CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE
FOOD AND AGRICULTURAL CODE
DIVISION 7, CHAPTER 6. COMMERCIAL FEED
AND
CALIFORNIA CODE OF REGULATIONS
TITLE 3, DIVISION 4, CHAPTER 2, SUBCHAPTER 2. COMMERCIAL FEED

EFFECTIVE 01/01/2025
FOOD AND AGRICULTURAL CODE
ADOPT 15061.1(a), (b)
AMEND 15053(a), 15061(b)
REPEAL 15061(c), (d), 15061(a), (b), (c)

EFFECTIVE 11/12/2024 - 05/13/2025
CALIFORNIA CODE OF REGULATIONS, TITLE 3
ADOPT 2770, 2771, 2772, 2773, 2774, 2775, 2776, 2777, 2778, 2779, 2780, 2781, 2782, 2783, 2784, 2785, 2786, 2787, 2788, 2789, 2790, 2791, 2792, 2793, 2794, 2795, 2796, 2798, 2799, 2800, 2801, 2802, 2803, 2804, 2805, 2806, 2807, 2808, 2809, 2810, 2811
AMEND 2675, 2675.1, 2680, 2683, 2688, 2694, 2696, 2697, 2702, 2707, 2734, 2735, 2750, 2751, 2760
REPEAL 2691, 2695, 2704, 2705, 2706, 2770, 2773, 2773.1, 2773.5, 2774, 2774.5, 2775, 2776, 2777, 2778, 2781, 2782, 2783, 2783.5, 2785, 2787, 2788, 2789, 2790, 2790.5, 2790.7, 2791, 2793, 2794, 2795, 2795.5, 2796, 2796.5, 2797, 2798, 2798.5, 2799, 2800, 2801, 2802, 2803, 2804

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CALIFORNIA CODE OF REGULATIONS, TITLE 3
AMEND 2675, 2683, 2684, 2685, 2686, 2697, 2701, 2717, 2733, 2750, 2751, 2765, 2766, 2767, 2768, 2769

EFFECTIVE 01/01/2024
FOOD AND AGRICULTURAL CODE
ADOPT 14902.1(a), (b)

EFFECTIVE 2023
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AMEND 2675, 2675.1, 2681, 2694

EFFECTIVE 2022
CALIFORNIA CODE OF REGULATIONS, TITLE 3
AMEND 2675, 2675.1, 2750, 2751, 2789, 2802, 2804

EFFECTIVE 2020
FOOD AND AGRICULTURAL CODE
AMEND 15053(a), 15061(a), (d), 15061(a), (c)

EFFECTIVE 2019
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EFFECTIVE 2016
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AMEND 14902.5, 14978.2(d)

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FOOD AND AGRICULTURAL CODE

DIVISION 7. AGRICULTURAL CHEMICALS, LIVESTOCK REMEDIES, AND COMMERCIAL FEEDS, CHAPTER 6. COMMERCIAL FEED [14901 - 15103]

ARTICLE 1. GENERAL PROVISIONS [SECTIONS 14901 – 14904]

14901. The Legislature hereby finds and declares that it is the intent of this chapter to do all of the following:

(a) Enable the feed and feeding industry, with the aid of the state, to ensure in every way possible a clean and wholesome supply of meat, milk, and eggs for the benefit of the consumer.

(b) Provide assurance to the consumer-buyer of commercial feed that the product he or she purchases is properly identified and of the quality and quantity represented by the manufacturer of the commercial feed.

(c) Provide funds for the administration and enforcement of this chapter by an inspection tonnage tax on commercial feed to be paid by any person that distributes commercial feed to a consumer-buyer in this state.

(d) Enable the commercial feed industry, pursuant to regulations or procedures adopted or established by the director, to implement and maintain an efficient program of inspection and analysis of commercial feed.

14902. Except as otherwise provided in Sections 14978 and 14979, the director shall enforce this chapter and adopt and enforce those regulations relating to the manufacture and distribution of, and to the manner of making inspection tonnage tax payments upon, commercial feed as the director determines is necessary to carry out this chapter.

14902.1. (a) Notwithstanding any other law, any commercial feed, feed additive, or drug approved by the United States Food and Drug Administration that is fed to livestock shall be under the oversight of the department as the primary state regulatory agency, including, but not limited to, products that make environmental and health claims.

(b) Nothing in this section shall be construed to limit the authority of the State Air Resources Board under Section 39730.7 of the Health and Safety Code.

14902.5. Notwithstanding any other law, the department shall continue to be the primary regulatory agency over medicated feed, responsible for regulating medicated feed quality assurance and medicated feed safety, and enforcing any handling and inspecting requirements imposed on medicated feed suppliers. The department shall also have primary responsibility over medicated feed ingredients and the sale of medicated feed that is subject to veterinarian oversight.

14903. The secretary shall establish, by regulation, good manufacturing practices, hazard analysis, and preventive control measures as the secretary determines are reasonably necessary to carry out the purposes of this chapter. The good manufacturing practices, hazard analysis, and preventive control measures, including verification and validation activities for all commercial feed and additives, including

medicated feed premixes and medicated feeds, shall be based upon federal food and drug laws and regulations, unless the secretary determines that the federal laws and regulations are not appropriate to the conditions that exist in this state. The regulations adopted pursuant to this section shall ensure that drug usage under this chapter shall not conflict with the provisions of Chapter 4 (commencing with Section 14200).

14904. The director shall adopt and enforce regulations for the manufacture, distribution, and labeling of feed used in connection with the production of food sold as organic pursuant to Article 7 (commencing with Section 110810) of Chapter 5 of Part 5 of Division 104 of the Health and Safety Code which shall be consistent with the requirements of that article.

ARTICLE 2. DEFINITIONS [SECTIONS 14921 – 14939]

14921. Unless the context otherwise requires, the definitions in this article govern the construction of this chapter.

14923. “Animal” means any animal, including birds, except a human being.

14924. “Board” means the Feed Inspection Advisory Board.

14925. “Commercial feed” includes all materials which are intended for use as feed or for mixing in feed except preparations which are manufactured and distributed for feeding to domestic pets, such as dogs, cats, and birds.

14926. “Consumer-buyer” means any person not licensed under this chapter who purchases [commercial] feed from a manufacturer or distributor of such feed for use in feeding animals.

14927. “Distribute” means to offer for sale, sell, exchange or barter.

14928. “Drug” means any substance which is intended, or represented, for use in the diagnosis, cure, mitigation, treatment, or prevention of any disease in any animal, and any other substance, except feed, which is intended to affect the structure or any function of the body of any animal.

14929. “Feed ingredient” means each of the constituent substances making up a formula feed.

14930. “Formula feed” means two or more feed ingredients, proportioned, mixed, and processed according to specifications.

14931. “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 which accompanies a commercial feed.

14932. “Licensee” means a person that has obtained a license pursuant to the provisions of this chapter.

14933. “Manufacture” means to grind, mix, or further process a [commercial] feed.

14934. “Medicated feeds” means [commercial] feeds that contain drugs.

14935. “Medicated feed premixes” means a concentrated combination of one or more substances, at least one of which is a drug, which must be diluted through manufacturing into a medicated feed.

14936. “Percent or percentages” means percentages by weight.

14937. “Person” means any individual, corporation, partnership, limited liability company, trust, association, cooperative association, or any other business unit or organization.

14938. “Special mix” means any commercial feed which is manufactured, processed, or mixed pursuant to specifications which are agreed upon by the purchaser and the manufacturer.

14939. “Ton” means a net weight of 2,000 pounds avoirdupois.

ARTICLE 3. FUNDS [SECTIONS 14961 – 14963]

14961. All of the money which is received by the director pursuant to this chapter shall be deposited in the Department of Food and Agriculture Fund and shall be expended solely for the administration and enforcement of this chapter, including reimbursement of the board or other entity for all of the expenses necessary to carry out the purposes of this chapter.

14962. The director shall prepare an annual statement of the operating expenditures and income related to this chapter which shall be presented to the board for review as soon as possible following the termination of the fiscal year. A copy of this statement will be made available to any interested person upon request.

14963. If this chapter is repealed, any funds received by the director pursuant to this chapter remaining after all expenses are paid, shall be rebated by the director in a manner prescribed by the board proportionately to the amount paid by those persons that made such payments.

ARTICLE 4. FEED INSPECTION ADVISORY BOARD [SECTIONS 14971 – 14979]

14971. There is in state government a Feed Inspection Advisory Board consisting of eight persons appointed by the director, who are licensed under this chapter, and who are subject to payment of the inspection tonnage tax in accordance with this chapter. The director may appoint one additional member to the board who shall be a public member. The members of the board shall receive no salary, but are entitled to payment of necessary traveling expenses in accordance with Department of Human Resources rules. These expenses shall be paid out of appropriations made to the department.

