplished by resuspending the silica pellet followed by centrifugation $(13,000 \times g)$. The DNA was extracted from the silica by use of 0.05 mL of Tris-EDTA buffer (10mM Tris-HCL, pH 8.0; 1mM EDTA, pH 8.0). Five microliters of the DNA-containing solution was used for the PCR assay. The PCR primers specific for canine, feline, and equine mitochondria were deduced and commercially prepared. Each PCR assay tube contained, in a 50-µL volume, 5 µL extracted DNA, 12.5 pmol of each primer (forward and reverse), 50 µM of each dNTP, 1.5mM MgCl₂, 2 to 2.5 U Taq, and 50mM KCL. Positive and negative controls were analyzed with all PCR runs. The bovine, porcine, ovine, poultry, and universal PCR primers were as previously described (Appendix 1). 9,12,13 Prior to use, all PCR primers were screened against a panel of animal DNA that included blood samples derived from 2 dogs (2 different breeds) and a cat, rabbit, chicken, turkey, horse, pig,

when used with DNA from any other species.

The PCR amplification was accomplished by 29 cycles of denaturing at 94°C for 1 minute (first denaturing step is performed for 2 minutes), annealing for 0.5 minutes, followed by extension at 72°C for 1 minute (Appendix 2). Sizes of PCR products were determined by use of an Hae III digest of θX -174 as the standard marker.

The positive controls were species-specific DNA isolated from peripheral blood samples, whereas the negative control was prepared by use of double-distilled water. The DNA was isolated from heparinized blood samples by use of a DNA purification kit, following manufacturers instructions. This method isolates genomic and mitochondrial DNA. The swine, bovine, and canine (Beagle) blood samples were obtained from animals housed at the Office of Research. The samples of elkd and deere blood were provided. All other blood samples were obtained from a commercial laboratory. After completion of the PCR assay, 30-μL samples (20-μL PCR product mixed with 10-µL gel loading buffer) were electrophoresed through 2% agarose gels containing ethidium bromide and viewed with ultraviolet light.

Results

A PCR primer set specific for a canine mtDNA sequence was found not to amplify mtDNA-derived blood samples of a cow, sheep, goat, pig, cat, deer, elk, chicken, turkey, rabbit, or horse (Fig 1). The potential

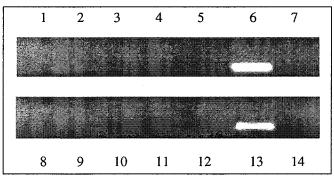


Figure 1-Detection of canine mitochondrial DNA (mtDNA) by use of polymerase chain reaction (PCR) primers specific for Canis familiaris. The PCR primers specific for Canis familiaris were used to amplify mtDNA obtained from numerous species. The PCR product was separated in a 2% agarose gel containing ethidium bromide. Lanes 1 to 7 (top panel) contained DNA obtained from the blood samples of a cow, elk, horse, goat, sheep, dog (Beagle), and pig, respectively. Lanes 8 to 14 (bottom panel) contained DNA obtained from blood samples of a chicken, goose, cat, rabbit, turkey, dog (mixed breed), and deer, respectively. Only mtDNA from the 2 dogs produced a PCR amplicon. Similar results were obtained when either the feline-specific primers or the equine-specific primers were used. That is, these latter primers only amplified mtDNA from their respective species.

for components in dog food to impact the PCR process were assessed in 2 ways. Ground dog food in which pentobarbital was not found (limit of detection, 1 µg/kg) was spiked with homogenized whole canine liver, with the DNA extracted from this mixture as detailed. The second approach used samples of DNA purified from these dog food samples that were spiked with varying amounts of purified canine DNA and subjected to PCR analysis (data not shown). The results from these 2 approaches indicated that nothing in the dog food was present that would interfere with either the DNA isolation step or the PCR process.

Some dog food samples previously analyzed for the presence of pentobarbital were then subjected to cow, deer, elk, sheep, or goat. The primers used in this study

Casewere specific; they did no primer be simplicons need to be simplicons need to be simplicons. The results indicated a complete of canine DNA. The results indicated a complete absence of canine DNA in all 31 samples (Fig 2) at a level exceeding 0.007% (wt/wt basis). Repeat analysis of the samples at a level of 0.0007% (wt/wt basis) by use of 50 µL of extracted DNA instead of 5 µL confirmed the absence of mtDNA (data not shown).

Cats and horses are other species that are euthanatized with pentobarbital, and thus might be the source of this drug in dog food. The PCR primer sets specific for either feline or equine mtDNA were developed as for the canine PCR primers (data not shown). These primers were used to test the dog food samples for presence of mtDNA that might have been derived from cats or horses. The results from these analyses indicated a complete absence of PCR amplicons specific for either cat or horse mtDNA in all 31 dog food samples (Table 1). This analysis was performed under conditions that achieved detection at the level of 0.007%

To ensure that DNA from species other than dogs and cats could be amplified from these dog food sam-

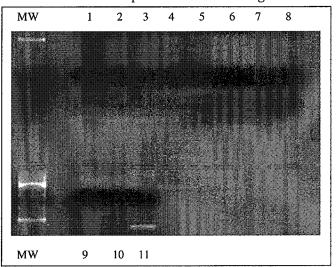


Figure 2—Results of PCR assay for canine mtDNA in dog food. Results are representative of those of the 31 dog food samples analyzed. All these particular samples had previously been found to contain pentobarbital. The DNA from the dog food samples was extracted and subjected to PCR amplification by use of the canine specific PCR primers. The PCR product was separated in a 2% agarose gel containing ethicium bromide. Lanes 1 to 9 contained dog food samples. Lane 10 contained the negative control. Lane 11 contained purified canine DNA (positive control). Only results of the positive control sample (Lane 11) indicated the presence of a PCR amplicon. MW = Molecular weight standards.

Table 1—Polymerase chain reaction (PCR) assay results for species-specific PCR primers used to analyze 31 dog food samples*

	Specificity of the PCR primer pair								
Sample No.	PtB†	Universal	Canine	Feline	Equine	Bovine	Porcine	Ovine	Avian
1	Pos	Pos	Neg	Neg	Neg	Pos	Neg	Neg	Pos
2	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Pos
3	Neg	Pos	Neg	Neg	Neg	Neg	Pos	Neg	Pos
4	Pos	Pos	Neg	Neg	Neg	Pos	Neg	Neg	Pos
5	Neg	Pos	Neg	Neg	Neg	Pos	Pos	Neg	Neg
6	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Pos
7	Pos	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Pos
8	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Pos
9	Poš	Pos	Neg	Neg	Neg	Pos	Pos	Neg	Pos
10	Neg	Pos	Neg	Neg	Neg	Pos	Pos	Neg	Neg
11	Pos	Pos	Neg	Neg	Neg	Pos	Pos	Neg	Pos
12	Neg	Pos	Neg	Neg_	Neg	Pos_	. Pos	, Neo	Pos
e 18:07-cv-21	122AoCMA	\ PЫ∂OCU	menn ∠58-	4 NegEnt	eredeğn	FLSD Doc	cket/leg/19	/200g	Page _s 11 (
14	Neg	Pos	Neg	Neg	Neg	Pos	Nea	Neg	Pos
15	Neg	Pos	Neg	Neg	Neg	Pos	Neg	Pos	Pos
16	Pos	Pos	Neg	Neg	Neg	Pos	Neg	Neg	Pos
17	Pos	Pos	Neg	Neg	Neg	Pos	Neg	Neg	Neg
18	Pos	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Pos
19	Pos	Pos	Neg	Neg	Neg	Pos	Poš	Neg	Pos
20	Pos	Pos	Neg	Neg	Neg	Pos	Neg	Neg	Pos
21	Neg	Pos	Neg	Neg	Neg	Pos	Neg	Neg	Pos
22	Neg	Pos	Neg	Neg	Neg	Pos	Neg	Neg	Pos
23	Pos	Pos	Neg	Neg	Neg	Pos	Neg	Neg	Neg
24	Pos	Pos	Neg	Neg	Neg	Pos	Neg	Neg	Poš
25	Neg	Pos	Neg	Neg	Neg	Neg	Pos	Neg	Pos
26	Neg	Pos	Neg	Neg	Neg	Pos	Neg	Neg	Pos
27	Pos	Pos	Neg	Neg	Neg	Pos	Poš	Neg	Pos
28	Pos	Pos	Neg	Neg	Neg	Pos	Neg	Neg	Pos
29	Neg	Pos	Neg	Neg	Neg	Pos	Neg	Neg	Pos
30	Neg	Pos	Neg	Neg	Neg	Pos	Neg	Neg	Pos
31	Pos	Pos	Neg	Neg	Neg	Pos	Poš	Neg	Pos

*The 31 dog food samples were all analyzed for the potential presence or absence of rendered meat and bone meal derived from various species. †Results for the presence or absence of pentobarbital. PtB = Pentobarbital. Pos = Positive result. Neg = Negative result.

ples, they were subjected to PCR amplification by use of a set of PCR primers (termed universal primers) shown to amplify only mtDNA from cows, deer, elk, sheep, goats, horses, and pigs. These species were considered as potential candidates for presence in these samples on the basis of the ingredient statements of the dog food samples. The results indicated that most, but not all samples had a PCR amplicon, indicating that rendered materials from 1 or more of these species were present in these dog food samples (Table 1). Interestingly, 2 of the 31 samples were positive for pentobarbital, but did not produce a PCR amplicon when the universal primers were used.

Further characterization of the dog food samples was performed by use of PCR primer sets specific for bovine, swine, or sheep mtDNA (Table 1). These results indicated the presence of rendered material derived from 1 or more of these species. As expected, samples that did not produce a PCR amplicon by use of the universal primers failed to produce amplicons when the species-specific primers were used. For the most part, the PCR assay results confirmed the ingredients as listed on the package label (Table 2). The exceptions to this were found in 4 of the 31 samples (samples 15, 22, 25, and 29). Of these 4 samples, only 2 had poultry and lamb-derived proteins listed (15 and 22), yet an amplicon specific for bovine DNA was observed in both samples, with no amplicon specific for sheep (lamb) observed in the results of 1 of the 2

samples (22). The remaining 2 of the 4 samples did not have a source of mammalian protein listed, only animal fat. The DNA from 1 sample produced PCR amplicons when the universal primers and swine-specific primers were used. The DNA from the other sample produced amplicons by use of universal and bovine-specific primers.

For the sake of completeness, the dog food samples were analyzed for the presence of poultry-derived products, although poultry are not euthanatized with pentobarbital. Poultry-derived products were listed as an ingredient for 21 samples. Of the 21 samples, 20 had a PCR amplicon when the poultry primer was used. Seven samples positive for poultry by PCR analysis did not have poultry products listed on the label, whereas 3 samples had negative results for poultry by PCR analysis and did not have poultry-derived products listed on the label.

