



RULE-MAKING ORDER

UR-103 (June 2004)
(Implements RCW 34.05.360)

Agency: Washington State Department of Agriculture

- Permanent Rule**
 Emergency Rule

Effective date of rule:

Permanent Rules

- 31 days after filing.
 Other (specify) _____ (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)

Effective date of rule:

Emergency Rules

- Immediately upon filing.
 Later (specify) _____

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

- Yes No If Yes, explain:

Purpose: These adopted amendments are necessary to ensure that chapter 16-252 WAC (Commercial Feed Rules-Pet Food and Specialty Pet Food) is consistent with current commercial feed law requirements (chapter 15.53 RCW Commercial Feed). Also, they are necessary to ensure that the references in chapter 16-252 WAC are correct so users of the chapter will find it easier to follow and comply with its requirements.

Citation of existing rules affected by this order:

Repealed: 16-252-001
 Amended: 16-252-007, 16-252-010, 16-252-095, 16-252-100, 16-252-120, 16-252-155, 16-252-165, 16-252-180
 Suspended:

Statutory authority for adoption: RCW 15.53 and RCW 34.05

Other authority :

PERMANENT RULE ONLY (Including Expedited Rule Making)

Adopted under notice filed as WSR 05-14-150 on July 6, 2005 (date).
 Describe any changes other than editing from proposed to adopted version:

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

Name: _____ phone () _____
 Address: _____ fax () _____
 e-mail _____

EMERGENCY RULE ONLY

Under RCW 34.05.350 the agency for good cause finds:

- That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.
 That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding:

Date adopted: September 7, 2005

NAME (TYPE OR PRINT)

Valoria Loveland

SIGNATURE

TITLE

Director

CODE REVISER USE ONLY

CODE REVISER'S OFFICE
STATE OF WASHINGTON
FILED

SEP 7 2005

TIME _____
 WSR _____ 05-18-093 AM/PM

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	0	Amended	0	Repealed	0
Federal rules or standards:	New	0	Amended	0	Repealed	0
Recently enacted state statutes:	New	0	Amended	1	Repealed	0

The number of sections adopted at the request of a nongovernmental entity:

	New	0	Amended	0	Repealed	0
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The number of sections adopted in the agency's own initiative:

	New	1	Amended	6	Repealed	1
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New	1	Amended	7	Repealed	1
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The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	1	Amended	7	Repealed	1

**Washington State Department of Agriculture
CR-103 Form-Attachment
Clarifying Details of the “Purpose” Statement:**

The following table identifies and explains the specific changes to chapter 16-252 WAC (Commercial Feed Rules-Pet Food and Specialty Pet Food) adopted by the Washington State Department of Agriculture with this filing. As the table illustrates, the changes are necessary to ensure that chapter 16-252 WAC:

- Is consistent with recent changes in Washington state commercial feed law (chapter 15.53 RCW Commercial Feed) requirements adopted by the legislature;
- Contains correct references;
- Is free of redundant references; and
- States requirements clearly so compliance is easier.

Rule Section	Adopted Change	Rationale
WAC 16-252-001 Effective date	Repealed	Repealed because stating the effective date of the original rule is no longer necessary.
WAC 16-252-007 The code of federal regulations	New	Added a new section stating that all references to the code of federal regulations refers to the 2002 edition. This allows the department to delete several references to “2002 edition” throughout the rule.
WAC 16-252-010 Commercial feed terms and definitions	Amended	<ul style="list-style-type: none"> • Numbered the definitions for quick reference. • Added a definition for “repackage” that was inadvertently omitted when the department’s pet food rules were completely rewritten and reformatted in 2003. • Moved the definition for “salvage specialty pet food” so it is in proper alphabetical order.
WAC 16-252-095 Drug and feed additive requirements	Amended	<ul style="list-style-type: none"> • Deleted the “2002 edition” reference in subsection (2)(a)(i) because it is redundant with the addition of new section WAC 16-252-007. • Deleted the word “Title” from subsection (2)(b)(ii) because it is not necessary. • Added “21 U.S. C. 151 et seq.” to subsection (2)(c) for clarity.
WAC 16-252-100 Directions for use and precautionary statement requirements	Amended	<ul style="list-style-type: none"> • Deleted the “2002 edition” reference in subsection (1)(b) because it is