Upon the director’s request, the board shall submit to the director the names of three or more natural persons, each of whom shall be a citizen and resident of this state and not a producer, shipper, or processor nor financially interested in any producer, shipper, or processor, for appointment by the director as a public member of the board. The director may appoint one of the nominees as the public member on the board. If all nominees are unsatisfactory to the director, the board shall continue to submit lists of nominees until the director has made a selection. Any vacancy in the office of the public member of the board shall be filled by appointment by the director from the nominee or

nominees similarly qualified submitted by the board. The public member of the board shall represent the interests of the general public in all matters coming before the board and shall have the same voting and other rights and immunities as other members of the board.

14971.5. It is hereby declared, as a matter of legislative determination, that persons appointed to the Feed Inspection Advisory Board pursuant to this article are intended to represent and further the interest of a particular agricultural industry concerned, and that such representation and furtherance is intended to serve the public interest. Accordingly, the Legislature finds that, with respect to persons who are appointed to such board, the particular agricultural industry concerned is tantamount to, and constitutes, the public generally within the meaning of Section 87103 of the Government Code.

14972. The term of office of the members of the board is three years. When the board is first appointed, two members shall be appointed for three years, two members for two years, and one member of one year. Thereafter appointment shall be for full three-year terms. Vacancies shall be filled for an unexpired term.

14975. Except as otherwise provided in Sections 14978 and 14979, the board shall be advisory to the director and may make recommendations on all matters pertaining to this chapter, including, but not limited to, the inspection and enforcement program, annual budget, necessary fees to provide adequate inspection services, and regulations required to accomplish the purposes of this chapter.

14976. The board shall elect a chairman, and from time to time such other officers as it may deem advisable.

14977. The board shall meet at the call of its chairman or the director or at the request of any three members of the board. The board shall meet at least once a year.

14978. (a) In order to avoid administrative charges which may adversely impact persons subject to this chapter, and to provide for more efficient implementation of this chapter, the board may, on or before January 15 of any year, establish or designate one or more entities to administer all or any part of this chapter for the fiscal year beginning July 1 of the same year through June 30 of the following year, in accordance with the regulations and procedures adopted or established by the director pursuant to Section 14979.

(b) Notwithstanding subdivision (a), the director shall be responsible for the enforcement of this chapter and for the establishment of enforcement procedures.

14978.1. The entity or entities that may be established or designated by the board pursuant to Section 14978 includes, but shall not be limited to, the following:

(a) The committee established pursuant to Section 14978.2.

(b) Agricultural councils, commissions, and any entity established in accordance with a marketing order.

(c) Federal, state, or county agencies.

(d) The University of California and cooperative extension service.

(e) Agricultural associations and cooperatives.

(f) State accredited or certified chemistry laboratories.

However, the board may not designate any entity that is a trade association whose membership is composed primarily of persons licensed under this chapter or that represents persons regulated by this chapter.

14978.2. (a) The board may establish the Commercial Feed Inspection Committee as an entity to administer this chapter. The committee shall consist of eight persons appointed by the board who shall be licensed under this chapter. The committee may, with the concurrence of the director, appoint one additional member to the committee, who shall be a public member. The public member shall be a citizen and resident of California who is not subject to the licensing requirements of this chapter, and who has no financial interest in any person licensed under this chapter.

(b) Each member shall have an alternate member appointed in the same manner as the member, who shall serve in the absence of the member for whom they are designated as alternate and who shall have all the duties and exercise the full rights and privileges of members.

(c) The committee may appoint its own officers, including a chairperson, one or more vice chairpersons, and other officers as it deems necessary. The officers shall have the powers and duties delegated to them by the committee.

(d) The members and alternate members, when acting as members, shall serve without compensation but shall be reimbursed for expenses necessarily incurred by them in the performance of their duties in accordance with the rules of the Department of General Services.

(e) A quorum of the committee shall be five members. A vote of the majority of the members present at a meeting at which there is a quorum shall constitute the act of the committee.

(f) No member or alternate member, or any employee or agent thereof, shall be personally liable for the actions of the committee or responsible individually in any way for errors in judgment, mistakes, or other acts, either by commission or omission, except for his or her own individual acts of dishonesty or crime.

14978.3. Any entity established or designated pursuant to Section 14978 shall do all of the following:

(a) Administer this chapter or any part thereof, and to do and perform all acts and exercise all powers deemed reasonably necessary.

(b) Keep accurate books and records of its activities, which shall be subject to annual audit by an auditing firm approved by the director. The audit shall be made a part of an annual report to all persons licensed under this chapter. The books and records shall be available for audit during regular business hours upon request of the director.

(c) Establish an annual budget, including, but not limited to, the allocation of funds required for inspection services necessary for the administration of this chapter.

(d) Make recommendations to the director concerning all of the following:

(1) Adoption, modification, and repeal of regulations and procedures.

(2) Procedures for employment, training, supervision, and compensation of inspectors and other personnel.

(3) Rate and collection of inspection tonnage tax and the collection of license fees and penalties related thereto.

(4) Acquisition and use of equipment.

(5) Posting and noticing changes in bylaws, general procedures, or orders.

14978.4. The director may require any entity or entities established or designated pursuant to Section 14978 to correct or cease any activity or function that is determined by the director not to be in the public interest, or that is in violation of this chapter, and shall notify the entity in writing of these specific acts.

14978.5. Persons subject to this chapter shall not have access to any information in the possession of any entity or entities established or designated pursuant to Section 14978 that would disclose proprietary information regarding any other person subject to this chapter, including feed test results, individual tonnage tax payment, and feed formula information.

14978.6. Any person licensed under this chapter may petition the director, in accordance with regulations adopted by the director, to review any action, order, or decision of the entity or entities established or designated pursuant to Section 14978.

14979. (a) The director shall adopt regulations to be used by the entity or entities established or designated by the board pursuant to Section 14978 to administer this chapter. The regulations shall include, but not be limited to, contracts for analytical services with commercial laboratories and for any additional services.

(b) The director shall establish procedures to be used by the entity or entities established or designated by the board pursuant to Section 14978 to administer this chapter. The procedures shall include, but not be limited to, all of the following:

(1) Employment, training, supervision, and compensation of inspectors and other personnel.

(2) Allocation of funds and use of existing equipment and acquisition of equipment.

(3) Collection of inspection tonnage tax, license fees and penalties related thereto.

(c) This section is not subject to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(d) In adopting regulations and procedures, the director shall accept the recommendations of the entity or entities established or designated pursuant to Section 14978 if he or she finds them to be practicable and in the interest of the commercial feed industry and the public. Within 30 days of the date the director receives a recommendation from any such entity, the director shall provide the entity with notice of

the acceptance of the recommendations or with a written statement of reasons if he or she does not accept the recommendation.

ARTICLE 5. LABELS [SECTIONS 14991 – 14996]

14991. (a) Except as otherwise provided in this chapter or by regulations of the secretary that declare that the statement required pursuant to this article is not applicable to certain products to carry out this chapter, every lot, parcel, or package of commercial feed distributed within this state shall have affixed to it, or be accompanied by, a label.

(b) The sale or distribution of any lot, parcel, or package of commercial feed without a label, as specified in this chapter, is a violation of this chapter.

14992. The label shall contain a legible and plainly printed statement which certifies all of the following:

(a) The net weight or volume of the contents of the lot or parcel unless accompanied by a certified certificate of weights and measures.

(b) The product name, brand name, or trademark.

(c) The name and principal address of the manufacturer or person that is responsible for placing the commodity on the market.

(d) The guaranteed analysis stated in terms as the director specifies by regulation.

(e) The recognized official name, as specified by the director, of each ingredient. The director may by regulation permit the use of a collective term for a group of ingredients which performs a similar function. The director may exempt a commercial feed, or any combination of commercial feeds from labeling requirements if he or she finds the listing is not necessary to comply with the intent of this chapter.

(f) Adequate directions, warnings and caution statements that may be necessary for the safe use of any feed.

14993. Any person that manufactures, processes, or mixes any special mix for another person, shall label it in accordance with regulations as specified by the director.

14994. A special mix shall not be resold unless relabeled.

14995. If a manufacturer or processor of any commercial feed makes a claim or guarantee relative to the content of the [commercial] feed on, or with, the package which contains it, and the claim or guarantee is in addition to those required by law, he is responsible for maintaining the claim or guarantee, and may be required to submit to the director information and records pertinent to the claim or guarantee.

14996. Commercial feed manufactured or distributed for feeding to animals on a contract or partnership basis is exempt from the labeling provisions of this chapter if the feeding location is of the same ownership as the feed manufacturing facility. The label information shall be provided by the manufacturer if the information is requested by a party to the contract or partnership or if the commercial feed contains a drug.