Discussion

It is widely presumed that the rendered remains of animals euthanatized at animal shelters is the principal source of pentobarbital in pet food. However, the absence of detectable feline or canine mtDNA in the samples indicates that, within the context of our limited survey, rendered proteins from euthanatized dogs and cats were not present in these dog food samples. The detection limit of the method as used in our study is, at a minimum, at a level of 0.0007% (wt/wt basis).

Table 2—Results of PCR assay for mammalian DNA in 31 dog food samples and feed ingredients from animals listed on the sample labels

		Listed ingredients				
Sample No.	Mammalian DNA*	Meals	Animal fat	Digest	Beef tallow	
1 2 3 4 5	Pos Neg Pos Pos Pos	MBM, BBM CK, PBPM MBM, CBPM CBPM, BBM BBM, MBM, PBPM, DCBP	None AF	AD None AD None None	None BT None None None	
6 7 8 9 9.07-0	Neg Neg Neg Pgs CV-2ds221	CBPM, DEP CBPM, PD CM MBM, FM I-CMBM	AF AF AF Docaime	None None None AD entag 58	None None None None B-4lone E	
11 12 13 14 15	Pos Pos Pos Pos Pos	MBM, CBPM MM, PBPM MBM, CBPM MBM LM, DCBP	None	AD None AD AD None	None None None None None	
16 17 18 19 20	Pos Pos Neg Pos Pos	MBM, CBPM BBM PM, PD MBM MBM, CBPM	AF None AF	AD None None AD AD	None None BT None None	
21 22 23 24 25	Pos Pos Pos Pos Pos	BF, BBM PM, LM, PD BBM MBM, PBPM PM, DEP	None None AF AF AF	AD None AD AD None	BT BT None None None	
26 27 28 29 30 31	Pos P Pos Pos Pos Pos	PBPM, MBM, C MBM MBM CBPM BBM, CBPM MBM, CBPM	AF AF AF None	None BD AD None None AD	None None None None BT None	

*PCR assay results for mammalian DNA.

AD = Animal digest. AF= Animal fat. BBM = Beef and bone meal. BD = Beef digest. BF = Beef. BT = Beef tallow. CBPM = Chicken by-product meal. CK = Chicken. CM = Chicken meal. DCBP = Digest of chicken by-product. DEP = Dried egg product. FM = Fish meal. LM = Lamb meal. MBM = Meat and bone meal. MM = Meat meal. PBPM = Poultry by-product meal. PD = Poultry digest. PF = Poultry fat. PM = Poultry meal.

See Table 1 for remainder of key.

This translates to 7 kg of rendered protein in 1,000 metric tons of dog food. Although it can be argued that there may be the rendered remains of dogs or cats below the detection limit, this amount of rendered meat and bone meal is insufficient to produce the amounts of pentobarbital detected in some of these dog food samples.

Horses are the other species euthanatized with pentobarbital in large numbers. Because of their large size, and the amount of drug needed for euthanasia, I horse would represent a substantial portion of a large batch of meat and bone meal. However, none of the 31 dog food samples examined in our study tested positive for equine-derived proteins. Similarly, no evidence of the presence of PCR amplicons specific for feline mtDNA was found in the dog food samples. Thus, the presence of pentobarbital in the dog food samples analyzed in our study do not appear to be the result of contamination of meat and bone meal containing the remains of euthanatized dogs, cats, or horses.

Further support for the hypothesis that meat

meals derived from euthanatized pets are not the source of the pentobarbital contamination in dog food comes from the analysis results of 2 of the 31 samples. These 2 samples were negative for mammalian mtDNA (cow, deer, elk, sheep, goat, horse, pig, cat, dog) but positive for poultry by-products. These results are in agreement with the product labels, which list only poultry-derived protein products. Although this method cannot conclusively state that there are no petderived proteins in these 2 samples (below the level of 0.007% [wt/wt basis]), the low amount of pentobarbital in these samples would preclude them from being the source of drug residue.

Results of analysis of the dog food samples by use ntereother universal primer and the 2 origus specife specife 33 ic PCR primers indicate that rendered materials from cattle, swine, or sheep were present. Cattle are only occasionally euthanatized with pentobarbital, and thus are not considered a likely source of pentobarbital in dog food. Comparison of the PCR assay results with the product labels reveals a lack of correlation between the various protein sources and the presence of pentobarbital. The only report² to follow the fate of pentobarbital through the rendering process found it was equally distributed in the meat and bone meal and tallow fractions. In our study, PCR assay results on the species of origin in the various dog food samples does not support a single point source of protein for the origin of the pentobarbital. The only common feature of all samples containing pentobarbital was the presence of animal fat. This suggests that animal fat might be the source for pentobarbital.

This hypothesis is supported by observations from the initial survey⁶ for pentobarbital in dog food. A relationship was observed between the ingredients listed on the package label and the likelihood a sample contained pentobarbital. Specifically, the higher the ranking of animal fat (tallow) on the ingredient list, the greater the likelihood that a given sample would be positive for pentobarbital. Although the results of our study narrow the search for the source of pentobarbital, it does not define the source (ie, species) responsible for the contamination.

The methods of our study may also be used in assuring the validity of label claims. Of the 31 samples, 27 had agreement between the PCR assay results and the package label for mammalian derived components. Only 4 samples had PCR assay results that did not agree with the label claims. In all 4 instances, bovine materials were detected by the PCR assay; however, no bovine protein sources were listed on the labels for these samples. However, 3 of these samples had either animal fat (2 samples) or beef tallow (1 sample) listed on the product label, suggesting that this component might be the source of the bovine material. Residual amounts of animal derived proteins contaminating the animal fat might explain these findings; whether this is the case cannot be determined at present. The results from the remaining 1 of the 4 samples are more difficult to explain. The only animal-derived products on the label for this sample were poultry meal and lamb meal. However, PCR analysis failed to detect lamb (sheep) specific mtDNA, but detected bovine mtDNA.

Cas

This finding could be the result of experimental error or sample misbranding. On the basis of previous results, the rates of false negatives and false positives are 1.25% and 0.83%, respectively.5 Finding bovine mtDNA but not finding lamb (sheep) mtDNA could represent a false positive and false negative, respectively. However, 2 different investigators analyzed this sample on 2 different occasions, with both analysts obtaining the same result, suggesting that the product is incorrectly labeled.

Similarly, 27 of the 31 samples were positive by PCR analysis for poultry, even though only 21 samples had poultry products listed on the label. Only 20 of these 21 samples yielded a PCR amplicon when the poultry case in 17 vas 12 to 28 to 18 amplicon when the pounty 1998;61:513-518 Case in 1998;61:518 Cas try by PCR analysis but did not list poultry by-products on the ingredient list. These 7 samples had animal digest or animal fat listed as ingredients, however.

One sample with 2 different poultry products on the ingredient list was negative by PCR analysis for poultry. The absence of a PCR amplicon in this sample could be because of experimental error or sample misbranding. However, repeat analysis by different investigators yielded the same result, suggesting that this sample is also incorrectly labeled.

The results of our study indicate that a lack of correlation exists between species identity and the presence of pentobarbital in dog food. They also provide evidence against the presumption that euthanatized pets are routinely rendered and used in pet food. In addition, our study establishes a method for identification of the types (ie, species) of meat and bone meal present in dog food. This method should prove useful for analysis of dog (and cat) food for the accuracy of the label claims.

References

- 1. Budavari S, ed. The Merck Index. 11th ed. Rahway, NJ: Merck & Co Inc, 1989.
- 2. O'Connor JJ, Stowe CM, Robinson RR. Fate of sodium pentobarbital in rendered products. Am J Vet Res 1985;46:1721-1724.
- Adam LA, Reeves VB. Procedure for detecting and confirming PtB residues in dog food by gas chromatography/mass spectrometry. J Assoc Off Anal Chem 1998;81:359-367.
- 4. Heller DN, Lewis KM, Cui W. Method for determination of pentobarbital in dry dog food by gas chromatography/mass spectrometry. J Agric Food Chem 2001;49:4597-4602.
- 5. Myers MJ, Friedman SL, Farrell DE, et al. Validation of a polymerase chain reaction method for the detection of rendered bovine-derived materials in feedstuffs. J Food Prot 2001;64:564-566.

- 6. Center for Veterinary Medicine, US FDA web site. Report on the risk from pentobarbital in dog food. Available at: www.fda.gov/cvm/efoi/DFreport.htm. Accessed Feb 28, 2002.
- 7. Kim KS, Lee SE, Jeong HW, et al. The complete nucleotide sequence of the domestic dog (Canis familiaris) mitochondrial genome. Mol Phylogenet Evol 1998;10:210-220.
- 8. Xu X, Arnason U. The complete mitochondrial DNA sequence of the horse, Equus caballus: extensive heteroplasmy of the control region. Gene 1994;148:357-362.
- 9. Lopez JV, Cevario S, O'Brien SJ. Complete nucleotide sequences of the domestic cat (Felis catus) mitochondrial genome and a transposed mtDNA tandem repeat (Numt) in the nuclear genome. Genomics 1996;33:229-246.
- 10. Tartaglia M, Saulle E, Pestalozza S, et al. Detection of bovine mitochondrial DNA in ruminant feeds: a molecular approach to test for the presence of bovine-derived materials. J Food Prot
- method for purification of nucleic acids. J Clin Microbiol 1990;28:495-503.
- 12. Lahiff S, Glennon M, O'Brien L, et al. Species-specific PCR for the identification of ovine, porcine and chicken species in meat and bone meal (MBM). Mol Cell Probes 2001;15:27-35.
- 13. Myers MJ, Yancy HF, Farrell DE. Characterization of a PCRbased approach for the simultaneous detection of multiple animalderived materials in animal feed. J Food Prot 2003;66:1085-1089.

Appendix 1

Polymerase chain reaction (PCR) primer sequences

Species	PCR primer sequences	
Bovine	S	GCCATATACTCTCCTTGGTGACA
	AS	GTAGGCTTGGGAATAGTACGA
Porcine	S	GCCTAAATCTCCCCTCAATGGTA
	AS	ATGAAAGAGGCAAATAGATTTTCG
Ovine	S	TTAAAGACTGAGAGCATGATA
Ovino	ĀŠ	ATGAAAGAGGCAAATAGATTTTCG
Poultry	Š	GGGACACCCTCCCCCTTAATGACA
· outury	ĀŠ	GGAGGGCTGGAAGAAGGAGTG
Universal	S	ACTITGAAAAATGATCTGCATCAA
0111101001	ĀŠ	TCGTTCATTTTGTTTCTCAAGGGGT
Canine	Š	ACTGATCGTCATATTCCCTTCCAT
ouo	AS	TCCCTGCTCATAGGGGAATTGCTA
Feline	S	AGCATTAACCTTTTAAGTTAAAGAC
	AS	CCTATTATTGTTGGGGTAG
Equine	S	TGGCGGTGCTTTACATCCCT
-440	AS	TTTGAGTGAAATCTTCTAGGTGTAA

Appendix 2

Expected reverse transcriptase (RT)-PCR fragment size, annealing temperature, and number of cycles used for amplification

Gene specificity	Annealing temperature (°C)	RT-PCR product (base pairs)	Final extension time (min)
Bovine	58	271	5
Canine	54	271	7
Feline	54	510	7
Equine	56	500	5
Swine	58	212	5
Poultry	58	280	5
Universal	48	271	5
Ovine	58	255	5

Primer Premier V 5.00 software program, Premier BioSoft Intl, Palo Alto, Calif.