		<p>redundant with the addition of new section WAC 16-252-007.</p> <ul style="list-style-type: none"> • Updated internet reference in subsection (1)(b) note. • Replaced "2002 edition" with "21 CFR" in subsection (1)(b) note for clarity.
WAC 16-252-120 Adulteration of pet food and specialty pet food	Amended	Deleted the "2002 edition" reference in subsection (1)(d) because it is redundant with the addition of new section WAC 16-252-007.
WAC 16-252-155 Tonnage fee requirements	Amended	Deletes the word "penalty" to make the section consistent with RCW 15.53.9018.
WAC 16-252-165 Registration requirements	Amended	Updated internet reference in subsection (2)(k) note.
WAC 16-252-180 Good manufacturing practices adopted	Amended	Deleted all references to "2002 edition" because they are redundant with the addition of new section WAC 16-252-007.

NEW SECTION

WAC 16-252-007 The code of federal regulation. Throughout these rules where the code of federal regulation is referred to, the reference is to the 2002 edition.

AMENDATORY SECTION (Amending WSR 03-23-129, filed 11/19/03, effective 7/1/04)

WAC 16-252-010 Commercial feed terms and definitions. Except for the specific terms and definitions contained in this section or in RCW 15.53.901, the terms and definitions used in reference to commercial feeds, in this chapter, are the official feed terms adopted by the Association of American Feed Control Officials (AAFCO) and published in the association's official publication. Throughout these rules where the Association of American Feed Control Officials (AAFCO) official publication is referred to, the reference is to the 2003 Official Publication.

Note: A copy of the official publication is on file with the department. Copies may be purchased from AAFCO Assistant Secretary-Treasurer, P.O. Box 478 Oxford, IN 47971.

(1) **"Animal wastes"** means a material composed of excreta, with or without bedding materials and/or animal drugs, collected from poultry, ruminants or other animals except humans.

(2) **"All life stages"** means gestation/lactation, growth, and adult maintenance life stages of a domesticated dog or cat.

(3) **"Canned"** means feed that has been processed, packaged, sealed, and sterilized for preservation in cans, pouches, or similar containers.

(4) **"Commercial feed"** means all materials or combination of materials that are distributed or intended for distribution for use as feed or for mixing in feed, unless such materials are specifically exempted.

The following commodities are exempted and are not considered "commercial feed" if they are not adulterated (see RCW 15.53.902 for a list of conditions that cause commercial feeds to be adulterated):

- Unmixed whole seeds and physically altered entire unmixed seeds when such seeds are not chemically changed.

- Raw meat, hay, loose salt, straw, stover, silage, cobs, husks, and hulls when such commodities are not ground, mixed or intermixed with other materials.

(5) **"Customer-formula feed"** means commercial feed that is a mixture of commercial feeds or feed ingredients, or both, each batch of which is manufactured according to the instructions of the

final purchaser.

(6) "**Department**" means the Washington state department of agriculture (WSDA).

(7) "**Director**" means the director of the Washington state department of agriculture or the director's designee.

(8) "**Distressed pet food**" means pet food (dog and cat) in distribution that is no longer available for retail sale. Examples of distressed pet food include, but are not limited to, dented cans, torn bags, or pet food past its sell-by date.

(9) "**Distressed specialty pet food**" means specialty pet food in distribution that is no longer available for retail sale. Examples of distressed specialty pet food include, but are not limited to, dented cans, torn bags, or specialty pet food past its sell-by date.

(10) "**Distribute**" means to:

(a) Offer for sale, sell, exchange or barter, commercial feed; or

(b) Supply, furnish, or otherwise provide commercial feed to a contract feeder.

(11) "**Distributor**" means a person who distributes.

(12) "**Drug**" means:

(a) Any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals other than man; and

(b) Articles other than feed intended to affect the structure or any function of the animal body.

(13) "**Enzyme**" means a protein made up of amino acids or their derivatives, which catalyses a defined chemical reaction. Required cofactors should be considered an integral part of the enzyme.

(14) "**Facility**" means any place where a commercial feed is manufactured, repackaged, sold, transloaded, or stored for later distribution.

(15) "**Family**" means a group of pet food products, which are nutritionally adequate for any or all life stages based on their nutritional similarity to a lead product, which has been successfully test-fed according to an AAFCO feeding protocol(s).

(16) "**Feed ingredient**" means each of the constituent materials making up a commercial feed.

(17) "**Grain mixture specialty pet food**" means mixed or intermixed whole or physically altered grains, that:

(a) Are not chemically altered;

(b) May or may not contain molasses; and

(c) Except for molasses, contain no other additives.