ARTICLE 6. STANDARDS AND TOLERANCES [SECTION 15011 – 15011]

15011. The director shall fix the standards for commercial feed ingredients, including drugs, tolerances for agricultural chemicals, and any additives used in the manufacture of the feed, so as to insure the safety of animals and the products of animals which are used for human consumption. The director shall enforce all medicated feed withdrawal periods as set by regulation.

ARTICLE 7. INSPECTION AND ANALYSIS [SECTION 15021 – 15021]

15021. The director, his agents, and his inspectors shall have free access at reasonable times to all premises or conveyances which are used in the manufacture, transportation, importation, distribution, storage, or feeding of any commercial feed. They shall have access to any lot or package which contains or is supposed to contain, any commercial feed, and take samples and analyze them.

ARTICLE 8. MISLABELING [SECTION 15031 – 15031]

15031. A commercial feed is mislabeled in each of the following cases:

(a) Its labeling is false or misleading in any particular.

(b) It is not labeled as required by this chapter.

(c) Any word, statement, or other information required pursuant to this chapter to appear on the label is not prominently placed thereon with such conspicuousness, as compared with other words, statements, designs, or devices in the labeling and in such terms as to render it likely to be read and understood under customary conditions of purchase and use.

ARTICLE 9. ADULTERATION [SECTIONS 15041 – 15042]

15041. A commercial feed is adulterated in the following cases:

(a) It bears or contains any poisonous, deleterious, or nonnutritive substance in amounts which are specified as being unsafe by the director by regulations.

(b) If any valuable constituent has been in whole or in part omitted or abstracted therefrom or any less valuable substance substituted therefor.

(c) Its composition differs from, or quality falls below, that which it is purported or is represented to possess by its labeling.

(d) It contains a drug or drugs or other additive and the methods used in or the facilities or controls used for its manufacture, processing, or packaging do not conform to current good manufacturing practice regulations adopted by the director to assure that the drug or drugs or other additive meets the requirement of this chapter as to safety and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess.

15042. The sale or distribution of any lot, parcel, or package of commercial feed deemed by the secretary to bear or contain a poisonous, deleterious, or nonnutritive substance in amounts that are specified as being unsafe by the secretary by regulation is a violation of this chapter.

ARTICLE 10. LICENSES [SECTIONS 15051 – 15056]

15051. (a) Each person shall obtain a license from the secretary for each location where commercial feed is manufactured, distributed, sold, or stored for later sale. Persons who do not have a permanent place of business, but who otherwise manufacture, sell, or store feed shall also obtain a license from the secretary.

(b) This section also shall apply to a person whenever the person's name and address appears on the label of commercial feed as guarantor.

(c) The following persons are exempt from this section:

(1) A person that makes only retail sales of commercial feed which bear the tag or other approved indication that the commercial feed is from a licensed manufacturer or guarantor who has assumed full tax responsibility for the tonnage tax due under this chapter.

(2) A person who manufactures commercial feed exclusively for feeding to his or her own animals.

15053. (a) Each application for a license shall be accompanied by an annual fee specified by the department for each location. The minimum license fee shall be one hundred dollars ($100) for each location and the maximum license fee for each location shall not exceed six hundred dollars ($600) for each location with the specific fee to be set by the secretary upon recommendation of the board. Those licensees with feed licenses on the effective date of the bill who have previously paid their license fees for the then current fiscal year shall not be subject to any new fees until their licenses are renewed. Beginning January 1, 2031, the license fee shall be one hundred dollars ($100) for each location. Those licensees with feed licenses on that date who have previously paid their license fees for the then current fiscal year shall not be subject to any new license fees until their licenses are renewed.

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(b) Revenues generated from license fees shall be used to replenish feed inspection program reserves to a minimum of 25 percent of program expenditures, after which point some of the revenues from these fees shall be used to reduce feed tonnage taxes provided for in this chapter upon recommendation of the board.

15054. All licenses shall be renewed on July 1 of each year and shall be valid until June 30 of the next year. Each application for renewal shall be accompanied by a fee in an amount specified by the department, pursuant to Section 15053, for each location operated.

15055. If a license is not renewed within one calendar month following its expiration, a penalty of one hundred dollars ($100) shall be added to the fee.

15056. The penalty for the manufacture or distribution of a commercial feed without a valid license as specified in Section 15051 is a violation of this chapter.

ARTICLE 11. INSPECTION TONNAGE TAX [SECTIONS 15061 – 15062]

15061. (a) An inspection tonnage tax at the maximum rate of twenty-five cents ($0.25) per ton of commercial feed sold, except whole grains, and whole hays when unmixed, shall be paid to the secretary by any person who distributes commercial feed to a

consumer-buyer in this state. The distributor shall also pay an inspection tonnage tax for purchased commercial feed fed to the distributor's own animals.

(b) The secretary may, based on a finding and recommendation of the board, determine the specific rate necessary to provide the revenue needed to carry out this chapter. The secretary and the board shall not exceed the maximum tonnage rate established by this section. The setting of the tonnage tax rate shall not be subject to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

15061.1. (a) The secretary may, based on a finding and recommendation of the board, designate 15 percent of the tonnage taxes collected pursuant to Section 15061, or two hundred thousand dollars ($200,000), whichever amount is greater, to provide funding for research and education regarding the safe manufacture, distribution, and use of commercial feed. These funds may only be spent on activities approved by the board, with approval being made before any expenditure.

(b) This section shall remain in effect only until January 1, 2031, and as of that date is repealed.

15062. Every person subject to payment of the inspection tonnage tax shall make reports and payments in the manner prescribed by the director by regulation.

If payment is delinquent, a penalty of 15 percent of the amount past due shall be charged. For payments more than 12 months delinquent, an additional penalty of 1 percent per month of the amount past due shall be charged. The secretary shall set a penalty fee, as necessary to cover administrative costs, for any delinquency in making a report.

ARTICLE 12. VIOLATIONS [SECTIONS 15071 – 15082]

15071. (a) The secretary may, after a hearing, refuse to issue or renew, or may suspend or revoke, a license for any violation of this chapter or any regulation that is adopted pursuant to this chapter.

(b) A person against whom a licensing action is initiated may appeal to the secretary by requesting a hearing. If a hearing is not requested, the licensing action shall constitute a final and nonreviewable order.

(c) An appeal pursuant to this section shall be submitted in accordance with subdivision (d) of Section 15071.1 and with Section 1094.5 of the Code of Civil Procedure.

15071.1. (a) The department shall levy an administrative penalty against a person who violates this chapter or the regulations adopted pursuant to this chapter in an amount of not more than five thousand dollars ($5,000) for the first violation and not less than five thousand dollars ($5,000) for each subsequent violation. The department may consider the severity, intent, and repeat nature of violations in issuing penalties. The department shall base the amount of the penalty assessed for each violation upon the nature of the violation, the seriousness of the effect of the violation upon the effectuation of the purposes and provisions of this chapter, and the impact of the penalty on the violator, including the deterrent effect on future violations.

(b) The secretary may issue a notice of warning, in lieu of an administrative penalty, upon a finding that the violation is minor or unintentional.

(c) A person against whom an administrative penalty is levied shall be afforded an opportunity for a hearing before the secretary, upon a request made within 30 days after the date of issuance of the notice of penalty. At the hearing, the person shall be given the right to present evidence on the person's own behalf. If a hearing is not requested, the administrative penalty shall constitute a final and nonreviewable order.

(d) If a hearing is held, review of the decision of the secretary may be sought by the person against whom the administrative penalty is levied within 30 days of the date of the final order of the secretary pursuant to Section 1094.5 of the Code of Civil Procedure.

(e) After completion of the hearing procedure pursuant to subdivision (c), the secretary may file a certified copy of the department's final decision that directs payment of an administrative penalty, and if applicable, any order denying a petition for a writ of administrative mandamus, with the clerk of the superior court of any county that has jurisdiction over the matter. Judgment shall be entered immediately by the clerk in conformity with the decision or order. Pursuant to Section 6103 of the Government Code, the clerk of the superior court shall not charge a fee for the performance of any official service required in connection with the entry of judgment pursuant to this section.

(f) Any funds recovered by the secretary pursuant to this section shall be deposited in a special account in the Department of Food and Agriculture Fund, and, notwithstanding Section 13340 of the Government Code, are continuously appropriated to the department to cover costs related to the enforcement of this chapter.

15071.3. (a) The department shall be entitled to receive reimbursement from any person who is found in violation of this chapter for any reasonable attorney's fees and other related costs, including, but not limited to, investigative costs, involved in enforcement of this chapter.

(b) The department shall use all funds received pursuant to this chapter for the purposes of this chapter.

15071.4. The procedures for the issuance of citations and penalties shall be prescribed in a citations policy adopted by the secretary, notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, upon the recommendation of the board.

