



- [NUTRO INFO](#)
- [PET CENTER](#)
- [DOG](#)
- [CAT](#)
- [PROGRAMS](#)
- [PROMOTIONS](#)

- [HOME](#)
- [WHERE TO BUY](#)
- [PRODUCTS](#)
- [HELP ME CHOOSE](#)



Benefits of Natural Choice Complete Care Indoor Adult:

- For cats 1 to 6 years
- Scientifically formulated for the unique needs of indoor cats
- Guaranteed* to improve skin & coat for less shedding, fewer hairballs
- Advanced antioxidants for a healthy immune system
- Formulated to reduce litter box and in-home odor
- Natural ingredients with vitamins & minerals
- Recommended by veterinarians



Natural Choice Complete Care Product Center

Click on the links below to learn more about this product.

[Feeding Guide](#)

[Ingredients](#)

[Guaranteed Analysis](#)

[See the Food Image](#)

Indoor Cats Have Special Nutritional Needs.

Indoor temperature, lighting and reduced opportunity for exercise can affect the health of your cat's skin and coat, muscle and bone condition and may cause weight gain. If your adult cat lives indoors most of the time, then feeding Natural Choice Complete Care Indoor Adult Formula can improve your cat's overall health and well-being.

Natural Choice Complete Care Indoor Adult is not just another cat food. Based on the latest scientific and nutritional research, our Indoor Adult formula is guaranteed to improve your indoor cat's skin and coat, reduce shedding, minimize hairballs, build strong muscles and bones and help limit excess weight gain*. It's formulated with unique ingredients like chicken meal, rice, sunflower oil, oat fiber and soy protein concentrate, which are especially important for indoor cats.

Healthy Growth for Indoor Cats

Guaranteed to Improve Skin & Coat*

A blend of nutrients, including high levels of linoleic acid, a healthy fatty acid proven essential for healthy skin and shiny coat, plus arachidonic acid (ARA), zinc and alpha-linolenic acid to help nourish the skin and make your kitten's coat shinier and more lustrous.

Less Shedding, Fewer Hairballs

Healthy skin and coat helps minimize flaking and shedding which means there is less hair swallowed during self-grooming for reduced hairball formation. Plus, FiberClean, a special blend of rice and oat fiber, helps to pass any hair that is swallowed gently through the digestive system and into the litter box. With less swallowed hair irritating your cat's stomach, fewer hairballs are expelled.

Formulated to Reduce Litter Box Odor

Contains OdorCheck™ System, an innovative blend of ingredients that effectively reduce litter box odor for a fresh home environment. Helps make living with kittens more enjoyable.

Helps Cats Utilize Fat & Increases Energy

Our special WeightCare™ System with L-Carnitine helps indoor cats convert fat to energy and build lean muscle mass to offset your indoor cat's reduced activity and exercise levels. The result is increased energy and strong muscles for your indoor cat's overall health.

Try these other products!



Exhibit 42

Nourishes Bones & Joints

Our exclusive BoneCare™ System helps develop strong bones and joints with calcium, phosphorus and manganese. Vitamin D enriched for better calcium absorption.

Natural Ingredients with Vitamins & Minerals

Made with an exclusive blend of the finest natural ingredients with vitamins and minerals, Natural Choice Complete Care provides optimal nutrition for your indoor cat. Fortified with iron to supply oxygen-rich red blood cells for stamina and energy and naturally preserved with Vitamin E to ensure freshness.

Advanced DentalCare™ System

Unique shape and texture helps scrub away plaque and tartar for healthy gums and teeth.

Easy To Digest for Sensitive Stomachs

Made with rice, the most digestible and gentle cereal grain—No ground corn. Made with high quality chicken protein for healthy digestion.

Advanced Antioxidants for a Healthy Immune System

A special blend of vitamins C, E, Beta-Carotene and Tocotrienols to help support the immune system for a long, healthy life. Antioxidants are known to help slow cellular damage from aging.

Nourishes Brain, Vision & Heart

Contains DHA and arachidonic acid (ARA) – nutrients essential for brain, vision and heart function to help keep cats alert. Taurine fortified for a healthy heart and good vision.

Great Taste Guaranteed*

With an ideally sized and shaped kibble for your kitten's mouth and added B vitamins for healthy appetite and metabolism, Natural Choice Complete Care Indoor Adult helps you make sure your kitten eats enough for proper nutrition and good health.

*or your money back

Feeding Guidelines

When you introduce Natural Choice Complete Care Indoor Adult Formula to your cat, it is always a good idea to mix it first with the old food for the first few days. Free choice feeding is recommended, and daily portions may vary according to your cat's age, weight and activity level. Place the total recommended amount in your cat's dish at the same time every day. This way your cat will nibble throughout the day, satisfying the natural instinct to eat smaller, more frequent meals. To realize all of the benefits that Natural Choice Complete Care Indoor has to offer, you should make it your cat's only source of nutrition. A supply of fresh drinking water should be provided at all times. See your veterinarian regularly.

Suggested Amounts To Feed Per Day (in cups)†

Weight of Cat (lbs.)	Amount to Feed
3 – 5	1/4– 3/8 cup
5 – 10	3/8 – 3/4 cup
10 – 15	3/4 – 1 1/4 cups
15 - 20	1 1/4 – 1 5/8 cups

†Use a standard 8 oz. measuring cup. A standard 8 oz. measuring cup holds 3.74 oz. of Natural Choice Complete Care Indoor Adult Formula.

Nutritional Adequacy Statement

Animal feeding tests using the AAFCO¹ procedures substantiate that **Nutro Natural Choice Complete Care Indoor Adult Formula** provides complete and balanced nutrition for adult cat maintenance.

¹Association of American Feed Control Officials.

Ingredients

Chicken Meal, Ground Rice, Corn Gluten Meal, Rice Flour, Poultry Fat (preserved with mixed Tocopherols, a source of Vitamin E), Sunflower Oil (preserved with mixed Tocopherols, a source of Vitamin E), Flaxseed, Tomato Pomace, Brewers Dried Yeast, Natural Flavors, Dried Plain Beet Pulp, Dried Vegetable Fiber (carrots, celery, beets, parsley, lettuce,

watercress and spinach), Potassium Chloride, Menhaden Fish Oil (preserved with mixed Tocopherols, a source of Vitamin E), Oat Fiber, Soy Protein Concentrate, Cranberry Powder, Choline Chloride, DL-Methionine, Taurine, Dried Egg Product, Zinc Sulfate, Ferrous Sulfate, Vitamin E Supplement, L-Carnitine, Inositol, Dried Bacillus Licheniformis Fermentation Extract, Dried Bacillus Subtilis Fermentation Extract, Dried Chicory Root, Yucca Schidigera Extract, Niacin, Copper Sulfate, Ascorbic Acid (source of Vitamin C), Manganous Oxide, Riboflavin Supplement (source of Vitamin B2), Beta-Carotene, Vitamin A Supplement, Calcium Iodate, Calcium Pantothenate, Vitamin B12 Supplement, Biotin, Pyridoxine Hydrochloride (source of Vitamin B6), Thiamine Mononitrate (source of Vitamin B1), Vitamin D3 Supplement, Menadione Sodium Bisulfite Complex (source of Vitamin K activity), Folic Acid, Sodium Selenite.

Nutro supports the safe, ethical and humane treatment of all animals.

Guaranteed Analysis

Crude Protein (minimum)	33.00%
Crude Fat (minimum)	14.00%
Crude Fiber (maximum)	4.00%
Moisture (maximum)	10.00%
Ash (maximum)	7.25%
Linoleic Acid (minimum)	4.00%
Arachidonic Acid (ARA) (minimum)	0.05%
Calcium (minimum)	0.90%
Phosphorus (minimum)	0.80%
Magnesium (maximum)	0.085%
Iron (minimum)	200 mg/kg
Manganese (minimum)	35 mg/kg
Zinc (minimum)	250 mg/kg
Vitamin D (minimum)	1,200 IU/kg
Vitamin E (minimum)	250 IU/kg
Taurine (minimum)	0.20%
Alpha-Linolenic Acid (minimum)**	0.70%
Ascorbic Acid (minimum)**	50 mg/kg
Beta-Carotene (minimum)**	3.2 mg/kg
Docosahexaenoic Acid (DHA) (minimum)**	0.06%
L-Carnitine (minimum)**	150 mg/kg
Total Bacillus Species (minimum)** (Bacillus licheniformis, Bacillus subtilis)	565 million CFU ± /lb

**Not recognized as an essential nutrient by the AAFCO Cat Food Nutrient Profiles.
 ‡ Colony Forming Units

Package Sizes:

4 lb.	8 lb.	20 lb.
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Kibble



This is the approximate size and color of the kibble.

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[PROMOTIONS](#)

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[HOME](#)

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Nutro Products Super Premium Dog and Cat Food

Nutro Products, Inc. has been a leader in natural, super premium dog and cat food for over 80 years. Each of our premium dog and cat food brands - MAX, Natural Choice, and Ultra - feature natural ingredients with vitamins and minerals for the best in cat and dog nutrition.

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Exhibit 43



- [NUTRO INFO](#)
- [PET CENTER](#)
- [DOG](#)
- [CAT](#)
- [PROGRAMS](#)
- [PROMOTIONS](#)

[MENU FOODS
RECALL
INFORMATION](#)

[HOME](#)

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**Benefits of MAX
Weight Control Formula:**

- For overweight, less active dogs
- Reduced fat & calories
- Glucosamine & chondroitin for healthy joints
- Natural ingredients with vitamins and minerals
- Formulated for healthy skin & coat
- No chicken heads, feet or intestines



**MAX Dog
Product Center**

Click on the links below to learn more about this product.

[Feeding Guidelines](#)

[Ingredients](#)

[Guaranteed Analysis](#)

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Try these other products!



Great Taste — Guaranteed!*

MAX Weight Control Formula is a tasty breakthrough in foods formulated for overweight and less active dogs. Your dog will love the taste of MAX Weight Control. It combines veterinarian and nutritionists' recommendations for overweight and less active dogs with the palatability, quality and attention you expect from MAX products. Both veterinarians and nutritionists recommend reduced calorie diets for overweight and less active dogs.

Everything from Antioxidants to Zinc

MAX Weight Control delivers these nutrients at recommended levels, plus much, much more. And to keep every bite fresh and filled with maximum nutritional benefits, MAX Weight Control is naturally preserved using vitamin E.

Recommended for Your Dog's Special Needs

Overweight or Less Active Dogs: Many veterinarians consider the overweight pet to be at increased risk for a number of health problems, such as heart disease, hypertension, and arthritis. MAX Weight Control may assist in weight problems because of its reduced calories and fat, while providing the nutrients necessary to maintain optimum health. MAX Weight Control contains 7.9% less calories and 37.5% less fat than Nutro MAX Natural dog food.

No Chicken Heads, Feet or Intestines

The chicken meal in MAX Weight Control Formula is made from the same parts of the chicken you feed your family –no chicken heads, feet or intestines which may be found in products that use chicken by-product meal. Chicken Meal is chicken with most of the water and some of the fat removed for a healthy protein source.

*Or your money back

Feeding Guidelines

The following feeding guidelines are for adult dogs and should be adjusted as needed to maintain optimum weight and condition. When feeding MAX Weight Control Formula for the first time, we suggest you blend increasing amounts of MAX with your old food for 6 days.

For Less Active Dogs: Feed according to guidelines under Maintenance
For Overweight Dogs: Feed according to guidelines under Weight Reduction. Once the target weight is achieved, switch to Maintenance feeding.

Dogs requiring a calorie-restricted diet may enjoy eating several small meals per day rather than a single large meal. Keep fresh drinking water available at all times. See your veterinarian regularly.

Suggested Amounts to Feed Per Day†

Weight of Dog	Maintenance	Weight Reduction
5 - 15 lbs.	3/4 – 1-3/4 cups	2/3 – 1-1/3 cups
16 - 25 lbs.	1-3/4 – 2-1/2 cups	1-1/3 – 1-3/4 cups
26 - 35 lbs.	2-1/2 – 3-1/4 cups	1-3/4 – 2-1/3 cups
36 - 55 lbs.	3-1/4 – 4-1/3 cups	2-1/3 – 3-1/4 cups
56 - 75 lbs.*	4-1/3 – 5-1/3 cups*	3-1/4 – 4 cups*

† 273 kcals/per cup. Use a standard 8 oz. measuring cup. Serve dry or lightly moistened.

Animal feeding tests using AAFCO* procedures substantiate that **Nutro MAX Weight Control Formula** provides complete and balanced nutrition for maintenance of adult dogs.

*Association of American Feed Control Officials.

Calorie Content

Nutro MAX Adult contains 3,400 kcal/kg of metabolizable energy (ME) on as-fed basis (calculated)

Nutro supports the safe, ethical and humane treatment of all animals.

Ingredients

Wheat Flour, Ground Rice, Rice Bran, Chicken Meal, Ground Whole Wheat, Poultry Fat (preserved with mixed Tocopherols, a source of Vitamin E), Natural Flavor, Sunflower Oil (preserved with mixed Tocopherols, a source of Vitamin E), Lamb Meal, Potassium Chloride, Dried Kelp, Dried Egg Product, Zinc Sulfate, Zinc Proteinate, Vitamin E Supplement, Ferrous Sulfate, Choline Chloride, Ascorbic Acid (source of Vitamin C), Biotin, Glucosamine Hydrochloride, Manganese Proteinate, Garlic, Chondroitin Sulfate, Manganous Oxide, Vitamin B12 Supplement, Niacin, Calcium Pantothenate, L-Carnitine, Riboflavin Supplement (source of Vitamin B2), Vitamin A Supplement, Copper Sulfate, Thiamine Mononitrate (source of Vitamin B1), Copper Proteinate, Pyridoxine Hydrochloride (source of Vitamin B6), Sodium Selenite, Menadione Sodium Bisulfite Complex (source of Vitamin K activity), Vitamin D3 Supplement, Calcium Iodate, Folic Acid.

Guaranteed Analysis

Crude Protein (minimum)	16.00%
Crude Fat (minimum)	8.00%
Crude Fat (maximum)	10.00%
Crude Fiber (maximum)	4.00%
Moisture (maximum)	10.00%
Linoleic Acid (minimum)	2.50%
Ascorbic Acid (minimum)**	35 mg/kg
L-Carnitine (minimum)**	15 mg/kg
Glucosamine Hydrochloride (minimum)**	475 mg/kg
Chondroitin Sulfate (minimum)**	375 mg/kg

**Not recognized as an essential nutrient by the AAFCO Dog Food Nutrient Profiles.

Package Sizes:

5 lb.	15 lb.	30 lb.
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Kibble



This is the approximate size and color of the kibble.

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Benefits of MAX Mini Chunk:

- For dogs who prefer a small bite size
- Real chicken and lamb proteins
- Natural ingredients with vitamins and minerals
- Formulated for healthy skin and coat
- Easy to digest for less clean-up
- No chicken heads, feet or intestines



The same unique formulation as MAX Adult, featuring chicken and lamb proteins and rice, but in a mini size kibble ideal for smaller dogs and dogs that prefer a small bite size.

Formulated For Healthy Skin & Coat

MAX Mini Chunk's advanced formula is designed to provide a high concentration of polyunsaturated fatty acids, such as linoleic acid, and essential vitamins and minerals. These ingredients help avoid nutritional deficiencies that can affect your dog's skin and coat, and ensure that your dog will have healthy skin and a shiny coat.

High Digestibility

The ingredients in MAX Mini Chunk are highly digestible. This important factor measures how much of the food is assimilated and is available for use by the dog. For superior digestibility, we use only premium quality chicken meal, wheat and rice — never any ground corn.

Great Taste – Guaranteed!*

Test after test proves that dogs love the great chicken and lamb taste of MAX Mini Chunk. And your dog will, too. We guarantee it. And to keep every bite fresh and filled with maximum nutritional benefits, MAX Mini Chunk is naturally preserved using Vitamin E.

Low Stool Volume

Another advantage of the MAX Mini Chunk diet is low stool volume. Small, firm, low-volume stools mean faster, easier cleanup, and a cleaner, more hygienic environment for your dog and family.

Performance & Economy

With its balanced nutrition, unique combination of ingredients, high digestibility and great taste, MAX Mini Chunk really performs. And because of its high nutritional density, you may actually find it less expensive to feed.

No Chicken Heads, Feet or Intestines

The chicken meal in MAX Mini Chunk is made from the same parts of the chicken you feed your family –no chicken heads, feet or intestines which may be found in products that use chicken by-product meal. Chicken Meal is chicken with most of the water and some of the fat removed for a healthy protein source.



MAX Dog Product Center

Click on the links below to learn more about this product.

[Feeding Guidelines](#)

[Ingredients](#)

[Guaranteed Analysis](#)

[See the Food Image](#)

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*Or your money back

Feeding Guidelines

The following feeding guidelines are for adult dogs with moderate activity levels. The guidelines should be adjusted as needed to maintain optimum weight. When feeding MAX for the first time, we suggest you blend increasing amounts of MAX Mini Chunk with your old food for 6 days.

- Pregnant Bitches:** Offer 50% more during pregnancy.
- Lactating Bitches:** Offer at least 2 to 3 times the normal amount of food.
- Puppies:** Feed twice the normal adult requirement. Feed puppies 3 times a day until 6 months of age, then twice daily until 14 months, depending on breed.
- All Dogs:** Keep fresh drinking water available at all times. See your veterinarian regularly.

Suggested Amounts to Feed Per Day

Weight of Dog	Amount to Feed†
5 - 15 lbs.	2/3 – 1-1/3 cups
16 - 25 lbs.	1-1/3 – 2 cups
26 - 35 lbs.	2 – 2-1/2 cups
36 - 55 lbs.	2-1/2 – 3-1/3 cups
56 - 75+ lbs.	3-1/3 – 4-1/4+ cups

†369 kcals/per cup. Use a standard 8 oz. measuring cup. Serve dry or lightly moistened.

Nutritional Adequacy Statement
 Animal feeding tests using AAFCO¹ procedures substantiate that **Nutro MAX Mini Chunk** provides complete and balanced nutrition for all life stages.
¹Association of American Feed Control Officials.

Calorie Content
 Nutro MAX Mini Chunk contains 3,690 kcal/kg of metabolizable energy (ME) on as-fed basis (calculated)

Nutro supports the safe, ethical and humane treatment of all animals.

Ingredients

Chicken Meal, Wheat Flour, Ground Whole Wheat, Rice Bran, Poultry Fat (preserved with mixed Tocopherols, a source of Vitamin E), Corn Gluten Meal, Ground Rice, Lamb Meal, Natural Flavors, Yeast Culture, Calcium Carbonate, Monosodium Phosphate, Potassium Chloride, Choline Chloride, Dried Buttermilk, Dried Kelp, Dried Egg Product, Lecithin, Zinc Sulfate, Iron Sulfate, Vitamin E Supplement, Iron Oxide, Garlic, Ascorbic Acid (source of Vitamin C), Biotin, Vitamin B12 Supplement, Niacin, Calcium Pantothenate, Vitamin A Supplement, Manganous Oxide, Thiamine Mononitrate (source of Vitamin B1), Vitamin D3 Supplement, Riboflavin (source of Vitamin B2), Calcium Iodate, Pyridoxine Hydrochloride (source of Vitamin B6), Menadione Sodium Bisulfite Complex (source of Vitamin K activity), Folic Acid, Copper Sulfate.

Guaranteed Analysis

Crude Protein (minimum)	26.00%
Crude Fat (minimum)	16.00%
Crude Fiber (maximum)	4.00%
Moisture (maximum)	10.00%
Linoleic Acid (minimum)	3.50%
Ascorbic Acid (minimum)**	35.0 mg/kg

**Not recognized as an essential nutrient by the AAFCO Dog Food Nutrient Profiles.

Package Sizes:

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5 lb.	17.5 lb.	35 lb.
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Kibble



This is the approximate size and color of the kibble.

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[PROMOTIONS](#)

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Benefits of MAX Beef Meal & Rice Dinner:

- For active adult dogs
- Great beefy taste—guaranteed!*
- Natural ingredients with vitamins and minerals
- Formulated for healthy skin and coat
- Easy to digest for less clean-up
- Real beef protein



Great Taste — Guaranteed!*

Test after test proves that dogs love the great beef and rice taste of MAX Beef Meal & Rice Dinner. That's important, because the most nutritious food in the world is worthless, if your dog won't eat it. Because we use our proprietary FlavorMAX® system, Nutro guarantees your dog will love the taste of MAX Beef Meal & Rice Dinner, or your money back.

Everything from Antioxidants to Zinc

MAX Beef Meal & Rice Dinner provides your dog complete and balanced nutrition. We use natural ingredients with the essential vitamins and minerals your dog needs for a long, healthy life, such as antioxidants that enhance the immune system and help retard the aging process.

High Digestibility

The ingredients in MAX Beef Meal & Rice Dinner are highly digestible. This important factor measures how much of the food is assimilated and is available for use by the dog. For superior digestibility, we use only premium quality beef meal, rice and wheat — never any ground corn.

Low Stool Volume

Another advantage of the MAX Beef Meal & Rice Dinner diet is low stool volume. High digestibility means more nutrition goes into your dog and less waste goes into your back yard. Small, firm, low-volume stools mean faster, easier cleanup and a cleaner, more hygienic environment for your dog and family.

Formulated for Healthy Skin & Coat

MAX Beef Meal & Rice Dinner contains high levels of linoleic acid. A high concentration of polyunsaturated fatty acids like linoleic acid, along with other essential vitamins and minerals also found in MAX, have been proven to produce a healthy skin and shiny coat.

Performance & Economy

With its balanced nutrition, unique combination of ingredients, high digestibility and great taste, MAX Beef Meal & Rice Dinner really performs. And because of its high nutritional density, you may actually find it less expensive to feed.

*Or your money back

Feeding Guidelines

The following feeding guidelines are for adult dogs with moderate activity



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[Feeding Guidelines](#)

[Ingredients](#)

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levels. The guidelines should be adjusted as needed to maintain optimum weight. When feeding MAX Beef Meal & Rice Dinner for the first time, we suggest you blend increasing amounts of MAX Beef Meal & Rice Dinner with your old food for 6 days.

Pregnant Bitches: Offer 50% more during pregnancy.
Lactating Bitches: Offer at least 2 to 3 times the normal amount of food.

Puppies: Feed twice the normal adult requirement. Feed puppies 3 times a day until 6 months of age, then twice daily until 14 months, depending on breed.

All Dogs: Keep fresh drinking water available at all times. See your veterinarian regularly.

Suggested Amounts to Feed Per Day

Weight of Dog	Amount to Feed†
5 - 15 lbs.	2/3 – 1-1/3 cups
16 - 25 lbs.	1-1/3 – 2 cups
26 - 35 lbs.	2 – 2-1/2 cups
36 - 55 lbs.	2-1/2 – 3-1/3 cups
56 - 75+ lbs.	3-1/3 – 4-1/4+ cups

†353 kcals/per cup. Use a standard 8 oz. measuring cup. Serve dry or lightly moistened.

Nutritional Adequacy Statement
 Animal feeding tests using AAFCO¹ procedures substantiate that **Nutro MAX Beef Meal & Rice Dinner** provides complete and balanced nutrition for all life stages.
¹Association of American Feed Control Officials.

Calorie Content
 Nutro MAX Beef Meal & Rice Dinner contains 3,690 kcal/kg of metabolizable energy (ME) on as-fed basis (calculated)

Nutro supports the safe, ethical and humane treatment of all animals.

Ingredients

Beef Meal, Ground Rice, Corn Gluten Meal, Ground Whole Wheat, Poultry Fat (preserved with mixed Tocopherols, a source of Vitamin E), Rice Bran, Wheat Flour, Natural Flavors, Calcium Carbonate, Monosodium Phosphate, Potassium Chloride, Yeast Culture, L-Lysine, Vitamin E Supplement, Zinc Sulfate, Ferrous Sulfate, Choline Chloride, Iron Oxide, Dried Buttermilk, Ascorbic Acid (source of Vitamin C), Dried Kelp, Dried Egg Product, Biotin, Lecithin, Vitamin B12 Supplement, Garlic, Niacin, Calcium Pantothenate, Vitamin A Supplement, Manganous Oxide, Thiamine Mononitrate (source of Vitamin B1), Vitamin D3 Supplement, Riboflavin (source of Vitamin B2), Pyridoxine Hydrochloride (source of Vitamin B6), Calcium Iodate, Folic Acid, Menadione Sodium Bisulfite Complex (source of Vitamin K activity), Copper Sulfate.

Nutro supports the safe, ethical and humane treatment of all animals.

Guaranteed Analysis

Crude Protein (minimum)	26.00%
Crude Fat (minimum)	16.00%
Crude Fiber (maximum)	4.00%
Moisture (maximum)	10.00%
Linoleic Acid (minimum)	3.50%
Ascorbic Acid (minimum)**	35.0 mg/kg

**Not recognized as an essential nutrient by the AAFCO Dog Food Nutrient Profiles.

Package Sizes:

5 lb.	17.5 lb.	35 lb.
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Kibble



This is the approximate size and color of the kibble.

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[DOG](#)

[CAT](#)

[PROGRAMS](#)

[PROMOTIONS](#)

[MENU FOODS
RECALL
INFORMATION](#)

[HOME](#)

[WHERE TO BUY](#)

[PRODUCTS](#)

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**NATURAL CHOICE
COMPLETE CARE**

Help me choose the correct Natural Choice Complete Care products for my Cat!

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Natural Choice® Complete Care® Cat Food Products

Everything Your Cat Needs in One Bag®

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[CUSTOMER TESTIMONIALS](#)

Natural Choice® Complete Care® provides everything your cat needs in one bag. Its natural ingredients with vitamins and minerals create a great tasting cat food that offers the optimum combination of premium ingredients and scientific research to provide complete care for your cat. It helps reduce hairballs and is formulated to reduce litter box odor, while also benefiting dental health, the digestive and immune systems, and the skin and coat of your cat. Natural Choice Complete Care represents the very best in feline nutritional solutions, improving the quality of life for your cat and you.