^bInVitrogen, Gaithersburg, Md.

Wizard Genomic DNA Purification Kit, Promega, Madison, Wis. ^dGift of Dr. Beth Williams, University of Wyoming, Laramie, Wyo. 'Gift of Vickie Solberg, Washington, DC.

^fRockland Laboratories, Gilbert, Pa.

SEPTEMBER 27, 1995-CITY PAPER

onsider these irems: Bozman the 221-Q660 dis Orice 6 Var 2 1221 quarter horse who died last summer in the line of duty. The grill grease and used frying oil from Camden Yards, the city's summer ethnic festivals, and nearly all Baltimore-area and Ocean City restaurants and hotels. A baby circus elephant who died while in Baltimore this summer. Millions of tons of waste meat and inedible animal parts from the region's supermarkets and slaughter-houses. Carcasses from the Baltimore Zoo. The thousands of dead dogs, cats, raccoons, possums, deer, foxes, snakes, and the rest that local animal shelters and road-kill patrols must dispose of each month.

These are the raw materials of Baltimore's fat-and-protein economy, which are processed into marketable products for high profit at the region's only rendering plant, in Curtis Bay. In a gruesomely ironic twist, most ined-ible dead-animal parts, including dead pets, end up in feed used to fatten up future gen-erations of their kind. Others are transmogrified into paint, car wax, rubber, and in-dustrial lubricants. Until the mid-1980s, some of the plant's products were used in

soap and cosmetics as well.

Like the use of human placenta in cosmetics and eating Rocky Mountain oysters, rendering is a phenomenon that many have heard

of but few are tempted to ponder. Unlike those odd human practices, though, ren-dering answers a vital societal question: What to do with the prodigious amount of carrion, offal, and fat that our society leaves in its dietary wake? Rather than classifying it as foul waste and incinerating it or burying it in a landfill, why not cook it into its constituent parts-fat and protein-and make a pretty

penny doing it? Valley Proteins does. The Winchester, Virginia–based company owns and runs Baltimore's only rendering plant, tucked along the grassy shores of Cabin Branch, a tributary of Curtis Bay in the extreme southern tip of the city. Although a few out-ofstate rendering plants attempt to compete in Baltimore, Valley Protein's Curtis Bay plant

has a regional lock on the profitable recycling of dead animal matter and kitchen grease into ingredients for feed and industrial prod-

Based on estimates from Neil Gagnon, genreal manager of the Curtis Bay plant, about 150 million pounds of rotting flesh and used kitchen grease from around Baltimore are fed into the plant's grinders and cookers each

year, resulting in about 80 million pounds of the plant's three products: meat and bone meal, tallow, and yellow grease. Most is re-constituted as chicken feed for North Carolina and Eastern Shore poultry farmers. Some goes for dry pet food. And some of the tal-low is used by chemical "splitters," who turn the far into farty acids, which in turn are used in thousands of products.

uring a midsummer day's visit to the plant, I gag upon first contact with the hot, putrescent air. My throat immediately becomes coated with the suety taste

of decayed, frying flesh.

"You picked a bad day to visit a rendering plant," Gagnon says, emphasizing the effect of the summer heat by describing the typical state of the "deadstock" picked up

from Pimlico Race Course, which is delivered to Valley Protein's pet-food operations in Pennsylvania. "By the time we get them, they're soup," he says. "Summertime is bad around here."

Gagnon himself is far from offended by the overwhelming miasma, though. "It smells like money," he likes to say. Later in the vis-it, back in his office, he estimates Valley

Protein's profit margin at somewhere in the neighborhood of 30 percent. A load of guts, heads, and legs, recently re-trieved from a local slaughterhouse, sits stewtrieved from a local saugnternouse, sits stew-ing in one of the raw-materials bins at the plant's receiving bay. "That's very fresh of-fal," Gagnon says. He explains how it will be fed into "the hogger," a shredder that grinds up the tissues and filters out trash, before it is deep-fried in cookers charged with spent restaurant grease and blood

After being thoroughly fried, the solid pro-tein is centrifuged, pressed, run through a magnet to remove metals, ground up, sift-ed, cooled, and stored in a silo. Today, midway through the process, cooker operator Bud Kellner smiles, grabs a warm, brown, fi-brous thatch of cooked tissues out of the production line in the cook room and shouts out above the mechanical din: "That's all protein material! I could eat that right now!"

Happens to Dead Animals? A Look at Baltimore's Only Remaining Rendering Plant Explains by VAN SMITH

stored in five tanks—two for tallow, a high-er-grade fat product, and three for yellow grease. Kellner doesn't mention whether he considers the fat potable.

The rendering processes at Valley Protein's Curtis Bay plant create three byproducts: waste water, which goes to the city's Patapsco Waste Water Treatment Plant at nearby Wagners Point; the stray fat and protein molecules in the air that generate the plant's hor-rid stench; and reclaimed dirt, metal, plastics, and other trash, which go to the nearby Quarantine Road Landfill. Two boilers, which jointly generate 2,000 horsepower, run the whole operation.

While waiting at the receiving bay to watch another truckload of offal (this one from Baltimore County slaughterer J. W. Treuth & Sons, Inc.) tumble into a raw-materials bin, Kellner sums up why rendering is im-portant. "If it don't go here, it'd be laying on

the side of the street somewhere."

Blood and body fluids leak out from under the trailer gate. "Cranberry juice," Gagnon remarks as we gaze at the repulsive pale-red effluvium. Suddenly a hot gust of wind blows droplets of it on our bare legs. As the bloated stomachs and broken body parts slide en masse from the trailer bed to the bin, Bud shouts out, "Watch out for the splatter!" After the load is delivered, a single jawbone rests on the pavement amid the bloody liquid. Bud adds a final piece of sage advice: "Make sure you take a shower.'

alley Proteins didn't always have a virtual monopoly over the rendering busi-ness in Baltimore. In 1927, The National Provisioner, a meat-industry newsletter, published a map and list showing the geographical distribution of the nation's renderers and slaughterhouses. At that time, Baltimore had 15 of Maryland's 21 rendering plants, and

there were 913 plants in the nation.
Today, according to Gagnon, Baltimore has one of the state's six to 10 plants, which

are concentrated on the Eastern Shore to serve the poultry industry. The nationwide figure has dropped to 286, according to Gary G. Pearl of the Fats and Oils Research

Foundation. (Affiliated with the National Renderers Association, the foundation sup-ports "increased utilization and new uses for products that are produced with the 50 per-

cent of the animal that is not acceptable for human consumption," Pearl says.) Valley Proteins' eight plants draw raw ma-

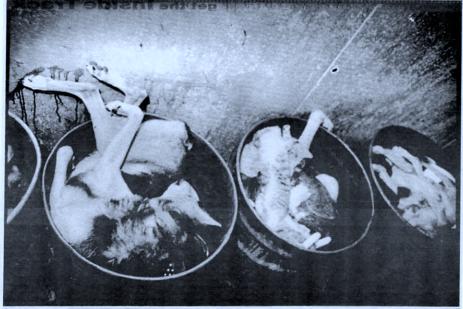
terials from the entire mid-Atlantic region, according to J. J. Smith, president of the com-pany. Smith describes the company's territory as "from Newark [New Jersey] to Savannah [Georgia], and 300 miles inland." Its threegeneration mini empire began in 1949 with company patriarch Clyde Smith's buyout of

an existing plant in Winchester, Virginia. According to Baltimore City land records, Valley Proteins purchased the Curtis Bay plant in 1984 for \$2 million from Benedict K. Hudson, president of another rendering company, Kavanaugh Products, which had purchased the property in the 1960s. Five of Valley Protein's' eight plants were originally owned by other renderers, Gagnon says.

J. J. Smith says the industry's trend toward concentration of ownership picked up mo-mentum about 20 or 30 years ago with the creation of a market for "boxed beef."

Whereas cattle used to be sent to market in halves or quarters, and every community had its own slaughter facilities," the company president explains, "now the slaugh-tering is consolidated in the Midwest, and they ship [the meat] out in boxes of 20- or

25-pound chunks." Boxed beef reduced the need for the neighborhood slaughterhouse, or abattoir. According to Smith, "a new movement toward close trim meat and tray-ready beef" similarly is eliminating the need for butchers and meat cutters in supermarkets because even more



Above: Barrels of dead pets and wildlife from the city animal shelter; below: tallow and yellow grease storage tanks—two of the end products



An average of 1,824 dead animals pass through the freezer at the city animal shelter and onto trucks bound for Valley Proteins' Curtis Bay plant, according to shelter statistics for the months of April, May, and June of this year.



A truck empties offal into a raw-materials bin.

of the meat preparation occurs in Midwest slaughter plants.

"Baltimore used to have abattoirs all over the place," Smith says. Now Baltimore City has only one, a kosher slaughterhouse in the Penn-North area. The 1927 Biennial Census of Manufactures, cited in the 1929 industry classic Inedible Animal Fats in the United States by Food Research Institute economist L. B. Zapoleon, indicates there were 40 slaughterers and meat packers in Baltimore at that time.

The decline of Baltimore's slaughterers and butchers has meant less raw material for rendering.

"In 1965, at any given supermarket, we used to pick up [waste meat] three to five times a week at 1,000 pounds each. Now we do it once a week at 600 pounds, Smith says. That's an 80 to 90 percent drop in volume, and, as Smith often points out, volume is what we thrive on in this busi-

Thirty years ago, according to Smith, 85 to 90 percent of renderers' material came from supermarkets and slaughterhouses. Today, he estimates that a little more than half of the raw material for the Curtis Bay plant is from those sources. The other half is kitchen grease and frying oils from restaurants, the proliferation of which he believes has made up for about a third of the loss resulting from the boxed-beef phenome-

"People used to eat at home more often," Smith says. "But now there are many, many restaurants, and people eat out all the time, so there has been an explosive growth at that level over the last 30 or 40 years."

During this same period, the industry also underwent a technology shift. In 1965, Dupps, a Germantown, Ohio, equipment manufacturer, started to make "continu-ous cookers," which quickly replaced "batch kers" as the industry standard.