15071.5. In lieu of any other penalty provided by this chapter, the secretary may initiate a proceeding for the issuance of a civil penalty.

15072. It is unlawful for any person to manufacture or distribute in this state any commercial feed without complying with the provisions of this chapter and the regulations which are adopted pursuant to it.

15072.5. It is unlawful for any person to use any commercial feed containing drugs or food additives except in compliance with all directions for use stated on any tag or label affixed to or accompanying the commercial feed.

15073. The director may seize and hold any lot of commercial feed which he has reasonable cause to believe is in violation of the provisions of this chapter or the regulations adopted pursuant to it.

15074. If the director seizes any lot of commercial feed, he shall immediately issue to the person that has control of such feed a hold order or notice. He may affix to the lot or package of such feed a warning tag which states that the lot is so held.

15075. (a) Any lot of commercial feed for which a hold order or notice is issued shall be held by the person having control of the feed and shall not be disturbed or moved except under the specific directions of the secretary pending final disposition pursuant to this chapter. This restriction does not prevent the person having control of the feed from inspecting any feed so seized, nor from taking therefrom, in the presence of a person designated by the secretary, a reasonable sample for evidence.

(b) The movement, distribution, or sale of all or part of any lot, parcel, or package of commercial feed that has been quarantined by the secretary, unless the movement has the prior approval of the secretary, is a violation of this chapter.

15076. Any lot of commercial feed which is seized and held pursuant to this chapter, unless previously analyzed by the director, shall be sampled and promptly analyzed within a reasonable period of time, as set by the director by regulation, after the seizure for the purpose of determining if such commercial feed is, in fact, in violation of the provisions of this chapter or the regulations adopted pursuant to it. The person having control of the feed shall be immediately notified by the director as to whether or not the sample was found to be in violation. If the results of analysis are not made known to the person having control of the feed within the period of time specified by the director by regulation, the lot of commercial feed being held shall be immediately released and the hold order or tag removed.

15077. Upon demand of the person having control of the seized feed and within 10 days of sampling by the director, a subsample shall be returned from the state laboratory to the person in control of the feed.

15078. If the seized and held lot, as determined by the director’s analysis, is not in violation, the director shall immediately release the seized and held lot and remove the hold order or tag.

15079. If the seized and held lot is found to be in violation, the director shall either:

(a) Continue to hold the lot until such time as the requirements of this chapter have been complied with, at which time the lot shall be released.

(b) Issue orders for the disposal of the lot in a manner specified by the director.

15080. The manufacturer or guarantor of a seized or held lot found to be in violation may appeal the result of analysis to the secretary in writing within 10 days of receiving the notice of violation. Upon receipt of the appeal, the secretary shall perform an additional analysis of the official sample representing the lot in question. The cost of analysis shall be at the expense of the person that requests the appeal. The findings from the appeal analysis are final.

15082. (a) It is unlawful for any person to manufacture or distribute in this state any commercial feed without complying with this chapter or any regulations adopted pursuant to this chapter.

(b) It is unlawful for any person to adulterate, misbrand, or alter any commercial feed with the result that the feed would be inconsistent with the label claims.

(c) The secretary may prohibit any person found in violation of subdivision (b) or Section 15076 from obtaining a license to sell feed for three years.

ARTICLE 13. PROCEDURE FOR PROSECUTION [SECTIONS 15091 – 15092]

15091. In addition to the remedies provided in this chapter, the department may bring an action in superior court and the court may grant a temporary or permanent injunction restraining any person from violating this chapter or the regulations adopted pursuant to this chapter. Any proceeding under the provisions of this section shall conform to the requirements of Chapter 3 (commencing with Section 525) of Title 7 of Part 2 of the Code of Civil Procedure. The department shall not, however, be required to allege facts necessary to show irreparable damage or loss. The court may require such acts or course of conduct as necessary to effectuate the purpose of this chapter.

15092. Nothing in this chapter requires the secretary to report for prosecution or to institute injunction proceedings for any minor violation of this chapter whenever the public interest would be adequately served by a suitable written notice of warning, and compliance with the notice.

ARTICLE 14. COMPLAINTS [SECTIONS 15101 – 15103]

15101. For purposes of this chapter, any person may file a complaint with the branch regarding the safety of whole hays if he or she submits a written complaint and pays a filing fee of two hundred fifty dollars ($250). The filing fee, which shall be used for purposes of investigating complaints filed pursuant to this article, shall be deposited in the Department of Food and Agriculture Fund to the account of the Commercial Feed Inspection Program.

15102. (a) Upon the filing of a complaint pursuant to Section 15101, the secretary shall conduct an investigation with regard to the safety of whole hays.

(b) Absent the filing of a complaint pursuant to Section 15101, the secretary may conduct an investigation with regard to the safety of whole hays if he or she determines that an investigation is necessary in order to protect animal health or the health of the public.

15103. (a) If the secretary determines that the complaint is valid and the hay is unsafe, the secretary may require the seller of the hay to reimburse the filing fee to the person filing the complaint.

(b) The secretary also may collect from any seller of hay the costs incurred by the secretary, not to exceed two thousand five hundred dollars ($2,500), in conducting any investigation regarding the safety of whole hay sold by that seller if the hay is ultimately deemed to be unsafe.

CALIFORNIA CODE OF REGULATIONS

TITLE 3. FOOD AND AGRICULTURE,
DIVISION 4. PLANT INDUSTRY,
CHAPTER 2. FIELD CROPS,
SUBCHAPTER 2. COMMERCIAL FEED [2675 - 2811]

ARTICLE 1. DEFINITIONS AND GENERAL PROVISIONS

§2675. Definitions.

Unless otherwise apparent from the context, the following definitions apply to this subchapter:

(a) “Mineral feed” means a commercial feed intended to supply primarily mineral elements or inorganic nutrients for animal nutrition.

(b) “Official sample” means a sample of commercial feed taken by the secretary or his agent for regulatory purposes.

(c) “Process” means any treatment that changes a feed ingredient so that it can no longer be restored to its previous form.

(d) “Recognized official name” means those official common or usual feed ingredient names defined in Article 14 of this subchapter, provided that the common English name shall be used for common foods.

(e) “Food additive” has the same meaning as defined in the Food, Drug and Cosmetics Act 21, United States Code, section 321(s).

(f) “Sell” includes offer for sale, expose for sale, possess for sale, exchange, barter, or trade.

(g) “Inert material” means ingredients that are not assimilated in the digestive process, including but not limited to sand, granite grit, charcoal and clay.

(h) “Prohibited Mammalian Tissue” is any protein-containing portion of mammalian animals, excluding: blood and blood products, gelatin, inspected meat products which have been cooked and offered for human food and further heat processed for feed (such as plate waste and used cellulosic food casings), milk products (milk and milk proteins), and any product whose only mammalian protein consists entirely of porcine or equine protein; or any material specified in Title 21, Code of Federal Regulations (CFR) Parts 589.2000 and 589.2001, April 1, 2022, hereby incorporated by reference.

(i) “Aflatoxins” means aflatoxin B_1, aflatoxin B_2, aflatoxin G_1 and aflatoxin G_2, collectively.

(j) "By-product" means a product produced in addition to the principal product, may be produced during processing, rejected as inferior during the process of grading or separating, or is produced via an industrial or biological process.

(k) “Manufacturing/processing” means making animal food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating animal food, including food crops or ingredients. Examples of manufacturing/processing activities

include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, extruding, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, pelleting, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

(l) "Bulk" means commercial feed distributed in nonpackaged form or in a container containing more than 50 kilograms or 110 pounds.

(m) "Packaged" means commercial feed distributed in packaged form or in a container containing equal to or less than 50 kilograms or 110 pounds.

(n) "Mixed feed" has the same meaning as formula feed as defined under Food and Agricultural Code Section 14930.

(o) “Custom formula feed” means:

(1) Special mix as defined under Food and Agricultural Code Section 14938, or

(2) Any commercial feed which is manufactured, processed, or mixed pursuant to specifications which are agreed upon by the purchaser’s nutritionist and the manufacturer.

(p) “Complete feed” means a nutritionally adequate commercial feed for animals other than man. By specific formula, it is compounded to be fed as the sole ration and is capable of maintaining life and/or promoting production without any additional substance being consumed except water.

(q) “Low nutrition ingredients” means ingredients that are not well assimilated in the digestive tract and/or provide minimal energy and nutrition to the animal. They contain (on a dry matter basis) less than seven percent crude protein and greater than 50 percent acid detergent fiber including, but not limited to rice hulls, almond shell, cottonseed hulls, sunflower hulls, and wheat straw.

(r) “Premix” means a concentrated uniform mixture of one or more micro-ingredients, such as vitamins and minerals, and diluent and/or carrier which must be diluted through further manufacturing prior to feeding. Premixes are used to facilitate uniform dispersion of the micro-ingredients in a large mix.