(18) "**Guarantee**" means a listing of specified nutrients or nonnutritive substances contained in a commercial feed that the manufacturer or distributor named on the feed label warrants as specified in these rules.

(19) "**Guaranteed analysis**" means a listing of the minimum, maximum or both minimum and maximum concentrations of specified nutrients contained in a commercial feed that the manufacturer or distributor named on the feed label warrants. Both minimum and maximum concentrations of specified nutrients contained in a

commercial feed are stated on an "as is" basis rather than on a "one hundred percent moisture free" basis in units specified by these rules.

(20) **"Initial distributor"** means a person who first distributes a commercial feed in or into Washington state.

(21) **"Ingredient statement"** means a contiguous listing on the label of all ingredients of which the commercial feed is composed.

(22) **"Label"** means a display of written, printed, or graphic matter upon or affixed to the container in which a commercial feed is distributed, or on the invoice or delivery slip with which a bulk commercial feed is distributed.

(23) **"Labeling"** means all labels and other written, printed, or graphic matter:

(a) Upon a commercial feed or any of its containers or wrappers; or

(b) Accompanying such commercial feed.

(24) **"Lot identifier"** means a unique identifier for each lot, batch or production run that enables the manufacturer to accurately trace the complete manufacturing and distribution history of the product. A lot identifier is an individual lot, batch or production run number, code, date, or other suitable identification applied to the label, container, or package. In the case of bulk feed, the lot identifier is on a label, invoice, or shipping document accompanying the feed.

(25) **"Net weight"** means the weight of a commodity excluding any materials, substances, or items not considered to be part of the commodity. Examples of materials, substances, or items not considered to be part of a commodity include, but are not limited to, containers, conveyances, bags, wrappers, packaging materials, labels, individual piece coverings, decorative accompaniments, and coupons. (See RCW 19.94.010 (1)(i).)

(26) **"Nutritionally adequate"** means the feed, when fed according to directions on the label, will meet the nutritional requirements of the class of animals for which the feed was manufactured.

(27) **"Nutritionally suitable"** means nutritionally adequate.

(28) **"Person"** means an individual, firm, partnership, corporation, or association.

(29) **"Pet food"** means a commercial feed prepared and distributed for consumption by domesticated dogs or cats.

(30) **"Principal display panel"** means the part of a label that is most likely to be displayed, presented, shown or examined under normal and customary conditions of display for retail sale.

(31) **"Prohibited mammalian protein"** means any protein-containing portion of mammalian animals, excluding:

- Blood and blood products;
- Gelatin;
- Inspected meat products that have been cooked and offered for human food and further heat processed for feed (such as plate waste and used cellulose food casings);
- Milk products (milk and milk proteins); and
- Products whose only mammalian protein is porcine or equine

protein.

(32) **"Processed,"** as applied to animal waste, means thermally dehydrated, dry-stacked, ensiled, oxidized, chemically treated, microbiologically digested, chemically or physically fractionated, or treated by other processes that enable an animal waste product to comply with the standards established in this chapter.

(33) **"Quantity statement"** means the part of the label expressing net weight (mass), net volume (liquid or dry) or count.

(34) **"Repackage"** means taking commercial feed from packages (no larger than one hundred pounds for dry feed or fifty-five gallons for liquid feed) and placing it into smaller packages for resale.

(35) **"Salvage pet food"** means pet food (dog and cat food) still under control of the original manufacturer and will not be offered for sale at retail. Examples include, but are not limited to, start-up and over-run product, unpelletted pet food, pet food fines, and other products not suitable for packaging for retail sale.

(36) **"Salvage specialty pet food"** means specialty pet food still under control of the original manufacturer and will not be offered for sale at retail. Examples include, but are not limited to, start-up and over-run product, unpelletted specialty pet food, specialty pet food fines, and other products not suitable for packaging for retail sale.

(37) **"Sell"** or **"sale"** includes exchange.

(38) **"Specialty pet"** means a domesticated animal pet normally maintained in a cage or tank, such as, but not limited to, gerbils, hamsters, canaries, psittacine birds, mynahs, finches, tropical fish, goldfish, snakes, and turtles.

~~((**"Salvage specialty pet food"** means specialty pet food still under control of the original manufacturer and will not be offered for sale at retail. Examples include, but are not limited to, start-up and over-run product, unpelletted specialty pet food, specialty pet food fines, and other products not suitable for packaging for retail sale.))~~

(39) **"Specialty pet food"** means a commercial feed prepared and distributed for consumption by specialty pets.