Batch cookers restricted the rate of pro-cessing because after each batch was cooked, the cookers had to be emptied and prepared for the next load. Continuous cookers made nonstop rendering possible, and the quantities the plants could handle grew greater over the ensuing years. Today Dupps makes a continuous cooker that can handle the equivalent of 22 batch cookers, according to Smith.

Exhibit 34

"TCBBE in tell To the want 1221 - matter of new ways to cook," Smith explains. "It was a matter of bigger and bigger scales. It was more efficient, but it was also more competitive for raw material."

In Baltimore's rendering industry, lower volumes of meat-packing and supermarket waste and higher production capacities combined with another factor—the dramatic rise of the poultry industry—to spell an end to all but one plant in the region. Baltimore was a red-meat-packing town caught completely off guard by the continuing surge in chicken consumption, which began about 20 years ago.

"There were very few poultry-eviscerating plants in the 1960s," Smith says. But as the poultry industry expanded in the South and on Maryland's Eastern Shore, those regions' need for rendering increased. Baltimose City, meanwhile, was left with closed-down meat-packing plants, slaughterhouses, and rendering plants. Only one of each remains.

Finally, the proliferation of environmental regulations has further encouraged

ownership concentration in the rendering business. "Environmental requirements got expensive, so it became a trend to sell out to competitors who can handle the changes," Smith explains. For the remaining firms, he says, increased regulation "was a two-edged sword. It was expensive because it required high capital investments, but it was also a barrier for a startup company to compete with you."

The changes amount to a classic case of "the bigger fish swallows the smaller fish." Smith says. Pearl of the Fats and Oils Research Foundation agrees: "The general rule has been fewer and larger, with individual plants covering larger geographic areas and the investment per plant becoming much greater in order to meet environmental and water-quality standards."

he use of dead pets, work animals, and wildlife as raw material is an aspect of the rendering business that neither Gagnon, Smith, nor Pearl likes to discuss. When they do address it, they emphasize its limited role and contend it is more a public service than a profitable practice.

"That is a very small part of the business that we don't like to advertise," Smith says. His main worry is bad publicity from animal-rights activists, who complain about the use of animal corpses for profit.

"We provide that as a service, not for profit," he says, pointing out that "there is not a lot of protein and fat" in dead pets and wildlife, "just a lot of hair you have to deal with somehow." Smith believes that "shaming the American public into taking care of their pets is the way to combat the problem the animal-rights people talk about, not hassling the compaires that manage the waste the pet industry produces in terms of dead animals."

Smith says that while Valley Proteins sells inedible animal parts and rendered material to Alpo, Heinz, and Ralston-Purina, among other pet-food makers, dead-pet byproducts are not among the products sold to these companies. "They are all very sensitive to the recycled-pet potential," he explains. "They want no pets in the food they sell. We guarantee them that the product we sell to them does not come from the pets we collect. We handle them separately."

A tiny amount of pet byproducts does

get into the material sold to pet-food makers, however, according to plant general manager Gagnon. Valley Proteins does have two production lines: one that uses only clean, fresh fat and bones from supermarkets and butcher shops, and another that includes the use of dead pets and wildlife. However, the protein material is a mix from both production lines. Thus the meat and bone meal made at the plant includes materials from pets and wildlife, and about five percent of that product goes to dry-pet-food manufacturers, Gagnon says.

The high-end production line—the one will have so a consumer appeal." Smith says. The low-end line makes yellow grease, which goes mostly for poultry and swine feed; as Smith notes, "the chicken doesn't give a shit what it's eating." Local feed makers that buy Valley Proteins' products include Southern States in Locust Point. Gagnon says there are no longer any local purchasers of the plant's tallow products.

ost of the dead pets that end up in Valley Protein's Curtis Bay plant originate from the city animal shelter in Southwest Baltimore. Earl Watson, administrator of the city Health Department's Animal Control Division, is very aware of the use of dead pets and wildlife in Baltimore's fat-and-protein economy, and he knows Valley Proteins' overarching role in it. "Anywhere there are dead animals, they pick them up," he says. "They have a monopoly on that because no one else does it. That means they can charge what they want to charge for the service."

An average of 1,824 dead animals per month pass through the freezer at the city animal shelter and onto trucks bound for Valley Proteins' Curtis Bay plant, according to shelter statistics for April, May, and June of this year. Most of them were euthanized (three-month average: 1,339), though many were DOAs (three-month average: 485). (DOAs went up significantly in July and August, with 655 and 815 respectively, because of the hot weather and the city's Clean Sweep program that targeted specific areas for cleanup.)

Here at the animal shelter, a staff of 10 wardens works every day but Sunday, picking up animals and bringing them to the shelter, while the shelter's two vet-

erinary technicians euthanize animals tomake room for the newcomers.

"Having to euthanize animals all day is not pleasant," Watson says, "especially if you like animals." He and shelter attendant Edward Rigney lead the way to Room 162—EUTHANASIA— and Watson bows out after Rigney pulls open the door to the freezer, in which a dead fox lies stretched out on a table surrounded by barrels filled mostly with dead dogs and cats. Fleas leap among the carcasses.

"Ten or 12 were euthanized this morning," Rigney says. "Sometimes it's thirtysome that get it. Things get backed up over the holidays."

Outside the freezer, atop another table, lie a bottle of the poison product Fatal-Plus, several syringes, a medical-waste container, and a hacksaw resting on a towel. The hacksaw is for rabies testing: "When people get bit, we have to cut the dogs' heads off and test their brains," Rigney explains, adding that the veterinary technician "never uses that—she just twists them off." Fatal-Plus is sodium pentobarbital; the warning label reads: "Do not use in animals intended for food." This warning apparently does not apply for animals intended for pet food, which is where the protein from these euthanized animals ends up.

ollowing Valley Proteins route driver Milton McCroy on his rounds is a colorful tour of Baltimore's fat and protein sources. Every Monday, Wednesday, and Friday, McCroy enters the STAFF & DELIVERIES entrance of the city animal shelter and loads dead animals into his truck. He then continues his rounds to Parks Sausage, the city's lone remaining meat-packing plant, where he picks up waste meat, and to the slaughterhouse in Penn-North, where he loads up with offal, before taking the shipment back to the Curtis Bay plant and dumping it in the raw materials bin.



Bud Kellner of Valley Proteins with a handful of fried animal tissue on its way to becoming meat and bone meal



"The Hogger": Part of the process that grinds up animal tissue and filters out trash before it is deep-fried

"It's a dirty, smelly job, yeah—but that's all it is, dirty and smelly," he says philosophically, leaving one wondering what could be worse.

At the animal shelter, McCroy hefts two dogs stiffened by rigor mortis into the trailer of his truck, which is rigged for the rendering business with a lift, a catwalk, and a barrel cleaner. He then empties and cleans 11 barrels of assorted animals. As he works, he describes where his load is bound. "Chicken feed, cosmetics, fertilizer, dog food, whatever—the way they cook that bad boy [the Curtis Bay plant] up, it don't make no difference what's in there," he says, then pauses and adds: "When they start putting human bodies in there, that's when I quit."

After a brief stop at Parks Sausage, where

McCroy empties 10 or so barrels of rancid meat and grease, he heads off to the slaughterhouse, next to a long-defunct animal-hospital building. He backs the truck up to a storage shed, hauls a bloated sheep carcass onto the lift, and dumps it in the trailer, then starts preparing to empty many barrels full of heads, legs, hides, and guts. Joking, he starts to make the jaws of a cow's head clack, then gives up on the puppet show. He hoists two sheeps' heads in the air, one in each hand,

and asks, "Which one do you want?" He punctures a stomach with a pocket knife and squeezes out the brown ooze inside.

The jocularity ends when the plant's owner catches wind that the press has entered the property. As we explain that we are following McCroy on his run for a story on rendering, he ushers us off to the adjacent sidewalk. "With all our problems with OSHA [Occupational Safety and Health Administration], MOSHA [Maryland OSHA], EPA [Environmental Protection Agency], and the rest, there just is no good publicity for us right now," he explains.

Smith believes that "shaming the American public into taking care of their pets is the way to combat the problem the animal-rights people talk about, not hassling the companies that manage the waste the pet industry produces."

A plant employee explained later that tightening environmental regulations and concerns about the bacteria *E. coli* are coming down hard on slaughterhouses; any attention would just mean more problems. (A subsequent check with state and local regulators did not reveal any outstanding cases or suspected violations at the city slaughterhouse.) Disappointed in being shunted from the property, we leave without a proper good-bye to the good-natured McCroy.

Baltimore's fat-and-protein economy has changed dramatically over the decades, but it remains essentially a profitable form of recycling. The National Renderers Association sums up the industry nicely in its 12-minute video, Food for Life:

The rendering industry provides many needed services to the community at large; it safely recycles materials that otherwise would be a nightmare to dispose of; it creates products that are essential to modern life; it provides the needed nutrition for our livestock and fisheries, so that a hungry world can be efficiently fed; and it supplies our pets with a healthy diet for longer, better lives.

So the next time you munch on fastfood fries (often cooked in grease the restaurants subsequently sell to Valley Proteins), or let your unneutered pet roam the city streets and backyards, or apply a little makeup to your face, or wax your car, or barbecue some chicken breasts, pause a second to think: Is this somehow connected to the Valley Proteins rendering plant in Curtis Bay, either on the donating or receiving end? Chances are,



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GET THE FACTS:

<u>What's Really in Pet Food</u>

lump whole chickens, choice cuts of beef, fresh grains, and all the wholesome nutrition your dog or cat will ever need.

These are the images pet food manufacturers promulgate through the media and advertising. This is what the \$15 billion per year U.S. pet food industry wants consumers to believe they are buying when they purchase their products.

This report explores the differences between what consumers think they are buying and what they are actually getting. It focuses in very general terms on the most visible name brands — the pet food labels that are mass-distributed to supermarkets and discount stores — but there are many highly respected brands that may be guilty of the same offenses.

What most consumers don't know is that the pet food industry is an extension of the human food and agriculture industries. Pet food provides a convenient way for slaughterhouse offal, grains considered "unfit for human consumption," and similar waste products to be turned into profit. This waste includes intestines, udders, heads, hooves, and possibly diseased and cancerous animal parts.

THE PLAYERS _

he pet food market has been dominated in the last few years by the acquisition of big companies by even bigger companies. With \$15 billion a year at stake in the U.S. and rapidly expanding foreign markets, it's no wonder that some are greedy for a larger piece of the pie.