(s) “Common foods” are commercially available and suitable for use in animal food but are not defined, including but not limited to certain whole seeds, vegetables, or fruits. Common food for animals may include common human foods that are known to be safe for the intended use in animal food. Manufacturers are responsible for determining whether a common food is safe and has utility for its intended use prior to commercial distribution as animal food.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14925, 14930, 14938, 14991, 14992(e), 15011 and 15042, Food and Agricultural Code.

§2675.1. General Provisions.

(a) All by-products used in commercial feed must adhere to the following:

(1) Must not bear or contain any substance which may render it injurious to health.

(2) Must be held under conditions that will protect against contamination, including the following:

(A) Containers and equipment used to convey or hold by-products before distribution must be designed, constructed of appropriate material, cleaned as necessary, and maintained to protect against the contamination of by-products;

(B) By-products held for distribution must be held in a way to protect against contamination from sources such as trash; and

(C) During holding, by-products must be accurately identified.

(3) Shipping containers and bulk vehicles used to distribute by-products must be examined prior to use to protect against the contamination of commercial feed from the container or vehicle when the facility is responsible for transporting the byproducts itself or arranges with a third party to transport the by-products.

(b) The manufacture, distribution and use of commercial feed shall comply with the requirements of Title 21, Code of Federal Regulations, Part 507, Subparts A, B, C, E, and F, April 1, 2022. The enumerated subparts, only as they pertain to commercial feed, are hereby incorporated by reference. For purposes of this section, the term “animal food” as used in the Code of Federal Regulations shall refer only to commercial feed as defined in Food and Agricultural Code Section 14925. Any requirements applicable to processed, fresh, or frozen pet food are not incorporated.

(c) Pursuant to Food and Agricultural Code Section 15021, it is unlawful for any person to deny the Department free access at reasonable times to all premises or conveyances which are used in the manufacture, transportation, importation, distribution, storage, or feeding of any commercial feed.

(1) “Free access” means access for the purposes of sampling and inspection.

(2) “Reasonable times” means normal business hours, Monday through Friday from 8 AM to 5 PM.

(3) “All premises or conveyances” means any location with commercial feed on-site, regardless of whether the location possesses a commercial feed license.

(d) Pursuant to Food and Agricultural Code Section 14902.1, notwithstanding any other law, any commercial feed, feed additive, or drug approved by the United States Food and Drug Administration (FDA) that is fed to livestock shall be under the oversight of the Department as the primary state regulatory agency, including, but not limited to, products that make environmental and health claims.

(1) For purposes of Chapter 6 (commencing with section 14901) of Division 7 of the Food and Agricultural Code, “approved by the United States Food and Drug Administration (FDA)” means an ingredient, additive, or drug that is listed in the

Code of Federal Regulations (CFR) or that has received a letter from FDA indicating the substance is generally recognized as safe (GRAS). The Secretary may also consider an ingredient, additive, or drug that has completed a safety review by FDA and has received a letter from FDA documenting enforcement discretion, no objection to use or sale, no questions to safety, and/or allowing market access.

Note: Authority cited: Sections 407, 14902, and 14903, Food and Agricultural Code. Reference: Sections 14902.1, 14903, 14925, 14991, 14992, 15011 and 15042, Food and Agricultural Code.

ARTICLE 2. COMMERCIAL FEED CONTAINING DRUGS, FOOD ADDITIVES, OR HARMFUL SUBSTANCES

§2676. Safety and Efficacy of Drugs and Food Additives.

(a) Prior to use or sale of commercial feed containing any additive (including any drug, food additive, or other special purpose additive, or non-nutritive additive) the distributor shall submit evidence to the secretary to show the safety and efficacy of the commercial feed when used according to the directions stated on the label.

(b) In determining whether satisfactory evidence of safety and efficacy is shown, the secretary will consider:

(1) Whether each additive conforms to the requirements of the applicable regulations in Title 21, Code of Federal Regulations, Parts 570, 573 and 582 or are “prior sanctioned” or “generally recognized as safe (GRAS)” for stated uses.

(A) “Prior Sanctioned” is defined in Title 21, Code of Federal Regulations, Part 570.3, as an explicit approval granted with respect to use of a substance in food prior to September 6, 1958, by the Food and Drug Administration or the United States Department of Agriculture pursuant to the Federal Food, Drug and Cosmetic Act, the Poultry Products Inspection Act, or the Meat Inspection Act.

(B) “Generally Recognized as Safe (GRAS)” is defined in Title 21, Code of Federal Regulations, Part 570.3, definition of safe, as a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use, and Part 570.30, where general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food.

(2) Whether the feed itself is a drug as defined in Section 14928 of the Food and Agricultural Code and is generally recognized as safe and effective for the label use, or is approved by the Food and Drug Administration under 21 United States Code 360 b.

(c) Premixes that contain more than 272.4 milligrams per pound (600 parts per million) added selenium shall be maintained by a daily inventory record that includes the following:

(1) The quantity of selenium premixes on hand at the beginning and end of the workday (up to 24 hours).

(2) A daily comparison of the actual amount of selenium premix used, with the theoretical or calculated usage.

(3) Actions taken to reconcile any discrepancies.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14903, 15011, 15031 and 15041, Food and Agricultural Code.

§2677. Unlawful Sale or Use of Poisonous Substances.

It is unlawful to use or sell a commercial feed containing any poisonous or deleterious substance or any substance which when fed in accordance with label directions or when used in accordance with usual feeding practices may impair the health of the animal being fed or result in an illegal or harmful residue or constituent in or on human food.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14903, 15011 and 15041(a), Food and Agricultural Code.

§2678. Unlawful Sale or Use of Material Containing Pesticide Residue.

(a) It is unlawful to sell or use commercial feed which contains pesticide residue or drug residue in excess of the tolerance permitted by regulations of the Food, Drug, and Cosmetic Act, Title 21, Part 556, and Title 40, Part 180, Code of Federal Regulations or tolerances set by the director.

(b) Tolerances established by the director are:

(1) DDT, DDD (TDE), and DDE, total residue: 0.5 part per million in or on commercial feed for animals.

(2) Toxaphene: 2.0 parts per million in or on commercial feed used by dairies for dairy animals; 7.0 parts per million for ruminant meat animal production and equines.

(3) Kelthane (1,1-bis (p-chlorophenyl)-2,2,2-trichloroethanol): 1.5 parts per million in or on commercial feed for ruminant meat animal production and equines.

(4) DEF (S,S,S, Tributyl Phosphorotrithioite), 4 parts per million in or on commercial feed for ruminant meat animal production and equines.

(5) Folex (Tributyl Phosphorotrithioite), 0.25 part per million in or on commercial feed for ruminant meat animal production and equines.

(c) This section does not authorize application of any pesticide.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14903, 15011 and 15041(a), Food and Agricultural Code.

§2679. Fluorine Tolerances.

(a) The fluorine content of any mineral or mineral mixtures to be used directly for feeding shall not exceed 0.20 percent for breeding and dairy cattle; 0.30 percent for slaughter cattle; 0.30 percent for sheep; 0.35 percent for lambs; 0.45 percent for swine; and 0.60 percent for poultry.

(b) Any fluorine bearing ingredients may be used only in such limited amounts in commercial feed so that they will not increase the flurorine content of the total ration, exclusive or roughage, above the following amounts: for breeding and dairy cattle 0.004 percent; for slaughter cattle 0.009 percent; for sheep 0.006 percent; for lambs 0.01 percent; for swine 0.015 percent; and for poultry 0.03 percent.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Section 15011, Food and Agricultural Code.

§2680. Heavy Metals Prohibited.

(a) It is unlawful to sell or use commercial feed which contains a heavy metal; however, the following tolerances are permitted in complete feed: arsenic thirty (30) parts per million (five (5) parts per million for fish), lead ten (10) parts per million, cadmium one-half (0.5) parts per million, and mercury (inorganic) two-tenths (0.2) parts per million.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Section 15011, Food and Agricultural Code.

§2681. Animal Proteins Prohibited in Ruminant Feed.

(a) The manufacture, distribution and use of commercial feed containing protein derived from prohibited mammalian tissues shall comply with the requirements of Title 21, Code of Federal Regulations, Parts 589.2000 and 589.2001, April 1, 2022, hereby incorporated by reference.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14903, 15011 and 15041, Food and Agricultural Code.

ARTICLE 3. CUSTOM FORMULA FEED

§2683. Custom Formula Feed.

(a) On or before the date of the first delivery of a load, each person that manufactures or prepares a custom formula feed for another person shall furnish to the purchaser either a label that meets the conditions of section 2694 or the following information on an invoice or other document furnished to the purchaser:

(1) A numbered invoice or an attached document stating the date of sale and formula number.