(40) **"Transload"** means to transfer commercial feed from one carrier to another carrier without processing or blending the ingredients. For example, transferred from rail cars to trucks or shipping containers.

AMENDATORY SECTION (Amending WSR 03-23-129, filed 11/19/03, effective 7/1/04)

WAC 16-252-095 Drug and feed additive requirements. (1) Before the department approves a registration application and/or a label for pet food or specialty pet food that contains additives

(including drugs, other special purpose additives, or nonnutritive additives), the distributor may be required to submit, to the department, satisfactory evidence proving the safety and effectiveness of the pet food or specialty pet food when used according to the directions on the label.

(2) Satisfactory evidence of the safety and effectiveness of a pet food or specialty pet food that contains additives (including drugs, other special purpose additives, or nonnutritive additives) is established if one or more of the following apply:

(a) When the use of a pet food or specialty pet food containing such additives either:

(i) Conforms to the requirements of the applicable regulation in 21 CFR (~~(, 2002 edition)~~); or

(ii) Are "prior sanctioned"; or

(iii) Are "informal review sanctioned"; or

(iv) "Generally recognized as safe" (GRAS) for such use.

(b) When the pet food or specialty pet food is itself a drug, and is:

(i) Generally recognized as safe (GRAS) and effective for the labeled use; or

(ii) Marketed subject to an application approved by the Food and Drug Administration under ((Title)) 21 U.S.C. 360 b as amended effective on the date these rules were adopted.

(c) When one purpose for feeding a pet food or specialty pet food is to immunize through some immunological process and the immunizing drugs or additives have been approved for the purpose through the Federal Virus, Serum and Toxins Act of 1913, as amended in 1985 (21 U.S.C. 151 et seq.).

(d) When the pet food or specialty pet food is a directly fed microbial product and the:

(i) Product meets the particular fermentation product definition as listed in the Association of American Feed Control Officials official publication; and

(ii) Required microbial content statement on the label is limited to the following: "Contains a source of live (viable) naturally occurring microorganisms"; and

(iii) Source is stated with a corresponding guarantee expressed according to WAC 16-252-076 requirements.

(e) When the pet food or specialty pet food is an enzyme product and the:

(i) Product meets the particular enzyme definition listed in the Association of American Feed Control Officials official publication; and

(ii) Enzyme is stated with a corresponding guarantee expressed according to WAC 16-252-076 requirements.

WAC 16-252-100 "Directions for use" and "precautionary statement" requirements. (1) Directions for use and precautionary statements on required labeling of all pet food and specialty pet foods containing additives (including, but not limited to, drugs, nonprotein nitrogen, special purpose additives, or nonnutritive additives) must:

(a) Be adequate to enable users with no special knowledge of the purpose and use of the feed to use it safely and effectively for its intended purposes; and

(b) Include all information described by all applicable regulations of 21 CFR, Parts 500-599 under the Federal Food, Drug and Cosmetic Act (~~(, 2002 edition)~~).

Note: The Food and Drug Administration's regulations are published in the Code of Federal Regulations, and are available in book format from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402. They are also available on the internet at (~~(http://www.access.gpo.gov/nara/cfr/cfr-retrieve.html#page1)~~) <http://www.gpoaccess.gov/cfr/retrieve.html>. A copy of (~~(the 2002 edition)~~) 21 CFR Parts 500-599 are also on file with the department.

(2) Adequate directions for use and precautionary statements identified in subsection (1) of this section are required for pet food and specialty pet food that is distributed to:

(a) Supply particular dietary needs; or

(b) Supplement or fortify the usual diet or ration with any vitamin, mineral, or other dietary nutrient or compound.

(3) (a) When a pet food or specialty pet food is intended for use by or under the supervision of a veterinarian, the statement "use only as directed by your veterinarian" must be on the label. When such a statement is on a pet food label, feeding instructions are not required, but may appear on the label. This regulation takes precedence over other regulations in this subsection.

(b) Pet food, including snacks or treats, labeled as "complete and balanced" for any or all life stages, must list feeding directions on the label. Any pet food labeled as "snacks" or "treats" that contains a drug, must list feeding directions on the label. These directions must:

(i) Be expressed in common terms;

(ii) Appear prominently on the label;

(iii) State the frequency of feeding; and

(iv) At a minimum state, "feed (weight or other measure of product) per (weight only) of dog (or cat)."