- Nestlé's bought Purina to form Nestlé Purina Petcare Company (Fancy Feast, Alpo, Friskies, Mighty Dog, Dog Chow, Cat Chow, Puppy Chow, Kitten Chow, Beneful, One, ProPlan, DeliCat, HiPro, Kit'n'Kaboodle, Tender Vittles, Purina Veterinary Diets).
- Del Monte gobbled up Heinz (MeowMix, Gravy Train, Kibbles 'n Bits, Wagwells, 9Lives, Cycle, Skippy, Nature's Recipe, and pet treats Milk Bone, Pup-Peroni, Snausages, Pounce).
- MasterFoods owns Mars, Inc., which consumed Royal Canin (Pedigree, Waltham's, Cesar, Sheba, Temptations, Goodlife Recipe, Sensible Choice, Excel).

Other major pet food makers are not best known for pet care, although many of their house hold and personal care products do use ingredients derived from animal by-products:

- Procter and Gamble (P&G) purchased The lams Company (lams, Eukanuba) in 1999. P&G shortly thereafter introduced lams into grocery stores, where it did very well.
- Colgate-Palmolive bought Hill's Science Diet (founded in 1939) in 1976 (Hill's Science Diet, Prescription Diets, Nature's Best).

Private labelers (who make food for "house" brands like Kroger and Wal-Mart) and co-packers (who produce food for other pet food makers) are also major players. Three major companies are Doane Pet Care, Diamond, and Menu Foods; they produce food for dozens of private label and brand names. Interestingly, all 3 of these companies have been involved in pet food recalls that sickened or killed many pets.

Many major pet food companies in the United States are subsidiaries of gigantic multinational corporations. From a business standpoint, pet food fits very well with companies making human products. The multinationals have increased bulk-purchasing power; those that make human food products have a captive market in which to capitalize on their waste products; and pet food divisions have a more reliable capital base and, in many cases, a convenient source of ingredients.

The Pet Food Institute — the trade association of pet food manufacturers — has acknowledged the use of by-products in pet foods as additional income for processors and farmers: "The growth of the pet food industry not only provided pet owners with better foods for their pets, but also created profitable additional markets for American farm products and for the byproducts of the meat packing, poultry, and other food industries which prepare food for human consumption."

LABEL BASICS

here are special labeling requirements for pet food, all of which are contained in the annually revised Official Publication of AAFCO. While AAFCO does not regulate pet food, it does provide model regulations and standards that are followed by U.S. pet food makers.

The name of the food provides the first indication of the food's content. The use of the terms "all" or "100%" cannot be used "if the product contains more than one ingredient, not including water sufficient for processing, decharacterizing agents, or trace amounts of preservatives and condiments."

The "95% Rule" applies when the ingredient(s) derived from animals, poultry, or fish constitutes at least 95% or more of the total weight of the product (or 70% excluding water for processing). Because all-meat diets are not nutritionally balanced and cause severe deficiencies if fed exclusively, they fell out of favor for many years. However, due to rising consumer interest in high quality meat products, several companies are now promoting 95% and 100% canned meats as a supplemental feeding option.

The "dinner" product is defined by the "25% Rule," which applies when "an ingredient or a combination of ingredients constitutes at least 25% of the weight of the product (excluding water sufficient for processing)", or at least 10% of the dry matter weight; and a descriptor such as "recipe," "platter," "entree," and "formula." A combination of ingredients included in the product name is permissible when each ingredient comprises at least 3% of the product weight, excluding water for processing, and the ingredient names appear in descending order by weight.

The "With" rule allows an ingredient name to appear on the label, such as "with real chicken," as long as each such ingredient constitutes at least 3% of the food by weight, excluding water for processing.

Document 258-4

The "flavor" rule allows a food to be designated as a certain flavor as long as the ingredient(s) are sufficient to "impart a distinctive characteristic" to the food. Thus, a "beef flavor" food may contain a small quantity of digest or other extract of tissues from cattle, or even an artificial flavor, without containing any actual beef meat at all.

The ingredient list is the other major key to what's really in that bag or can. Ingredients must be listed in descending order of weight. The ingredient names are legally defined. For instance, "meat" refers to only cows, pigs, goats and sheep, and only includes specified muscle tissues. Detailed definitions are published in AAFCO's Official Publication, revised annually, but can also be found in many places online.

The guaranteed analysis provides a very general guide to the composition of the food. Crude protein, fat, and fiber, and total moisture are required to be listed. Some companies also voluntarily list taurine, Omega fatty acids, magnesium, and other items that they deem important by marketing standards.

PET FOOD STANDARDS AND REGULATIONS

he National Research Council (NRC) of the Academy of Sciences set the nutritional standards for pet food that were used by the pet food industry until the late 1980s. The original NRC standards were based on purified diets, and required feeding trials for pet foods claimed to be "complete" and "balanced." The pet food industry found the feeding trials too restrictive and expensive, so AAFCO designed an alternate procedure for claiming the nutritional adequacy of pet food, by testing the food for compliance with "Nutrient Profiles." AAFCO also created "expert committees" for canine and feline nutrition, which developed separate canine and feline standards.

While feeding trials are sometimes still done, they are expensive and time-consuming. A standard chemical analysis may also be used to make sure that a food meets the profiles. In either case, there will be a statement on the label stating which method was used. However, because of the "family rule" in the AAFCO book, a label can say that feeding tests were done if it is "similar" to a food that was actually tested on live animals. There is no way to distinguish the lead product from its "family members." The label will also state whether the product is nutritionally adequate (complete and balanced), and what life stage (adult or growth) the food is for. A food that says "all life stages" meets the growth standards and can be fed to all ages.

Chemical analysis, however, does not address the palatability, digestibility, or biological availability of nutrients in pet food. Thus it is unreliable for determining whether a food will provide an animal with sufficient nutrients. To compensate for the limitations of chemical analysis, AAFCO added a "safety factor," which was to exceed the minimum amount of nutrients required to meet the complete and balanced requirements.

In 2006, new NRC standards were published; but it will take several years for AAFCO's profiles to be updated and adopted, let alone accepted by the states.

The pet food industry loves to say that it's more highly regulated than human food, but that's just not true. Pet food exists in a bit of a regulatory vacuum; laws are on the books, but enforcement is another story. The FDA has nominal authority over pet foods shipped across state lines. But the real "enforcers" are the feed control officials in each state. They are the ones who actually look at the food and, in many instances, run basic tests to make sure the food meets its Guaranteed Analysis, the chart on the label telling how much protein, fat, moisture, and fiber are present. But regulation and enforcement vary tremendously from state to state. Some, like Texas, Minnesota, and Kentucky, run extensive tests and strictly enforce their laws; others, like California. do neither.

THE MANUFACTURING PROCESS: HOW PET FOOD IS MADE.

Dry Food

■he vast majority of dry food is made with a machine called an extruder. First, materials are blended in accordance with a recipe created with the help of computer programs that provide the nutrient content of each proposed ingredient. For instance, corn gluten meal has more protein than wheat flour. Because the extruder needs a consistent amount of starch and low moisture to work properly, dry ingredients — such as rendered meat-and-bone-meal, poultry by-product meal, grains, and flours — predominate.

The dough is fed into the screws of an extruder. It is subjected to steam and high pressure as it is pushed through dies that determine the shape of the final product, much like the nozzles used in cake decorating. As the hot, pressurized dough exits the extruder, it is cut by a set of rapidly whirling knives into tiny pieces. As the dough reaches normal air pressure, it expands or "puffs" into its final shape. The food is allowed to dry, and then is usually sprayed with fat, digests, or other compounds to make it more palatable. When it is cooled, it can be bagged.

Although the cooking process kills bacteria in the ingredients, the final product can pick up more bacteria during the subsequent drying, coating, and packaging process. Some experts warn that getting dry food wet can allow the bacteria on the surface to multiply and make pets sick. Do not mix dry food with water, milk, canned food, or other liquids.

A few dog foods are baked at high temperatures (over 500oF) rather than extruded. This produces a sheet of dense, crunchy material that is then broken into irregular chunks, much like crumbling crackers into soup. It is relatively palatable without the sprayed-on fats and other enhancers needed on extruded dry food.

Semi-moist foods and many pet treats are also made with an extruder. To be appealing to consumers and to keep their texture, they contain many additives, colorings, and preservatives; they are not a good choice for a pet's primary diet.

Wet Food

Let or canned food begins with ground ingredients mixed with additives. If chunks are required, **V** a special extruder forms them. Then the mixture is cooked and canned. The sealed cans are then put into containers resembling pressure cookers and commercial sterilization takes place. Some manufacturers cook the food right in the can.

Wet foods are quite different in content from dry or semi-moist foods. While many canned foods contain by-products of various sorts, they are "fresh" and not rendered or processed (although they are often frozen for transport and storage). Wet foods usually contain much more protein, and it's often a little higher quality, than dry foods. They also have more moisture, which is better for cats. They are packaged in cans or pouches.

COMPARING FOOD TYPES ___

Because of the variation in water content, it is impossible to directly compare labels from different kinds of food without a mathematical conversion to "dry matter basis." The numbers can be very deceiving. For instance, a canned food containing 10% protein actually has much more protein than a dry food with 30% protein.

To put the foods on a level playing field, first calculate the dry matter content by subtracting the moisture content given on the label from 100%. Then divide the ingredient by the dry matter content. For example, a typical bag of dry cat food contains 30% protein on the label, but 32% on a dry-matter basis (30% divided by its dry matter content, 100-6% moisture = 94%). A can of cat food might contain 12% protein on the label, but almost 43% on a dry-matter basis (12% divided by its dry matter content, 100-72% moisture = 28%). Dry food typically contains less than 10% water, while canned food contains 78% or more water.

PET FOOD INGREDIENTS __

Animal Protein

Dogs and cats are carnivores, and do best on a meat-based diet. The protein used in pet food comes from a variety of sources. When cattle, swine, chickens, lambs, or other animals are slaughtered, lean muscle tissue is trimmed away from the carcass for human consumption, along with the few organs that people like to eat, such as tongues and tripe.

However, about 50% of every food animal does not get used in human foods. Whatever remains of the carcass — heads, feet, bones, blood, intestines, lungs, spleens, livers, ligaments, fat trimmings, unborn babies, and other parts not generally consumed by humans — is used in pet food, animal feed, fertilizer, industrial lubricants, soap, rubber, and other products. These "other parts" are known as "by-products." By-products are used in feed for poultry and livestock as well as in pet food.

The nutritional quality of by-products, meals, and digests can vary from batch to batch. James Morris and Quinton Rogers, of the University of California at Davis Veterinary School, assert that, "[pet food] ingredients are generally by-products of the meat, poultry and fishing industries, with the potential for a wide variation in nutrient composition. Claims of nutritional adequacy of pet foods based on the current Association of American Feed Control Officials (AAFCO) nutrient allowances ('profiles') do not give assurances of nutritional adequacy and will not until ingredients are analyzed and bioavailability values are incorporated."

Meat or poultry "by-products" are very common in wet pet foods. Remember that "meat" refers to only cows, swine, sheep, and goats. Since sheep and goats are rare compared to the 37 million cows and 100 million hogs slaughtered for food every year, nearly all meat by-products come from cattle and pigs.