(2) A guaranteed analysis stating the following:

(A) Crude Protein, minimum percent.

(B) Equivalent Crude Protein from Non-Protein Nitrogen, maximum (If Present) percent.

(C) Crude Fat, minimum percent.

(D) Crude Fiber, maximum percent.

(E) Ash, maximum percent.

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(F) Maximum percentage of sodium, if more than one-half of one percent (0.5%) of sodium is present.

(G) In the case of any formula feed which contains more than nine percent ash, the minimum and maximum percentage of calcium (Ca), minimum percentage of phosphorus (P) and the maximum percentage of sodium (if present).

(3) The recognized official name and percent or pounds of each ingredient and if any formula feed is used, the percent or pounds of the formula feed.

(4) If a formula feed is used, the label for the formula feed meeting the requirements of section 2694 must be attached to the numbered invoice.

(5) A custom formula feed that contains a drug must be accompanied by all information required in section 2701 with each delivery.

(b) The shipping document that accompanies each subsequent delivery shall provide a label which meets the terms of section 2694, or shall plainly and prominently show the original custom formula feed in the following manner: “Ingredient listings and guarantee of analysis accompanying formula number ( ) applies to this delivery.” The shipping document must also contain the name, address and telephone number of the purchaser. Whenever any change is made in the composition of the custom formula feed the purchaser shall be supplied with a newly numbered formula showing the required information on or before the date of the first delivery. Upon request, the manufacturer must provide the above documentation as required by the director.

(c) The seller shall retain a copy of each formula for one year subject to inspection by the director. No two formulas issued in one calendar year shall bear the same number.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992(e), 14993 and 14994, Food and Agricultural Code.

§2684. Bulk Sale.

(a) The net weight of any custom formula feed which is sold in bulk shall be affirmed by a weighmaster's certificate of weight and measure.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Section 14993, Food and Agricultural Code.

§2685. Packaged Sale.

(a) If packaged, each package of a custom formula feed shall have attached to it a label with all the information required in Section 2683.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14991, 14992 and 14993, Food and Agricultural Code.

§2686. Resale.

(a) It is unlawful to resell a custom formula feed unless properly labeled to meet the requirements of this subchapter.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14991 and 14994, Food and Agricultural Code.

ARTICLE 4. LABELING AND USE REQUIREMENTS

§2688. Required Use of Recognized Official Names.

(a) The official name of each ingredient in reference to commercial feed in labeling and advertising shall be from the recognized official names found in Article 14.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14991 and 14992(e), Food and Agricultural Code.

§2689. Classification of Ingredients.

The director will examine all ingredients used in feed on the basis of materials, label and advertising claims, and generally accepted usage, and determine whether each is a drug, food additive, special purpose additive or nutritional ingredient.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14991 and 14992(e), Food and Agricultural Code.

§2690. Specificity of Directions.

The director may disapprove directions which are incapable of being followed, or are unlikely to be followed in usual feeding practices.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14991 and 14992(f), Food and Agricultural Code.

§2692. Inert Materials.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14991, 14992(d) and 15011, Food and Agricultural Code.

§2693. Complete Label Required.

Each lot or parcel of commercial feed shall bear a complete label as required by sections 14991 and 14992 of the Food and Agricultural Code. Any supplemental representation of the commercial feed, whether or not attached to the label, must correspond fully with the information stated on the label and apply to the complete feed.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14991 and 14992, Food and Agricultural Code.

§2694. Label Statements.

The tag or label shall contain a legible and plainly printed statement which certifies to all of the following:

(a) Minimum percent of crude protein.

(1) Commercial feeds containing non-protein nitrogen must be labeled in accordance with Section 2707.

(b) Minimum percent of crude fat.

(c) Maximum percent of crude fiber.

(d) Maximum percent of ash.

(1) Guarantees for the minimum and maximum percentage calcium, minimum percentage phosphorus, and maximum percentage of sodium or salt may be stated in lieu of the ash guarantee.

(2) In the case of any formula feed which contains more than nine (9.0) percent ash, the minimum and maximum percentage of calcium, minimum percentage of phosphorus and maximum percentage of sodium shall be guaranteed, if added. Salt maximum percent guaranteed is acceptable in lieu of sodium.

(e) All guarantees shall be on an “as-fed” (as-is) basis, and not represented on a 100 percent dry matter basis.

(f) Recognized official name of each ingredient in order of decreasing amounts present. The name of each ingredient shall appear in the same size, style and color and shall not be misleading. The use of collective terms, other than those identified under Section 2778, is prohibited.

(g)(1) A single ingredient product using the official name defined in Article 14, Definitions and Standards, is not required to have an ingredient statement.

(2) The labeling for a single ingredient shall contain guarantees required by this section and the minimum and/or maximum specifications included in the product definition in Article 14, Definitions and Standards.

(3) A single ingredient is not required to guarantee maximum percentage of ash unless it is specified by definition in Article 14.

(h) Maximum percentage of low nutrition ingredients in a formula feed if they singly or collectively make up more than one percent.

(i) Trademarked products can be contained in the ingredient listing in parentheses with the ingredients in the product listed in decreasing amounts present.

(j) Inert materials contained in a formula feed shall be guaranteed if they singly or collectively make up more than one percent.

(k) Maximum percentage of sodium, if more than 0.5 percent of sodium is present. Salt maximum percent guaranteed is acceptable in lieu of sodium.

(l) Numerical value shall be guaranteed for any special quality claimed, including vitamin potency, amino acid content or special mineral content.

(m) Maximum percentage of moisture or minimum percentage dry matter shall be guaranteed when moisture exceeds 15.0 percent.

(n) Vitamins shall be guaranteed in the terms specified in section 2702. Guarantees for vitamins are not required when commercial feed is neither formulated for nor represented in any manner as a vitamin supplement.

(o) Any ingredient that is used as a carrier for vitamin, medicated or mineral premixes, may be omitted from the label and substituted with the collective term “roughage products,” if the premix makes up one percent or less of the formula feed. The term “roughage products” may be omitted from the formula feed listing of ingredients.

(p) Additional guarantees must be measurable by an analytical method approved by the Secretary.

(q) Commercial feeds containing added selenium must be labeled in accordance with section 2697 (Labeling for Special Purposes).

(r) Each batch or production run of formula feed shall be identified with its own individual batch or production run number, code, date, or other suitable identification. Bulk feed shall have this information stated on the label, invoice, or shipping document. Sacked or packaged feed shall have the lot number applied to the label, sack or package. This identification shall be adequate to facilitate the tracing of the complete manufacturing and distribution history of the product.

(s) Any feed ingredients which exceed the maximum moisture as specified in their recognized official name as defined in Article 14 and are safe and suitable commercial feed that is not damaged or adulterated, must be labeled as "high moisture [recognized official name]".

Note: Authority cited: Sections 407, 14902, 14903, and 14992, Food and Agricultural Code. Reference: Sections 14903, 14992, 15011 and 15042, Food and Agricultural Code.

§2696. Guarantees.

(a) All guarantees shall apply to the whole feed rather than any single ingredient, except as required in section 2683, and shall be based on a recognized laboratory method of determination.

(b) Misleading and indefinite statements concerning ingredients and value of ingredients of the feed are prohibited. Included within this prohibition is the use of such terms as “better,” “high,” “increased,” “greater,” “low,” “decreased,” and “less.”

(c) All guarantees shall be stated in percent unless expressly provided to the contrary as required by sections 2683 and 2702.

(d) All guarantees stated on the label shall accurately represent the composition and/or quality of the commercial feed.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Section 14992(d), Food and Agricultural Code.

§2697. Labeling for Special Purposes.

(a) Each delivery of commercial feed, other than a custom formula feed, shall be accompanied by a label containing the information required by section 2694.

(b) The guarantees required by section 2694 may be replaced with guarantees pertinent to special purpose commercial feeds and feed ingredients when the feed is sold

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primarily for drug, mineral, or vitamin content; or when the commercial feed is a single ingredient labeled in accordance with the definition provided in Article 14.

(c) Premixes processed by a manufacturer for use in commercial feed shall be identified. These products are subject to inspection, and shall conform to the definitions and standards which apply to the product or the claims made.

(d) Commercial feeds containing more than 0.3 parts per million (ppm) added selenium shall include the following on the label:

(1) A guaranteed analysis statement for the minimum and the maximum parts per million (ppm) of selenium.

(2) Feeding and/or mixing instructions that bear adequate directions for the safe and permitted use of a feed containing added selenium, including the maximum permitted levels of use for a specific species.

(3) The statement “Caution: Follow label directions: Feeding added selenium at levels in excess of 0.3 ppm in the total diet is prohibited.”

(e) Computer generated labels may be used provided all labeling requirements are met.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14903, 14993, 15011 and 15041, Food and Agricultural Code.

§2698. Labeling Liquid Feed.