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[INDOOR CANNED](#)

[INDOOR POUCH](#)

[DRY](#)

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[POUCH](#)

Natural Choice Complete Care Indoor Dry

[Kitten](#)

NEW [Kitten](#)

[Adult](#)

[Adult](#)

NEW [Oceanfish Flavor](#)

[Weight Management](#)

Natural Choice Complete Care Dry

[Kitten](#)

[Kitten](#)

[Adult](#)

[Adult](#)

[Lamb Flavor](#)

[Oceanfish Flavor](#)

[Weight Management](#)

[Weight Management](#)

NEW [Weight Management](#)

NEW [Oceanfish Flavor](#)

Senior

[Senior](#)

**Natural Choice
Complete Care Indoor
Pouches**

Adult

NEW [Chicken & Giblets](#)

NEW [Turkey & Liver](#)

NEW [Oceanfish & Shrimp](#)

NEW [Whitefish & Tuna](#)

**Natural Choice
Complete Care Indoor
Canned**

Adult

[Oceanfish & Rice](#)

[Chicken & Rice](#)

Senior

[Chicken & Lamb](#)

Senior

[Senior](#)

**Natural Choice
Complete Care Pouches**

Kitten

[Chicken & Liver](#)

[Oceanfish & Tuna](#)

[Salmon & Oceanfish](#)

Adult

[Chicken & Liver](#)

[Turkey & Giblets](#)

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[Oceanfish & Tuna](#)

Weight Management

[Chicken & Liver](#)

Senior

[Chicken & Turkey](#)

**Natural Choice
Complete Care Canned**

Kitten

[Chicken & Lamb](#)

[Tuna & Chicken](#)

[Beef & Chicken](#)

Adult

[Chicken & Liver Entree](#)

[Salmon & Shrimp Chowder](#)

[Chicken Casserole](#)

[Chicken & Lamb Stew](#)

[Chicken & Turkey Platter](#)



[NUTRO INFO](#)

[PET CENTER](#)

[DOG](#)

[CAT](#)

[PROGRAMS](#)

[PROMOTIONS](#)

[MENU FOODS
RECALL
INFORMATION](#)

[HOME](#)

[WHERE TO BUY](#)

[PRODUCTS](#)

[HELP ME CHOOSE](#)



Benefits of Natural Choice Complete Care Weight Management:

- For overweight or less active cats
- 30% less fat than our adult formula to help manage your cat's weight
- Natural ingredients with vitamins & minerals
- Less shedding, fewer hairballs
- Cleans teeth, freshens breath
- Easy to digest for sensitive stomachs
- Guaranteed to improve skin & coat*
- Recommended by veterinarians
- Everything your cat needs in one bag®



Natural Choice Complete Care Product Center

Click on the links below to learn more about this product.

[Feeding Guide](#)

[Ingredients](#)

[Guaranteed Analysis](#)

[See the Food Image](#)

Natural Choice Complete Care provides less fat to help you manage your overweight or less active cat's weight. Natural Choice Complete Care features natural ingredients with vitamins and minerals to provide everything your cat needs in one bag. It's a great tasting adult cat food that offers the optimum combination of premium ingredients and scientific research. Complete Care Weight Management is formulated to help reduce litter box odor, while benefiting the digestive and immune systems and skin and coat of your cat. Natural Choice Complete Care represents the very best in feline nutrition, improving the quality of life for your cat and you.

WeightCare™ System for Overweight & Less Active Cats

With 30% less fat than Natural Choice Complete Care Adult and L-Carnitine to help your cat's body burn fat, Natural Choice Weight Management helps limit excess weight gain in overweight and less active cats.

Natural Ingredients with Vitamins & Minerals

Made with an exclusive blend of the finest natural ingredients with vitamins and minerals, Natural Choice Complete Care provides optimal nutrition for your indoor kitten. Fortified with iron to supply oxygen-rich red blood cells for stamina and energy and naturally preserved with Vitamin E to ensure freshness.

Less Shedding, Fewer Hairballs

Healthy skin and coat helps minimize flaking and shedding which means there is less hair swallowed during self-grooming for reduced hairball formation. Plus, FiberClean, a special blend of rice and oat fiber, helps to pass any hair that is swallowed gently through the digestive system and into the litter box. With less swallowed hair irritating your cat's stomach, fewer hairballs are expelled.

Advanced DentalCare™ System

Unique shape and texture helps scrub away plaque and tartar for healthy gums and teeth.

Easy To Digest for Sensitive Stomachs

Made with rice, a highly digestible and gentle cereal grain, instead of ground corn. We also use high quality chicken protein for healthy

Try these other products!



digestion.

Nourishes Bones & Joints

Our exclusive BoneCare™ System helps develop strong bones and joints with calcium, phosphorus and manganese. Vitamin D enriched for better calcium absorption.

Guaranteed to Improve Skin & Coat

A blend of nutrients, including high levels of linoleic acid, a healthy fatty acid proven essential for healthy skin and shiny coat, plus arachidonic acid (ARA), zinc and alpha-linolenic acid to help nourish the skin and make your kitten's coat shinier and more lustrous.

Advanced Antioxidants for a Healthy Immune System

A special blend of vitamins C, E, Beta-Carotene and Tocotrienols helps support the immune system for a long, healthy life. Antioxidants are known to help slow cellular damage from aging.

Formulated to Reduce Litter Box Odor

Contains OdorCheck™ System, an innovative blend of ingredients that is effective in reducing litter box odor for a fresh home environment. Helps make living with kittens more enjoyable.

Healthy Brain, Vision & Heart Function

Contains DHA and arachidonic acid (ARA) – nutrients essential for brain, vision and heart function to help keep cats alert. Taurine fortified for a healthy heart and good vision.

Great Taste Guaranteed*

With an ideally sized and shaped kibble for your kitten's mouth and added B vitamins for healthy appetite and metabolism, Natural Choice Complete Care Indoor Kitten helps you make sure your kitten eats enough for proper nutrition and good health.

*Or your money back.

Feeding Guidelines

If your cat is overweight, feed according to the guidelines under Weight Reduction. When the cat's target weight is achieved, switch to Maintenance Feeding. When you introduce Complete Care to your cat, it is always a good idea to mix it first with the old food for a few days. Free choice feeding is recommended, and daily portions may vary according to your cat's age, weight and activity level. Place the total recommended amount in your cat's dish at the same time every day. This way your cat can nibble throughout the day, and satisfy his or her natural instinct to eat smaller, more frequent meals. To realize all of the benefits Complete Care has to offer, you should make it your cat's only source of nutrition. A supply of fresh drinking water should be provided at all times. See your veterinarian regularly.

Suggested Amounts to Feed Per Day (In Cups)†

Weight of Cat (lbs.)	Maintenance Feeding	Weight Reduction Feeding
4 - 5	3/8 - 1/2	1/4 - 1/3
6 - 8	1/2 - 3/4	1/3 - 1/2
9 -11	3/4 - 1 1/8	1/2 - 3/4
12 - 15	1 1/8 - 1 1/2	3/4 - 1 1/8
16 - 18	1 1/2 - 1 3/4	1 1/8 - 1 1/3
19 - 21	1 3/4 - 2	1 1/3 - 1 1/2

†Use a standard 8 oz. measuring cup.

Nutritional Adequacy Statement

Animal feeding tests using AAFCO¹ procedures substantiate that **Natural Choice Complete Care Weight Management** provides complete and balanced nutrition for adult cat maintenance.

¹Association of American Feed Control Officials.

Ingredients

Chicken Meal, Ground Rice, Corn Gluten Meal, Rice Flour, Dried Beet Pulp, Poultry Fat (preserved with mixed Tocopherols, a source of Vitamin E), Sunflower Oil (preserved with mixed Tocopherols, a source of Vitamin E), Natural Flavors, Dried Vegetable Fiber (Carrots, Celery, Beets, Parsley, Lettuce, Water Cress, Spinach) , Oat Fiber, Yeast Culture, Potassium Chloride, Menhaden Fish Oil (preserved with mixed Tocopherols, a source of Vitamin E), Choline Chloride, Dried Egg Product, Taurine, DL-Methionine, Vitamin E Supplement, Ferrous Sulfate, Zinc Sulfate, Dried Bacillus licheniformis Fermentation Extract, Dried Bacillus subtilis Fermentation Extract, Ascorbic Acid (source of Vitamin C), Zinc Proteinate, Inositol, Dried Chicory Root, Cranberry Powder, L-Carnitine, Niacin, Manganese Proteinate, Manganous Oxide, Biotin, Riboflavin Supplement (source of Vitamin B2), Vitamin A Supplement, Calcium Pantothenate, Sodium Selenite, Copper Sulfate, Pyridoxine Hydrochloride (source of Vitamin B6), Vitamin B12 Supplement, Copper Proteinate, Thiamine Mononitrate (source of Vitamin B1), Vitamin D3 Supplement, Menadione Sodium Bisulfite Complex (source of Vitamin K activity), Calcium Iodate, Folic Acid.
Nutro supports the safe, ethical and humane treatment of all animals.

Guaranteed Analysis

Crude Protein (minimum)	33.00%
Crude Fat (minimum)	10.00%
Crude Fat (maximum)	13.00%
Crude Fiber (maximum)	4.50%
Moisture (maximum)	10.00%
Ash (maximum)	7.00%
Linoleic Acid (minimum)	3.00%
Arachidonic Acid (ARA) (minimum)	0.05%
Magnesium (maximum)	0.088%
Iron (minimum)	210 mg/kg
Manganese (maximum)	35 mg/kg
Zinc (minimum)	225 mg/kg
Vitamin D (minimum)	1,500 IU/kg
Vitamin E (minimum)	250 IU/kg
Taurine (minimum)	0.18%
Ascorbic Acid (minimum)**	50 mg/kg
Beta-Carotene (minimum)**	3.8 mg/kg
Docosahexaenoic Acid (DHA) (minimum)**	0.06%
L-Carnitine (minimum)**	100 mg/kg
Total Bacillus Species (minimum)** (Bacillus licheniformis, Bacillus subtilis)	565 Million CFU [‡] /lb

**Not recognized as an essential nutrient by the AAFCO Cat Food Nutrient Profiles.
 ‡Colony forming units.

Package Sizes:

4 lb.	8 lb.	20 lb.
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Kibble



This is the approximate size and color of the kibble.

[Dogs](#) | [Cats](#) | [Where to Buy](#) | [Promotions](#) | [Press Releases](#) | [Information](#) | [Site Map](#) | [Contact Us](#)

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NUTRO INFO

PET CENTER

DOG

CAT

PROGRAMS

PROMOTIONS

MENU FOODS
RECALL
INFORMATION

HOME

WHERE TO BUY

PRODUCTS

HELP ME CHOOSE



Benefits of Natural Choice Complete Care Senior:

- For cats 7 years and older
- Scientifically formulated for senior cats
- Natural ingredients with vitamins & minerals
- Easy to digest for sensitive stomachs
- Less shedding, fewer hairballs
- Cleans teeth, freshens breath
- Guaranteed to improve skin & coat
- Recommended by veterinarians
- Everything your cat needs in one bag@



Natural Choice Complete Care Product Center

Click on the links below to learn more about this product.

[Feeding Guide](#)

[Ingredients](#)

[Guaranteed Analysis](#)

[See the Food Image](#)

As your cat ages, its nutritional needs are changing. Proper nutrition is essential. Natural Choice Complete Care features natural ingredients with vitamins and minerals to provide everything your cat needs in one bag. It's a great tasting adult cat food that offers the optimum combination of premium ingredients and scientific research. Complete Care Senior is formulated to help reduce litter box odor, while benefiting the digestive and immune systems and skin and coat of your cat. Natural Choice Complete Care represents the very best in feline nutrition, improving the quality of life for your cat and you.

Complete Care to Help Keep Senior Cats Healthy

Moderate protein and fat levels to help keep seniors fit with chelated minerals for better absorption. Low in sodium, phosphorus and magnesium, minerals that senior cats need less of.

Natural Ingredients with Vitamins & Minerals

Made with an exclusive blend of the finest natural ingredients with vitamins and minerals, Natural Choice Complete Care provides optimal nutrition for your indoor kitten. Fortified with iron to supply oxygen-rich red blood cells for stamina and energy and naturally preserved with Vitamin E to ensure freshness.

Easy To Digest for Sensitive Stomachs

Made with rice, a highly digestible and gentle cereal grain, instead of ground corn. We also use high quality chicken protein for healthy digestion.. An optimum blend of soluble and insoluble fiber, including Complete Care's Unique Vegetable Blend, helps maintain digestive health.

Advanced Antioxidants for a Healthy Immune System

A special blend of vitamins C, E, Beta-Carotene and Tocotrienols helps support the immune system for a long, healthy life. Antioxidants are known to help slow cellular damage from aging.

Advanced DentalCare™ System

Unique shape and texture helps scrub away plaque and tartar for healthy gums and teeth.

Helps Maintain Strong Bones & Joints

Our exclusive BoneCare™ System helps develop strong bones and joints with calcium, phosphorus and manganese. Vitamin D enriched for better calcium absorption.

Try these other products!



Less Shedding, Fewer Hairballs

Healthy skin and coat helps minimize flaking and shedding which means there is less hair swallowed during self-grooming for reduced hairball formation. Plus, FiberClean, a special blend of rice and oat fiber, helps to pass any hair that is swallowed gently through the digestive system and into the litter box. With less swallowed hair irritating your cat's stomach, fewer hairballs are expelled.

Guaranteed to Improve Skin & Coat

A blend of nutrients, including high levels of linoleic acid, a healthy fatty acid proven essential for healthy skin and shiny coat, plus arachidonic acid (ARA), zinc and alpha-linolenic acid to help nourish the skin and make your kitten's coat shinier and more lustrous.

Formulated to Reduce Litter Box Odor

Contains OdorCheck™ System, an innovative blend of ingredients that is effective in reducing litter box odor for a fresh home environment. Helps make living with kittens more enjoyable.

Healthy Brain, Vision & Heart Function

Aging and environmental factors impact cognitive, vision and heart function. Natural Choice Complete Care contains DHA and arachidonic acid (ARA) – nutrients essential for brain, vision and heart function to help nourish the central nervous system and help keep cats alert. Taurine fortified for a healthy heart and good vision.

Great Taste Guaranteed*

With an ideally sized and shaped kibble for your kitten's mouth and added B vitamins for healthy appetite and metabolism, Natural Choice Complete Care Indoor Kitten helps you make sure your kitten eats enough for proper nutrition and good health.

*Or your money back.

Feeding Guidelines

When you introduce Natural Choice Complete Care to your cat, it is always a good idea to mix it first with the old food for the first few days. Free choice feeding is recommended, and daily portions may vary according to your cat's age, weight and activity level. Place the total recommended amount in your cat's dish at the same time every day. Then your cat will nibble throughout the day, satisfying the natural instinct to eat smaller, more frequent meals. To realize all of the benefits that Natural Choice Complete Care has to offer, you should make it your cat's only source of nutrition. A supply of fresh drinking water should be provided at all times. See your veterinarian regularly.

Suggested Amounts To Feed Per Day*

Weight of Cat (lbs.)	Amount to Feed *
3 - 5	1/4 - 1/2
6 - 10	1/2 - 7/8
11 - 15	7/8 - 1 3/8
16 - 20	1 3/8 - 1 7/8
21+	1 7/8+

*332kcal/per cup. Use a standard 8 oz. measuring cup.

Nutritional Adequacy Statement

Animal feeding tests using AAFCO¹ procedures substantiate that **Natural Choice Complete Care Senior** provides complete and balanced nutrition for adult cat maintenance.

¹Association of American Feed Control Officials.

Ingredients

Chicken Meal, Ground Rice, Corn Gluten Meal, Rice Flour, Poultry Fat (preserved with mixed Tocopherols, a source of Vitamin E), Dried Beet Pulp, Sunflower Oil (preserved with mixed Tocopherols, a source of Vitamin E), Natural Flavors, Dried Vegetable Fiber (Carrots, Celery, Beets, Parsley, Lettuce, Water Cress, Spinach), Oat Fiber, Yeast Culture, Potassium Chloride, Menhaden Fish Oil (preserved with mixed Tocopherols, a source of Vitamin E), Choline Chloride, Dried Egg

Product, Taurine, DL-Methionine, Vitamin E Supplement, Ferrous Sulfate, Zinc Sulfate, Dried Bacillus licheniformis Fermentation Extract, Dried Bacillus subtilis Fermentation Extract, Ascorbic Acid (source of Vitamin C), Zinc Proteinate, Inositol, Dried Chicory Root, Cranberry Powder, Niacin, Manganese Proteinate, Manganous Oxide, Biotin, Riboflavin Supplement (source of Vitamin B2), Vitamin A Supplement, Calcium Pantothenate, Sodium Selenite, Copper Sulfate, Pyridoxine Hydrochloride (source of Vitamin B6), Vitamin B12 Supplement, Copper Proteinate, Thiamine Mononitrate (source of Vitamin B1), Vitamin D3 Supplement, Menadione Sodium Bisulfite Complex (source of Vitamin K activity), Folic Acid.

Nutro supports the safe, ethical and humane treatment of all animals.

Guaranteed Analysis

Crude Protein (minimum)	30.00%
Crude Fat (minimum)	14.00%
Crude Fiber (maximum)	4.00%
Moisture (maximum)	10.00%
Ash (maximum)	6.50%
Linoleic Acid (minimum)	4.00%
Arachidonic Acid (ARA) (minimum)	0.05%
Phosphorus (maximum)	1.00%
Sodium (maximum)	0.40%
Magnesium (maximum)	0.085%
Iron (minimum)	210 mg/kg
Manganese (minimum)	35 mg/kg
Zinc (minimum)	250 mg/kg
Vitamin D (minimum)	1,350 IU/kg
Vitamin E (minimum)	250 IU/kg
Taurine (minimum)	0.18%
Ascorbic Acid (minimum)**	50 mg/kg
Beta-Carotene (minimum)**	2.9 mg/kg
Docosahexaenoic Acid (DHA) (minimum)**	0.06%
Total Bacillus Species (minimum)** (Bacillus licheniformis, Bacillus subtilis)	565 Million CFU [‡] /lb

**Not recognized as an essential nutrient by the AAFCO Cat Food Nutrient Profiles.

[‡]Colony forming units.

Package Sizes:

4 lb.	8 lb.	20 lb.
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Kibble



This is the approximate size and color of the kibble.

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[Home](#)

[Company](#)

[Ingredients](#)

[Products](#)

[Performance](#)

[Where to Buy](#)



What's Ultra Holistic Nutrition? It's simply the best combination of holistic dog food ingredients that we could find. We know that dogs need protein and we've combined three animal proteins—chicken, lamb and salmon meals to provide essential amino acids for better muscle development and overall performance. Okay, we know you understand chicken and lamb, but why salmon? Well, salmon naturally contains essential amino acids like DHA. Dogs need animal proteins to grow and stay strong and it's the combination of poultry, meat and fish that makes Ultra a protein-rich holistic dog food that your pet will gobble up.

But, Ultra is more than protein. We know from experience that many essential nutrients can be found naturally in flowers, vegetables and grains. These days, more and more of us are becoming aware just how nutritious foods like tomatoes, cranberries and garlic are. Tomatoes contain Lycopene and Tomatoes provide vitamin C, both of these are powerful antioxidants. These antioxidants fight free radicals and help fight the effects of aging—that's something that all of us can appreciate.



And by adding natural amino acids and omega-3 and omega-6 fatty acids from sunflower and fish oils, we've made a food that is not only rich in naturally occurring nutrients like DHA and linoleic acid, Ultra tastes great too. What good is a highly nutritious food if no one wants to eat it! We don't want to brag—or maybe we do—but we've tested Ultra with dogs and found that more dogs prefer Ultra than other comparable brands*. We know your dog's biggest concern is taste and Ultra has the taste your dog will love! We know that *your* concern is whether your dog is getting the healthiest diet he or she possibly can. With Ultra, the answer is a resounding YES!

The best part of Ultra is that you can see the difference. Healthy skin and a shiny, lustrous coat are one hallmark of an Ultra dog. We've also been told that dogs fed Ultra seem to be more easily trained with a better ability to understand commands. But the best thing is that a well-nourished dog is going to be a healthy and happy companion for you and your family.



Oh, and lets not forget that Ultra contains absolutely no chemical preservatives—no BHA, BHT, ethoxyquin or propyl gallate. So you can be sure that you are getting a food that is good

for your dog's sustained vitality and well-being. We think Ultra is the best formula for your dog's health and happiness—so we invite you to try it!

[*For a list of other comparable brands, click here.](#)

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Home

The Holistic Food that Outperforms the Competition.

Company

Ultra combines highly digestible natural proteins and grains with vitamins and minerals to produce a wholesome, holistic food that provides whole body health to build and sustain your dog's vitality and performance.



Ingredients

Products

Ultra has the*...

Performance

- Highest level of linoleic acid for healthy skin and lustrous coat ([see chart](#))
- Highest level of DHA for improved learning and easier training
- Highest level of alpha linolenic acid (ALA) to help reduce inflammation
- Highest palatability – up to 95% of dogs prefer the taste of Ultra ([see chart](#))
- Lowest stool volume ([see chart](#))

Where to Buy

**Ultra Adult was compared to the following brands: 1) Blue™ Chicken & Brown Rice Recipe for Adult Dogs, 2) Eagle Pack® Holistic Select® Lamb Meal & Rice, 3) Canidae®, 4) Innova® Dog, 5) Wellness® Super5Mix® Lamb, and 6) Solid Gold® Holistique Blendz™ Adult Dog*

[Home](#)


[Company](#)

[Ingredients](#)

[Products](#)

[Performance](#)

[Where to Buy](#)



Small Breed Adult

Essential proteins for better muscle development and overall performance. Combines chicken, lamb and salmon meals to provide essential amino acids.

Natural oils for healthy skin and lustrous coat. Sunflower oil is high in linoleic acid, an essential fatty acid known to improve canine skin and coat. Fish oil is an excellent source of the omega-3 fatty acid DHA for central nervous system health and good vision.

Carbohydrates for energy and performance. Whole brown rice and wholesome oatmeal are high quality carbohydrates that provide energy and stamina and are easy on the stomach.

Direct Fed Microbials. A source of *Bacillus licheniformis* and *Bacillus subtilis* that promote beneficial bacteria in a dog's digestive tract.

Unique antioxidants that help support a healthy immune system. Tomato Pomace, a natural source of Lycopene, and Cranberry powder, a natural source of vitamin C, help fight the effects of aging. Taurine, an amino acid and antioxidant, helps maintain a strong, healthy heart.

[Click on product to learn more.](#)

[Home](#)

[Company](#)

[Ingredients](#)

[Products](#)

[Performance](#)

[Where to Buy](#)



Weight Management

Essential proteins for better muscle development and overall performance. Combines chicken, lamb and salmon meals to provide essential amino acids.

Natural oils for healthy skin and lustrous coat. Sunflower oil is high in linoleic acid, an essential fatty acid known to improve canine skin and coat. Fish oil is an excellent source of the omega-3 fatty acid DHA for central nervous system health and good vision.

Carbohydrates for energy and performance. Whole brown rice and wholesome oatmeal are high quality carbohydrates that provide energy and stamina and are easy on the stomach.

Direct Fed Microbials. A source of *Bacillus licheniformis* and *Bacillus subtilis* that promote beneficial bacteria in a dog's digestive tract.

Unique antioxidants that help support a healthy immune system. Tomato Pomace, a natural source of Lycopene, and Cranberry powder, a natural source of vitamin C, help fight the effects of aging. Taurine, an amino acid and antioxidant, helps maintain a strong, healthy heart.



Biscuit



Can

[Click on a product to learn more.](#)

SUPREMIUM NUTRITION

WHY FEED PREMIUM PET FOOD?

MORE NUTRITION FEED LESS

Only the highest-quality ingredients are used in Premium Pet Foods, so they are more nutritious and digestible than Supermarket Brands. It takes less food to meet the nutritional needs of your pet.

BETTER VALUE SPEND LESS

Rich in nutrients, Premium Pet Food packs more protein and energy per mouthful than Supermarket Brands. It takes less food to feed your pet, so you get more for your money.

EASIER CLEAN UP LESS WASTE

Feeding smaller amounts of highly digestible Premium Pet Food means lower stool volume and easier backyard clean up.



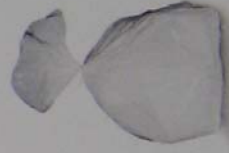
SUPERMARKET BRAND FOOD



PREMIUM PET FOOD



STOOL VOLUME FOR SUPERMARKET BRAND FOOD



STOOL VOLUME FOR PREMIUM PET FOOD

Exhibit 44

MENU FOODS INCOME FUND



Home

Recall Information

Press Release

Cat Product Information

[Dog Product Information](#)

FAQ's for Consumers

Recalled Dog Product Information Recall Information 1-866-895-2708

Variety or Multi-Packs:

If you are in possession of a variety or multi-pack, please be sure to check the individual can or pouch rather than relying solely on the date coding on the side of the carton.

Menu Foods Income Fund
8 Falconer Drive
Streetsville, ON
Canada L5N 1B1

1. [Americas Choice, Preferred Pets](#) Last Updated: May 2, 2007
2. [Authority](#) Last Updated: May 2, 2007
3. [Award](#) Last Updated: May 2, 2007
4. [Best Choice](#) Last Updated: May 2, 2007
5. [Big Bet](#) Last Updated: May 2, 2007
6. [Big Red](#) Last Updated: May 2, 2007
7. [Bloom](#) Last Updated: May 2, 2007
8. [Cadillac](#) Last Updated: May 2, 2007
9. [Companion](#) Last Updated: May 2, 2007
10. [Compliments](#) Last Updated: May 2, 2007
11. [Co-Op Gold](#) Last Updated: May 2, 2007
12. [Demoulas Market Basket](#) Last Updated: May 2, 2007
13. [Eukanuba](#) Last Updated: April 5, 2007
14. [Food Lion](#) Last Updated: May 2, 2007
15. [Giant Companion](#) Last Updated: May 2, 2007
16. [Grreat Choice](#) Last Updated: May 2, 2007
17. [Hannaford](#) Last Updated: May 2, 2007
18. [Health Diet Gourmet Cuisine](#) Last Updated: May 2, 2007
19. [Hill Country Fare](#) Last Updated: May 2, 2007
20. [Hy-Vee](#) Last Updated: May 2, 2007
21. [Iams](#) Last Updated: April 5, 2007
22. [La Griffe](#) Last Updated: May 2, 2007
23. [Laura Lynn](#) Last Updated: May 2, 2007
24. [Loving Meals](#) Last Updated: May 2, 2007
25. [Master Choice](#) Last Updated: May 2, 2007
26. [Meijers Main Choice](#) Last Updated: May 2, 2007
27. [Mighty Dog Pouch](#)
28. [Mixables](#) Last Updated: May 2, 2007
29. [Natural Life](#) Last Updated: May 3, 2007
30. [Nu Pet](#) Last Updated: May 2, 2007
31. [Nutriplan](#) Last Updated: May 2, 2007
32. [Nutro Max](#) Last Updated: May 2, 2007
33. [Nutro Natural Choice](#) Last Updated: May 2, 2007
34. [Nutro Ultra](#) Last Updated: May 2, 2007
35. [Nutro](#) Last Updated: May 2, 2007
36. [O!Roy Canada](#) Last Updated: May 2, 2007
37. [O!Roy US](#) Last Updated: May 2, 2007
38. [Paws](#) Last Updated: May 2, 2007
39. [Performtrin Ultra](#) Last Updated: May 3, 2007
40. [Pet Essentials](#) Last Updated: May 2, 2007

Exhibit 45

41. [Pet Pride - Good n Meaty](#) Last Updated: May 2, 2007
42. [Presidents Choice](#) Last Updated: May 2, 2007
43. [Price Chopper](#) Last Updated: May 2, 2007
44. [Priority Canada](#) Last Updated: May 2, 2007
45. [Priority US](#) Last Updated: May 2, 2007
46. [Publix](#) Last Updated: May 2, 2007
47. [Roche Brothers](#) Last Updated: May 2, 2007
48. [Save-A-Lot Choice Morsels](#) Last Updated: May 2, 2007
49. [Schnucks](#) Last Updated: May 2, 2007
50. [Shep Dog](#) Last Updated: May 2, 2007
51. [Springfield Prize](#) Last Updated: May 2, 2007
52. [Sprout](#) Last Updated: May 2, 2007
53. [Stater Brothers](#) Last Updated: May 2, 2007
54. [Stop & Shop Companion](#) Last Updated: May 2, 2007
55. [Tops Companion](#) Last Updated: May 2, 2007
56. [Triumph](#) Last Updated: May 2, 2007
57. [Truly](#) Last Updated: May 2, 2007
58. [Wegmans Bruiser](#) Last Updated: May 2, 2007
59. [Weis Total Pet](#) Last Updated: May 2, 2007
60. [Western Family Canada](#) Last Updated: May 2, 2007
61. [Western Family US](#) Last Updated: May 2, 2007
62. [White Rose](#) Last Updated: May 2, 2007
63. [Winn Dixie](#) Last Updated: May 2, 2007
64. [Your Pet](#) Last Updated: May 2, 2007

MENU FOODS INCOME FUND



Home

Recall Information

Press Release

[Cat Product Information](#)

Dog Product Information

FAQ's for Consumers

Recalled Cat Product Information

Recall Information **1-866-895-2708**

Variety or Multi-Packs:

If you are in possession of a variety or multi-pack, please be sure to check the individual can or pouch rather than relying solely on the date coding on the side of the carton.