The better brands of pet food, such as many "super-premium," "natural," and "organic" varieties, do not use by-products. On the label, you'll see one or more named meats among the first few ingredients, such as "turkey" or "lamb." These meats are still mainly leftover scraps; in the case of poultry, bones are allowed, so "chicken" consists mainly of backs and frames—the spine and ribs, minus their expensive breast meat. The small amount of meat left on the bones is the meat in the pet food. Even with this less-attractive source, pet food marketers are very tricky when talking about meat, so this is explained further in the section on "Marketing Magic" below.

Meat meals, poultry meals, by-product meals, and meat-and-bone meal are common ingredients in dry pet foods. The term "meal" means that these materials are not used fresh, but have been rendered. While there are chicken, turkey, and poultry by-product meals there is no equivalent term for mammal "meat by-product meal" — it is called "meat-and-bone-meal." It may also be referred to by species, such as "beef-and-bone-meal" or "pork-and-bone-meal."

What is rendering? As defined by Webster's Dictionary, to render is "to process as for industrial use: to render livestock carcasses and to extract oil from fat, blubber, etc., by melting." In other words, raw materials are dumped into large vat and boiled for several hours. Rendering separates fat, removes water, and kills bacteria, viruses, parasites, and other organisms. However, the high temperatures used (270°F/130°C) can alter or destroy natural enzymes and proteins found in the raw ingredients.

Because of persistent rumors that rendered by-products contain dead dogs and cats, the FDA conducted a study looking for pentobarbital, the most common euthanasia drug, in pet foods. They found it. Ingredients that were most commonly associated with the presence of pentobarbital were meat-and-bone-meal and animal fat. However, they also used very sensitive tests to look for canine and feline DNA, which were *not* found. Industry insiders admit that rendered pets and roadkill were used in pet food some years ago. Although there are still no laws or regulations against it, the practice is uncommon today, and pet food companies universally deny that their products contain any such materials. However, so-called "4D" animals (dead, dying, diseased, disabled) were only recently banned for human consumption and are still legitimate ingredients for pet food.

Vegetable Protein

Case 1:07-cv-21221-CMA

he amount of grain and vegetable products used in pet food has risen dramatically over time. Plant products now replace a considerable proportion of the meat that was used in the earliest commercial pet foods. This has led to severe nutritional deficiencies that have been corrected along the way, although many animals died before science caught up.

Most dry foods contain a large amount of cereal grain or starchy vegetables to provide texture. These high-carbohydrate plant products also provide a cheap source of "energy" — the rest of us call it "calories." Gluten meals are high-protein extracts from which most of the carbohydrate has been removed. They are often used to boost protein percentages without expensive animalsource ingredients. Corn gluten meal is the most commonly used for this purpose. Wheat gluten is also used to create shapes like cuts, bites, chunks, shreds, flakes, and slices, and as a thickener for gravy. In most cases, foods containing vegetable proteins are among the poorer quality foods.

A recent fad, "low-carb" pet food, has some companies steering away from grains, and using potatoes, green peas, and other starchy vegetables as a substitute. Except for animals that are allergic to grains, dry low-carb diets offer no particular advantage to pets. They also tend to be very high in fat and, if fed free-choice, will result in weight gain. Canned versions are suitable for prevention and treatment of feline diabetes, and as part of a weight loss program, as well as for maintenance.

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Animal and Poultry Fat

here's a unique, pungent odor to a new bag of dry pet food — what is the source of that smell? It is most often rendered animal fat, or vegetable fats and oils deemed inedible for humans. For example, used restaurant grease was rendered and routed to pet foods for several years, but a more lucrative market is now in biodiesel fuel production.

These fats are sprayed directly onto extruded kibbles and pellets to make an otherwise bland or distasteful product palatable. The fat also acts as a binding agent to which manufacturers add other flavor enhancers such as "animal digests" made from processed by-products. Pet food scientists have discovered that animals love the taste of these sprayed fats. Manufacturers are masters at getting a dog or a cat to eat something she would normally turn up her nose at.

WHAT HAPPENED TO THE NUTRIENTS?

ooking and other processing of meat and by-products used in pet food can greatly diminish their nutritional value, although cooking increases the digestibility of cereal grains and starchy vegetables.

To make pet food nutritious, pet food manufacturers must "fortify" it with vitamins and minerals. Why? Because the ingredients they are using are not wholesome, their quality may be extremely variable, and the harsh manufacturing practices destroy many of the nutrients the food had to begin with.

Proteins are especially vulnerable to heat, and become damaged, or "denatured," when cooked. Because dry foods ingredients are cooked twice — first during rendering and again in the extruder - problems are much more common than with canned or homemade foods. Altered proteins may contribute to food intolerances, food allergies, and inflammatory bowel disease.

ADDITIVES IN PROCESSED PET FOODS.

Many chemicals are added to commercial pet foods to improve the taste, stability, characteristics, or appearance of the food. Additives provide no nutritional value. Additives include emulsifiers to prevent water and fat from separating, antioxidants to prevent fat from turning rancid, and artificial colors and flavors to make the product more attractive to consumers and more palatable to their companion animals.

A wide variety of additives are allowed in animal feed and pet food, not counting vitamins and minerals. Not all of them are actually used in pet food. Additives can be specifically approved, or they can fall into the category of "Generally Recognized as Safe" (GRAS).

Anticaking agents Curing agents Grinding agents

Humectants Antigelling agents Drying agents

Emulsifiers Antimicrobial agents Leavening agents

Antioxidants Essential oils Lubricants

Color additives Flavor enhancers **Palatants**

Condiments Flavoring agents Pelleting agents and binders Petroleum derivatives Seasonings Sweeteners

pH control agents Spices Texturizers

Preservatives Stabilizers Thickeners

CHEMICAL VS. NATURAL PRESERVATIVES _

All commercial pet foods must be preserved so they stay fresh and appealing to our animal companions. Canning is itself a preserving process, so canned foods need little or no additional help. Some preservatives are added to ingredients or raw materials by the suppliers, and others may be added by the manufacturer. The U.S. Coast Guard, for instance, requires fish meal to be heavily preserved with ethoxyquin or equivalent antioxidant. Evidently, spoiling fish meal creates such intense heat that ship explosions and fires resulted.

Because manufacturers need to ensure that dry foods have a long shelf life (typically 12 months) to remain edible through shipping and storage, fats used in pet foods are preserved with either synthetic or "natural" preservatives. Synthetic preservatives include butylated hydroxyanisole (BHA) and butylated hydroxytoluene (BHT), propyl gallate, propylene glycol (also used as a less-toxic version of automotive antifreeze), and ethoxyquin. For these antioxidants, there is little information documenting their toxicity, safety, interactions, or chronic use in pet foods that may be eaten every day for the life of the animal. Propylene glycol was banned in cat food because it causes anemia in cats, but it is still allowed in dog food.

Potentially cancer-causing agents such as BHA, BHT, and ethoxyquin are permitted at relatively low levels. The use of these chemicals in pet foods has not been thoroughly studied, and long term build-up of these agents may ultimately be harmful. Due to questionable data in the original study on its safety, ethoxyquin's manufacturer, Monsanto, was required to perform a new, more rigorous study. This was completed in 1996. Even though Monsanto found no significant toxicity associated with its own product, in July 1997 the FDA's Center for Veterinary Medicine requested that manufacturers voluntarily reduce the maximum level for ethoxyquin by half, to 75 parts per million. While some pet food critics and veterinarians believe that ethoxyquin is a major cause of disease, skin problems, and infertility in dogs, others claim it is the safest, strongest, most stable preservative available for pet food. Ethoxyquin is approved for use in human food for preserving spices, such as cayenne and chili powder, at a level of 100 ppm — but it would be very difficult for even the most hard-core spice lover to consume as much chili powder every day as a dog would eat dry food. Ethoxyquin has never been tested for safety in cats. Despite this, it is commonly used in veterinary diets for both cats and dogs.

Many pet food makers have responded to consumer concern, and are now using "natural" preservatives such as Vitamin C (ascorbate), Vitamin E (mixed tocopherols), and oils of rosemary, clove, or other spices, to preserve the fats in their products. The shelf life is shorter, however — only about 6 months.

Individual ingredients, such as fish meal, may have preservatives added before they reach the pet food manufacturer. Federal law requires fat preservatives to be disclosed on the label; however, pet food companies do not always comply with this law.

DANGER AHEAD _

Potential Contaminants

iven the types of things manufacturers put in pet food, it is not surprising that bad things sometimes happen. Ingredients used in pet food are often highly contaminated with a wide variety of toxic substances. Some of these are destroyed by processing, but others are not.

- Bacteria. Slaughtered animals, as well as those that have died because of disease, injury, or natural causes, are sources of meat, by-products, and rendered meals. An animal that died on the farm might not reach a rendering plant until days after its death. Therefore the carcass is often contaminated with bacteria such as Salmonella and E. Coli. Dangerous E. Coli bacteria are estimated to contaminate more than 50% of meat meals. While the cooking process may kill bacteria, it does not eliminate the endotoxins some bacteria produce during their growth. These toxins can survive processing, and can cause sickness and disease. Pet food manufacturers do not test their products for bacterial endotoxins. Because sick or dead animals can be processed as pet foods, the drugs that were used to treat or euthanize them may still be present in the end product. Penicillin and pentobarbital are just two examples of drugs that can pass through processing unchanged. Antibiotics used in livestock production are also thought to contribute to antibiotic resistance in humans.
- *Mycotoxins*. Toxins from mold or fungi are called mycotoxins. Modern farming practices, adverse weather conditions, and improper drying and storage of crops can contribute to mold growth. Pet food ingredients that are most likely to be contaminated with mycotoxins are grains such as wheat and corn, and fish meal.
- Chemical Residue. Pesticides and fertilizers may leave residue on plant products. Grains that are condemned for human consumption by the USDA due to residue may legally be used, without limitation, in pet food.
- GMOs. Genetically modified plant products are also of concern. By 2006, 89% of the planted area of soybeans, 83% of cotton, and 61% of maize (corn) in the U.S. were genetically modified varieties. Cottonseed meal is a common ingredient of cattle feed; soy and corn are used directly in many pet foods.
- Acrylamide. This is a carcinogenic compound formed at cooking temperatures of about 250°F in foods containing certain sugars and the amino acid asparagine (found in large amounts in potatoes and cereal grains). It is formed in a chemical process called the Maillard reaction. Most dry pet foods contain cereal grains or potatoes, and they are processed at high temperatures (200–300°F at high pressure during extrusion; baked foods are cooked at well over 500°F); these are perfect conditions for the Maillard reaction. iv,v In fact, the Maillard reaction is considered desirable in the production of pet food because it imparts a palatable taste, even though it reduces the bioavailability of some amino acids, including taurine and lysine. vi The content and potential effects of acrylamide formation in pet foods are unknown.