All liquid feed supplements shall be labeled in accordance with the requirements found in Section 2694. In addition, the label shall include the minimum percentage of total sugar expressed as invert and maximum percentage of moisture or the minimum percentage of dry matter. Guarantees for crude fat or crude fiber are not required in liquid feed when there is less than one percent of either constituent.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14991, 14992 and 14993, Food and Agricultural Code.

ARTICLE 5. COMMERCIAL FEEDS CONTAINING DRUGS AND SPECIAL PROVISIONS

§2700. Use of Drugs in Commercial Feed.

All feeds containing drugs and food additives shall comply with the requirements of Title 21, Code of Federal Regulations, Parts 225, 558, 570, 573 and 582.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14903, 15011, 15031 and 15041, Food and Agricultural Code.

§2701. Labeling of Medicated Feeds.

(a) Without exception, each delivery of medicated feed must be accompanied by a label, invoice or delivery document stating in a prominent manner:

(1) The name and quantity of each drug and active ingredient.

(2) The purpose of each drug and active ingredient.

(3) The term “MEDICATED” prominently displayed immediately above or below the name of the feed.

(4) Adequate directions for use.

(5) Warnings against use of the feed under contra-indicated conditions, including danger to the health of the animal, and warnings against use of the animal or its products for particular purposes when necessary.

(6) Withdrawal warnings where necessary to assure compliance with residue limitations imposed by regulation.

(7) Each batch or production run of medicated feed shall be identified with its own individual batch or production run number, code, date or other suitable identification. Bulk feed shall have this information stated on the label, invoice or delivery document. Sacked or packaged feed shall have the lot number applied to the label, sack or package. This identification shall be adequate to facilitate the tracing of the complete manufacturing and distribution history of the product.

(b) It is unlawful to use any medicated feed except in compliance with all directions on the label, invoice or delivery document.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14903, 14992(f), 15011, and 15073, Food and Agricultural Code.

§2702. Drug and Food Additive Guarantees.

Drugs and food additives in commercial feed shall be guaranteed in percentage except:

(a) Drugs, where the statement of dosage is in milligrams, shall be guaranteed in milligrams per pound.

(b) Antibiotics shall be guaranteed in milligrams per pound, except as required by subsection (c).

(c) Commercial feed containing antibiotics in amounts less than 2,000 grams per ton of feed shall be labeled to show the grams of antibiotic per ton; or if present in amounts more than 2,000 grams per ton shall be labeled to show the grams of antibiotic per pound of feed.

(d) Vitamin A shall be guaranteed in International Units (I.U.) per pound.

(e) Vitamin D shall be stated in International Units (I.U.) per pound.

(f) Vitamin E shall be guaranteed in International Units (I.U.) per pound.

(g) All other vitamins shall be guaranteed in milligrams per pound.

(h) All guarantees for vitamin content shall be stated as true vitamins, not compounds. Vitamin K shall be guaranteed as Menadione. The actual form of the vitamin added may be stated as the true vitamin (examples include D-Activated Animal Sterol, Vitamin A Acetate, A-Tocopherol Acetate) or as other commonly recognized terms (examples include Vitamin D_3 Supplement, Vitamin A Supplement, Vitamin E Supplement).

(i) When stated, guarantees for minimum and maximum total sodium and salt; minimum potassium, magnesium, sulfur, and phosphorous; and maximum fluorine shall be in terms of percentage. Other minimum mineral guarantees shall be stated in parts per million (ppm) when the concentration is less than 10,000 ppm and in percentage when the concentration is 10,000 ppm (one percent) or greater.

(j) Products labeled with a quantity statement (e.g., tablets, capsules, granules) may state mineral and vitamin guarantees in milligrams per unit consistent with the quantity statement and directions for use.

(k) Guarantees for lysine, methionine and other amino acids shall be in terms of percentage.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14903, 14991 and 14992(e), Food and Agricultural Code.

§2703. Net Weight Statement.

The net weight statement on the label shall comply with requirements of Division 5 of the Business and Professions Code.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Section 14992(a), Food and Agricultural Code.

§2707. Use of Non-Protein Nitrogen Products.

(a) Ingredient sources of non-protein nitrogen such as Urea, DiAmmonium Phosphate, Ammonium Polyphosphate Solution, Ammonium Sulfate, or other basic non-protein nitrogen ingredients defined by regulation shall be guaranteed as follows:

(1) Minimum percentage of Nitrogen.

(2) Minimum percentage of Equivalent Crude Protein from Non-Protein Nitrogen.

(b) Formula feed containing non-protein nitrogen products shall be labeled as follows: The maximum percent of equivalent crude protein from non-protein nitrogen shall appear immediately below the guarantee for the minimum percent of crude protein.

(c) If the commercial feed, including liquid feed, contains more than 8.75 percent equivalent crude protein from all forms of non-protein nitrogen, or if the equivalent crude protein from all forms of non-protein nitrogen exceeds one-third of the total crude protein, the label shall bear a warning statement followed by feeding directions for the safe use of the feed. The warning statement shall be in prominent bold type against a contrasting background.

WARNING EXCESSIVE CONSUMPTION MAY RESULT IN ADVERSE TOXIC REACTION USE ONLY AS DIRECTED

(d) Directions for use must be stated in a manner that when followed correctly will prevent toxic reaction from over-consumption. The directions shall include the following: Consumption should be carefully controlled until animals become adjusted to the feed. Additional care should be exercised with starved, stressed or debilitated animals.

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Recommended daily intake levels shall be given, as well as the statement that all manufacturer's directions for use must be followed carefully.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992(d) and (f), Food and Agricultural Code.

§2708. Vitamin Premixes.

All vitamin premixes shall be labeled to show all vitamin potencies in terms described in Section 2702. The carrier shall be stated, if the premix is to make up more than one percent of the total ration; otherwise, the collective term “roughage products” may be used. When mineral compounds are present they shall be listed and guaranteed in percent of the elemental form. Premixes carrying drugs shall be labeled in conformity with Section 2701. The label shall include a statement showing the date manufactured.

Note: Authority cited: Sections 407, 14902 and 14992, Food and Agricultural Code. Reference: Sections 14991 and 14992(e), Food and Agricultural Code.

ARTICLE 6. ADVERTISING

§2712. Misleading Advertising Prohibited.

No printed, written, or advertising matter concerning commercial feed shall contain any statement, design, or device which is false, or misleading.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Section 15031, Food and Agricultural Code.

ARTICLE 7. REPORTS OF INSPECTION AND ANALYSIS

§2717. Reports of Inspection and Analysis.

(a) When an official sample has been taken and the analysis made, all financially interested parties shall be supplied with a copy of the report of inspection and analysis.

(b) If the analysis of an official sample shows that a lot of commercial feed has been sold or offered for sale in violation of any requirement of law or regulation, the report of inspection and analysis shall state the violations found.

(c) Reports of inspection and analysis apply only to the specific lot represented by the sample.

(d) Subsamples shall be provided to financially interested parties upon request after laboratory analysis by the Department, with the condition that the requesting party agrees to provide analytical results of the subsample to the Department within 30 days of receipt. If results are not provided within 30 days of receipt, the Department shall refuse future subsample requests.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14902, 15021, and 15076, Food and Agricultural Code.

§2719. Use of Reports in Advertising Prohibited.

It is unlawful to use the name of the Department of Food and Agriculture or any of its employees or any reference to a report of inspection and analysis made by the Department in connection with any advertising of commercial feed.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Section 14902, Food and Agricultural Code.

ARTICLE 8. CONTAINERS

§2725. Reuse of Containers.

Containers used in the manufacture, distribution and sale of commercial feed shall be suitable for the intended use, sanitized when necessary and cleaned after use, when necessary, to prevent contamination or adulteration of the product.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Section 14902, Food and Agricultural Code.

ARTICLE 9. MISBRANDING ADULTERATION

§2733. Misbranding.

A commercial feed shall be deemed to be misbranded:

(a) If it is distributed under the name of another commercial feed.

(b) If it purports to be or is represented as a commercial feed, or if it purports to contain or is represented as containing a feed ingredient or ingredients, unless the commercial feed or feed ingredients conform to the definitions prescribed in this subchapter.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Section 15031, Food and Agricultural Code.

§2734. Adulteration.

(a) A commercial feed shall be deemed to be adulterated:

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such commercial feed shall not be considered adulterated under this subsection if the quantity of such substance in such commercial feed does not render it injurious to health; or

(2) If it bears or contains any added poisonous, added deleterious, or added nonnutritive substance which is unsafe within the meaning of section 406 of the Federal Food, Drug, and Cosmetic Act (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; or (ii) a food additive); or

(3) If it is, or it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act; or

(4) If it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408(a) of the Federal Food, Drug, and Cosmetic Act: Provided, that where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance

prescribed under section 408 of the Federal Food, Drug, and Cosmetic Act and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed feed shall not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed feed is not greater than the tolerance prescribed for the raw agricultural commodity unless the feeding of such processed feed will result or is likely to result in a pesticide residue in the edible product of the animal, which is unsafe within the meaning of section 408(a) of the Federal Food, Drug, and Cosmetic Act.