Menu Foods Income Fund
8 Falconer Drive
Streetsville, ON
Canada L5N 1B1

1. [Americas Choice, Preferred Pets](#) Last Updated: May 2, 2007
2. [Authority](#) Last Updated: May 2, 2007
3. [Best Choice](#) Last Updated: May 2, 2007
4. [Cats Choice](#) Last Updated: May 3, 2007
5. [Companion](#) Last Updated: May 2, 2007
6. [Compliments](#) Last Updated: May 2, 2007
7. [Co-Op Gold](#) Last Updated: May 2, 2007
8. [Demoulas Market Basket](#) Last Updated: May 2, 2007
9. [Despar](#) Last Updated: May 2, 2007
10. [Drs Foster & Smith](#) Last Updated: May 3, 2007
11. [Eukanuba](#) Last Updated: April 5, 2007
12. [Fame](#) Last Updated: May 2, 2007
13. [Feline Classic](#) Last Updated: May 2, 2007
14. [Feline Cuisine](#) Last Updated: May 2, 2007
15. [Fine Feline Cat](#) Last Updated: May 2, 2007
16. [Food Lion](#) Last Updated: May 2, 2007
17. [Foodtown](#) Last Updated: May 2, 2007
18. [Giant Companion](#) Last Updated: May 2, 2007
19. [Giant Eagle](#) Last Updated: May 2, 2007
20. [Hannaford](#) Last Updated: May 2, 2007
21. [Hill Country Fare](#) Last Updated: May 2, 2007
22. [Hy-Vee](#) Last Updated: May 2, 2007
23. [Iams](#) Last Updated: April 5, 2007
24. [J.E. Mondou](#) Last Updated: May 2, 2007
25. [La Griffe](#) Last Updated: May 2, 2007
26. [Laura Lynn](#) Last Updated: May 2, 2007
27. [Li'l Red](#) Last Updated: May 2, 2007
28. [Loving Meals](#) Last Updated: May 2, 2007
29. [Master Choice](#) Last Updated: May 2, 2007
30. [Medi-Cal](#) Last Updated: May 2, 2007
31. [Meijer's Main Choice](#) Last Updated: May 2, 2007
32. [Natural Ultramix](#) Last Updated: May 2, 2007
33. [Nu Pet](#) Last Updated: May 2, 2007
34. [Nutriplan](#) Last Updated: May 2, 2007
35. [Nutro](#) Last Updated: May 2, 2007
36. [Nutro Max Gourmet Classics](#) Last Updated: May 2, 2007
37. [Nutro Natural Choice](#) Last Updated: May 2, 2007
38. [Nutro Products](#) Last Updated: May 2, 2007
39. [Paws](#) Last Updated: May 2, 2007
40. [Performatrin Ultra](#) Last Updated: May 3, 2007

41. [Pet Pride](#) Last Updated: May 2, 2007
42. [Presidents Choice](#) Last Updated: May 2, 2007
43. [Price Chopper](#) Last Updated: May 2, 2007
44. [Priority Canada](#) Last Updated: May 2, 2007
45. [Priority US](#) Last Updated: May 2, 2007
46. [Publix](#) Last Updated: May 2, 2007
47. [Roche Brothers](#) Last Updated: May 2, 2007
48. [Roundy's](#) Last Updated: May 2, 2007
49. [Save-A-Lot Special Blend](#) Last Updated: May 2, 2007
50. [Schnucks](#) Last Updated: May 2, 2007
51. [Science Diet Feline Savory Cuts Cans](#) Last Updated: April 12, 2007
52. [Sophistacat](#) Last Updated: May 2, 2007
53. [Special Kitty Canada](#) Last Updated: May 2, 2007
54. [Special Kitty US](#) Last Updated: May 2, 2007
55. [Springfield Prize](#) Last Updated: May 2, 2007
56. [Sprout](#) Last Updated: May 2, 2007
57. [Stop & Shop Companion](#) Last Updated: May 2, 2007
58. [Stuzzy Gold](#) Last Updated: May 2, 2007
59. [Tops Companion](#) Last Updated: May 2, 2007
60. [Triumph](#) Last Updated: May 2, 2007
61. [Wegmans](#) Last Updated: May 2, 2007
62. [Weis Total Pet](#) Last Updated: May 2, 2007
63. [Western Family Canada](#) Last Updated: May 2, 2007
64. [Western Family US](#) Last Updated: May 2, 2007
65. [White Rose](#) Last Updated: May 2, 2007
66. [Winn Dixie](#) Last Updated: May 3, 2007
67. [Your Pet](#) Last Updated: May 2, 2007



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INFORMATION FOR CONSUMERS
FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

FDA's REGULATION OF PET FOOD

The following consumer information is provided by Sharon Benz, Ph.D., P.A.S.,
Division of Animal Feeds, Center for Veterinary Medicine

FDA is charged with the enforcement of the Federal Food, Drug, and Cosmetic Act (the Act). Under the Act, a part of FDA's responsibility is to ensure that human and animal foods are safe and properly labeled. Within FDA, the Center for Veterinary Medicine is responsible for the regulation of animal drugs, medicated feeds, food additives and feed ingredients, including pet foods. The regulations based, in part, on this law are found in the Code of Federal Regulations, Title 21, Food and Drugs, Part 500.

The Act is this country's basic food and drug law. It defines food as "articles used for food or drink for man or other animals...and articles used for components of any such article." There is no requirement that pet foods have pre-market approval by FDA. The Act does require that pet foods, like human foods, be pure and wholesome, contain no harmful or deleterious substances, and be truthfully labeled. Additionally, canned pet foods must be processed in conformance with low acid canned food regulations (Title 21, Code of Federal Regulations, Part 113, abbreviated as 21 CFR 113).

In the Act a "drug" is, in part, an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, or an article intended to affect the structure or function of the body other than food (Sec. 201 (g)(1)). In the drug definition, the courts have interpreted "food" as something that provides nutrition, taste, or aroma. If a food affects the structure or function of the body, it does so by these properties (for example, a food may provide nutrients such as calcium for proper bone structure or taurine for healthy heart function in cats). However, if a substance affects the structure or function of the body apart from its nutritive value, such as urine acidification or improvement in joint function, it may be considered a drug. Structure/function effects extending beyond the "food" umbrella also include claims for improved or increased production and performance, or alteration or improvement in function.

When a substance, including one considered food, is intended to be used for the treatment or prevention of disease or "non-food" structure/function effect, FDA considers it a drug. Under the law, a new animal drug must be shown to be safe and effective for its intended use by adequate data from controlled scientific studies as part of a New Animal Drug Application (21 CFR, Part 514). If a product on the market is not approved, it may be deemed an adulterated drug and subject to regulatory action.

In 1958, in response to public concern about the increased use of chemicals in foods and food processing, Congress amended the Act to require the pre-marketing clearance of additives whose safety was not generally recognized. The Act was also amended to deem food unsafe and adulterated if it contains an unapproved food additive. Under the definition for food additive in Sec. 201 (s) of the Act, it provides that substances added to food that qualified scientists generally recognize as safe (GRAS) under the conditions of the intended use are not "food additives" and as such are exempt from pre-clearance approval.

A food additive petition is the pre-clearance mechanism developed by the FDA for demonstrating that a food additive is safe for its intended use and has utility. If the FDA agrees with the petition, a regulation is published in the Federal Register and 21 CFR, Part 573, Food Additives Permitted in the Feed and Drinking Water of Animals, is amended. The information needed in a food additive petition is described in Part 571 of Title 21. Briefly, a petition contains a description of the chemical identity, manufacturing process and controls, analytical methods, utility data, human food safety data, target animal safety data, product labeling, and in some cases an environmental assessment.

CVM has used regulatory discretion and not required food additive petitions for substances that do not raise any safety concerns. In this case, we ask the company to submit the information needed to list the ingredient in the Official Publication of the Association of American Feed Control Officials (AAFCO). This ingredient definition process is done to conserve agency resources, as food additive approval is time-consuming. CVM reviews the data to ensure the ingredient has utility and can be manufactured consistently to meet product specifications. Although ingredients used under regulatory discretion are still unapproved food additives, we agree we will not take regulatory action as long as the labeling is consistent with the accepted intended use, the labeling or advertising does not make drug claims, and new data are not received that raise questions concerning safety or suitability.

A GRAS substance is GRAS only for an intended purpose. For example, sodium aluminosilicate is GRAS as an anticaking agent. It has been purported to bind mycotoxins and prevent absorption from the intestinal tract but would not be GRAS for this use. A food substance also cannot be GRAS for the prevention, treatment, or mitigation of a disease. So, chondroitin sulfates cannot be GRAS to prevent or treat arthritis. For this use it would be a drug.

It is very important to recognize that general recognition of safety of a substance for an intended use may only be based on

Exhibit 46

the views of experts qualified by scientific training and experience to evaluate the safety of the substance. As interpreted by FDA and the courts, there are two requirements that must be satisfied before a substance can be GRAS -- general recognition and safety:

1. For general recognition, there must be an expert consensus that the substance is safe for use as a component of food, and;
2. This expert consensus of safety must be based on either (a) generally available data and information to show common use of the substance in animal feed prior to 1958 or (b) scientific procedures, which require the same quantity and quality of scientific data needed for FDA approval of the substance as a food additive. In addition, this information must be published in the scientific literature.

Both of these requirements, general recognition and safety, must be met for a substance to be considered as GRAS. The GRAS standard is actually more stringent than that required for a food additive approval because for a substance to be GRAS there must exist the same quality and quantity of information needed for a food additive approval. In addition, the data must be published and there must be a consensus among qualified experts, based on the data, that the substance is safe for that use. Publication of data in a company's annual report does not meet the publication standard. For general recognition of safety to exist, the data must be available to the experts by publication in the scientific literature. The Act permits companies to make their own GRAS determination, and many times GRAS Panels will be assembled that are comprised of scientific experts in a particular field to evaluate the safety of a substance for an intended use. However, regardless of who makes the determination, the FDA or the company, the standard for GRAS is the same.

On April 17, 1997, the Center for Food Safety and Applied Nutrition (CFSAN) and CVM published a proposed rule in the *Federal Register* (62 FR 18938) to amend the regulations to replace the current GRAS affirmation process with a notification procedure. Under the notification procedure, any person could notify the agency of a determination that a particular use of a substance is GRAS. The notification would include a description of the substance, the conditions of use, and the basis of the GRAS determination. The FDA would not conduct its own detailed evaluation of the data, as was done previously for GRAS affirmation petitions. Rather, FDA would evaluate whether the notice provides sufficient basis for a GRAS determination and whether the information in the notification or otherwise available to FDA raises issues on whether the use of the substance is GRAS. In the proposal FDA would have 90 days to respond to the notifier. The summary of the GRAS notifications would be available on the FDA Home Page, as would the FDA's responses to the person submitting the notification. CVM is not currently accepting GRAS notifications under the proposed rule; however, CFSAN is. A listing of the notifications that have been submitted can be found on <http://www.cfsan.fda.gov/~dms/>.

Once the final rule is published, CVM will accept GRAS notifications. It is anticipated that GRAS notifications submitted for use of substances in animal feed will be posted on the [CVM Home Page](#). When a GRAS notification raises no issue of concern to CVM, the AAFCO Feed Ingredient Chair will be notified so that the substance and its use can be listed in the AAFCO publication.

The Dietary Supplement and Health Education Act

When Congress enacted the Dietary Supplement and Health Education Act (DSHEA) on October 25, 1994, it created a new category of substances and new regulatory scheme. The Act was amended to define a dietary supplement as a product intended to supplement the diet and that contains at least one or more of the following ingredients: a vitamin; a mineral; a herb or other botanical; an amino acid; a dietary substance for use to supplement the diet by increasing total dietary intake; or a concentrate, metabolite, constituent, extract or combination of any of the previously mentioned ingredients (Sec. 201 (ff) of the Act). The main effect of DSHEA was to remove certain dietary ingredients from regulation as food additives, which requires pre-market approval. On April 22, 1996, CVM published a notice in the *Federal Register* outlining the reasons why FDA believes that Congress did not intend DSHEA to apply to substances for use in animals. This has been upheld in at least one court case. Thus, substances marketed as dietary supplements for humans still fall under the pre-DSHEA regulatory scheme when marketed for animals; that is, they are considered food, food additives, new animal drugs, or GRAS depending on the intended use. Most of these types of products on the market would be considered unapproved and unsafe food additives or new animal drugs based on current intended uses.

It is important to note that DSHEA defines the term "dietary supplement" to exclude products intended for use as conventional foods. For example, St. John's Wort would not be considered a dietary supplement if it were added to soup. Soup is a conventional food and any ingredient added to conventional foods must be used in accordance with the food additive regulation or be GRAS.

Health Claims

Congress also amended the Act when it enacted the Nutrition Labeling and Education Act in 1990. This law required FDA to write regulations to permit health claims on human food. A number of these claims have been approved for various foods. These can be found on the CFSAN web page.

CVM has incorporated the philosophy of NLEA in its policies in order to permit meaningful health information on pet foods. Examples are the use of urinary tract health claim on cat food diets, and development of AAFCO regulations for light, lean, less or reduced calories, lean, and less or reduced fat. Recently, CVM has been asked about complete cat foods for the control of hairballs. We would likely not take regulatory action provided the effect is achieved by ingredients already permitted for use in cat food, such as fiber sources. In this case, we ask that the firm submit information for review on the quantitative diet formulation, nutrient analysis, and labeling, and discussion on the basis for the claim, i.e., scientific studies or common knowledge of ingredients biological properties. If novel ingredients are used to achieve the effect, then we believe data demonstrating ingredient safety should be obtained prior to marketing.

Interaction with AAFCO

FDA also plays an active role in pet food regulation in partnership with AAFCO. An FDA representative serves on the

AAFCO Board of Directors. FDA has served on the Pet Food Committee. CVM staff also serves on other standing AAFCO committees and as investigators. We believe that continued partnership with AAFCO is vital to the effective regulation of pet food products because FDA has limited enforcement resources that are focused on human food safety issues. For this reason, an important role of CVM staff is to serve as scientific resources for State regulatory officials.

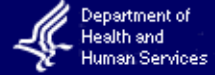
Summary

In summary, within the FDA, CVM has primary responsibility for enforcing the Act to ensure that animal foods, including pet foods, are safe and labeled appropriately and animal drugs are safe and effective. While FDA has tried to incorporate some of the philosophy of NLEA to permit health claims for pet foods, we believe that DSHEA was not intended by Congress to apply to animal foods. Thus, substances sold as dietary supplements for humans may not be legally distributed for use in animals unless the substances are food, approved animal food additives, GRAS, or approved new animal drugs.

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Search

GO

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Table of Contents

- [Animal Feed](#)
- [Product Regulation](#)
- [Biotechnology Products](#)
- [Feed Contaminants](#)
- [Survey Assignments](#)
- [Feed Ingredients](#)
- [Food Additives](#)
- [Feed Mill Licensing](#)
- [Import and Export](#)
- [Pet Foods](#)
- [Veterinary Feed Directive](#)
- [Prior Notice](#)
- [Food Facility Registration](#)
- [Animal Feed Safety Sys](#)
- [More Information](#)

CVM and Animal Food, Feed Ingredients, and Additives

Biotechnology Products

Biotechnology products are a growing proportion of the feed components regulated by the Center for Veterinary Medicine. We anticipate that "new" biotechnology will become an even greater source of products in the future. The spectrum of products being presented to CVM for regulation includes biotechnology products from plants, microbes and animals. For more information about the uses of products produced using this technology, see the [CVM Biotechnology in Animals and Animal Feeds](#) page.

Feed Contaminants

There are two classes of feed contaminants. The first is a toxic or deleterious substance that is an inherent, naturally occurring constituent of an animal food and is not the result of environmental, agricultural, industrial or other contaminations. Examples of this class include some of the mycotoxins, such as aflatoxin and [fumonisin](#), the glucosinolates, and the heavy metals, like lead and cadmium. The second class is made up of industrial toxic or deleterious substances, which are not naturally occurring and are increased to abnormal levels in the animal food through mishandling or other intervening acts. Examples of this class are the polychlorinated biphenyls ([PCBs](#)) and certain pesticides, like DDT (1,1'-(2,2,2-Trichloroethylidene)bis[4-chlorobenzene]). CVM may prohibit any detectable amount of a contaminant or establish a regulatory limit for the contaminant, taking into account the protection of the public health, the extent to which the presence of the contaminant cannot be avoided, and other ways in which the consumer may be affected by the presence of the contaminant.

- CVM Compliance Program Guidance Manual 7371.003 [Feed Contaminants Program](#)

CVM Feed Sampling Survey Assignments

- [Nationwide Survey of Distillers Grains for Aflatoxins](#), November 21, 2006
- [Nationwide Assignment to Collect Samples of Direct-Human-Contact Feeds and Analyze Them for Salmonella and E. coli O157:H7](#), October, 17, 2006

Additional Information

- [Mycotoxins in Feeds: CVM's Perspective Presentation by Michael H. Henry, Ph.D. to the Risk Management Agency](#), August 23, 2006
- CVM Update - [Animal Feed Safety System Website Posted](#), March 29, 2006
- [Animal Feed Safety System 2005 Public Meeting](#), April 5 – 6, 2005
Crowne Plaza Hotel, Omaha, NE
- [FDA Animal Feed Safety System \(AFSS\) Public Meeting](#), September 23-24, 2003
Hyatt Dulles International Airport, Herndon, VA
- Docket No. 94D-0147, CVM 200035. [Guidance for Industry: Studies to Evaluate the Utility of Anti-Salmonella Chemical Food Additives in Feeds](#); Availability. Pages 70752-70753 [FR Doc. 02-29925] November 26, 2002 | [htm](#) | | [pdf](#) |

Exhibit 47

- Guidance for Industry #80: Studies to Evaluate the Utility of Anti-Salmonella Chemical Food Additives in Feeds, November 21, 2002 | [pdf](#) | | [doc](#) |

Feed Ingredients

A feed ingredient is a component part or constituent or any combination/mixture added to and comprising the feed. Feed ingredients might include grains, milling byproducts, added vitamins, minerals, fats/oils, and other nutritional and energy sources. Animal feeds provide a practical outlet for plant and animal byproducts not suitable for human consumption. The Official Publication of the Association of American Feed Control Officials (AAFCO) contains a list of feed ingredients with their definitions. Many of these ingredients are not approved food additives and may not meet the criteria needed to be recognized as GRAS (21 CFR 570.30). Nevertheless, FDA has not objected to the listing of certain ingredients (e.g., those used as sources of nutrients, aroma, or taste) in the AAFCO Official Publication or their marketing in interstate commerce, provided there were no apparent safety concerns about the use or composition of the ingredient.

Federal regulations require ingredients be listed on the product label by their common or usual name in descending order of predominance according to weight (21 CFR 501.4). A common or usual name is one that accurately identifies or describes the basic nature of the ingredient (21 CFR 502.5). FDA has recognized the definitions as they appear in the Official Publication of AAFCO as the common or usual name for animal feed ingredients including pet food ([Compliance Policy Guide 7126.08](#)). There is only one exception to the requirement to list the common or usual name on the label--when the ingredient is part of a collective name. Regulation 21 CFR 501.110 describes the use of collective names. The following are acceptable collective names: animal protein products, forage products, grain products, plant protein products, processed grain byproducts and roughage products. These collective names may be used in the ingredient list for livestock and poultry feeds, but not pet foods.

Association of American Feed Control Officials (AAFCO)

AAFCO is composed of state, federal, and international regulatory officials who are responsible for the enforcement of state laws regulating the safe production and labeling of animal feed, including pet food. FDA and AAFCO work together in the area of feed regulation, particularly in the establishment of definitions to describe new feed ingredients. Each year AAFCO publishes its Official Publication which includes a model feed bill for states to adopt in regulating feed products and a list of accepted feed ingredients. Most states have adopted all or part of the model feed bill and allow feed ingredients listed in the publication to be used in their respective territories. For more information about [AAFCO](#), please see its internet site

Food Additives (Food Additive Petitions)

Any substance intentionally added to an animal feed, including pet food, must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use. The basis of a food additive regulation is an approved food additive petition. The food additive petition should include an adequate factual basis to establish that the food additive is safe for its intended use, under the conditions of use specified in the petition. If the petitioner meets this burden of proof, the food additive can be approved for use in animal feed.

There are several types of food additives based on its composition and intended use. A food additive generally provides one or more of the following, i.e., nutrient, aroma/flavor, taste, soluble or insoluble fiber, stabilizer, emulsifier, sequestrant, chemical preservative, anti-oxidant, anti-caking agent, etc.

Section 571 of Part 21 of the Code of Federal Regulations (CFR) prescribes the kinds of data that must be submitted by the petitioner and the format which the food additive petition must follow when sent to FDA. While the actual content may vary from petition to petition, depending primarily on the food additive's composition and intended use, each of the following subject areas must be addressed: human food safety, target animal safety, environmental impact, utility, labeling, proposed regulation, assay methodology, and manufacturing process and controls. Subsequently, when the FDA concludes that the available data for a food additive are sufficient to meet current criteria, the FDA issues a regulation permitting the petitioned use of the additive.

- CVM Update - [FDA Permits the Use of Selenium Yeast in Horse Feed](#), October 14, 2004

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INFORMATION FOR CONSUMERS
FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

INTERPRETING PET FOOD LABELS

The following consumer information is provided by David A. Dzanis, DVM, Ph.D., DACVN.

Pet food labeling is regulated at two levels. The Federal regulations, enforced by the FDA's Center for Veterinary Medicine (CVM), establish standards applicable for all animal feeds: proper identification of product, net quantity statement, manufacturer's address, and proper listing of ingredients. Some States also enforce their own labeling regulations. Many of these have adopted the model pet food regulations established by the Association of American Feed Control Officials (AAFCO). These regulations are more specific in nature, covering aspects of labeling such as the product name, the guaranteed analysis, the nutritional adequacy statement, feeding directions, and calorie statements.

Product Name

The product name is the first part of the label noticed by the consumer, and can be a key factor in the consumer's decision to buy the product. For that reason, manufacturers often use fanciful names or other techniques to emphasize a particular aspect. Since many consumers purchase a product based on the presence of a specific ingredient, many product names incorporate the name of an ingredient to highlight its inclusion in the product. The percentages of named ingredients in the total product are dictated by four AAFCO rules.

The "95%" rule applies to products consisting primarily of meat, poultry or fish, such as some of the canned products. They have simple names, such as "Beef for Dogs" or "Tuna Cat Food." In these examples, at least 95% of the product must be the named ingredient (beef or tuna, respectively), not counting the water added for processing and "condiments." Counting the added water, the named ingredient still must comprise 70% of the product. Since ingredient lists must be declared in the proper order of predominance by weight, "beef" or "tuna" should be the first ingredient listed, followed often by water, and then other components such as vitamins and minerals. If the name includes a combination of ingredients, such as "Chicken 'n Liver Dog Food," the two together must comprise 95% of the total weight. The first ingredient named in the product name must be the one of higher predominance in the product. For example, the product could not be named "Lobster and Salmon for Cats" if there is more salmon than lobster in the product. Because this rule only applies to ingredients of animal origin, ingredients that are not from a meat, poultry or fish source, such as grains and vegetables, cannot be used as a component of the 95% total. For example, a "Lamb and Rice Dog Food" would be misnamed unless the product was comprised of at least 95% lamb.

The "25%" or "dinner" rule applies to many canned and dry products. If the named ingredients comprise at least 25% of the product (not counting the water for processing), but less than 95%, the name must include a qualifying descriptive term, such as "Beef Dinner for Dogs." Many descriptors other than "dinner" are used, however. "Platter," "entree," "nuggets" and "formula" are just a few examples. Because, in this example, only one-quarter of the product must be beef, it would most likely be found third or fourth on the ingredient list. Since the primary ingredient is not always the named ingredient, and may in fact be an ingredient that is not desired, the ingredient list should always be checked before purchase. For example, a cat owner may have learned from his or her finicky feline to avoid buying products with fish in it, since the cat doesn't like fish. However, a "Chicken Formula Cat Food" may not always be the best choice, since some "chicken formulas" may indeed contain fish, and sometimes may contain even more fish than chicken. A quick check of the ingredient list would avert this mistake.

If more than one ingredient is included in a "dinner" name, they must total 25% and be listed in the same order as found on the ingredient list. Each named ingredient must be at least 3% of the total, too. Therefore, "Chicken n' Fish Dinner Cat Food" must have 25% chicken and fish combined, and at least 3% fish. Also, unlike the "95%" rule, this rule applies to all ingredients, whether of animal origin or not. For example, a "Lamb and Rice Formula for Cats" would be an acceptable name as long as the amounts of lamb and rice combined totaled 25%.

The "3%" or "with" rule was originally intended to apply only to ingredients highlighted on the principal display panel, but outside the product name, in order to allow manufacturers to point out the presence of minor ingredients that were not added in sufficient quantity to merit a "dinner" claim. For example, a "Cheese Dinner," with 25% cheese, would not be feasible or economical to produce, but either a "Beef Dinner for Dogs" or "Chicken Formula Cat Food" could include a side burst "with cheese" if at least 3% cheese is added. Recent amendments to the AAFCO model regulations now allow use of the term "with" as part of the product name, too, such as "Dog Food With Beef" or "Cat Food With Chicken." Now, even a minor change in the wording of the name has a dramatic impact on the minimum amount of the named ingredient required, e.g., a can of "Cat Food With Tuna" could be confused with a can of "Tuna Cat Food," but, whereas the latter example must contain at least 95% tuna, the first needs only 3%. Therefore, the consumer must read labels carefully before purchase to ensure that the desired product is obtained.