Pet Food Recalls

↑ ↑ hen things go really wrong and serious problems are discovered in pet food, the company usually works with the FDA to coordinate a recall of the affected products. While many recalls have been widely publicized, guite a few have not.

In 1995, Nature's Recipe recalled almost a million pounds of dry dog and cat food after

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consumers complained that their pets were vomiting and losing their appetite. The problem was a fungus that produced vomitoxin contaminating the wheat.

- In 1999, Doane Pet Care recalled more than a million bags of corn-based dry dog food contaminated with aflatoxin. Products included Ol' Roy (Wal-Mart's brand) and 53 other brands. This time, the toxin killed 25 dogs.
- In 2000, lams recalled 248,000 pounds of dry dog food distributed in 7 states due to excess DL-Methionine Amino Acid, a urinary acidifier.
- In 2003, a recall was made by Petcurean "Go! Natural" pet food due to circumstantial association with some dogs suffering from liver disease; no cause was ever found.
- In late 2005, a similar recall by Diamond Foods was announced; this time the moldy corn contained a particularly nasty fungal product called aflatoxin; 100 dogs died.
- Also in 2005, 123,000 pounds of cat and dog treats were recalled due to Salmonella contamination.
- In 2006, more than 5 million cans of Ol' Roy, American Fare, and other dog foods distributed in the southeast were recalled by the manufacturer, Simmons Pet Food, because the cans' enamel lining was flaking off into the food.
- Also in 2006, Merrick Pet Care recalled almost 200,000 cans of "Wingalings" dog food when metal tags were found in some samples.
- In the most deadly recall of 2006, 4 prescription canned dog and cat foods were recalled by Royal Canin (owned by Mars). The culprit was a serious overdose of Vitamin D that caused calcium deficiency and kidney disease.
- In February 2007, the FDA issued a warning to consumers not to buy "Wild Kitty," a frozen food containing raw meat. Routine testing by FDA had revealed Salmonella in the food. FDA specifically warned about the potential for illness in humans, not pets. There were no reports of illness or death of any pets, and the food was not recalled.
- In March 2007, the most lethal pet food in history was the subject of the largest recall ever. Menu Foods recalled 95 brands including lams, Eukanuba, Hill's Science Diet, Purina Mighty Dog, and many store brands including Wal-Mart's — 60 million individual cans and pouches. Thousands of pets became sick and an estimated 20% died from acute renal failure caused by the food. Cats were more frequently and more severely affected than dogs. The toxin was initially believed to be a pesticide, the rat poison "aminopterin" in one of the ingredients, but the investigation is ongoing.

Nutrition-Related Diseases

he idea that one pet food provides all the nutrition a companion animal will ever need for its entire life is a dangerous myth.

Today, the diets of cats and dogs are a far cry from the variable meat-based diets that their ancestors ate. The unpleasant results of grain-based, processed, year-in and year-out diets are common. Health problems associated with diet include:

• Urinary tract disease. Plugs, crystals, and stones are more common in cats eating dry diets, due to the chronic dehydration and highly concentrated urine they cause. "Struvite" stones used to be the most common type in cats, but another more dangerous type, calcium oxalate, has increased and is now tied with struvite. Manipulation of manufactured cat food formulas to increase the acidity of urine has caused the switch. Dogs can also form stones as a result of their diet.

- Kidney disease. Chronic dehydration associated with dry diets may also be a contributing factor in the development of kidney disease and chronic renal failure in older cats. Cats have a low thirst drive; in the wild they would get most of their water from their prey. Cats eating dry food do not drink enough water to make up for the lack of moisture in the food. Cats on dry food diets drink more water, but the total water intake of a cat eating canned food is twice as great.vii
- · Dental disease. Contrary to the myth propagated by pet food companies, dry food is not good for teeth. VIII Given that the vast majority of pets eat dry food, yet the most common health problem in pets is dental disease, this should be obvious. Humans do not floss with crackers, and dry food does not clean the teeth.
- Obesity. Feeding recommendations or instructions on the packaging are sometimes inflated so that the consumer will end up feeding — and purchasing — more food. One of the most common health problems in pets, obesity, may also be related to high-carb, high-calorie dry foods. Both dogs and cats respond to low-carb wet food diets. Overweight pets are more prone to arthritis, heart disease, and diabetes. Dry cat food is now considered the cause of feline diabetes; prevention and treatment include switching to a high protein, high moisture, low-carb diet.
- Chronic digestive problems. Chronic vomiting, diarrhea, constipation, and inflammatory bowel disease are among the most frequent illnesses treated. These are often the result of an allergy or intolerance to pet food ingredients. The market for "limited antigen" or "novel protein" diets is now a multi-million dollar business. These diets were formulated to address the increasing intolerance to commercial foods that pets have developed. Even so, an animal that tends to develop allergies can develop allergies to the new ingredients, too. One twist is the truly "hypoallergenic" food that has had all its proteins artificially chopped into pieces smaller than can be recognized and reacted to by the immune system. Yet there are documented cases of animals becoming allergic to this food, too. It is important to change brands, flavors, and protein sources every few months to prevent problems.
- Bloat. Feeding only one meal per day can cause the irritation of the esophagus by stomach acid, and appears to be associated with gastric dilitation and volvulus (canine bloat). Feeding two or more smaller meals is better.
- Heart disease. An often-fatal heart disease in cats and some dogs is now known to be caused by a deficiency of the amino acid taurine. Blindness is another symptom of taurine deficiency. This deficiency was due to inadequate amounts of taurine in cat food formulas, which in turn had occurred due to decreased amounts of animal proteins and increased reliance on carbohydrates. Cat foods are now supplemented with taurine. New research suggests that some dog breeds are susceptible to the same condition. Supplementing taurine may also be helpful for dogs, but as yet few manufacturers are adding extra taurine to dog food.
- · Hyperthyroidism. There is also evidence that hyperthyroidism in cats may be related to diet. This is a relatively new disease that first surfaced in the 1970s. Some experts theorize that excess iodine in commercial cat food is a factor. New research also points to a link between

the disease and pop-top cans, and flavors including fish or "giblets." This is a serious disease, and treatment is expensive.

Many nutritional problems appeared with the popularity of cereal-based commercial pet foods. Some have occurred because the diet was incomplete. Although several ingredients are now supplemented, we do not know what ingredients future researchers may discover that should have been supplemented in pet foods all along. Other problems may occur from reactions to additives. Others are a result of contamination with bacteria, mold, drugs, or other toxins. In some diseases the role of commercial pet food is understood; in others, it is not. The bottom line is that diets composed primarily of low quality cereals and rendered meals are not as nutritious or safe as you should expect for your cat or dog.

PET FOOD INDUSTRY SECRETS.

Co-Packing

The 2007 Menu Foods recall brought to light some of the pet food industry's dirtiest secrets.

Most people were surprised — and appalled — to learn that all lams/Eukanuba canned foods are not made by The lams Company at all. In fact, in 2003 lams signed an exclusive 10-year contract for the production of 100% of its canned foods by Menu.

This type of deal is called "co-packing." One company makes the food, but puts someone else's label on it. This is a very common arrangement in the pet food industry. It was first illustrated by the Doane's and Diamond recalls, when dozens of private labels were involved. But none were as large or as "reputable" as lams, Eukanuba, Hill's, Purina, Nutro, and other high-end, so-called "premium" foods.

The big question raised by this arrangement is whether or not there is any real difference between the expensive premium brands and the lowliest generics. The recalled products all contained the suspect ingredient, wheat gluten, but they also all contained by-products of some kind, including specified by-products such as liver or giblets.

It's true that a pet food company that contracts with a co-packer can provide its own ingredients, or it can require the contractor to buy particular ingredients to use in its recipes. But part of the attraction of using a co-packer is that it can buy ingredients in larger bulk than any one pet food maker could on its own, making the process cheaper and the profits larger. It's likely that with many of the ingredients that cross all types of pet foods, those ingredients are the same.

Are one company's products — made in the same plant on the same equipment with ingredients called the same name — really "better" than another's? That's what the makers of expensive brands want you to think. The recalled premium brands claim that Menu makes their foods "according to proprietary recipes using specified ingredients," and that "contract manufacturers must follow strict quality standards." Indeed, the contracts undoubtedly include those points. But out in the real world, things may not go according to plan. How well are machines cleaned between batches, how carefully are ingredients mixed, and just how particular are minimumwage workers in a dirty smelly job going to be about getting everything just perfect?

Whatever the differences are between cheap and high-end food, one thing is clear. The purchase price of pet food does not always determine whether a pet food is good or bad or even safe. However, the very cheapest foods can be counted on to have the very cheapest ingredients. For

example, Ol' Roy, Wal-Mart's store brand, has now been involved in 3 serious recalls.

Menu manufactures canned foods for many companies that weren't affected by the recall, including Nature's Variety, Wellness, Castor & Pollux, Newman's Own Organics, Wysong, Innova, and EaglePack. It's easy to see from their ingredient lists that those products are made from completely different ingredients and proportions. Again, the issue of cleaning the machinery out between batches comes up, but hopefully nothing so lethal will pass from one food to another.

Animal Testing

Another unpleasant practice exposed by this recall is pet food testing on live animals. Menu's own lab animals, who were deliberately fed the tainted food, were the first known victims. Tests began on February 27 (already a week after the first reports); animals started to die painfully from kidney failure a few days later. After the first media reports, Menu quickly changed its story to call these experiments "taste tests." But Menu has done live animal feeding, metabolic energy, palatability, and other tests for lams and other companies for years. Videotapes reveal the animals' lives in barren metal cages; callous treatment; invasive experiments; and careless cruelty.

Although feeding trials are not required for a food to meet the requirements for labeling a food "complete and balanced," many manufacturers use live animals to perform palatability studies when developing a new pet food. One set of animals is fed a new food while a "control" group is fed a current formula. The total volume eaten is used as a gauge for the palatability of the food. Some companies use feeding trials, which are considered to be a much more accurate assessment of the actual nutritional value of the food. They keep large colonies of dogs and cats for this purpose, or use testing laboratories that have their own animals.

There is a new movement toward using companion animals in their homes for palatability and other studies. In 2006, The lams Company announced that it was cutting the use of canine and feline lab animals by 70%. While it proclaims this moral victory, the real reasons for this switch are likely financial. Whatever the reasons, it is a very positive step for the animals.

Finally, it is important to remember that the contamination that occurred in the Menu Foods recall could have happened anywhere at any time. It was not Menu's fault; the toxin was unusual and unexpected. All companies have quality control standards and they do test ingredients for common toxins before using them. They also test the final products. However, there is a baseline risk inherent in using the raw materials that go into pet foods. When there are 11 recalls in 12 years, it's clear that "freak occurrences" are the rule, not the exception.