(c) Directions must be consistent with the intended use(s) indicated in the nutritional adequacy statement, unless a limited use or more limited life stage designation is declared elsewhere (for example, "adult formula").

(d) Directions must be given for each life stage stated on the label.

(4) (a) Pet food and specialty pet food snacks and treats do not require feeding directions on the label except when they:

(i) Are labeled as "complete and balanced"; or

(ii) Contain a drug.

(b) Feeding directions may be on the label for snacks and treats even when not required.

(5) Pet food and specialty pet food labels must contain the statement "This product is intended for intermittent or supplemental feeding only," if the product does not meet the nutrient requirements of the appropriate AAFCO recognized nutrient profile, feeding protocol, or any other special nutritional or dietary need, thus making it suitable only for limited, intermittent, or supplementary feeding.

AMENDATORY SECTION (Amending WSR 03-23-129, filed 11/19/03, effective 7/1/04)

WAC 16-252-120 Adulteration of pet food and specialty pet food. (1) The terms "poisonous or deleterious substances" as used in RCW 15.53.902 include, but are not limited to, the following:

(a) Any ingredient, pet food or specialty pet food that contains more than twenty parts per billion aflatoxin B1, B2, G1, G2, individually or in total.

(b) Soybean meal, flakes or pellets or other vegetable meals, flakes or pellets that have been extracted with trichloroethylene or other chlorinated solvents.

(c) Sulfur dioxide, sulfurous acid, and salts of sulfurous acid when used in or on pet food or pet food ingredients that are considered or reported to be a significant source of vitamin B1 (thiamine).

(d) Any substance that is prohibited by 21 CFR, Part 589 (~~(7-2002 edition)~~).

(2) When screenings are used in a pet food or specialty pet food, the screenings and the finished product must comply with the requirements in WAC 16-252-110 or the pet food will be considered adulterated.

(3) Pet food or specialty pet food containing raw or unprocessed animal waste will be considered adulterated.

AMENDATORY SECTION (Amending WSR 04-14-076, filed 7/6/04, effective 1/1/05)

WAC 16-252-155 Tonnage fee required. Each initial distributor of a pet food or specialty pet food in or into Washington state must pay the department an inspection fee of twelve cents per ton on all pet food or specialty pet food they sold, for distribution within Washington state, during the year. The minimum inspection fee, the late ((penalty)) fee, and exceptions to payment of the fee are as authorized in RCW 15.53.9018.

AMENDATORY SECTION (Amending WSR 03-23-129, filed 11/19/03, effective 7/1/04)

WAC 16-252-165 Registration requirements. (1) All registration applications for pet food and specialty pet food must be on forms available from the department.

(2) The application for pet food and specialty pet food registration, to be completed by applicants and registrants, must include:

- (a) The company name (registrant);
- (b) Complete business mailing address;
- (c) Complete physical address of the business, if different than the mailing address;
- (d) Telephone number;
- (e) Company name on label if different than the registrant;
- (f) Number of products sold in small packages of less than ten pounds;
- (g) Number of products sold in large packages of ten pounds or more;
- (h) Company registrar's name;
- (i) Company registrar's title;
- (j) Registrar's signature; and
- (k) Date signed.

Note: The application for registration of pet food and specialty pet food products may be downloaded from the internet at ((<http://www.wa.gov/agr/FoodAnimal/AnimalFeed/Forms/Form4307.pdf>))
<http://agr.wa.gov/FoodAnimal/AnimalFeed/Forms.htm>.

AMENDATORY SECTION (Amending WSR 03-23-129, filed 11/19/03, effective 7/1/04)

WAC 16-252-180 Good manufacturing practices adopted. The following good manufacturing practices are adopted:

(1) Regulations prescribing current good manufacturing practices for Type B and Type C medicated feeds as published in 21 CFR, Part 225, Sections 225.1-225.202 (~~(, 2002 edition)~~).

(2) Regulations prescribing good manufacturing practices for Type A Medicated Articles as published in 21 CFR, Part 226, Sections 226.1-226.115 (~~(, 2002 edition)~~).

(3) Regulations pertaining to animal proteins prohibited in ruminant feed as published in 21 CFR, Part 589.2000 (~~(, 2002 edition)~~).

REPEALER

The following section of the Washington Administrative Code is repealed:

WAC 16-252-001

Effective date.