Under the "flavor" rule, a specific percentage is not required, but a product must contain an amount sufficient to be able to be detected. There are specific test methods, using animals trained to prefer specific flavors, that can be used to confirm this claim. In the example of "Beef Flavor Dog Food," the word "flavor" must appear on the label in the same size, style and

color as the word "beef." The corresponding ingredient may be beef, but more often it is another substance that will give the characterizing flavor, such as beef meal or beef by-products.

With respect to flavors, pet foods often contain "digests," which are materials treated with heat, enzymes and/or acids to form concentrated natural flavors. Only a small amount of a "chicken digest" is needed to produce a "Chicken Flavored Cat Food," even though no actual chicken is added to the food. Stocks or broths are also occasionally added. Whey is often used to add a milk flavor. Often labels will bear a claim of "no artificial flavors." Actually, artificial flavors are rarely used in pet foods. The major exception to that would be artificial smoke or bacon flavors, which are added to some treats.

Net Quantity Statement

The net quantity statement tells you how much product is in the container. There are many FDA regulations dictating the format, size and placement of the net quantity statement. None of these do any good if the consumer does not check the quantity statements, especially when comparing the cost of products. For example, a 14-ounce can of food may look identical to the one-pound can of food right next to it. Also, dry products may differ greatly in density, especially some of the "lite" products. Thus, a bag that may typically hold 40 pounds of food may only hold 35 pounds of a food that is "puffed up." A cost-per-ounce or per-pound comparison between products is always prudent. **Manufacturer's Name and Address** The "manufactured by..." statement identifies the party responsible for the quality and safety of the product and its location. If the label says "manufactured for..." or "distributed by..." the food was manufactured by an outside manufacturer, but the name on the label still designates the responsible party. Not all labels include a street address along with the city, State, and zip code, but by law, it should be listed in either a city directory or a telephone directory. Many manufacturers also include a toll-free number on the label for consumer inquiries. If a consumer has a question or complaint about the product, he or she should not hesitate to use this information to contact the responsible party. **Ingredient List** All ingredients are required to be listed in order of predominance by weight. The weights of ingredients are determined as they are added in the formulation, including their inherent water content. This latter fact is important when evaluating relative quantity claims, especially when ingredients of different moisture contents are compared.

For example, one pet food may list "meat" as its first ingredient, and "corn" as its second. The manufacturer doesn't hesitate to point out that its competitor lists "corn" first ("meat meal" is second), suggesting the competitor's product has less animal-source protein than its own. However, meat is very high in moisture (approximately 75% water). On the other hand, water and fat are removed from meat meal, so it is only 10% moisture (what's left is mostly protein and minerals). If we could compare both products on a dry matter basis (mathematically "remove" the water from both ingredients), one could see that the second product had more animal-source protein from meat meal than the first product had from meat, even though the ingredient list suggests otherwise.

That is not to say that the second product has more "meat" than the first, or in fact, any meat at all. Meat meal is not meat *per se*, since most of the fat and water have been removed by rendering. Ingredients must be listed by their "common or usual" name. Most ingredients on pet food labels have a corresponding definition in the AAFCO Official Publication. For example, "meat" is defined as the "clean flesh of slaughtered mammals and is limited to...the striate muscle...with or without the accompanying and overlying fat and the portions of the skin, sinew, nerve and blood vessels which normally accompany the flesh." On the other hand, "meat meal" is "the rendered product from mammal tissues, exclusive of any added blood, hair, horn, hide trimmings, manure, stomach and rumen contents." Thus, in addition to the processing, it could also contain parts of animals one would not think of as "meat." Meat meal may not be very pleasing to think about eating yourself, even though it's probably more nutritious. Animals do not share in people's aesthetic concerns about the source and composition of their food. Regardless, the distinction must be made in the ingredient list (and in the product name). For this reason, a product containing "lamb meal" cannot be named a "Lamb Dinner."

Further down the ingredient list, the "common or usual" names become less common or usual to most consumers. The majority of ingredients with chemical-sounding names are, in fact, vitamins, minerals, or other nutrients. Other possible ingredients may include artificial colors, stabilizers, and preservatives. All should be either "Generally Recognized As Safe (GRAS)" or approved food additives for their intended uses.

If scientific data are presented that show a health risk to animals of an ingredient or additive, CVM can act to prohibit or modify its use in pet food. For example, propylene glycol was used as a humectant in soft-moist pet foods, which helps retain water and gives these products their unique texture and taste. It was affirmed Generally Recognized As Safe (GRAS) for use in human and animal food before the advent of soft-moist foods. It was known for some time that propylene glycol caused Heinz Body formation in the red blood cells of cats (small clumps of proteins seen in the cells when viewed under the microscope), but it could not be shown to cause overt anemia or other clinical effects. However, recent reports in the veterinary literature of scientifically sound studies have shown that propylene glycol reduces the red blood cell survival time, renders red blood cells more susceptible to oxidative damage, and has other adverse effects in cats consuming the substance at levels found in soft-moist food. In light of this new data, CVM amended the regulations to expressly prohibit the use of propylene glycol in cat foods.

Another pet food additive of some controversy is ethoxyquin, which was approved as a food additive over thirty-five years ago for use as an antioxidant chemical preservative in animal feeds. Approximately ten years ago, CVM began receiving reports from dog owners attributing the presence of ethoxyquin in the dog food with a myriad of adverse effects, such as allergic reactions, skin problems, major organ failure, behavior problems, and cancer. However, there was a paucity of available scientific data to support these contentions, or to show other adverse effects in dogs at levels approved for use in dog foods. More recent studies by the manufacturer of ethoxyquin showed a dose-dependent accumulation of a hemoglobin-related pigment in the liver, as well as increases in the levels of liver-related enzymes in the blood. Although these changes are due to ethoxyquin in the diet, the pigment is not made from ethoxyquin itself, and the health significance of these findings is unknown. More information on the utility of ethoxyquin is still needed in order for CVM to amend the maximum allowable level to below that which would cause these effects, but which still would be useful in preserving the food. While studies are being conducted to ascertain a more accurate minimum effective level of ethoxyquin in dog foods, CVM has asked the pet food industry to voluntarily lower the maximum level of use of ethoxyquin in dog foods from 150 ppm (0.015%) to 75 ppm. Regardless, most pet foods that contained ethoxyquin never exceeded the lower amount, even before this recommended change.

Guaranteed Analysis

At minimum, a pet food label must state guarantees for the minimum percentages of crude protein and crude fat, and the maximum percentages of crude fiber and moisture. The "crude" term refers to the specific method of testing the product, not to the quality of the nutrient itself.

Some manufacturers include guarantees for other nutrients as well. The maximum percentage of ash (the mineral component) is often guaranteed, especially on cat foods. Cat foods commonly bear guarantees for taurine and magnesium as well. For dog foods, minimum percentage levels of calcium, phosphorus, sodium, and linoleic acid are found on some products.

Guarantees are declared on an "as fed" or "as is" basis, that is, the amounts present in the product as it is found in the can or bag. This doesn't have much bearing when the guarantees of two products of similar moisture content are compared (for example, a dry dog food versus another dry dog food). However, when comparing the guaranteed analyses between dry and canned products, one will note that the levels of crude protein and most other nutrients are much lower for the canned product. This can be explained by looking at the relative moisture contents. Canned foods typically contain 75-78% moisture, whereas dry foods contain only 10-12% water. To make meaningful comparisons of nutrient levels between a canned and dry product, they should be expressed on the same moisture basis.

The most accurate means of doing this is to convert the guarantees for both products to a dry matter basis. The percentage of dry matter of the product is equal to 100% minus the percentage of moisture guaranteed on the label. A dry food is approximately 88-90% dry matter, while a canned food is only about 22-25% dry matter. To convert a nutrient guarantee to a dry matter basis, the percent guarantee should be divided by the percentage of the dry matter, then multiplied by 100. For example, a canned food guarantees 8% crude protein and 75% moisture (or 25% dry matter), while a dry food contains 27% crude protein and 10% moisture (or 90% dry matter). Which has more protein, the dry or canned? Calculating the dry matter protein of both, the canned contains 32% crude protein on a dry matter basis ($8/25 \times 100 = 32$), while the dry has only 30% on a dry matter basis ($27/90 \times 100 = 30$). Thus, although it looks like the dry has a lot more protein, when the water is counted out, the canned actually has a little more. An easier way is to remember that the amount of dry matter in the dry food is about four times the amount in a canned product. To compare guarantees between a dry and canned food, multiply the guarantees for the canned food times four first.

It is especially important to look at the moisture guarantee for canned foods, even when comparing a canned food with another canned. Under AAFCO regulations, the maximum percentage moisture content for a pet food is 78%, except for products labeled as a "stew," "in sauce," "in gravy," or similar terms. The extra water gives the product the qualities needed to have the appropriate texture and fluidity. Some of these exempted products have been found to contain as much as 87.5% moisture. This doesn't sound like much difference until the dry matter contents are compared. For example, a product with a guarantee of 87.5% moisture contains 12.5% dry matter, only half as much as a product with a 75% moisture guarantee (25% dry matter).

Nutritional Adequacy Statement

Any claim that a product is "complete," "balanced," "100% nutritious," or similarly suggests that a product is suitable for sole nourishment that is not, in fact, nutritionally adequate is a potentially unsafe product. For this reason, an AAFCO nutritional adequacy statement is one of the most important aspects of a dog or cat food label. A "complete and balanced" pet food must be substantiated for nutritional adequacy by one of two means.

The first method is for the pet food to contain ingredients formulated to provide levels of nutrients that meet an established profile. Presently, the AAFCO Dog or Cat Food Nutrient Profiles are used. Products substantiated by this method should include the words, "(Name of product) is formulated to meet the nutritional levels established by the AAFCO (Dog/Cat) Food Nutrient Profiles." This means the product contains the proper amount of protein, calcium, and other recognized essential nutrients needed to meet the needs of the healthy animal. The recommendations of the National Research Council (NRC) were once used as the basis for nutritional adequacy, but they are no longer considered valid for this purpose.

The alternative means of substantiating nutritional adequacy is for the product to be tested following the AAFCO Feeding Trial Protocols. This means that the product, or "lead" member of a "family" of products, has been fed to dogs or cats under strict guidelines and found to provide proper nutrition. These products should bear the nutritional adequacy statement "Animal feeding tests using AAFCO procedures substantiate that (name of product) provides complete and balanced nutrition."

Regardless of the method used, the nutritional adequacy statement will also state for which life stage(s) the product is suitable, such as "for maintenance," or "for growth." A product intended "for all life stages" meets the more stringent nutritional needs for growth and reproduction. A maintenance ration will meet the needs of an adult, non-reproducing dog or cat of normal activity, but may not be sufficient for a growing, reproducing, or hard-working animal. On the other hand, an all life stages ration can be fed for maintenance. Although the higher levels of nutrients would not be harmful to the healthy adult animal, they are not really necessary. Occasionally a product may be labeled for a more specific use or life stage, such as "senior" or for a specific size or breed. However, there is little information as to the true dietary needs of these more specific uses, and no rules governing these types of statements have been established. Thus, a "senior" diet must meet the requirements for adult maintenance, but no more. A product that does not meet either of these methods must state that "this product is intended for intermittent or supplemental feeding," except if it is conspicuously identified as a snack or treat.

Feeding Directions

Feeding directions instruct the consumer on how much product should be offered to the animal. At minimum, they should include verbiage such as "feed ___ cups per ___ pounds of body weight daily." On some small cans, this may be all the information that can fit. The feeding directions should be taken as rough guidelines, a place to start. Breed, temperament, environment, and many other factors can influence food intake. Manufacturers attempt to cover almost all contingencies by setting the directions for the most demanding. The best suggestion is to offer the prescribed amount at first, and then to

increase or cut back as needed to maintain body weight in adults or to achieve proper rate of gain in puppies and kittens. A nursing mother should be offered all the food she wants to eat. **Calorie Statement** Pet foods can vary greatly in calorie content, even among foods of the same type (dry, canned) and formulated for the same life stage. Feeding directions vary among manufacturers, too, so the number of calories delivered in a daily meal of one food may be quite different from another. The number of calories in a product roughly relates to the amount of fat, although varying levels of non-calorie-containing components, such as water and fiber, can throw this correlation off. The best way for consumers to compare products and determine how much to be fed is to know the calorie content. However, until recently, calorie statements were not allowed on pet food labels. New AAFCO regulations were developed to allow manufacturers to substantiate calorie content and include a voluntary statement.

If a calorie statement is made on the label, it must be expressed on a "kilocalories per kilogram" basis. Kilocalories are the same as the "Calories" consumers are used to seeing on food labels. A "kilogram" is a unit of metric measurement equal to 2.2 pounds. Manufacturers are also allowed to express the calories in familiar household units along with the required statement (for example, "per cup" or "per can"). Even without this additional information, however, consumers can make meaningful comparisons between products and pick the product best suited for their animals' needs. As with the guaranteed analysis, the calorie statement is made on an "as fed" basis, so corrections for moisture content must be made as described above. To roughly compare the caloric content values between a canned and a dry food, multiply the value for the canned food by four.

Other Label Claims

Many pet foods are labeled as "premium," and some now are "super premium" and even "ultra premium." Other products are touted as "gourmet" items. Products labeled as premium or gourmet are not required to contain any different or higher quality ingredients, nor are they held up to any higher nutritional standards than are any other complete and balanced products.

The term "natural" is often used on pet food labels, although that term does not have an official definition either. For the most part, "natural" can be construed as equivalent to a lack of artificial flavors, artificial colors, or artificial preservatives in the product. As mentioned above, artificial flavors are rarely employed anyway. Artificial colors are not really necessary, except to please the pet owner's eye. If used, they must be from approved sources, the same as for human foods. Especially for high-fat dry products, some form of preservative must be used to prevent rancidity. Natural-source preservatives, such as mixed tocopherols (a source of vitamin E), can be used in place of artificial preservatives. However, they may not be as effective.

"Natural" is not the same as "organic." The latter term refers to the conditions under which the plants were grown or animals were raised. There are no official rules governing the labeling of organic foods (for humans or pets) at this time, but the United States Department of Agriculture is developing regulations dictating what types of pesticides, fertilizers and other substances can be used in organic farming.

Summary

Pet owners and veterinary professionals have a right to know what they are feeding their animals. The pet food label contains a wealth of information, if one knows how to read it. Do not be swayed by the many marketing gimmicks or eye-catching claims. If there is a question about the product, contact the manufacturer or ask an appropriate regulatory agency.

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INFORMATION FOR CONSUMERS

FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

INTERPRETING PET FOOD LABELS -- SPECIAL USE FOODS

The following consumer information is provided by David A. Dzanis, DVM, Ph.D., DACVN.

Treats and Chews

Snacks and treats for pets are implicitly intended to be offered on an occasional basis, and by no means should be fed as the mainstay of the diet. Although pet treats must meet all the other FDA and state regulations for labeling of pet foods, they are exempt from the need to include an AAFCO nutritional adequacy statement. "Biscuits" are not exempt, unless they are identified as a "snack" or "treat" as well. Regardless, some treats and biscuits are formulated to be nutritionally complete, and some are not.

Dog chews made from rawhide, bone or other animal materials or parts (for example, pig ears) are still considered "food" under FDA law, since they are comprised of materials that are consumable by the pet. As long as the label for the chew does not include any reference to nutritional value (such as "high protein"), it may not have to follow the AAFCO pet food regulations. Thus, many labels for chews may not have a guaranteed analysis or follow the AAFCO rules for product names. However, they should still bear the information required under FDA regulations, such as the net quantity statement, the manufacturer's name and address, and the ingredient list (if it contains more than one ingredient or the single ingredient is not declared in the product name). For products sold in bulk, the required information should appear in a placard on the bin or container.

Health Claims

Many of the products intended for special uses involve the dietary management of a disease or condition. Recent laws have affected the way FDA regulates these types of products for human consumption. The Nutrition Labeling and Education Act (NLEA) provides for specified "health claims" (claims that state that consumption of a food may help in the reduction of risk for disease) to appear on human food product labels. The Dietary Supplement Health and Education Act (DSHEA) has allowed for the boom of dietary supplements available for human use, many which include claims of "nutritional support" for specific organs or body functions. Since pet foods follow many similar marketing trends to foods for human consumption, it is not surprising that many pet food and supplement labels also bear these types of claims. However, since the rules for pet foods are very different, some of these claims are not legally allowed.

The Federal Food, Drug, and Cosmetic Act (FFDCA) defines "food" as an article used for food or drink for man or other animals. On the other hand, a "drug" is, in part, an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, or an article (other than food) intended to affect the structure or function of the body of man or other animals. "Food," in the parenthetical "other than food," has been further interpreted by the courts as a substance that provides "taste, aroma, or nutritive value." If a food affects the structure or function of the body, it does so by these properties (for example, a food may provide nutrients such as calcium for proper bone structure, or taurine for healthy heart function in cats). However, if a product affects the structure or function of the body apart from its nutritive value, such as urine acidification or improvement in joint function, it may be considered a drug.

The legal definitions of food and drug become intertwined when a food label bears a claim that consumption of the product will treat, prevent, or otherwise affect a disease or condition, or to affect the structure or function of the body in a manner distinct from what would normally be described as from its "nutritive value." Also, implied drug claims may include a discussion of a medical condition, reference to an equivalent drug product, or the presence of medical symbols. Such claims establish an intent to offer the product as a drug (i.e., it makes a "drug claim"). Furthermore, since the product was not subject to the normal premarket clearance mechanism to demonstrate safety and efficacy as required for drugs, it is unsafe by definition. Pet food products with labels bearing drug claims are subject to regulation by CVM as drugs as well as foods. A pet food company must then remove these claims to restore its regulatory status to simply food.

FDA's authority to prohibit drug claims extends beyond what is commonly considered the product "label." The FFDCA defines "labeling" as all labels and other written, printed or graphic matter upon any article or any of its containers or wrappers, or accompanying such article. Thus, brochures, flyers, signs or similar promotional material found at the point of sale may be labeling and subject to the same laws. Also, although food advertising is not regulated by the FDA, but by the Federal Trade Commission, FDA does have some authority. Advertisements or even verbal representations that establish the "intended use" of the product can be used as relevant evidence that it is a drug.

FLUTD Products

CVM has incorporated some of the philosophy of NLEA in its policies in order to allow meaningful health-related information on pet food labels. Much of CVM's efforts to date have focused on label claims related to cat foods and the prevention of Feline Lower Urinary Tract Disease (FLUTD). Although FLUTD occurs in less than 1% of cats, it is a concern for cat

owners. The exact causes of FLUTD are still unclear, and a number of dietary and non-dietary factors may be involved.

Label claims to prevent or reduce the risk of FLUTD, cystitis, urinary problems or similar verbiage are drug claims and are not allowed under the law. However, in an effort to get some meaningful health-related information to the consumer, CVM is exercising regulatory discretion in not taking action against products that bear claims akin to "reduce urine pH to help maintain urinary tract health" or to have low magnesium levels. With respect to urine pH claims, this discretion is contingent upon adequate controlled studies to demonstrate that consumption of the product results in an appropriately acidic urine. Since too much acidification of the urine can also result in serious health problems, data to demonstrate safety of the product are reviewed as well. With respect to dietary magnesium levels, the "cut-off" criteria to support a "low magnesium" claim are less than 0.12% on a dry matter basis and less than 25 mg per 100 kilocalories of metabolizable energy. Companies submit the results of proximate analyses (including crude protein, crude fat, crude fiber, moisture, and ash) and magnesium analyses of a number of production runs of the product. Demonstration that the product formulation consistently meets the cut-off criteria supports the label claim. The estimation of magnesium content as calculated by using guaranteed analysis values on the product label must also meet the criteria.

In order to be most useful in reducing the risk of FLUTD, products must also be used correctly. If the product is mixed with other foods or "meal fed" (offered for only a short period of time per day), it might not be able to maintain the proper urine pH to be beneficial. Thus, feeding directions are added to recommend the product be fed alone and to be made available throughout the day. Also, the nutritional adequacy statement on the label must be for adult maintenance only. This disease occurs primarily in young to middle-aged adults, and the most serious problems occur in males. Since the safety of these products for kittens and pregnant or nursing queens has not been established, it is recommended not to use these products for these life stages.

Another FLUTD-related claim, "low ash," is not allowed on cat food labels. The current scientific consensus is that ash per se is not related to the incidence of FLUTD. There are no valid reasons to reference ash on the product label (other than in the guaranteed analysis) except in regard to this outdated theory. Thus, "low ash" or similar claims, even without reference to FLUTD, are inherently false and misleading, which render the product misbranded and subject to regulatory action.

Weight Control Products

Obesity in pets is probably the most common nutritional problem today. Reduced calorie products have been on the market for many years. However, following the lead of marketing niches for human foods, more and more "lite" pet food products are now available. FDA regulations promulgated under the NLEA established the rules for human products labeled as "lite," "low calorie" or similar terms, but do not apply to pet foods.

Recent AAFCO regulations governing the use of terms such as "lite" became effective this year. Under the new rules, the term "lite" must be based on a standard reference for all products, regardless of manufacturer. For example, a "lite" or "low calorie" dry dog food cannot contain more than 3100 kilocalories per kilogram (kcal/kg), while a similarly named dry cat food cannot contain more than 3250 kcal/kg. Canned foods contain much more moisture, so the maximum allowable calories are even lower (900 and 950 kcal/kg for dog and cat foods, respectively).

For products that are reduced in calories but not enough to merit a "lite" claim, the rules also allow for comparative claims. For example, if a company makes a very high calorie product and a lower calorie alternative, it can still make statements such as "25% less calories than our regular product." A calorie content statement must also appear on any product bearing a calorie-based claim. In addition to "lite" and "low calorie" claims, a similar set of rules were established for "lean" and "low fat" products, except based on maximum allowable fat percentages instead of calories.

A successful weight loss program takes owner involvement, too. Even a "lite" food can cause weight gain if fed to excess. Owners should follow the feeding directions suggested for weight loss, be careful not to give their pets snacks or table scraps, and even institute an exercise program as the pet's health dictates. Involvement of the veterinarian in the process is also the most prudent in ensuring both the success of the weight loss program and avoidance of potential health risks.

Dental Products

Label claims for "clean teeth" have been on pet food labels for many years, particularly on dry, hard biscuit products. As the field of veterinary dentistry and the awareness of the importance of proper dental hygiene have grown, a number of products have borne much more explicit claims. Claims to treat or prevent gingivitis or periodontal disease are drug claims and should not appear on pet food labels. Plaque or tartar control claims may also be implied drug claims, as they directly relate to dental disease. However, CVM has exercised some regulatory discretion with respect to plaque and tartar claims for products that achieve their effects by mechanical actions. The Veterinary Oral Health Center, an outside organization formed under the auspices of the American Veterinary Dental College, has developed an experimental protocol for companies to follow to demonstrate that their products are useful in reducing plaque and tartar. This organization will also review data from companies to verify that the claim is true, and if so, allow them to carry its logo on the package. CVM has worked with the Veterinary Oral Health Center in this process, so consumers can be assured that products that bear the logo are useful for plaque and tartar control.

Skin and Coat Products

Pet food labels abound with promises for "healthy skin" and "glossy coat." Any normal animal receiving adequate nutrition through use of a complete and balanced product should have these qualities. However, claims to uncategorically "improve" skin and coat or to cure or prevent disease signs such dry skin, flaky skin, or itching may be drug claims.

Perhaps most notorious is the claim for a product to be "hypoallergenic." Elimination diets are used by veterinarians in the diagnosis and management of food allergies. An elimination diet is one devoid of food ingredients likely to cause an allergy, often characterized by itchy, inflamed skin. Resolution of these clinical signs while the animal is on the diet is diagnostic of a food allergy, and trial and error then could be used to determine exactly to what the pet was allergic and what ingredients to avoid. Traditionally, lamb and rice was used as the elimination diet. There is nothing special or unique about these

ingredients in terms of allergenicity, and prolonged exposure to these ingredients could also induce an allergic condition. However, they were historically novel sources of protein, since the use of these ingredients was uncommon in commercial dog foods. As such, a pre-existing allergy to lamb or rice would be unlikely.

In recent years, a plethora of products containing lamb and rice entered the consumer market. Many of these products were labeled as "hypoallergenic," or otherwise espoused the benefits of lamb and rice in the treatment or prevention of food allergies and other skin problems. Such claims were made even for products that contained other sources of protein that would disqualify them as effective elimination diets.

CVM does not object to the use of lamb or rice in pet foods. Foods that contain these products in sufficient quantities to meet AAFCO labeling criteria may make claims to the presence of these ingredients. However, any claim to be "hypoallergenic," or any other expressed or implied claim relating these ingredients with benefits to the skin and coat beyond their normal nutritive value is a drug claim.

The same may also be true of other ingredients. For example, many fat sources may contain substances known as omega-3 fatty acids. There are some studies in the veterinary literature to suggest that when used pharmacologically, these substances may have an effect on inflammatory skin disease. However, omega-3 fatty acids are not recognized as essential nutrients at this time. In other words, dogs and cats cannot have an "omega-3 fatty acid deficiency," and unqualified claims relating to omega-3 fatty acid content may falsely imply nutritional benefit where none has been established. Thus, if a product label bears a claim for omega-3 fatty acids, it must also guarantee its level in the product, accompanied by a disclaimer that it is "not recognized as an essential nutrient by the AAFCO (Dog or Cat) Food Nutrient Profiles."

Veterinary Medical Foods

A "medical food" was originally defined in the Orphan Drug Act as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on sound scientific principles, are established by medical evaluation." Historically, even though medical foods are specifically intended for use in disease conditions, they were regulated by FDA as foods, not drugs. This was because the market for medical foods was relatively small, confined mainly to products such as infant formulas designed for babies with rare genetic conditions. Since the cost of obtaining a drug approval for the product grossly outweighed any profit manufacturers could expect from use in such limited circumstances, FDA allowed this exemption so that the products could be available for those who needed them.

The definition cited above is in reference to foods for human consumption. However, it could also apply to a category of foods for veterinary use that can be characterized as "veterinary medical foods" ("VMF"). These products are generally intended to be offered as the sole source of nutrition to animals with specific medical conditions. Historically, they usually contained restricted amounts of certain nutrients to aid in the mitigation of some disease processes. For example, low protein/low phosphorus diets could be used for some forms of kidney disease, while a low sodium diet could be helpful in some forms of heart disease.

These products are often identified on the market by the label bearing the phrase "use only as directed by your veterinarian," and are often sold only by veterinarians.

As foods, VMF are subject to the same labeling requirements as are any other pet food. As such, labels may not bear drug claims. This restriction also applies to product names. Thus, these products are often given names that would not be easily recognized by the average consumer, such as initials or numbers. Also, VMF labels must meet the same criteria for substantiation of nutritional adequacy as other pet foods. Previously, foods labeled "for veterinary use" were exempt from meeting other AAFCO requirements for "complete and balanced" foods. This appeared contradictory, since assurances of nutritional completeness take on even greater significance when used on sick animals. This fact has been borne out by several well-publicized incidents of nutritional deficiencies in animals fed VMF (for example, taurine and potassium deficiencies were discovered in cats on VMF). Thus, products must now substantiate adequacy by meeting the AAFCO nutrient profile or passing an AAFCO feeding trial protocol for adult maintenance, or include the phrase "for intermittent or supplemental feeding only." Some companies have attempted to circumvent these requirements by listing "intermittent use" on the label, but claiming complete nutritional adequacy in brochures or other sources. Regardless of what the brochures say, if this last statement appears on the label it means that the product has not been shown to be complete and balanced for the normal animal. Thus, it should be used only for certain medical conditions as directed by a veterinarian. Directions for use are presumed to be provided by the veterinarian to the pet owner, so VMF labels are exempt from the AAFCO requirement to include feeding directions.