Marketing Magic

A trip down the pet food aisle will boggle the mind with all the wonderful claims made by pet food makers for their repertoire of products. Knowing the nature of the ingredients helps sort out some of the more outrageous claims, but what's the truth behind all this hype?

Niche claims. Indoor cat, canine athlete, Persian, 7-year old, Bloodhound, or a pet with
a tender tummy, too much flab, arthritis, or itchy feet — no matter what, there's a food
"designed" just for that pet's personal needs. Niche marketing has arrived in a big way in
the pet food industry. People like to feel special, and a product with specific appeal is bound
to sell better than a general product like "puppy food." The reality is that there are only two
basic standards against which all pet foods are measured: adult and growth, which includes

gestation and lactation. Everything else is marketing.

- "Natural" and "Organic" claims. The definition of "natural" adopted by AAFCO is very broad, and allows for artificially processed ingredients that most of us would consider very unnatural indeed. The term "organic", on the other hand, has a very strict legal definition under the USDA National Organic Program. However, some companies are adept at evading the intent of both of these rules. For instance, the name of the company or product may be intentionally misleading. Some companies use terms such as "Nature" or "Natural" or even "Organic" in the brand name, whether or not their products fit the definitions. Consumers should also be aware that the term "organic" does not imply anything at all about animal welfare; products from cows and chickens can be organic, yet the animals themselves are still just "production" units" in enormous factory farms.
- Ingredient quality claims. A lot of pet foods claim they contain "human grade" ingredients. This is a completely meaningless term — which is why the pet food companies get away with using it. The same applies to "USDA inspected" or similar phrases. The implication is that the food is made using ingredients that are passed by the USDA for human consumption, but there are many ways around this. For instance, a facility might be USDA-inspected during the day, but the pet food is made at night after the inspector goes home. The use of such terms should be viewed as a "Hype Alert."
- "Meat is the first ingredient" claim. A claim that a named meat (chicken, lamb, etc.) is the #1 ingredient is generally seen for dry food. Ingredients are listed on the label by weight, and raw chicken weighs a lot, since contains a lot of water. If you look further down the list, you're likely to see ingredients such as chicken or poultry by-product meal, meat-and-bone meal, corn gluten meal, soybean meal, or other high-protein meal. Meals have had the fat and water removed, and basically consist of a dry, lightweight protein powder. It doesn't take much raw chicken to weigh more than a great big pile of this powder, so in reality the food is based on the protein meal, with very little "chicken" to be found. This has become a very popular marketing gimmick, even in premium and "health food" type brands. Since just about everybody is now using it, any meaning it may have had is so watered-down that you may just as well ignore it.
- Special ingredient claims. Many of the high-end pet foods today rely on the marketing appeal of people-food ingredients such as fruits, herbs, and vegetables. However, the amounts of these items actually present in the food are small; and the items themselves may be scraps and rejects from processors of human foods — not the whole, fresh ingredients they want you to picture. Such ingredients don't provide a significant health benefit and are really a marketing gimmick.

Pet food marketing and advertising has become extremely sophisticated over the last few years. It's important to know what is hype and what is real to make informed decisions about what to feed your pets.

WHAT CONSUMERS CAN DO ___

• Write or call pet food companies and the Pet Food Institute and express your concerns about commercial pet foods. Demand that manufacturers improve the quality of ingredients in their products.

- Print out a copy of this report for your veterinarian to further his or her knowledge about commercial pet food.
- Direct your family and friends with companion animals to www.api4animals.org to alert them
 to the dangers of commercial pet food. Print out copies of API's Fact Sheet on Selecting a
 Good Commercial Food or download more copies of this report.
- Stop buying commercial pet food; or at least stop buying dry food. Dry foods have been the
 subject of many more recalls, and have many adverse health effects. If that is not possible,
 reduce the quantity of commercial pet food and supplement with fresh, organic foods, especially
 meat. Purchase one or more of the many books available on pet nutrition and make your own
 food. Be sure that a veterinarian or a nutritionist has checked the recipes to ensure that they
 are balanced for long-term use.
- If you would like to learn about how to make healthy food for your companion animal, visit www.api4animals.org and type "Sample Diets" into the search box for simple recipes and important nutritional information.
- Please be aware that API is not a veterinary hospital, clinic, or service. API does not and will
 not offer any medical advice. If you have concerns about your companion animal's health or
 nutritional requirements, please consult your veterinarian.

Because pet food manufacturers frequently change the formulations of their products, and API cannot conduct the necessary testing, we are unable to offer endorsements for particular brands of pet food. Many of our staff choose to make their own pet food, or to purchase natural or organic products from feed and specialty pet stores or online, but we cannot recommend brands that would be right for your companion animal or animals.

For Further Reading about Animal Nutrition

The Animal Protection Institute recommends the following books (listed in alphabetical order by author), many of which include recipes for home-prepared diets:

- Michelle Bernard. 2003. *Raising Cats Naturally How to Care for Your Cat the Way Nature Intended*. Available at www.raisingcatsnaturally.com.
- Chiclet T. Dog and Jan Rasmusen. 2006. Scared Poopless: The Straight Scoop on Dog Care. Available at www.dogs4dogs.com. ISBN-10: 0977126501, ISBN-13: 978-0977126507.
- Rudi Edalati. 2001. Barker's Grub: Easy, Wholesome Home-Cooking for Dogs. ISBN-10: 0609804421, ISBN-13: 978-0609804421.
- Jean Hofve, DVM. 2007. What Cats Should Eat. Available at www.littlebigcat.com.
- Richard H. Pitcairn, DVM, and Susan Hubble Pitcairn. 2005. Dr. Pitcairn's New Complete Guide to Natural Health for Dogs and Cats. Rodale Press, Inc. ISBN-10: 157954973X, ISBN-13: 978-1579549732. Note: The recipes for cats were not revised in this new edition and date back to 2000; they may contain too much grain, according to recent research.
- Kate Solisti. 2004. The Holistic Animal Handbook: A Guidebook to Nutrition, Health, and Communication. Council Oaks Books. ISBN-10: 1571781536, ISBN-13: 978-1571781536.
- Donald R. Strombeck. 1999. Home-Prepared Dog & Cat Diets: The Healthful Alternative. lowa

State University Press. ISBN-10: 0813821495, ISBN-13: 978-0813821498. Note: Veterinary nutritionists have suggested that the taurine and calcium are too low in some of these recipes. Clam juice and sardines are poor sources of taurine; use taurine capsules instead.

 Celeste Yarnall. 2000, Natural Cat Care: A Complete Guide to Holistic Health Care for Cats; and 1998, Natural Dog Care: A Complete Guide to Holistic Health Care for Dogs. Available at www.celestialpets.com.

The books listed above are a fraction of all the titles currently available, and the omission of a title does not necessarily mean it is not useful for further reading about animal nutrition.

Please note: The Animal Protection Institute is not a bookseller, and cannot sell or send these books to you. Please contact your local book retailer, an online bookstore, or the website indicated, who can supply these books based on the ISBN provided for each title.

Who to Write

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FDA Center for Veterinary Medicine Sharon Benz 7500 Standish Place Rockville, MD 20855 301-594-1728 www.fda.gov/cvm/

Pet Food Institute 2025 M Street, NW, Suite 800 Washington, DC 20036 202-367-1120 Fax 202-367-2120

References

Association of American Feed Control Officials Incorporated. *Official Publication* 2007. Atlanta: AAFCO, 2007.

Case LP, Carey DP, Hirakawa DA. *Canine and Feline Nutrition: A Resource for Companion Animal Professionals*. St. Louis: Mosby, 1995.

FDA Enforcement Reports, 1998-2007. www.fda.gov.

Hand MS, Thatcher CD, Remillard RL, et al., eds. *Small Animal Clinical Nutrition, 4th Edition.* 2002. Topeka, KS: Mark Morris Institute.

Logan, et al., Dental Disease, in: Hand et al., ibid.

Mahmoud AL. Toxigenic fungi and mycotoxin content in poultry feedstuff ingredients. *J Basic Microbiol*, 1993; 33(2): 101–4.

Morris JG, and Rogers QR. Assessment of the Nutritional Adequacy of Pet Foods Through the Life Cycle. *Journal of Nutrition*, 1994; 124: 2520S–2533S.

Mottram DS, Wedzicha BL, Dodson AT. Acrylamide is formed in the Maillard reaction. *Nature*, 2002 Oct 3; 419(6906): 448–9.

Pet Food Institute. Fact Sheet 1994. Washington: Pet Food Institute, 1994.

Phillips T. Rendered Products Guide. Petfood Industry, January/February 1994, 12–17, 21.

Roudebush P. Pet food additives. J Amer Vet Med Assoc, 203 (1993): 1667–1670.

Seefelt SL, Chapman TE. Body water content and turnover in cats fed dry and canned rations. *Am J Vet Res*, 1979 Feb; 40(2): 183–5.

Strombeck, DR. Home-Prepared Dog and Cat Foods: The Healthful Alternative. Ames: Iowa State University Press, 1999.

Tareke E, Rydberg P, Karlsson P, et al. Analysis of acrylamide, a carcinogen formed in heated foodstuffs. *J Agric Food Chem*, 2002 Aug 14; 50(17): 4998–5006.

Zoran D. The carnivore connection to nutrition in cats. *J Amer Vet Med Assoc*, 2002 Dec 1; 221(11): 1559–67.

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Footnotes:

- Pet Food Institute. Fact Sheet 1994. Washington: Pet Food Institute, 1994.
- Association of American Feed Control Officials. *Official Publication*, 2007. Regulation PE3, 120–121.
- Morris, James G., and Quinton R. Rogers. Assessment of the Nutritional Adequacy of Pet Foods Through the Life Cycle. *Journal of Nutrition*, 124 (1994): 2520S–2533S.
- ^{iv} Tareke E, Rydberg P, Karlsson P, et al. Analysis of acrylamide, a carcinogen formed in heated foodstuffs. *J Agric Food Chem*, 2002 Aug 14; 50(17): 4998–5006.
- Mottram DS, Wedzicha BL, Dodson AT. Acrylamide is formed in the Maillard reaction. Nature, 2002 Oct 3; 419(6906): 448–9.
- vi Hand MS, Thatcher CD, Remillard RL, et al., eds. *Small Animal Clinical Nutrition, 4th Edition*. 2002. Topeka, KS: Mark Morris Institute.
- vii Seefelt SL, Chapman TE. Body water content and turnover in cats fed dry and canned rations. *Am J Vet Res*, 1979 Feb; 40(2): 183–5.
- Viii Logan, et al., Dental Disease, in: Hand et al., eds., *Small Animal Clinical Nutrition, Fourth Edition*. Topeka, KS: Mark Morris Institute, 2000.