Labeling of VMF with statements regarding their use in the mitigation of disease processes would imply therapeutic use and thus is not permitted. However, CVM recognizes that VMF have a scientifically sound basis, and they serve a purpose. Thus CVM generally exercises regulatory discretion with respect to distributing truthful information on VMF in materials intended only for veterinarians. Proper use of these types of products requires adequate veterinary supervision. An owner who feeds a VMF product for its desired therapeutic effect solely on the basis of labeling or advertising claims may cause harm resulting from improper diagnosis or treatment.

Dietary Supplements and "Nutraceuticals"

With the availability of today's "complete and balanced" products, nutritional supplements are needed only in very rare circumstances. Injudicious use of supplements runs a greater risk of causing dietary imbalances or toxicity than it does to actually improve the diet. Therefore, unless the pet is being fed a homemade diet that requires additional sources of certain nutrients, or unless a veterinarian diagnoses a medical condition that could benefit from supplementation, it is best not to give supplements to pets.

"Dietary supplements" describe a much broader range of products. Some provide essential nutrients, such as vitamins and minerals, but others contain substances that are not recognized as essential for the intended species (for example, vitamin C for dogs and cats, omega-3 fatty acids). Herbs, plant or organ extracts, enzymes, and a host of other substances are also

often marketed as dietary supplements. The market for dietary supplements was boosted by passage of DSHEA. This law changed the way FDA regulated these products for humans. Briefly, it said that FDA could not call a substance a "drug" or "food additive" if it met the definition for a dietary supplement and was not already regulated as a drug or food additive. Thus, it shifted the burden of the manufacturer having to prove a product was safe before it went on the market to the FDA having to prove it was unsafe before it could be removed. This prompted a sizable increase in the number and range of dietary supplements available on the market today.

DSHEA only applies to human products, not pet products. Some of the substances allowed for sale as human dietary supplements may not be legally permitted to be sold for animals. Although some of the supplements, such as herbal products, may have "thousands of years of history of safe use," this does not include history of use in animals. Animals may react very differently to substances than people, and even small doses can cause adverse effects. For example, aspirin and chocolate, both substances that are used by people every day without ill effect, can be toxic to pets and even cause death. Therefore, since it's not known what the true effects an herb or other supplement may have on pets, it's safest not to allow marketing for that use.

On a case-by-case basis, CVM has reviewed safety information for some substances and allowed them to be used in animal feeds (for example, L-carnitine in dog foods), even though they were officially "unapproved food additives." If included in a pet food or supplement, they must be properly declared on the label. If the substance is not an essential nutrient, the disclaimer "not recognized as an essential nutrient by the AAFCO (Dog or Cat) Food Nutrient Profiles" must also appear on the label.

The term "nutraceuticals" was coined to describe the increasing number of products offered for the prevention or treatment of disease but marketed under the guise of dietary supplements. The promise of a "safe" and "natural" remedy for disease is very appealing. However, since the product has not undergone the same testing for safety and efficacy as required for approved drugs, it's impossible to know whether the product works at all or is even unsafe. Presently, these substances are drugs if the labeling bears claims to treat or prevent disease, or if the intended use as a drug can be established by other means.

Summary

An informed consumer is the best consumer. It is easy to be confused by all the claims and promises made for pet foods and supplements, but keeping the rules described above in mind should help. If the pet owner has any questions, he or she should not hesitate to contact the manufacturer. Asking for advice from parties other than the manufacturer, such as FDA or state regulatory officials or university experts, may also be a good source of unbiased information. Also, as with other health matters, the pet's veterinarian should be consulted on dietary choices, especially with respect to any special use products.

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Revised --

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR VETERINARY MEDICINE

Supportive Data for Cat Food Labels Bearing "Reduces Urinary pH" Claims: Guideline in Protocol Development

Guidelines state procedures or practices that may be useful to the persons whom they are directed, but they are not legal requirements. Guidelines represent the agency's position on a procedure or a practice at the time of their issuance. A person may follow the guideline or may choose to follow alternate procedures or practices. If a person chooses to use alternate procedures or practices, that person may wish to discuss the matter further with the agency to prevent the expenditure of money or effort on activities that may later be determined to be unacceptable to FDA. A guideline does not bind the agency, and it does not confer any rights, privileges, or benefits for or on any person. When a guideline states a requirement imposed by statute or regulation, however, the requirement is law and its force and effect are not changed in any way by virtue of its inclusion in the guideline.

David A. Dzanis, DVM, Ph.D., DACVN
Center for Veterinary Medicine
June, 1994

Docket No. 94D-0230

Supportive Data for Cat Food Labels Bearing "Reduces Urinary pH" Claims: Guideline in Protocol Development

1. Test diet formulations should be nutritionally complete and balanced. This should be demonstrated by, at minimum, the successful passage of an adult maintenance feeding trial using current AAFCO protocols. Formulations should be limited to ingredients that are justifiable on a nutritional basis, and amounts of ingredients should be consistent with sound nutritional practices.
2. Product utility (i.e., the ability of the diet to produce an appropriately acidic urine) should be demonstrated by means of well controlled, scientifically sound studies. At minimum, a concurrent control group of cats fed a non-acidifying diet is needed to allow for meaningful comparisons. To facilitate data collection, cats should be housed individually, not in groups. The control diet may be a commercially available product or an experimental formulation (such as the test diet minus its acidifying components). It should also be nutritionally complete and balanced, preferably determined by previous testing using AAFCO protocols. Adequate numbers of animals in control and test groups, as determined by appropriate statistical methodology, should be used in order to be able to detect statistically significant differences between groups.
3. Data sufficient to demonstrate product safety are paramount. At minimum, data should include veterinary observations on cat health, as well as measurements of body weight, food consumption, urinalysis (including sediment examination), serum chemistries, blood gases, and mineral balances (Ca, P, Mg, K). Appropriate statistical comparisons should be conducted, using suitable methodology and numbers of animals to confidently (95 %) detect statistically significant (10%) differences, should they exist. Particular attention should be paid to parameters that assess renal and bone function. A necropsy should be performed on any animal that dies during the study, and the findings recorded. The reason for any medical treatment or removal of any animal from the study should be noted.
4. The length of the studies should be sufficient to assure product safety. At minimum, a six-month study, consistent with the length of time to conduct an AAFCO maintenance feeding trial, is needed. Food consumption and body weight determinations should be measured routinely. Data on other parameters should be collected on at least four occasions during the course of the study, including the beginning and termination of the study.
5. The submission should include all data generated, and include both data on individual animals and group summaries. Full discussion of product formulation, experimental methodology, statistical methods, and interpretation of findings should be included.
6. Data on additional parameters and/or longer studies may be required depending on the study findings. It is prudent to keep animals on test and to continue data collection while the six-month data is under review. Aliquots of serum and urine samples should be frozen for possible additional testing.

Exhibit 50

7. These key points cannot address all specifics in protocol design. Submission of protocols for review is strongly encouraged. Questions on details of the protocols should be resolved before the study is begun.

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Exhibit 51

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The term **AAFCO** stands for the **Association of American Feed Control Officials**. A basic goal of AAFCO is to provide a mechanism for developing and implementing uniform and equitable laws, regulations, standards and enforcement policies for regulating the manufacture, distribution and sale of animal feeds; resulting in safe, effective, and useful feeds. The Association thereby promotes new ideas and innovative procedures and urges their adoption by member agencies, for uniformity.

Purpose and Function of AAFCO:

The purpose of the corporation shall be to establish and maintain an Association through which officials of any state, dominion, federal or other governmental agency and employees thereof charged with a responsibility in enforcing the laws regulating the production, labeling, distribution, or sale of animal feeds or livestock remedies may unite to explore the problems encountered in administering such laws, to develop just and equitable standards, definitions and policies to be followed in enforcing such laws, to promote uniformity in such laws, regulations and enforcement policies, and to cooperate with members of the industry producing such products in order to promote the effectiveness and usefulness of such products.

Our website has been redesigned to be more user friendly and to better accommodate the needs of the association and you. We will be continuously making changes to the website, so please visit us often to track our progress.

Feel free to drop an email and let us know what you think.

Sharon@aafco.org

If you need to contact the webmaster, please click here:

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Exhibit 52



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INFORMATION FOR CONSUMERS
 FOOD AND DRUG ADMINISTRATION
 CENTER FOR VETERINARY MEDICINE

SELECTING NUTRITIOUS PET FOODS

*The following consumer information is provided by David A. Dzanis, D.V.M., Ph.D., DACVN
 Division of Animal Feeds, Center for Veterinary Medicine.*

November 1997

Most pet owners have heard that it is better to feed their animals specially formulated food for pets rather than table scraps. An occasional treat is fine, but table scraps used to excess may unbalance a pet's diet. Purchasing pet foods labeled as "complete and balanced" can help ensure that your pet's diet is nutritionally adequate.

Dog and cat foods labeled as "complete and balanced" must meet standards established by the Association of American Feed Control Officials (AAFCO) either by meeting a nutrient profile or by passing a feeding trial. The AAFCO's Canine Nutrition Expert (CNE) Subcommittee and Feline Nutrition Expert (FNE) Subcommittee have established new nutrient profiles for "complete and balanced" dog and cat foods. Dog Food Nutrient Profiles were established in 1991 and Cat Food Nutrient Profiles were established in 1992. Both were updated in 1995 to incorporate new scientific information.

The new nutrient profiles replaced the recommendations of the National Research Council (NRC) as the AAFCO-recognized authority on canine and feline nutrition. Dog and cat foods labeled as "complete and balanced" based on the AAFCO Dog or Cat Food Nutrient Profile must meet all the nutrient minimum and maximum levels as established by the Subcommittee. The Subcommittee set these levels after considering the most current information on good nutrition for dogs and cats. The profiles are designed to provide practical information for manufacturers of dog and cat foods.

There are now two separate nutrient profiles -- one for growth and reproduction and one for adult maintenance, instead of just one for all lifestages. This allows dog and cat foods made for adult animals only to contain lower amounts of some nutrients, eliminating unnecessary excesses. Also, maximum levels of intake of some nutrients have been established for the first time, because of concern that overnutrition, rather than undernutrition, is a bigger problem with many pet foods today.

The protocols for conducting the feeding trials for dog and cat foods have also been updated. With these improvements, label reference to either the AAFCO nutrient profile or AAFCO feeding trials better assures the consumer of the validity of a "complete and balanced" claim. Endorsements, seals of approval, etc., from other organizations do not add assurances of safety and may be misleading.

Attached are tables which list the AAFCO nutritional profiles for dog and cat foods. It must be noted that the levels of nutrients are expressed on a "dry matter" basis, while the levels listed in the guaranteed analysis on the label are expressed on an "as fed" basis. To allow for meaningful comparisons, the "as fed" guarantees must be converted to "dry matter." For a canned product that is 75 percent moisture (25 percent dry matter), multiply the guaranteed level times 4. For a 10 percent moisture dry product, multiply by 1.1.

TABLE 1 -- AAFCO Dog Food Nutrient Profiles^a

Nutrient	Units DM Basis	Growth and Reproduction Minimum	Adult Maintenance Minimum	Maximum
Protein	%	22.0	18.0	
Arginine	%	0.62	0.51	
Histidine	%	0.22	0.18	
Isoleucine	%	0.45	0.37	
Leucine	%	0.72	0.59	
Lysine	%	0.77	0.63	
Methionine-cystine	%	0.53	0.43	

Exhibit 53

Phenylalanine-tyrosine	%	0.89	0.73	
Threonine	%	0.58	0.48	
Tryptophan	%	0.20	0.16	
Valine	%	0.48	0.39	
Fat ^b	%	8.0	5.0	
Linoleic acid	%	1.0	1.0	
Minerals				
Calcium	%	1.0	0.6	2.5
Phosphorus	%	0.8	0.5	1.6
Ca:P ratio		1:1	1:1	2:1
Potassium	%	0.6	0.6	
Sodium	%	0.3	0.06	
Chloride	%	0.45	0.09	
Magnesium	%	0.04	0.04	0.3
Iron ^c	mg/kg	80.0	80.0	3000.0
Copper ^d	mg/kg	7.3	7.3	250.0
Manganese	mg/kg	5.0	5.0	
Zinc	mg/kg	120.0	120.0	1000.0
Iodine	mg/kg	1.5	1.5	50.0
Selenium	mg/kg	0.11	0.11	2.0
Vitamins				
Vitamin A	IU/kg	5000.0	5000.0	250000.0
Vitamin D	IU/kg	500.0	500.0	5000.0
Vitamin E	IU/kg	50.0	50.0	1000.0
Thiamine ^e	mg/kg	1.0	1.0	
Riboflavin	mg/kg	2.2	2.2	
Pantothenic acid	mg/kg	10.0	10.0	
Niacin	mg/kg	11.4	11.4	
Pyridoxine	mg/kg	1.0	1.0	
Folic Acid	mg/kg	0.18	0.18	
Vitamin B12	mg/kg	0.022	0.022	
Choline	mg/kg	1200.0	1200.0	

a Presumes an energy density of 3.5 kcal ME/g DM, based on the "modified Atwater" values of 3.5, 8.5, and 3.5 kcal/g for protein, fat, and carbohydrate (nitrogen-free extract, NFE), respectively. Rations greater than 4.0 kcal/g should be corrected for energy density; rations less than 3.5 kcal/g should *not* be corrected for energy.

^b Although a true requirement for fat per se has not been established, the minimum level was based on recognition of fat as a source of essential fatty acids, as a carrier of fat-soluble vitamins, to enhance palatability, and to supply an adequate caloric density.

^c Because of very poor bioavailability, iron from carbonate or oxide sources that are added to the diet should not be considered as components in meeting the minimum nutrient level.

^d Because of very poor bioavailability, copper from oxide sources that are added to the diet should not be considered as components in meeting the minimum nutrient level.

^e Because processing may destroy up to 90 percent of the thiamine in the diet, allowance in formulation should be made to ensure the minimum nutrient level is met after processing.

TABLE 2 -- AAFCO Cat Food Nutrient Profiles^a

Nutrient	Units DM Basis	Growth and Reproduction Minimum	Adult Maintenance Minimum	Maximum
Protein	%	30.0	26.0	
Arginine	%	1.25	1.04	
Histidine	%	0.31	0.31	
Isoleucine	%	0.52	0.52	
Leucine	%	1.25	1.25	
Lysine	%	1.20	0.83	
Methionine-cystine	%	1.10	1.10	
Methionine	%	0.62	0.62	1.50
Phenylalanine-tyrosine	%	0.88	0.88	
Phenylalanine	%	0.42	0.42	
Threonine	%	0.73	0.73	
Tryptophan	%	0.25	0.16	
Valine	%	0.62	0.62	
Fat ^b	%	9.0	9.0	
Linoleic acid	%	0.5	0.5	
Arachidonic acid	%	0.02	0.02	
Minerals				
Calcium	%	1.0	0.6	
Phosphorus	%	0.8	0.5	
Potassium	%	0.6	0.6	
Sodium	%	0.2	0.2	
Chloride	%	0.3	0.3	
Magnesium ^c	%	0.08	0.04	
Iron ^d	mg/kg	80.0	80.0	
Copper (extruded) ^e	mg/kg	15.0	5.0	
Copper (canned) ^e	mg/kg	5.0	5.0	
Manganese	mg/kg	7.5	7.5	
Zinc	mg/kg	75.0	75.0	2000.0
Iodine	mg/kg	0.35	0.35	
Selenium	mg/kg	0.1	0.1	
Vitamins				
Vitamin A	IU/kg	9000.0	5000.0	750000.0
Vitamin D	IU/kg	750.0	500.0	10000.0

Vitamin E ^f	IU/kg	30.0	30.0	
Vitamin K ^g	mg/kg	0.1	0.1	
Thiamine ^h	mg/kg	5.0	5.0	
Riboflavin	mg/kg	4.0	4.0	
Pantothenic acid	mg/kg	5.0	5.0	
Niacin	mg/kg	60.0	60.0	
Pyridoxine	mg/kg	4.0	4.0	
Folic Acid	mg/kg	0.8	0.8	
Biotin ⁱ	mg/kg	0.07	0.07	
Vitamin B12	mg/kg	0.02	0.02	
Choline ^j	mg/kg	2400.0	2400.0	
Taurine (extruded)	%	0.10	0.10	
Taurine (canned)	%	0.20	0.20	

^a Presumes an energy density of 4.0 kcal/g ME, based on the "modified Atwater" values of 3.5, 8.5, and 3.5 kcal/g for protein, fat, and carbohydrate (nitrogen-free extract, NFE), respectively. Rations greater than 4.5 kcal/g should be corrected for energy density; rations less than 4.0 kcal/g should *not* be corrected for energy.

^b Although a true requirement for fat per se has not been established, the minimum level was based on recognition of fat as a source of essential fatty acids, as a carrier of fat-soluble vitamins, to enhance palatability, and to supply an adequate caloric density.

^c If the mean urine pH of cats fed ad libitum is not below 6.4, the risk of struvite urolithiasis increases as the magnesium content of the diet increases.

^d Because of very poor bioavailability, iron from carbonate or oxide sources that are added to the diet should not be considered as components in meeting the minimum nutrient level.

^e Because of very poor bioavailability, copper from oxide sources that are added to the diet should not be considered as components in meeting the minimum nutrient level.

^f Add 10 IU vitamin E above minimum level per gram of fish oil per kilogram of diet.

^g Vitamin K does not need to be added unless diet contains greater than 25 percent fish on a dry matter basis.

^h Because processing may destroy up to 90 percent of the thiamine in the diet, allowance in formulation should be made to ensure the minimum nutrient level is met after processing.

ⁱ Biotin does not need to be added unless diet contains antimicrobial or antivitamin compounds.

^j Methionine may substitute choline as methyl donor at a rate of 3.75 parts for 1 part choline by weight when methionine exceeds 0.62 percent.



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GET THE FACTS:

What's Really in Pet Food

Plump 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

The 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 household and personal care products do use ingredients derived from animal by-products:

- Procter and Gamble (P&G) purchased The Iams Company (Iams, Eukanuba) in 1999. P&G shortly thereafter introduced Iams 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."ⁱ

LABEL BASICS

There are special labeling requirements for pet food, all of which are contained in the annually revised *Official Publication* of AAFCO.ⁱⁱ 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.

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

The 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

The 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

Wet or canned food begins with ground ingredients mixed with additives. If chunks are required, 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.”ⁱⁱⁱ

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

The 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 animal-source 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.

Animal and Poultry Fat

There'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?

Cooking 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
Antigelling agents	Drying agents	Humectants
Antimicrobial agents	Emulsifiers	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

Given 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

When 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, quite a few have not.

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

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*, Iams 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 Iams, 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

The 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 dilatation 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 Iams/Eukanuba canned foods are not made by The Iams Company at all. In fact, in 2003 Iams 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 Iams, 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 minimum-wage 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 Iams 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 Iams 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*. Iowa

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

AAFCO Pet Food Committee
David Syverson, Chair
Minnesota Department of Agriculture
Dairy and Food Inspection Division
625 Robert Street North
St. Paul, MN 55155-2538
www.aaftco.org

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

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Information on Reprints:

API receives many requests to reprint all or portions of our “What’s Really in Pet Food” report in newsletters, on websites, and elsewhere.

Permission is usually granted under the following conditions:

- Full acknowledgment is made to the Animal Protection Institute as the source of the material.
- API’s copyright is preserved.
- Our URL — www.api4animals.org — is included in the reprint.
- Under no circumstances is the reprint to be used for fundraising of any kind.

Please email or write first for permission so that we can track your requests. *Thank you.*

Footnotes:

- ⁱ Pet Food Institute. *Fact Sheet* 1994. Washington: Pet Food Institute, 1994.
- ⁱⁱ Association of American Feed Control Officials. *Official Publication*, 2007. Regulation PE3, 120–121.
- ⁱⁱⁱ 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.
- ^v Mottram DS, Wedzicha BL, Dodson AT. Acrylamide is formed in the Maillard reaction. *Nature*, 2002 Oct 3; 419(6906): 448–9.
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[GO BACK](#)

Meat Processing: Operations

Meat Processing Operations

[Beef Processing](#)

[Pork Processing](#)

[Poultry Processing](#)

[Fish Processing](#)

[Rendering Process](#)

Beef Processing Description

"Beef" is meat from full-grown cattle that are about two years of age. A live steer weighs about 1,000 pounds and yields about 450 pounds of edible meat. At least 50 breeds of beef cattle exist, but fewer than 10 make up most cattle produced. The live weight of cattle slaughtered for meat production varies from 550 to 1,300 pounds, depending on the age and breed of the animal. During the last few decades, the basic slaughtering procedure has become more automated and efficient. Processing rates in the United States average 350 head per hour (Slavell and Smith, 1999). The diagram following this section illustrates the flow of beef processing.

Pre-handling of Cattle: Most processors schedule receipt from producers of the live animals for slaughter to provide a continuous supply of animals for processing. Live animals are received from the supplier at the meat plant and are placed in holding areas where they are rested for typically one day before slaughter. This practice eliminates the need for feeding and reduces manure accumulation in the holding pens. Water is provided to minimize weight loss. The holding areas should have adequate facilities for livestock inspection including walkways over pens, crushes and other containment structures. These areas may be covered or totally enclosed to provide some protection from weather conditions and primarily to reduce runoff from precipitation events. Water pollutant concentrations from this activity depend on whether the pens are scraped (dry cleaned) prior to washing with water.

Sick animals and those unfit for human consumption are identified and removed from the normal processing flow. Processors should have separate isolation and holding pens for the unhealthy animals. The cows are weighed prior to processing so the yield can be accurately determined.

Stunning & Bleeding: After leaving the holding areas, the animals are located in a stunning or immobilization area where they are rendered unconscious. Cattle stunning in the United States is usually done by a bolt pistol or electric shock. The anesthetized animals are then shackled and hoisted (hind quarters up) onto a overhead rail or dressing trolley. Bleeding (exsanguination) or sticking is conducted with the blood collected in a trough or floor drain for disposal or further processing.

Dressing & Hide Removal: The bled carcasses are conveyed to the slaughter area where dressing (cleaning) and evisceration occurs. Dressing is performed from the overhead position or by placing the carcass in a cradle. The skin is removed from the head and the head separated from the body. The fore and hind feet are then removed to prevent contamination of the carcass with manure and dirt dropped from the hooves (shanking or legging). Each leg is then skinned. The remaining hide is removed from the carcass with electric or air-powered rotary skinning knives. The hides are preserved by salting or chilling on ice before being sent to a tannery for processing into leather.

Evisceration: The skinned carcasses are opened to remove the viscera (internal body organs). The abdomen is opened from the top to bottom where the internal organs are loosened and removed from the body. The abdominal organs are inspected and the stomach and intestine are emptied of manure and cleaned for further processing. A handsaw is used to halve the remaining carcass by cutting through the center of the backbone. The inedible materials are collected and sent to a rendering plant for manufacture of feed materials. The beef sides are washed to remove any remaining blood or bone dust and the carcasses are physically or chemically decontaminated. The simplest physical decontamination method

involves spraying with high pressure water or steam. Chemical decontaminants include acetic and lactic acids, and aqueous solutions of chlorine, hydrogen peroxide and inorganic acids.

Carcass Storage: Clean carcasses are then conveyed to a cold storage area for rapid chilling. A thorough chilling is essential within the first 24 hours of slaughtering otherwise the carcasses may sour. Air chilling is the most common method for cooling beef sides. The most desirable temperature for chilling beef is 32 F or 0 C. Since warm carcasses will raise the temperature of a chilled room, it is good practice to lower the temperature of the room to 5 degrees below freezing before the carcasses are brought in for storage. Beef undergoes maturation and should be held for at least a week at 32 F/0 C before butchery in retail establishments.

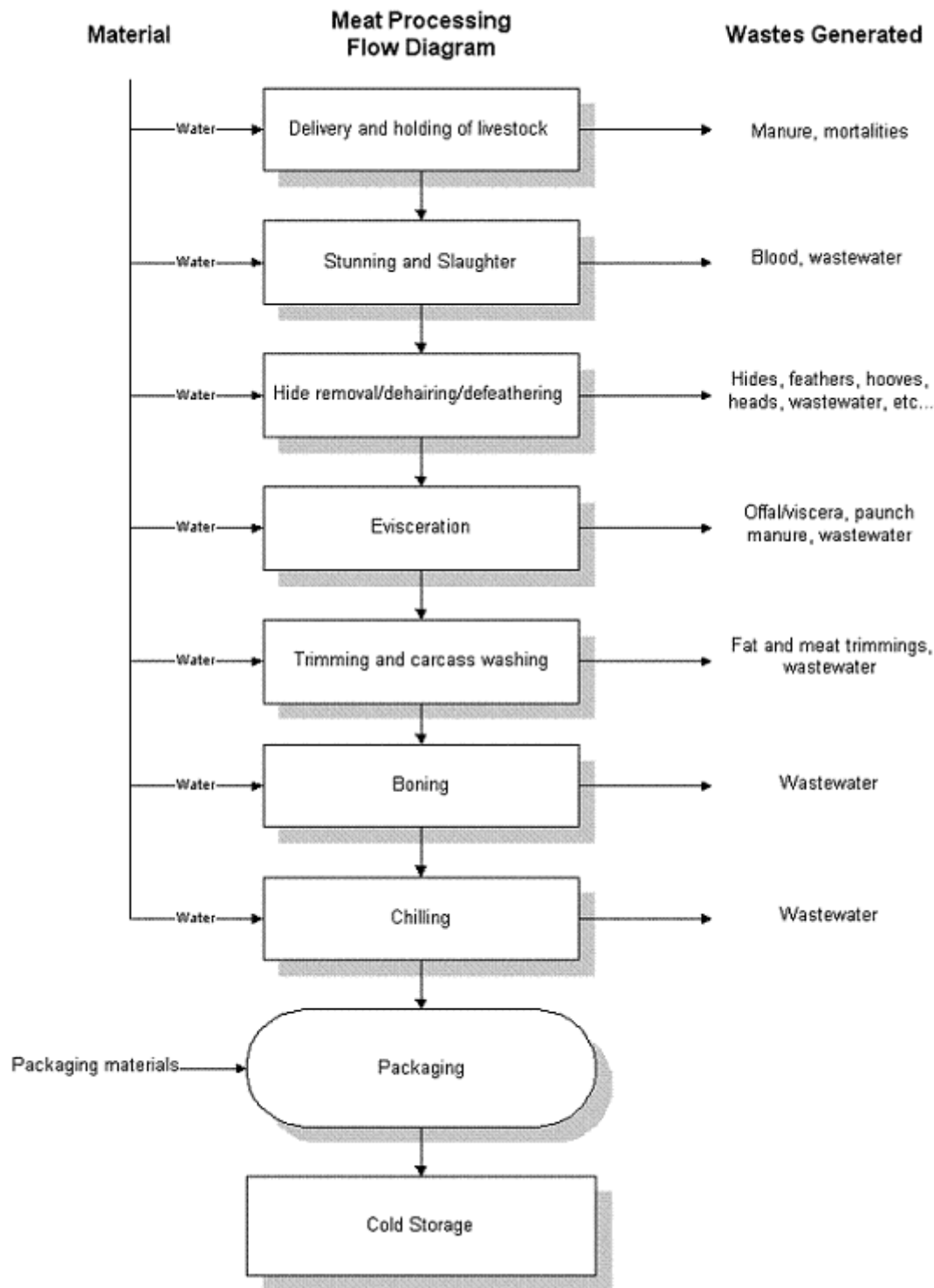
Cutting: Carcass cutting and boning typically occurs after chilling, since a cold carcass is easier to handle and cut. In the past, beef sides remained intact up to the time of butchery; however, current practice is to break down the carcasses into primal joints (wholesale cuts) then vacuum pack. Preparation of primal joints in processing plants reduces refrigeration and transport costs and is a convenient pre-packing operation for retailers.

Inspection: Carcasses and viscera are inspected to determine if they are suitable for human consumption. Each carcass and its components are identified and kept together wherever possible until inspection is complete.

Cleaning: Federal and state regulations require equipment and facilities used for processing of live animals for human consumption be completely cleaned at least every eight hours of operation to maintain sanitary conditions. The daily schedule for meat processors consists of one or two eight-hour production shifts followed by a six- to eight-hour cleaning period. For a typical cleanup procedure, equipment, walls and floor surfaces are initially rinsed with water to remove loose solids. The surfaces are then scrubbed with detergents and sanitizers and rerinsed.

Byproducts: At various stages in the process, inedible byproducts such as bone, fat, heads, hair and condemned offal are generated. These materials are sent to a rendering plant on- or off-site for processing into feed products. Refer to the [Rendering Process Description](#) for further information on this subject.

Specific information on meat processing wastes is contained in the [Environmental Impacts](#) Section.



Pork Processing Description [▲TOP](#)

Approximately 100 million hogs are processed annually in the United States. The live weight of swine slaughtered for meat production averages 250 pounds per animal. Up to 70 percent of the pig carcass can be used, which is greater than other farm animal species. This high recovery rate is due to the fact that a hog has one stomach (where a cow has four) and is dressed with the feet and skin intact instead of removed. However, some processors remove the feet before processing. Additionally, the portion of edible components is higher than that of cattle. The diagram following this section illustrates the flow of pork processing.

Animal Pre-handling: Swine are delivered to the processing plant from the market or farm and placed in holding yards for one to two days. They are generally made to fast for a day to reduce intestinal contents. Most processors schedule receipt from producers of the live animals for slaughter to provide a continuous supply of animals for processing. Live animals are received from the supplier at the meat plant and are placed in holding areas where they are rested for

typically one day before slaughter. This practice eliminates the need for feeding and reduces manure accumulation in the holding pens. Water is provided to minimize weight loss.

The holding areas should have adequate facilities for livestock inspection including walkways over pens, crushes and other containment structures. These areas may be covered or totally enclosed to provide some protection from weather conditions and primarily to reduce runoff from precipitation events. Water pollutant concentrations from this activity depend on whether the pens are scraped (dry cleaned) prior to washing with water. Sick animals and those unfit for human consumption are identified and removed from the normal processing flow. Processors should have separate isolation and holding pens for the unhealthy animals. The pigs are weighed prior to processing so the yield can be accurately determined.

Stunning and Bleeding: Hogs must be rendered completely unconscious prior to being shackled and hoisted for exsanguination (bleeding). Stunning must be conducted with a federally acceptable device (mechanical, chemical or electrical) and is typically done by electric shock or anesthetization using carbon dioxide. In large commercial operations, a series of chutes and restrainer conveyors move the animals into position for stunning. Once unconscious, the animals are bled, usually with a hollow knife that directs the blood to a collection trough. The blood is then pumped to an agitated tank for further processing.

Dehairing and Finishing: Before further processing, hair is removed from the carcasses by scalding in hot water followed by scraping. Carcasses are then singed to take out any remaining hair. In large operations, the carcasses are transported through a scalding tub by an automated conveyor moving at a calibrated speed to ensure proper scalding times. In these automated systems, the carcasses are continually moved and turned for uniform scalding. In small plants without automation, hair condition is checked periodically during the scalding period. Some processors also remove hair by passing the carcass through gas flames to singe the hair. Rotating brushes remove the remaining hair, then the carcasses are scraped a final time and thoroughly washed from the hind feet to the head.

Some processors skin the hogs after exsanguination. The head and belly of the carcass are hand-skinned and the legs are either hand-skinned or removed. The pigskins are trimmed, salted, folded and stored in 50-gallon drums.

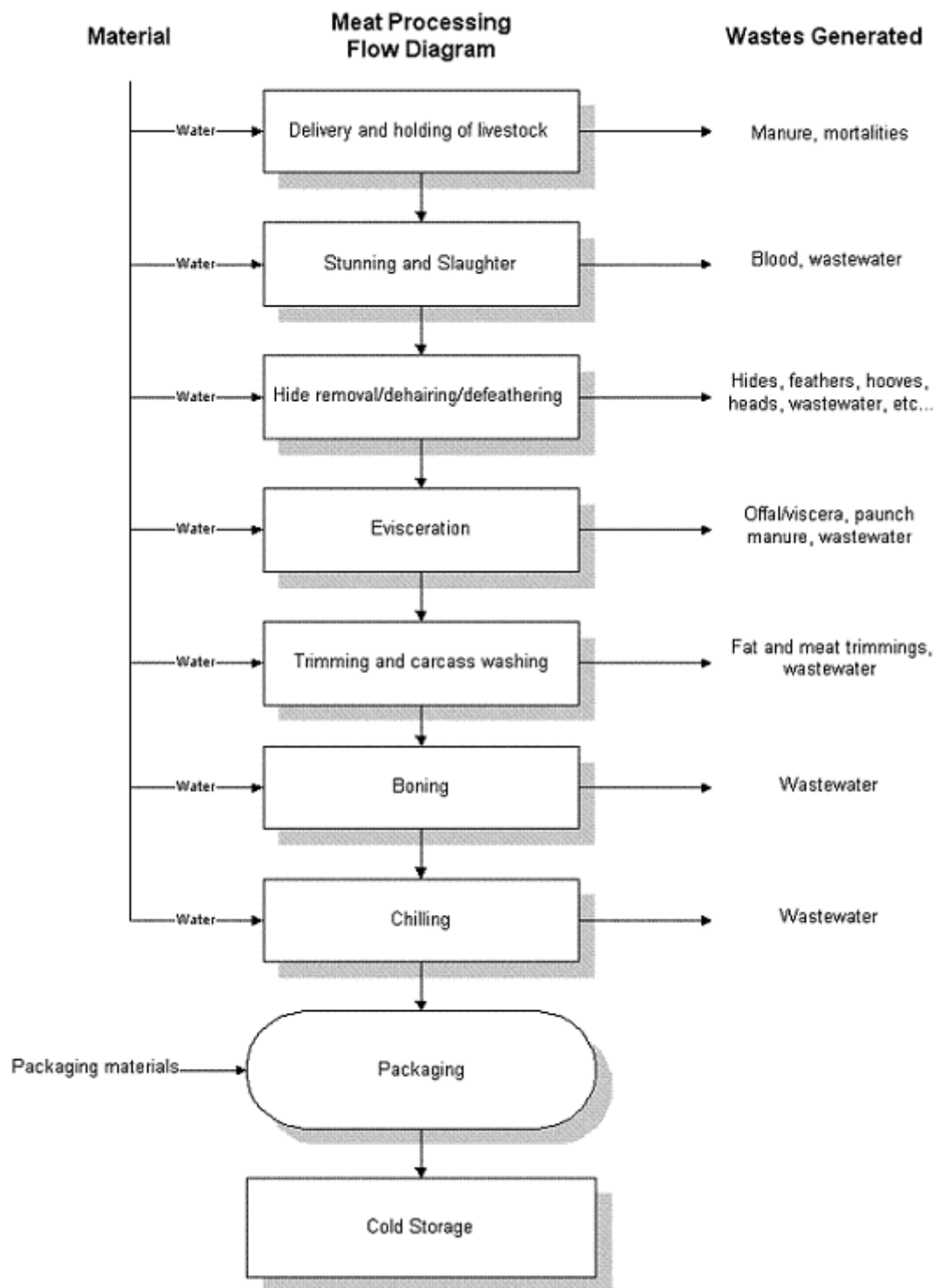
Evisceration and Splitting: After dehairing and hide finishing, the carcasses are eviscerated to remove the abdominal organs. All of the internal organs are inspected, and those intended for human consumption are separated and the remainder discarded into a rendering barrel. After evisceration, the heads are separated and the carcasses split in half. The carcass is washed from the top down to remove any bone dust, blood or bacterial contamination. After sanitizing, the carcass is inspected a final time and the inspection stamp applied to the wholesale cut.

Chilling: Inspected carcasses are placed in coolers at 0-1 °C (32-34 °F) with air velocity typically at 5-15 mph for a 24-hour chill time. For thorough chilling, the internal ham temperature should be at least 3 °C or 37 °F. Spray chilling is permitted by the USDA to reduce cooler shrink. Spray solutions may contain chlorine, which acts as a sanitizer. Some carcasses are sent directly to a freezer, which reduces shrinkage. After adequate chilling has occurred, cutting and boning is performed.

Cleaning: Federal and state regulations require equipment and facilities used for processing of live animals for human consumption be completely cleaned at least every eight hours of operation to maintain sanitary conditions. The daily schedule for meat processors consists of one or two eight-hour production shifts followed by a six to eight-hour cleaning period. For a typical cleanup procedure, equipment, walls and floor surfaces are initially rinsed with water to remove loose solids. The surfaces are then scrubbed with detergents and sanitizers and rinsed.

Byproduct Processing: Edible offal and casings (intestinal tract) are separated from the viscera and sent for cleaning and further processing. At various stages in processing, inedible materials such as bone, fat, heads, hair and condemned offal are generated. These materials are sent to a rendering plant for processing into feed and tallow. See the [Rendering Process Description](#) for further information.

Specific information on meat processing wastes is contained in the [Environmental Impacts](#) Section.



Poultry Processing Description [▲TOP](#)

More than seven billion birds are processed annually in the United States (USDA), with daily averages of 20,000 at individual plants. Poultry slaughtering consists of hanging, stunning, bleeding, scalding, defeathering, picking and washing. The diagram following this section illustrates the flow of poultry processing.

Receiving and Hanging: Birds are transported to the processing plant with the delivery scheduled so the poultry is processed on the day of receipt. Birds are not fed for one to four hours before slaughter to ensure their crops are empty for cleaner production. Live birds are delivered by truck from the supplier in cages where they are unloaded onto a dock area. The live bird holding areas are usually covered and have cooling fans to reduce bird weight loss and mortality during hot weather conditions (Sams, 2001). Birds are removed from the cages and then transported by conveyor to the live hang area inside the processing plant. The empty crates are returned to a wash area where they are cleaned and disinfected before leaving the facility. Washing and sanitizing of cages and trucks is common in turkey processing but not

in the broiler chicken industry (USEPA, 1975).

Employees lift live poultry from the supply conveyer and hang the birds by their feet from a shackle conveyer. For the best poultry quality, the live birds should not be stressed prior to slaughter. Thus, noise and light are kept to a minimum in the hang room. Many processors use red lights in the hanging room so that employees can see but birds cannot.

Bleeding and Defeathering: From the hang room, the birds are conveyed to the kill room. Upon arrival, the birds are lowered into an electric water vat where they are anesthetized. A machine usually equipped with a circular saw blade then cuts the throats. Bleeding may take 1-3 minutes but must be complete to produce the desirable white or yellow skin color in the final dressed bird.

The birds enter a hot water scald tank with troughs and flumes to keep them totally submerged. Scalding loosens the feathers and makes for easier plucking and fine feather removal. Scalding temperatures and times vary from 123 F to 140 F and from 30 to 90 seconds. The higher temperatures require shorter scald times; however, elevated temperatures may result in removal of portions of the skin. Optimum conditions should be established for the type of bird being dressed. The FDA requires a minimum of one quart of hot water be used per bird for feather removal; however, many processors use much more.

Additional defeathering is performed by a mechanical device with rotating rubber fingers that beat and rub the feathers away from the carcass. Water washes away the feathers and acts as a lubricant. Carcasses are then singed for final hair and feather removal. The defeathered birds are washed with water and scrubbed with mechanical rubber fingers. Blood and feathers are collected and sent to rendering either on- or off-site for transformation into byproduct meal.

Evisceration and Inspection: The carcasses are removed from the kill line by cutting off the feet and rehang on shackles in the evisceration line. A mechanical arm removes the internal organs of the bird. Each bird is inspected for signs of disease and the viscera from the body cavity is also presented for USDA inspection. The giblets (hearts, livers and gizzards) are removed and further processed. The remaining organs are sent to offal or waste. The giblets are trimmed and washed, packed in a giblet bag, and returned to the body cavity. The whole bird is removed from the conveyer, weighed and classified. (Chlorination for Poultry and Meat Processing, Severn Trent Services, Capitol Controls, 2000)

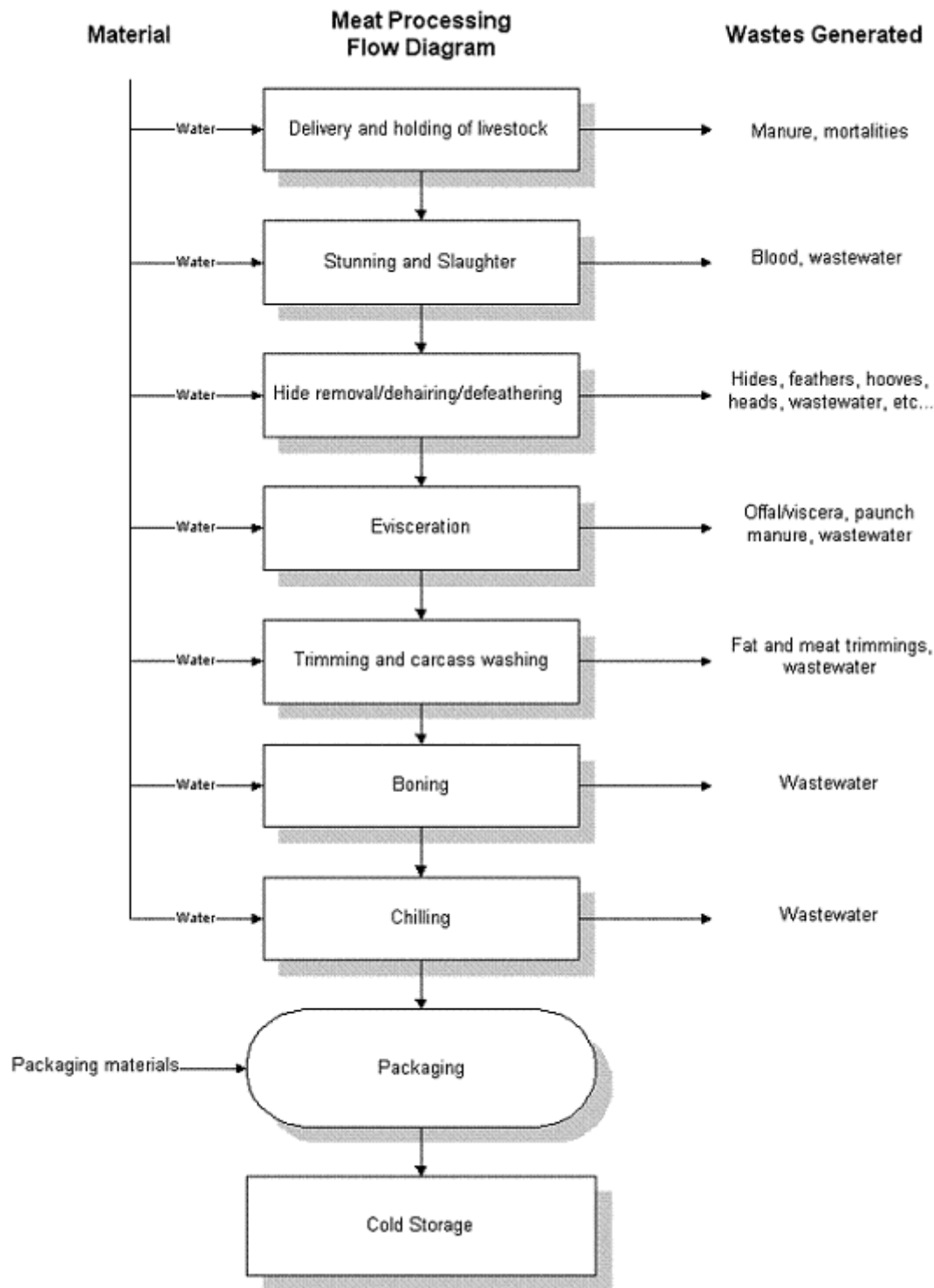
Cutting and Deboning: After a chicken has been eviscerated and cleaned, it is either prepared for packaging as a whole bird or sent through additional cutting and deboning steps. The cutting only prepares a bone-in product, while the cutting and deboning produce boneless cuts. In the cutting process, the wings and legs/thighs are removed from the carcass and the back is cut away from the breast. Bones are not removed. At this point parts can be packaged as a consumer product, bulk-packed for delivery to other processors, or shipped for further processing into a variety of products, including breaded or marinated goods. For additional information on further processing for poultry, refer to [4.5.2 Poultry Further Processing Operations, EPA's Meat and Poultry Products Industry Overview](#).

Within-plant processing of cut-up parts generally involves creating a boneless product. Deboning involves cutting meat away from the bone with knives, and trimming and cleaning with bladed knives or scissors. The deboned parts are generally packaged as a fresh or flash-frozen consumer product.

Chilling: Birds passing inspection are thoroughly washed inside and out and then rapidly chilled at 30-35 F to preserve quality and prevent spoilage. Chilling is performed with cold water or ice slush. The birds absorb small amounts of moisture and are sized and graded for quality. The FDA requires a chilled water flow rate of about two gallons per bird.

Packaging: No matter how a bird is packaged, it is almost always placed in a large cardboard box for shipping. Packaging is necessary to get the processed product from the plant to the consumer. The graded poultry is packaged fresh in boxes containing crushed ice. Birds must be kept below 40 F and quickly transported to retail distributors since the product's shelf-life may be only a few days. Poultry is often frozen to prolong storage life. The birds are vacuum-packed in low-moisture and low oxygen transmission bags or films, since the chicken fat is highly susceptible to microorganism growth.

Specific information on poultry processing wastes is contained in the [Environmental Impacts](#) Section.



Fish Processing Description [▲TOP](#)

The fish and shellfish processing industry includes marketing of fish, shellfish and marine plant and animals as well as byproducts such as fish meal and oil. Fish meal is used as a livestock feed and the oil is used in margarine and paints. Fish canning and byproduct manufacturing are conducted at 136 plants in the United States. Exports of canned fish and fish meal are increasing due to the diminishing supply in other countries. About 30 percent of fish processed for human consumption is marketed as fresh; the remainder is frozen fish and filets in ready-to-eat meals and other convenience products.

Fish processing most commonly occurs at onshore facilities; however, some takes place at sea or aboard fishing vessels. This description covers on-shore operations. Additionally, some industry sectors operate seasonally. Salmon processing typically occurs less than 100 days of the year during the harvesting season with plants operating at full capacity.

The diagram following this section illustrates the flow of seafood processing.

Pretreatment: Fish are kept on ice in boxes before delivery to the processing plant. Upon arrival, the fish may be re-iced and placed in cold storage until required for further processing. Pretreatment involves ice removal, washing, grading according to size and de-heading. Large fish may also be scaled before additional processing. Some fish such as mackerel are skinned by immersing into a warm caustic bath. The effluent from this process has a high organic load and has to be neutralized before discharge.

Filleting: The filleting areas are generally separated from the pretreatment department to prevent workers and materials from the nonsterile pretreatment from contaminating the sterile filleting area. Filleting is performed by machines with mechanical knives that cut the fillets from the backbone and remove the collarbone. Some fillets may be skinned at this step in the process.

Trimming and Inspection: In the trimming department, pin bones are removed and operators inspect the fillets. Any defects and any inferior parts are removed. Offcuts are collected and minced. Depending upon the final product, the fillets can be cut into portions according to weight or final product requirements. The fillets are inspected to ensure they meet product standards.

Fresh Packaging/Storage: Fresh products are packaged in boxes with ice which is separated from the product by a layer of plastic. Fillets or pieces can be individually frozen and wrapped in plastic. The most common method is packaging in 12-25 lb blocks in waxed cartons. The blocks are typically frozen and kept in cold storage.

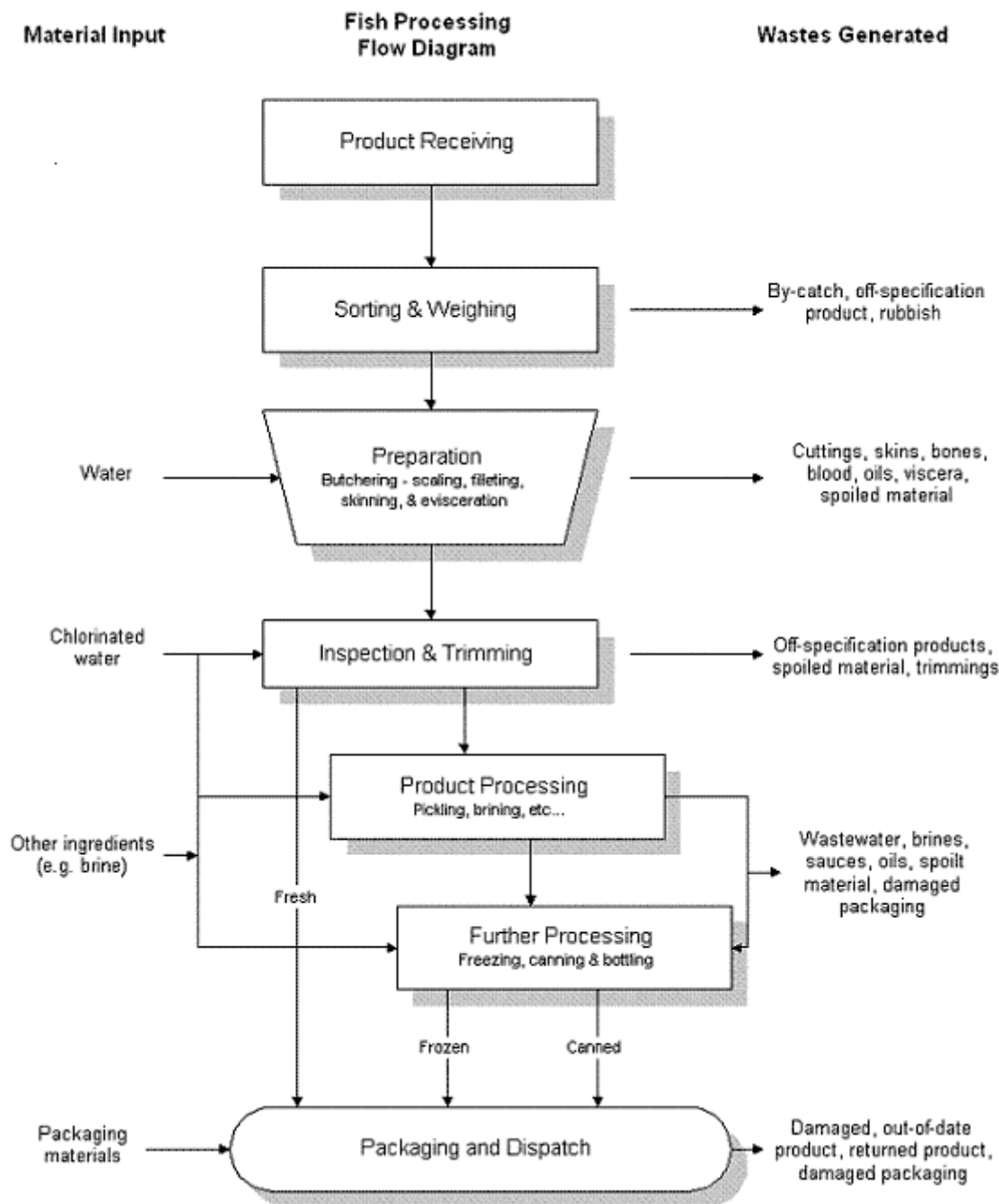
Canning: Canning is performed by two methods: precooking and raw pack. Precooking begins with thawing of the fish which are then eviscerated, washed and cooked. Cooking occurs with steam, oil, hot air or smoke for up to 10 hours, depending upon the fish size. The cooked fish are then cooled. Refrigeration may be used to reduce cooling time. After cooling, the head, fins, bones and undesirable meat are removed and the remainder is cut/chopped and placed in cans. Oil, brine and/or water are added to the cans which are sealed and pressure-cooked before shipment.

The raw pack method begins with thawing and weighing of the fish. They are then washed and possibly brined as well as "nobbed," which is the removal of the head, viscera and tails. The fish are placed in cans, then cooked, drained and dried. After drying, liquid (oil, brine, water, sauce) is added to the cans. Finally, the cans are sealed, washed and sterilized with steam or hot water and then stored.

Fish Meal and Oil Production: Most large canneries also operate a fish meal plant, where the fish not suitable for canning are combined with offal and processed into fish meal. Fish meal is derived from the dry components of the fish and the oil from the oily component. The water that makes up the remainder of the fish matter is evaporated during the process. Most fish meal and oil production processes are automated and continuous. Production rates vary according to season and types of fish being processed.

The fish byproducts are cooked in a process that coagulates the protein and releases the water and oil. The mixture is screened and the liquid from the mixture is squeezed out through a perforated casing. The pressed cake is shredded and dried with steam or direct flame dryers. The meal passes through a vibrating screen and to a hammer mill where it is ground to the desired size. The ground meal is automatically weighed and bagged. The meal is used in animal and pet feed due to its high protein content.

The oil is further processed by passing through a decanter to remove sludge which is then fed back into the meal dryer. Oil is separated from the liquid by centrifuge and is "polished" by using hot water washes and additional centrifuging. The removed water is evaporated to concentrate the solids and the remaining oil is refined to remove any impurities. See the Rendering Process Description for additional information on byproduct manufacturing. Discussion of wastes generated from meat and fish processing is included in the [Environmental Impacts](#) section.



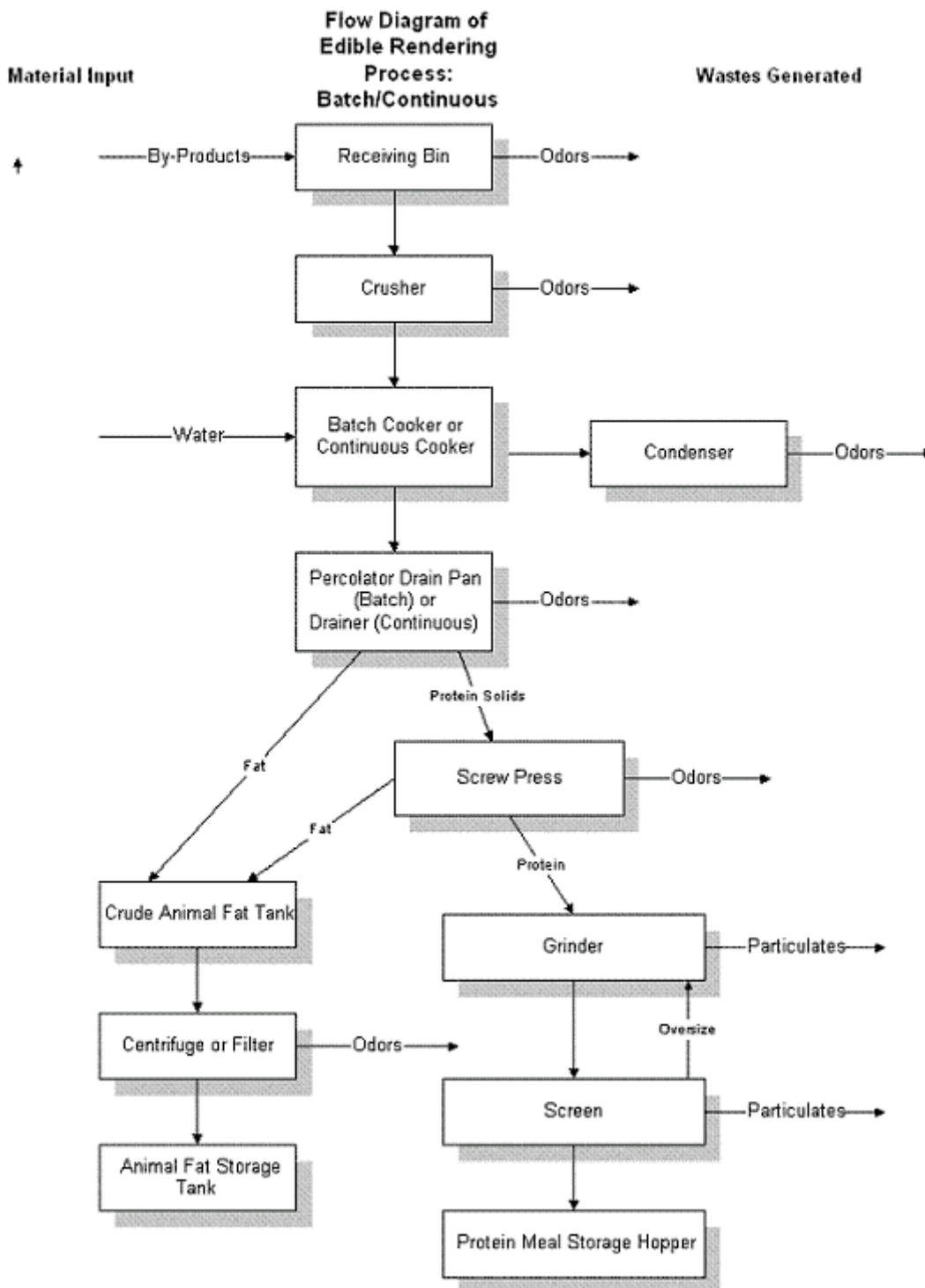
Rendering Process Description [▲TOP](#)

Having commercial value, meat byproducts contribute significantly to the profits of slaughter operations. The United States produces an average seven million tons of rendered products annually with a value of \$3 billion. Use of byproducts also reduces the overall environmental impacts of processing operations. Rendering converts meat, poultry and fish byproducts into marketable goods for agricultural and industrial use. Materials include viscera, meat scraps, bone, blood, feathers and dead animals.

Rendering involves cooking, separating and drying processes where edible (fit for human consumption) and inedible (not suitable for human consumption) animal derivatives are made into useful commodities. Edible rendering facilities process fatty animal tissue into edible fats and proteins. The inedible rendering plants produce tallow and grease, which are used in livestock and poultry feed, soap and production of fatty acids. Currently, an estimated 150 independent, off-site rendering facilities and 100 integrated plants (rendering on-site at processing plant) are operating in the United States. The independent renderers gather raw materials from small slaughterhouses, supermarkets and butcher shops where the on-site processors receive offal and other goods directly from plant operations.

Edible Rendering: The diagram following this section illustrates the flow of edible byproduct processing. Animal

byproducts are chopped or ground into small pieces then cooked. As the material is heated, moisture and fats are released. The proteinaceous solids are separated from the melted fat and water by a centrifuge. The edible fat is then separated from the water with additional centrifuging. The water is discharged as sludge and the fat is pumped to storage.



Inedible Rendering: The diagram following this section illustrates the flow of inedible byproduct processing. Inedible rendering is performed by wet or dry processing. Wet methods separate the fat from the raw materials by boiling in water. Water and live steam are used to cook the raw substances for fat separation. Dry rendering is a batch or continuous process that dehydrates the matter to release the fat. Following dehydration, the melted fat and protein solids are separated. At present, only dry rendering is used in the United States. Wet rendering is no longer used due to its high energy consumption and related costs and adverse effects on the fat quality.

In batch rendering of nonedible foodstuffs, multiple cookers are used. Raw material is crushed to 1-2 inches diameter and cooked. The final contents are screened and pressed to separate the fats from the protein solids. The solids, called

"cracklings," are ground to produce protein meal. The fat is centrifuged or filtered to remove any remaining protein solids and is then stored in a tank.

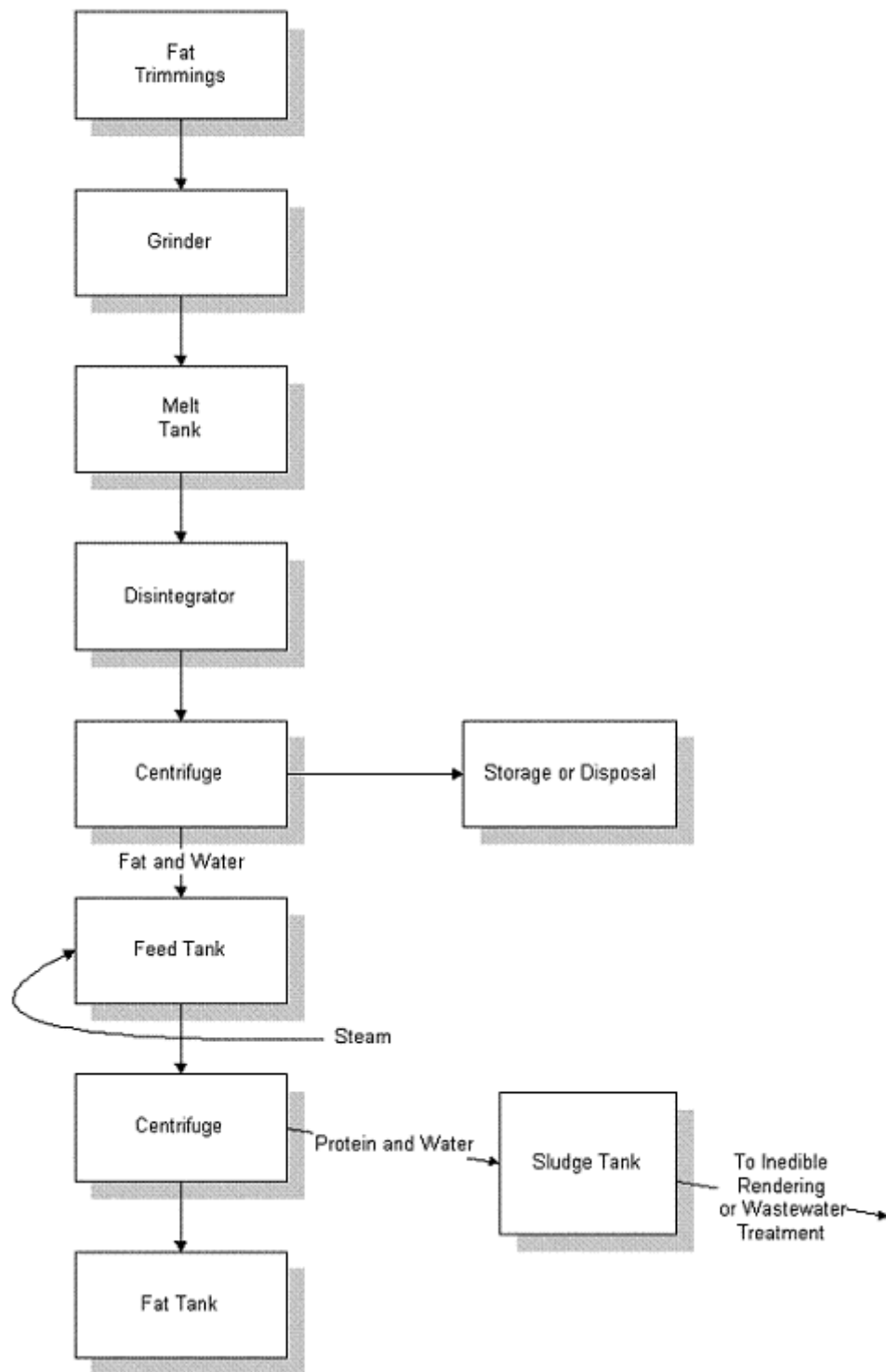
Since the 1960s, continuous rendering systems have been installed to replace batch systems at some plants. This system is similar to the batch configuration except that a single, continuous cooker is used rather than several parallel batch cookers. Continuous cookers cook the material faster than batch cookers and usually produce a higher quality of fat. From the cooker, the material is filtered to remove any solids and the fat is placed in an animal fat storage tank.

Inedible Products Processing: Blood processing and drying is an auxiliary process in meat rendering operations. Whole blood from animal slaughterhouses is used to recover protein as blood meal, which is a valuable ingredient in animal feed due to its high lysine content. Poultry feathers and hog hair are rendered to convert keratin into amino acids. Restaurant grease is also used as another raw feed material.

Many of the byproducts from meat processing can be processed further into value added products. For example, pet food from viscera, gelatin from head pieces, meat meal from hoofs, chicken parts, bone and horn, glue from hides and blood meal and small goods from blood like adhesives. Significant environmental gains can be achieved from maximizing the utilization of these materials so that they become a resource rather than a waste.

The efficient recovery and segregation of blood is an important means of reducing the pollution loads in wastewaters, since blood is a highly polluting substance. An operation with an efficient blood recovery system will have a 40 percent lower polluting load than one that allows blood to flow to the wastewater stream (Nielsen, 1989).

Inedible Rendering Process



DRAFT LIST OF POTENTIALLY HAZARDOUS CONTAMINANTS IN ANIMAL FEED AND FEED INGREDIENTS

1. BIOLOGICAL CONTAMINANTS

- A. Transmissible Spongiform Encephalopathies
 - i. Bovine spongiform encephalopathy (BSE)
 - ii. Chronic wasting disease (CWD)
- B. Microbiological Contaminants
 - i. Bacteria
 - 1. Bacillus spp.
 - 2. Clostridium spp.
 - 3. Escherichia coli
 - 4. Mycobacterium spp.
 - 5. Pseudomonas spp.
 - 6. Salmonella enterica (various serotypes)
 - 7. Staphylococcus spp.

2. CHEMICAL CONTAMINANTS

- A. Pesticides/Pesticide residues
 - i. Aldrin
 - ii. Benzene hexachloride
 - iii. Chlordane
 - iv. Chlorpyrifos
 - v. Chlorpyrifos-methyl
 - vi. Diazinon
 - vii. Dieldrin
 - viii. DDT+TDE+DDE
 - ix. Dicofol
 - x. Endosulfan
 - xi. Endrin
 - xii. Ethion
 - xiii. HCH alpha
 - xiv. HCH beta
 - xv. HCH gamma (lindane)
 - xvi. Heptachlor
 - xvii. Heptachlor + heptachlor epoxide
 - xviii. Hexachlorobenzene
 - xix. Malathion
 - xx. Methoxychlor
 - xxi. Mirex
 - xxii. Parathion
 - xxiii. Toxaphene (camphechlor)
 - xxiv. Tribuphos

DRAFT LIST OF POTENTIALLY HAZARDOUS CONTAMINANTS IN ANIMAL FEED AND FEED INGREDIENTS

Page 2

B. Mycotoxins

- i. Aflatoxins (B₁+B₂+G₁+G₂)
- ii. Fumonisin (B₁+B₁+B₃)
- iii. Deoxynivalenol (DON or vomitoxin)
- iv. Ochratoxin
- v. Zearalonone

C. Heavy Metals/Radionuclides

- i. Arsenic
- ii. Cadmium
- iii. Chromium
- iv. Lead
- v. Americium 241
- vi. Cesium 134
- vii. Iodine 131
- viii. Plutonium 238
- ix. Ruthenium 103
- x. Ruthenium 106
- xi. Strontium 90

D. Other Chemicals

- i. Ethoxyquin
- ii. Dioxins
- iii. Mercury
- iv. Perchlorate
- v. Polychlorinated biphenyls (PCBs)
- vi. Polyethylene glycol
- vii. Selenium

3. PHYSICAL CONTAMINANTS

- A. Plastic
- B. Glass
- C. Metal
- D. Other

- i. Bones (vermin, etc.)
- ii. Radiation from implanted devices in animals (see Radionuclides))

**U.S. Food and Drug Administration****CENTER FOR VETERINARY MEDICINE**[FDA Home Page](#) | [CVM Home Page](#) | [CVM A-Z Index](#) | [Contact CVM](#) | [Site Map](#)

**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 57

Rendered ingredients (position in ingredient list)	Confirmed for the presence of pentobarbital?	Brand Name	Formulation Name	Lot Number
Beef Meal(1)	yes	Nutro	Premium	10:19 2AR7JJ
Beef Meal(1)	yes	Nutro	Premium	00:512BA7256259101069704
MBM(2) AF(6) AD(7)	yes	Oi'Roy	Krunchy Bites & Bones	V033
MBM(2) AF(5) AD(8)	yes	Oi'Roy	Premium Formula with Chicken Protein and Rice	V093
MBM(2) AF(5) AD(8)	yes	Oi'Roy	Premium Formula with Chicken Protein and Rice	V071
MBM(2) AF(6) AD(9)	yes	Oi'Roy	High Performance with Chicken Protein and Rice	V073
MBM(2) AF(6) AD(9)	no result	Oi'Roy	High Performance with Chicken Protein and Rice	V073
MBM(2) AF(6) AD(7)	yes	Oi'Roy	Krunchy Bites & Bones	V153
MBM(2) AF(5)	yes	Trailblazer	Chunk Premium Quality	029813:30A/2
MBM(2) AF(5)	yes	Trailblazer	Chunk Premium Quality	A5981315A/R (?)
MBM(2) AF(5)	yes	Trailblazer	Bite Size Ration	A5889911A/A/1
MBM(2) AF(5)	yes	Trailblazer	Bite Size Ration	030800113A/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	Oi'Roy	Lean Formula	V013
MBM(3) AD(5) AF(6)	no	Oi'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

Rendered ingredients (position in ingredient list)	Confirmed for the presence of pentobarbital?	Brand Name	Formulation Name	Lot Number
MBM(3) AF(5) Beef Dgst(7)	no	Super G	Gravy Style Dog Food	V093
MBM(3) AF(5) AD(6)	yes	Super G	Chunk Style	V003
MBM(3) AF(5) AD(6)	yes	Super G	Chunk Style	V113
MBM(3) AF(4)	yes	Pet Essentials	Chunk Style	0-0046-L9
MBM(3) AF(4)	yes	Pet Essentials	Chunk Style	D-1106-L9
MBM(3) AF(5)	yes	America's Choice	Krunchy Kibble	3R
MBM(3) AF(5)	yes	America's Choice	Krunchy Kibble	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)	yes	Weis Value	High Protein Dog Food	N072
BBM(3) AD(4) AF(5)	yes	Oi'Roy	Meaty Chunks and Gravy	K5 0825
BBM(3) AD(4) AF(5)	no	Oi'Roy	Meaty Chunks and Gravy	V90051
BBM(3) AF(4) AD(5)	yes	Ken-L Ration	Gravy Train Beef, Liver and Bacon Flavor	W20351
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
BBM(4) BT(6)	no	Fieldmaster	Fieldmaster	C1334-L3
BBM(4) AF(6)	no	Fieldmaster	Fieldmaster	U2108-L5
BBM(4) BT(6)	no	Purina	High Pro	U1829L6
BBM(4) BT(6)	no	Purina	High Pro	U1749-L6
BBM(4) AF(6)	no	Purina	Grrravy	U1643-L7
BBM(4) AF(6)	no	Purina	Grrravy	U1059-L6

Rendered ingredients (position in ingredient list)	Confirmed for the presence of pentobarbital?	Brand Name	Formulation Name	Lot Number
BBM(4) AF(6) AD(7)	yes	Heinz	Kibbles 'n Bits Puppy	L1-0343
BBM(4) BT(7) Dried AD (10)	no	Purina	Dog Chow Senior	U2055L3
BBM(4) BT(7) Dried AD (10)	no	Purina	Dog Chow Senior	U0303L4
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 ingredient list)	Measured (ppb)	Confirmed for presence of pentobarbital?	Brand Name	Formulation Name	Lot Number
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)	a	no	Richfood	Dog Food Chunk Style	50 09:50 1
MBM(2) AF(6) AD(9)	a		Old Roy	High Performance Chicken and Rice	0417002
MBM(2) AF(5)	---		Pedigree	Meaty Chunks Mealtime	046DT0117C
MBM(2) AF(5) AD(7)	a		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)	a	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 it--Beef, 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)	a		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

BT(3)	11.6	yes	PetGold	Rice Master Diet Puppy Formulation	11:17 EA
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 Flavor	C234 L1
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)	a		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

February 28, 2001

Edited for Typographical Errors -- March 1, 2002



February 28, 2002
Edited for Typographical Errors, March 1, 2002

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

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](#)

Headlines

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Published on Sunday, January 6, 2002 in the [Los Angeles Times](#)

Outcry Over Pets in Pet Food

The practice of boiling down euthanized dogs and cats for industrial fat and protein causes an uproar in St. Louis
 by **Stephanie Simon**

ST. LOUIS -- It started with footage of Blacky and Scoop, melt-your-heart dogs with no one to claim them, alone at the city pound--and due to be put to death within hours. "No one wants them. Alive, that is," the reporter said.

The film then cut to a rendering plant that boils down the city's euthanized dogs, along with dead pigs and cows from local farms and leftover bones, hooves and innards from slaughterhouses. The end products are used to make cosmetics and fertilizer, gelatin and poultry feed, pharmaceuticals and pet food.

It was the pet food that got people. [The report last month](#) by KMOV-TV's Jamie Allman--headlined "What's Getting Into Your Pets"--suggested that dead dogs and cats from local shelters were ending up in kibble. As proof, Allman aired footage of a tanker truck entering the rendering plant, a truck emblazoned with the motto "Serving the Pet Food Industry."

Pet owners went nuts.

Thousands turned to KMOV's online polls to register their disgust. Scores more called animal control departments to demand an end to the practice. The St. Louis Post-Dispatch ran a cartoon showing a mangled collar poking out of a bowl of dog food. "It was unbelievable, the amount of reaction we got," Allman said.

The Millstadt Rendering Co., a small family business that for decades had been taking the region's euthanized animals free, in what the owners thought was a public service, reeled in the face of so much rage. "A disaster for the industry," groaned Clifton Smith, a consultant to the firm. "There's too many people out there who think their pets are like children."

Hoping to free themselves from the public-relations fiasco, the rendering plant announced just before Christmas that it would stop accepting euthanized dogs and cats.

But the local animal shelters couldn't stop euthanizing. And so in counties and small towns throughout the region, animal carcasses began to pile up.

"We were taken flat-footed," said Chris Byrne, an animal control official in St. Louis County.

Every solution was pricey. Hauling the animals to the nearest industrial-scale crematory would cost the county more than \$57,000 a year. Building a crematory

Also See:

[The Dark Side of Recycling](#)

by Keith Woods / Earth Island Journal - Fall 1990

[Food not Fit for a Pet](#)

by Wendell O. Belfield DVM / Earth Island Journal - Spring 1996

would cost up to \$100,000. And there would be the contentious question of where to put it.

In the short term, with freezer space limited, the county has been forced to send its dead dogs and cats to a landfill. The city of St. Louis has taken the same route, arranging for a refrigerated trash truck to pick up the carcasses.

This makeshift solution has prompted still more concerns. If the landfills are not properly lined, the decaying corpses could leach into ground water. If they're not promptly covered, scavengers can pick off the dead dogs and cats. And, as some have pointed out, chucking Fido in a dump scarcely seems a more dignified end than cooking him in a vat with dead cows.

It's a conundrum for animal control officers like Richard Steveson, who has to find a way to dispose of up to 3,500 animals a year in St. Louis. "I like for everything to be done as humanely as possible, even though the animal has already expired," Steveson said. But, given the alternatives, he figures rendering was as good a method as any. He didn't know that the rendered material could end up in pet food, he said. "But even if I had, I don't know what I would have done about it."

Lost in all the emotion have been the facts about rendering--and about pet food.

Rendering has long been considered one of the most environmentally friendly ways to dispose of animal carcasses, because it recycles them into useful fat and protein. By far the bulk of rendered material comes from slaughterhouses. But some plants also mix in road kill, the trimmings from supermarket delis, dead farm animals and euthanized pets from shelters. Los Angeles city and county shelters send more than 120,000 dead dogs and cats to be rendered in a typical year.

Members of The Pet Food Institute, who make 95% of the dog and cat food sold in the United States, use rendered material from livestock in their chow. But they insist there are no ground up pets in their pet food.

"It's a matter of good business," spokesman Stephen Payne said. "We've decided that if this is upsetting to people--and it clearly is--we should take extraordinary measures to make sure it never happens."

Still, it is not illegal to use rendered material from dogs and cats in pet food. And while no one keeps official figures, there's some evidence it happens.

The Food and Drug Administration has found "very, very low levels" of sodium pentobarbital--the chemical used to euthanize animals--in some brands of dog food, said Stephen Sundloff, director of the FDA's Center for Veterinary Medicine. The agency is investigating whether the traces are "of any significance at all," Sundloff said.

Overall, experts see little health risk in rendered pets entering the animal (or human) food chain, because the high temperatures used in the process kill most agents of disease.

As for the Millstadt Rendering Co., its owners are trying to get back to business as usual.

They maintain that the TV report unfairly linked their product to pet food (the tanker truck with the pet industry logo, they say, was headed to a separate rendering plant that handles restaurant grease). Still, they acknowledge they have no idea where their product ends up. It's sold to brokers who sell it to manufacturers. The way they look at it, they don't need to know the details--and the public probably doesn't want to.

"We don't have anything to hide," Smith said, "but people really don't want to hear about rendering. It's an ugly thing."

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consider these items: Bozman, the Baltimore Oriole, died in a 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 slaughterhouses. 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 inedible dead-animal parts, including dead pets, end up in feed used to fatten up future generations of their kind. Others are transmogrified into paint, car wax, rubber, and industrial 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, rendering 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-of-state 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 products.

Based on estimates from Neil Gagnon, general 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 reconstituted as chicken feed for North Carolina and Eastern Shore poultry farmers. Some goes for dry pet food. And some of the tallow is used by chemical "splitters," who turn the fat into fatty acids, which in turn are used in thousands of products.

During 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 visit, 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 retrieved from a local slaughterhouse, sits stewing in one of the raw-materials bins at the plant's receiving bay. "That's very fresh offal," 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 protein is centrifuged, pressed, run through a magnet to remove metals, ground up, sifted, cooled, and stored in a silo. Today, midway through the process, cooker operator Bud Kellner smiles, grabs a warm, brown, fibrous 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!"

What's Cookin'?

The liquid fat is cleaned, filtered, cooled, and stored in five tanks—two for tallow, a higher-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 horrid 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 important. "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 effluvia. 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."

Valley Proteins didn't always have a virtual monopoly over the rendering business 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 supports increased utilization and new uses for products that are produced with the 50

percent of the animal that is not acceptable for human consumption," Pearl says.)

Valley Proteins' eight plants draw raw materials from the entire mid-Atlantic region, according to J. J. Smith, president of the company. Smith describes the company's territory as "from Newark [New Jersey] to Savannah [Georgia], and 300 miles inland." Its three-generation 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.

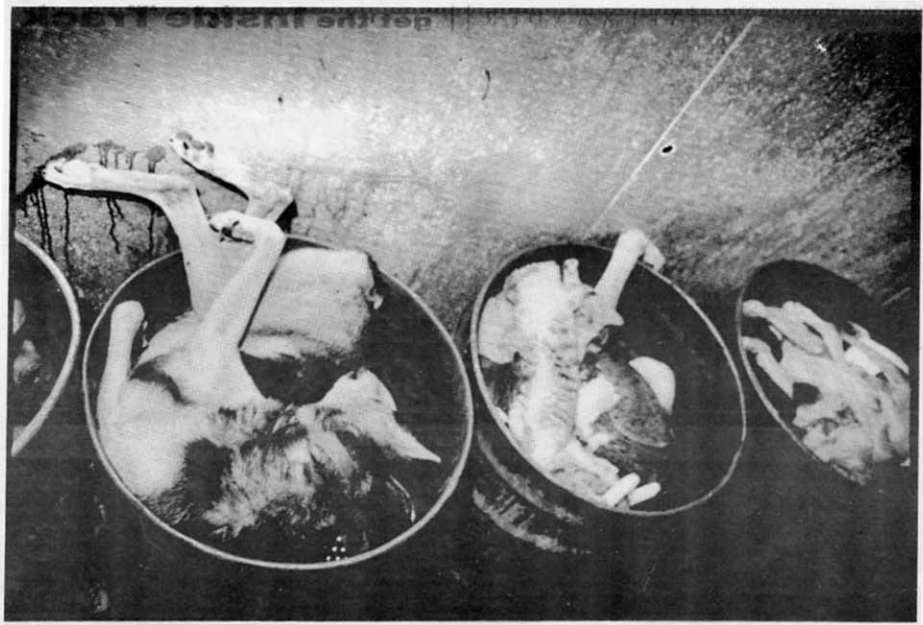
J. J. Smith says the industry's trend toward concentration of ownership picked up momentum about 20 or 30 years ago with the creation of a market for "boxed beef."

"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 slaughtering is consolidated in the Midwest, and they ship [the meat] out in boxes of 20- or 25-pound chunks."

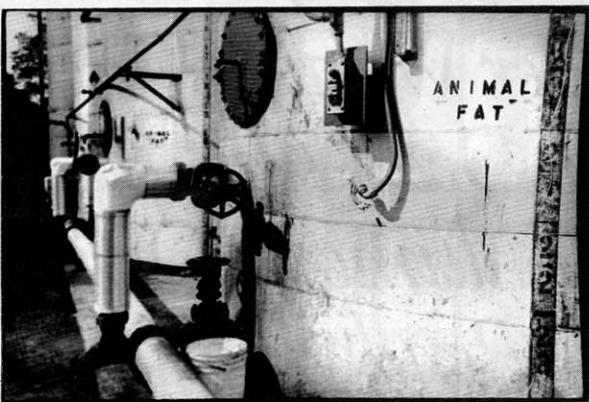
Boxed beef reduced the need for the neighborhood slaughterhouse, or abattoir. According to Smith, "a new movement toward close-trim meat and tray-ready beef" similarly is eliminating the need for butchers and meat cutters in supermarkets because even more

Ever Wonder What Happens to Dead Animals? A Look at Baltimore's Only Remaining Rendering Plant Explains

BY VAN SMITH



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 business."

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 phenomenon.

"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 "continuous cookers," which quickly replaced "batch cookers" as the industry standard.

Batch cookers restricted the rate of processing 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.

Case 1:07-cv-21221-CMA Document 156-11

The high-end production line—the one that produces the “light colors give good 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.

Most 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 veter-

inary technicians euthanize animals to make 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.

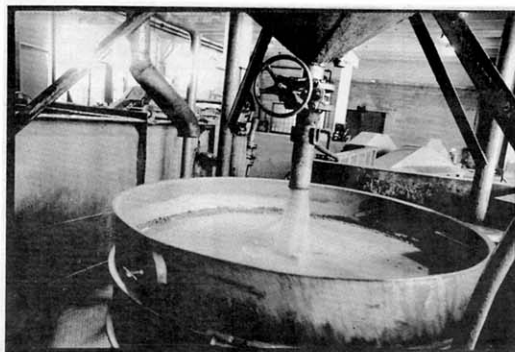
“Ten or 12 were euthanized this morning,” Rigney says. “Sometimes it’s thirtysome that get it. Things get backed up over the holidays.”

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.

Following 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 Hoggar.” 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 jocularly 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 fast-food 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, it is. ■

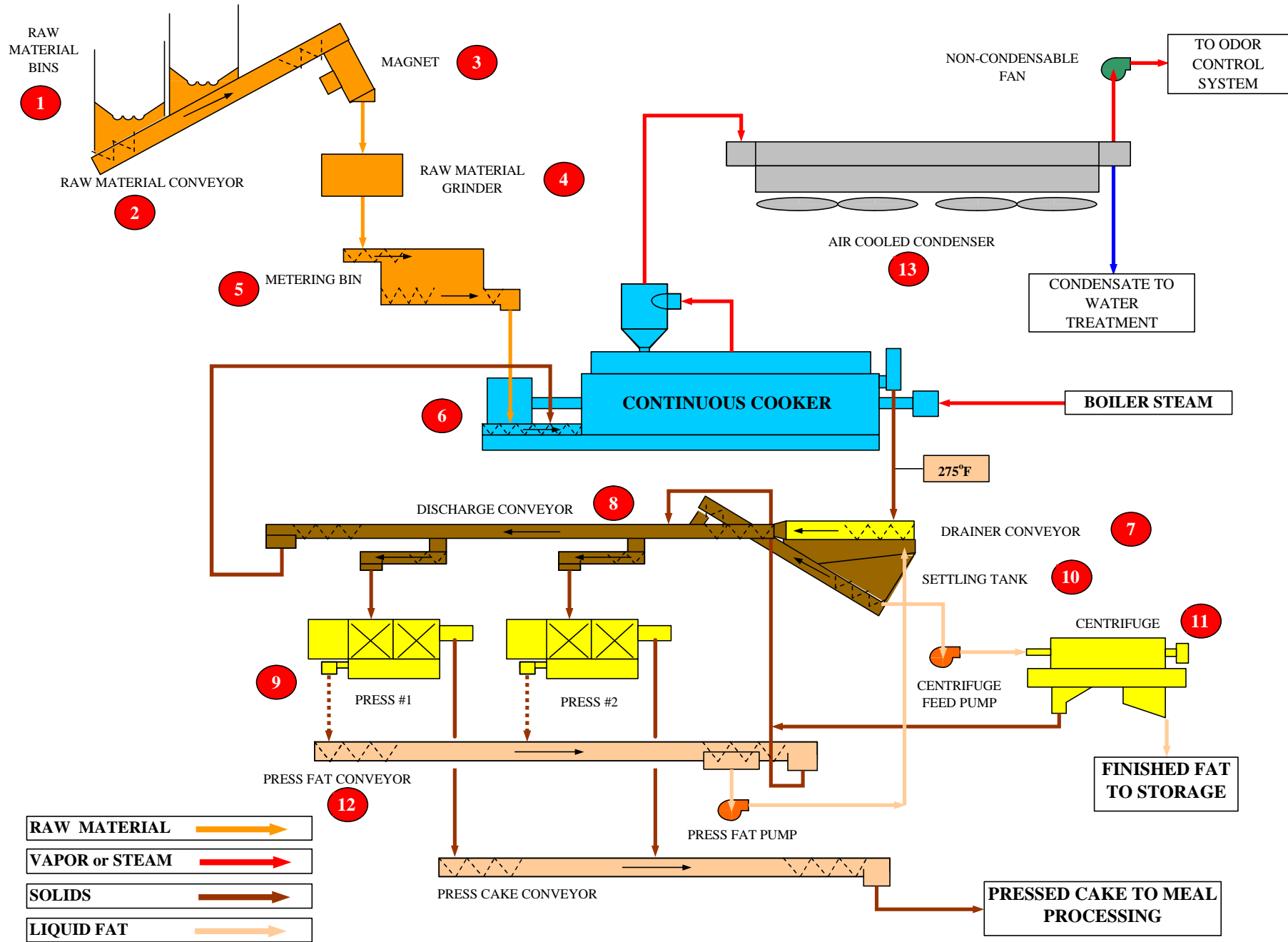


Exhibit 61

CONTINUOUS SYSTEM

DESCRIPTION OF A CONTINUOUS RENDERING SYSTEM

Material to be rendered is received for temporary storage in Raw Material Bins (1). Raw material is conveyed from the bins by a Raw Material Conveyor (2) and discharged across a Magnet (3) to remove ferrous metal contaminants.

A Raw Material Grinder (4) then reduces the raw material to a uniform particle size for material handling and improved heat transfer in the cooking step.

The ground raw material is fed at a controlled rate from a Metering Bin (5) into a Continuous Cooker (6). The Continuous Cooker is an agitated vessel generally heated by boiler steam. It brings the raw material to a temperature between 250°F and 280°F, evaporating moisture and freeing fat from protein and bone.

A dehydrated slurry of fat and solids is discharged from the Continuous Cooker at a controlled rate. The discharged slurry is transported to a Drainer Conveyor (7). The Drainer Conveyor separates liquid fat from the solids, which are then conveyed from the Drainer Conveyor by a Discharge Conveyor (8). In the Discharge Conveyor, solids from the Drainer Conveyor are combined with the solids discharge from the Settling Tank (10) and from the decanter-type Centrifuge (11).

The solids from the Discharge Conveyor go to the Screw Presses (9), which reduce the solids' fat content to about 10 to 12 percent. Solids that bypass the Screw Presses are recycled back to the Cooker. Solids discharged from the Screw Presses in the form of Pressed Cake go to the Pressed Cake Conveyor for transport to further processing into meal. The fat removed in the Screw Presses goes to the Press Fat Conveyor (12), which separates large particles from the liquid fat and returns them to the Discharge Conveyor. The fat from the Press Fat Conveyor is pumped to the Settling Tank (10).

Fat discharged from the Drainer Conveyor (7) goes into the Settling Tank (10). In the Settling Tank the heavier bone and protein particles settle to the bottom, where they are discharged by screw conveyor into the Discharge Conveyor (8).

Liquid fat from the Settling Tank is pumped to the Centrifuge (11), which removes residual solid impurities from the fat. The solids from the Centrifuge go to the Discharge Conveyor (8). The clarified fat is transported to further processing or to storage as finished fat.

Water vapor exits the Continuous Cooker (6) through a vapor duct system that generally includes an entrainment trap to separate and return entrained particles to the Continuous Cooker. The vapor duct system transports the vapor stream to an Air Cooled Condenser (13), which condenses the water vapor. (Other forms of condensers, such as direct contact or indirect shell and tube units, may also be used.) Non-condensable gases are removed from the Condenser by a non-condensable fan.

Odorous gases generated at various points in the process are collected by a ductwork system and are transported along with the non-condensable gases from the Condenser to an Odor Control System (not shown) for neutralization of odorous components.

Director, Division of Compliance, HFV-230
Office of Surveillance and Compliance, CVM

"Assignment to Collect and Analyze Domestic-Import Samples Suspected of PCB and Dioxin Contamination"

CVM Assignment # VA9-DXN
ORA Clearance # 19960621

ALL: RFDDs, DDs, DIBs, DCBs, and Lab Directors:

ASSIGNMENT MEMORANDUM-TOP PRIORITY

Top Priority, takes precedence over work of this and other Centers. This assignment has the concurrence of ORA, concurrence # 19960621

Objective

To collect and analyze animal feeds (medicated and non-medicated), feed ingredients, and pet foods to determine levels of polychlorinated biphenyl's (PCBs) and/or dioxins. To remove unsafe or violative product from consumer channels.

Background

FDA has received information that fat from a rendering company in Belgium was contaminated with dioxins and/or PCBs in January of 1999. This product was shipped to animal feed manufacturers and incorporated into animal feed distributed to poultry, hog and cattle farms in Belgium, France, and the Netherlands, with the majority of the product going to Belgium. Analysis of chickens and eggs in Belgium revealed PCBs and dioxins.

On June 4, 1999 FDA issued an Import Bulletin to the field directing animal feed, and animal By-Products for animal food from France, Belgium and Netherlands; and egg-containing products, from Belgium offered for entry into the U.S. to be held at the port of entry. On June 11, 1999 FDA issued Import Alert 99-24 "Detention Without Physical Examination of Human Food Products and Animal Feeds Contaminated with Dioxin and/or PCB Compounds", [Attachment A].

CVM extended the import ban to all European countries (see Import Alert, Attachment A for a complete list) for animal feeds and pet foods because of the uncertainty on the extent of the contamination and the lack of measures to prevent exposed animals from being recycled into the feed supply. CVM is monitoring the situation in Europe daily and will update the field when more information becomes available.

Page 2 - Dioxin Contamination

Dioxins and PCBs persist in the environment. Any animals fed contaminated feed products and subsequently slaughtered may have levels of dioxins/PCBs remaining in slaughter by-products. These may be rendered and subsequently used in other animal feeds, allowing the dioxins/PCBs to continue to be recycled through the food chain. It is critical that human foods sampled and found to contain dioxin not be used for animal food. Any requests for reconditioning by this means must be sent to CVM for review.

SAMPLING

This assignment is requesting each district to accomplish the following:

- 1) Collect an official sample(s) of products in attachment C.

When at the firm, check to see if any of the products identified in attachment C as having been manufactured from the foreign manufacturer during 1999 are available. It may be advisable to first telephone the importer listed in attachment C to determine the actual location of the shipment.

The targeted products were selected from printouts of entries from January 1999 to about June 11 and focus on recently arrived large volume entries of high fat content feeds and pet foods.

Collect one product per consignee listed in Attachment C. In some cases multiple shipments for the same consignee are listed to provide the best chance the product will be available. Do not collect more than one sample per product from the same consignee. Where different products have been received by the same consignee, as identified on attachment C, collect one sample of each product.

Samples should not be split. Submit each sample to your district's servicing laboratory for PCB analysis. Do not send samples to another location unless specifically requested. The composite prepared by the field pesticide lab will be used for any subsequent dioxin analyses. CVM will determine which samples will go for necessary dioxin analysis after review of the PCB results.

- 2) If samples are not available at the firms listed in Attachment C:
If the firm has none of the product available, determine consignees where the product was shipped, shipping dates, quantity of product shipped and an estimate of the expected time the product would normally be available for sale. Record the lot number identified on the product distributed if available.

Page 3 - Dioxin Contamination

Districts should use discretion in attempting to follow-up at sub distribution points and issuing assignment for follow-up at sub-distribution point in foreign districts. For instance, consider the size and date of shipment and other pertinent information supplied by the referenced firm when considering the need to follow-up at consignees. Determine if the firm is expecting additional shipments of the product in the near future and when.

While the problem in Europe began in January of this year, it is likely that the consignees may not be able to identify specific codes and dates that the product was manufactured and/or received. Do the best you can.

3. If the firm can conclusively prove (through shipping records, etc.) that the product was manufactured and/or received prior to January 1999, or the product is not labeled as being of animal origin, or is a product of a country other than those listed in the Import Alert #99-24, do not sample. If no country of origin is labeled on the product, assume that the product origin is from the suspect country and collect an official sample.

Use the guidance in the IOM, Sample Schedule Chart 15, Veterinary Products, Feeds, & By-Products for Animal Feeds, for determining sample size.

Inform the firm management of the purpose of your visit and provide the firm with a copy of the FDA Talk Paper 99-27, "All Eggs and Egg-Containing Products From Belgium, France, and The Netherlands and Animal Feed from European Countries To Be Detained At Ports of Entry" (Attachment B), identifying the nature of dioxin/PCB problem in Europe. (Note - this attachment is a text file and needs to be printed out on FDA Talk Paper letterhead). Tell firm management that the samples are to be analyzed by FDA and that the removal of any product found to be violative is the responsibility of the firm. Ask firm management if they have any plans to recover distributed product or to hold sampled product. Report this information in the "Remarks" section of the collection report.

Ship samples for overnight delivery to your district's domestic pesticide servicing laboratory. Coordinate shipment with the lab especially for samples shipped on Thursdays or Fridays.

Page 4 - Dioxin Contamination

Districts are to inform Dr. Daniel McChesney, HFV-222 via e-mail or FAX of the results of the sampling effort for each product listed on the attachment. (Responding by fax, please send to 301-594-1812.) For products sampled, fax a copy of each collection report; for products not sampled report on the information obtained above.

Analytical

Analyze all samples for PCBs using PAM Vol. I Chapter 3, section 303 or 304 for non-fatty and fatty foods, respectively. Perform a check analysis immediately for products found to contain PCBs at or above the limit of quantitation of 0.1 ppm on a *whole product basis*. This includes products that have PCB tolerances listed in 21 CFR 509.30 above 0.1 ppm. Original PCB analysis should be completed within 48 hours of sample receipt; check analysis within 24 hours of completion of original analysis.

Laboratories must notify collecting districts IMMEDIATELY of analytical results.

The labs are also to report all analytical results, including negative findings, as they are obtained to CVM, ATT: Dr. Daniel McChesney, HFV-222 via fax or e-mail. (Responding by fax, please send to 301-594-1812.) Maintain composites for all samples until further notice by CVM. CVM will make a determination of further analytical requirements (e.g. dioxin analysis) and analyzing laboratory for selected samples, including some that may have had no PCBs found.

REPORTING

Collection Reports and information on the outcome of the trace-forward on each of the products listed in Attachment C are to be faxed to Dr. Daniel McChesney, HFV-222 phone 301-827-6653, fax 301-594-1812.

PAC: 71R842

Product Codes: See Import Alert and attachment C.

Regulatory Action

Samples that exceed PCB tolerances listed in 21 CFR 509.30 are adulterated and follow-up action would be appropriate. However, some products sampled will not be covered by the tolerances. CVM will evaluate all findings of PCBs for products not covered by CFR tolerances and advise the home district of recommended follow-up action.

For products that exceed CFR tolerances or products containing PCBs at levels CVM determines to be of regulatory significance, immediately notify the firm at which the sample was collected and inquire as to their intentions to recall. If recall is not forthcoming, seizure or other regulatory action, as appropriate should be considered.

Page 5 - Dioxin Contamination

This assignment is TOP priority and is to be implemented upon receipt. This assignment has the concurrence of ORA.

CVM/ORA Contacts

CVM- Assignment and Compliance Issues

Gloria Dunnavan, Director, Division of Compliance HFV-230

301-594-1726

John Young, CSO 301-594-1791

FAX for both, 301-594-1812

CVM –Scientific Issues

Dr. Randall Lovell, VMO HFV-222

301-827-0176

ORA –Barbara Marcelletti

301-827-5635

DFS Analytical Contact:

Len Valenti, HFC-140,

301-827-1027

Gloria Dunnavan

Attachments

Attachment A - Import Alert 99-24

Attachment B- Talk Paper 99-27

Attachment C - Consignee and product listing by country by district.

cc: HFC-1
HFC-102
HFC-130 Weitzman, Pierce, Marcelletti
HFC-140 Olson, Valenti
HFC-150 Arbaugh
HFC-170 McCallion, Notzon
HFV-1 Sundlof
HFV-200 Tollefson, Raynes, Matheson
HFV-220 Graber, McChesney, Lovell
HFV-230 Dunnavan
HFV-232 Young, Gushee
HFV-235 Washington
HFA-224
Draft: jyoung:6-21-99
Reviewed: jgushee:6-21-99
Revised: jyoung:6-22-99
Final:tvwooten: 6/22/99

ATTACHMENT A

To: ORA IO HQ Alerts@LISTS.local@FDAORAHQ, ORA DDs@LISTS@FDAORAHQ
cc:ORA RFDDs@LISTS@FDAORAHQ, Deborah Ralston@ORO@FDAORAHQ,
cc:ORA RFDDs@LISTS@FDAORAHQ, Deborah Ralston@ORO@FDAORAHQ,
David
Eggholm@OPPE@FDA.CFSAN, Gloria Duranara@OSC@FDACVM, John
Young@OSC@FDACVM, Matthew Eckel@OGC.FDA@FDAOC, Patrick
Wilson@OIA@FDAOC, Janice F Oliver@OCD@FDA.CFSAN, ORA IO Systems
Branch@LISTS.local@FDAORAHQ, Stella Notzon@IO@FDAORAHQ, Joseph

From: Import Alerts@IO@FDAORAHQ
Date: Fri Jun 11 12:26:28 1999
Attached: None

DATE: June 11, 1999 (Updated 6/15/99)

FROM: ACTING DIRECTOR, DIVISION OF IMPORT OPERATIONS & POLICYHFC-
(HFC-170)

SUBJECT: IMPORT ALERT #99-24, "DETENTION WITHOUT PHYSICAL
EXAMINATION OF HUMAN FOOD PRODUCTS AND ANIMAL FEEDS
CONTAMINATED WITH DIOXIN AND/OR PCB COMPOUNDS"

TO: IMPORT PROGRAM MANAGERS

TYPE OF ALERT: Detention Without Physical Examination

(Note: This import alert contains the agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or product(s) at issue. It does not create or confer any rights for, or on any person, and does not operate to bind FDA or the public.)

PRODUCTS: HUMAN PRODUCTS
-All egg and egg containing products
-Meats

ANIMAL PRODUCTS
-All medicated and non-medicated animal feed
-All animal feed ingredients
-All pet food

PRODUCT CODES: See Attachment

PROBLEM: Chemical Contamination - Dioxin and/or PCB Compounds

PAC FOR
COLLECTION: 04R842
71003A

PAF: PES

COUNTRY: HUMAN PRODUCTS: Belgium
France
Netherlands

ANIMAL PRODUCTS: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom

MANUFACTURER/ N/A
FEI:

CHARGE: The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to contain dioxins and/or PCB compounds, poisonous or deleterious substances and/or unapproved food additives, which may render it injurious to health [Adulteration, Section 402(a)(1), 402(a)(2)(C)(i), 402(a)(2)(A)].

RECOMMENDING

OFFICE: CFSAN, Office of Field Programs, (HFS-600)
CVM, Division of Compliance, (HFV-230)

REASON FOR

ALERT: FDA has received information that animal fat from a rendering company in Belgium was contaminated with dioxins and/or PCB compounds in January of 1999. This product was shipped to animal feed manufacturers and incorporated into animal feed. Contaminated feed was fed to chickens, which resulted in contaminated eggs, and may have been fed to other domestic animals. Dioxins and PCBs persist in the environment. Any animals fed contaminated product and subsequently slaughtered may have levels of dioxins/PCBs remaining in slaughter by-products. These may be rendered and subsequently used in other animal feeds, allowing the dioxins/PCBs to continue to be recycled through the food chain.

GUIDANCE: Districts may detain without physical examination shipments of any of the products as noted above and in the attachment.

In order to gain release of detained product, importers should provide laboratory test results for dioxin TEQ (Toxic Equivalents which will include all 17 congeners, 2,3,7,8 chloro-substituted dioxins and furans) and/or for PCBs.

At this time, a government or industry certificate of compliance alone, without laboratory analysis, should not be accepted as evidence for allowing entry of detained product.

CONTACTS: CFSAN, HFS-606, Brian Landesburg (202) 205-5247
CVM, HFV-230, Gloria Dunnavan (301) 594-1726
DIOP, HFC-170, Stella Notzon (301) 443-6553

PRIORITIZATION

GUIDANCE: I

FOI: No purging is required

KEYWORDS: Dioxin, feed, egg, PCB

PREPARED BY: CFSAN, HFS-606, Dave Egelhofer
CVM, HFV-230, Gloria Dunnavan
DIOP, HFC-170, Stella Notzon

DATE LOADED
INTO FIARS: June 11, 1999

\s\

Joseph L. McCallion

ATTACHMENT

Product Codes:

A). For Belgium, France, and the Netherlands - [HUMAN PRODUCTS]

03- Bakery Products, Doughs, Bakery Mixes and Icings

All Products EXCEPT:

03L [][[]]- Prepared Dry Cookie, Biscuit & Wafer Mixes w/o Eggs

04- Macaroni and Noodle Products

All Products

07- Snack Food Items (Flour, Meal or Vegetable Base)

07A [][[]]01 - Snack Food, Baked-Bread Sticks, ONLY

07B [][[]]01 - Snack Food, Fried - Bread Sticks, ONLY

13- Ice Cream and Related Products

All Products EXCEPT:

13D[][[]] - Sherbet

13F[][[]] - Fruit Flavored Ices

15- Egg and Egg Products

All Products

16- Fishery/Seafood Products

16W[][[]] - Mixed Fishery/Seafood Products, ONLY

17- Meat/Meat Products

All Products

24-25 Vegetable and Vegetable Products

24V[] [] [] - Leaf & Stem Vegetables with Sauce, ONLY
25H[] [] [] - Mixed Vegetables with Sauce, ONLY
25N[] [] [] - Root and Tuber Vegetables with Sauce, ONLY
25Y[] [] [] - Vegetables & Vegetable Products nec, ONLY

27- Dressings and Condiments

27A[] [] [] - Standardized Dressings, ONLY
27B[] [] [] - Non-Standardized Dressings, ONLY
27Y[] [] 07 - Sandwich Spreads, ONLY
27Y[] [] 99 - Condiments, ONLY

35- Gelatin, Rennet, Pudding Mixes and Pie Fillings

35C[] [] [] - Custard Pudding (Pie)Mixes, ONLY
35D[] [] [] - Pudding (Pie Filling)Mixes other than Custard, ONLY

37- Multiple Food Dinners, Gravies, Sauces and Specialties

All Products

39 - Prepared Salad Products

39B---- Salad with Egg, Meat, or Poultry Products
39Y----Prepared Salad, n.e.c. (Only those containing Eggs, Egg Yolk Solids, Milk/Dairy)

40-Baby (Infant and Junior)Products

40A[] [] []- Baked Goods
40C[] [] []- Formula Products (Milk and Milk Substitutes)
40F[] [] []- Meats and Combination Meat Dinners
40G[] [] []- Poultry and Combination Poultry Dinners
40H[] [] []- High Meat Dinners and Cheese Foods
40J[] [] []- Egg Products
40K[] [] []- Desserts (puddings, custards, etc.)
40L[] [] []- Soups and soup mixes
40Y[] [] []- Baby(Infant and Junior)Foods, nec

B. For Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Liechtenstein, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom

[Animal Products]

54- Vitamins and Minerals for Animals

All products EXCEPT:
54A[] [] [] - Vitamins
54B[] [] [] - Minerals

69- Medicated Animal Feeds

All Products

70- Non-Medicated Animal Feeds

All Products

71- By-products for Animal Food

All products EXCEPT:

71F[][][] - Brewery & Distillery

71G[][][] - Corn Products

71H[][][] - Flour Mill

71I[][][] - Rice Mill

71J[][][] - Fruit

71K[][][] - Vegetable

71L[][][] - Oilseed

72- Pet and Laboratory Animal Foods

All Products

ATTACHMENT B

FDA TALK PAPER

T99-27
June 11, 1999

Judith Foulke: 202-205-4144
Broadcast Media:
Consumer Inquiries: 888-INFO-FDA

**ALL EGGS AND EGG-CONTAINING PRODUCTS FROM BELGIUM, FRANCE AND
THE NETHERLANDS AND ANIMAL FEED FROM EUROPEAN COUNTRIES TO BE
DETAINED AT PORTS OF ENTRY**

The Food and Drug Administration announced today that all imports of eggs, products containing eggs, and game meats (FDA regulated) from Belgium, France and the Netherlands, and all animal products including animal derived medicated and non-medicated feeds, feed ingredients, and pet foods from all European countries will be detained at U.S ports of entry.

These products are being detained because of the possibility that they may be contaminated with polychlorinated byphenyls (PCB's) and dioxins. Dioxins and PCB's are groups of compounds that may be potential carcinogens at low levels of exposure over extended periods of time and may have other types of toxicological effects. FDA is detaining these products as a precautionary step.

FDA is taking this action in response to recent reports that a fat product from a rendering company in Europe was

- MORE -

T99-27, Page 2, Belgium

contaminated with PCB's and dioxins in January 1999. This fat was subsequently sold to European animal feed manufacturers. Most of these feed manufacturers are in Belgium although some of the contaminated feed has reportedly been shipped to feed manufacturers in France and the Netherlands. Food producing animals may have consumed the feed resulting in potentially contaminated food products, for example, eggs. Since some animals that ate the contaminated feed may have been rendered and the renderings added to feed shipped to other European countries, FDA is also detaining all animal-derived feed and feed ingredients as well as pet food from all European countries.

FDA is gathering information on food products that may be affected. Because this was a one-time incident with eggs being only one component of many in egg-containing products, FDA believes that the exposure of U.S. consumers to harmful levels of PCB's and dioxins is minimal. However, FDA is continuing its investigation and is sampling and analyzing products that have been imported since the incident in question. FDA is working with officials in Europe as the investigation progresses.

At this time, in order for products to be released from detention, importers must provide laboratory test results showing PCB's are not detectable and/or that dioxins do not

- MORE -

Page 3, T99-27, Belgium

exceed 1 part-per-trillion (ppt).

The United States Department of Agriculture is holding poultry and pork from all European Community member states because of the possibility that the livestock may have been fed the contaminated feed. USDA is initiating investigations and analyses of these products.

FDA will continue to provide updates to this information. For updated information, consult the FDA web site at WWW.CFSAN.FDA.GOV, under the heading "What's New."

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