(5) If it is, or it bears or contains any color additive which is unsafe within the meaning of section 721 of the Federal Food, Drug and Cosmetic Act.

(6) If it contains more than 20 parts per billion aflatoxins.

(b) The use or intended use in ruminant feed of any material that contains protein derived from prohibited mammalian tissues causes the feed to be adulterated and in violation of the Food and Agricultural Code.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 15011 and 15041, Food and Agricultural Code.

§2735. Supplemental Cottonseed Product Controls.

(a) This section supplements the control of cottonseed products to ensure that these products meet the tolerance for aflatoxins, established in Section 2734(a)(6).

(b) Each lot, or truck, railcar, ship, barge, container, air transport, or any other means of transportation of cottonseed products originating outside of California, as a condition of entry into California, shall be accompanied by the following:

(1) A completed form furnished by the secretary (Certificate of Movement of Cottonseed Products, Rev. 12-09), incorporated by reference, stating the origin and destination of the cottonseed products.

(2) An analysis certificate reporting the results of sampling and laboratory testing for aflatoxins, showing compliance with the aflatoxins tolerances stated in Section 2734(a)(6), the name of the testing laboratory, and the testing laboratory report number representing the lot of cottonseed products identified on the certificate.

(3) A label with guaranteed analyses that complies with Section 2694 and Section 2780.

(c) Shipment of cottonseed products which do not meet the tolerance for aflatoxins established in Section 2734(a)(6) shall be refused entry into California, except for entry for transportation to a site operating under authority of the secretary for aflatoxin detoxification or oil extraction, with the exception of products intended for export or non-feed usage.

(d) Documentation for all shipments, originating outside of California, by railcar, truck, ship, barge, container, or air transportation, with the exception of products intended for export or non-feed usage, shall be submitted to the Department on or before the

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shipment date and documents shall be affixed to, or accompany the lot to the purchaser. All truck shipments shall submit to inspection at California border stations and a copy of all required documentation shall accompany the lot to the purchaser. Failure to obtain such document inspection, or diversion after document inspection, shall be grounds for seizure and quarantine of the shipment.

(e) Cottonseed products originating in Riverside and Imperial counties of California shall move only to a detoxification or oil extraction site approved by the secretary, unless the products are certified by laboratory testing showing that the product is within the tolerance for aflatoxins established in Section 2734(a)(6). Such laboratory certifications shall be affixed to or accompany the lot to the purchaser.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 15041, 15071, 15071.5, 15072 and 15073, Food and Agricultural Code.

ARTICLE 10. REMOVAL FROM SALE

§2746. Removal from Sale.

(a) The results of analysis determining whether the seized commercial feed is in violation of law shall be made known to the person having control of the feed within 5 working days.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Section 15076, Food and Agricultural Code.

ARTICLE 11. INSPECTION TAX AND PLANT LICENSES

§2750. Tax Payment.

(a) The inspection tonnage tax on packaged commercial feed sold or distributed in California shall be paid by the licensee whose name appears on the label as the manufacturer, guarantor, or distributor. The inspection tonnage tax on bulk commercial feed sold or distributed in California shall be paid by the last licensee selling or distributing the commercial feed to a consumer buyer.

(b) Reports of taxable sales shall be made quarterly to the director not later than one calendar month after March 31, June 30, September 30, and December 31 on a form furnished by the director. Quarterly reports and payments become delinquent on May 1, August 1, November 1, and February 1, for the respective preceding quarter.

(1) Delinquent reports shall be subject to the following late fees based on the amount of tonnage sold or distributed during the quarter.

(A) Delinquent reports for zero tons sold or distributed shall be subject to a late fee of $100.

(B) Delinquent reports for less than 10,000 tons sold or distributed shall be subject to a late fee of $200.

(C) Delinquent reports for greater than or equal to 10,000 tons sold or distributed shall be subject to a late fee of $500

(2) Delinquent payments shall be subject to a late fee of 15 percent of the amount

past due. Payments more than 12 months delinquent shall be assessed an additional late fee of one percent per month of the amount past due.

(c) A completed tax report must be filed for each quarter whether or not taxable sales have been made in that period.

(d) Each licensee shall keep accurate records of sales of commercial feed which shall be available for examination by the director and shall include the date of sale, to whom sold, the name and net weight of the product sold. The records shall be maintained to support the reports for the previous three (3) years.

(e) Eligible human food by-products that are diverted to animal feed without further manufacturing/processing beyond what is stated in the ingredient definition are subject to reduced inspection tonnage tax set by the Secretary. Firms shall be exempt from paying inspection tonnage tax on the first one thousand (1,000) tons of human food by-products diverted to animal feed during the license period as defined in Section 15054 of the Food and Agricultural Code.

(1) Eligible human food by-products include the following recognized official names of ingredients as defined in Article 14 of this subchapter:

(A) Brewers Products: Brewers Wet Grains and Brewers Liquid Yeast.

(B) Human Food By-products: Cereal Food Fines, Cull Fruit or Vegetables, Dried Bakery Product, Wet Food Processing Waste, Restaurant Food Waste, and Recovered Retail Food.

(C) Milk Products: Condensed Whey Permeate, Condensed Whey Product, Condensed Delactosed Whey Permeate, Dairy Food By-products, and Whey.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 15061 and 15062, Food and Agricultural Code.

§2751. Licensing.

(a) Exemptions from license requirements provided in Section 15051 of the Food and Agricultural Code shall apply only to retail stores selling bagged or packaged commercial feed labeled by a licensed feed manufacturer.

(b) Beginning July 1, 2015, the annual commercial feed license fee shall be five hundred dollars ($500.00) for each location.

(c) The annual commercial feed license fee for firms solely engaged in the diversion of eligible human food by-products specified under Section 2750(e)(1) without further manufacturing/processing beyond what is stated in the ingredient definition shall be one hundred dollars ($100.00) for each location.

(d) The commercial feed license fee is non-refundable and shall not be reduced to cover a fraction of a year.

(e) If a license is not renewed within one calendar month following its expiration, a late fee of one hundred dollars ($100) shall be added to the fee. To renew an expired license, a licensee shall be required to pay all past due license fees, tonnage tax, and

applicable late fees for each year the licensee conducted commercial feed business with an expired license.

(f) A commercial feed licensee shall notify the Department within thirty (30) calendar days if any of the information provided on the license application or renewal changes after the license is issued.

(g) The Department shall send any notices to the address provided on the license application, renewal or provided to the Department pursuant to (f), whichever is most current. Any notices issued shall be considered effective, even if delivery is refused or if the notice is not accepted at the address provided.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 15051, 15053, and 15055, Food and Agricultural Code.

ARTICLE 12. DAMAGED FEED

§2760. Damaged Feed.

(a) Damaged feed shall be deemed adulterated and unlawful for sale except under permit of the director. Feed shall be deemed damaged when it or any ingredient has been affected by smoke, heat, water, mold, or contamination by any foreign substance to such an extent as to affect the nutritive value, therapeutic value, palatability, or wholesomeness of the feed.

(b) Any person in possession of damaged feed shall notify the director as soon as practicable after the event causing the damage and shall withhold use of the damaged feed until approved by the director. Within 5 working days of receipt of notification, except in emergency conditions, the director will make such inquiry and tests as he deems necessary, or may require the person in possession to demonstrate the extent of damage by sampling, testing, and other procedures as the director deems necessary.

(c) If the director determines that the damaged feed is suitable for use as commercial feed without restriction, he shall so notify the person in possession. Such feed shall not be deemed adulterated.

(d) If the director finds that the damaged feed should be permitted to be used only upon certain conditions, including reconditioning and special labeling, he may issue a permit to the person in possession for such use, requiring such conditions to be met, and may require protective controls and reports as he deems necessary.

(e) If the director determines that the feed is damaged to such an extent as to be unsuitable for use as commercial feed, he shall require the person in possession to destroy the feed or dispose of it in such a manner that it cannot be used as feed and may require controls and reports as he deems necessary.

(f) The director will require that all damaged feed containing drugs be disposed of as provided in subsection (e) and it is unlawful to sell or use such damaged feed.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Section 15041, Food and Agricultural Code.

ARTICLE 13. VIOLATIONS AND ADMINISTRATIVE PENALTIES

§2765. Violations.

(a) Failure to comply with any provision of Chapter 6 (commencing with Section 14901) of Division 7 of the Food and Agricultural Code or Subchapter 2 (commencing with Section 2675) of Chapter 2 of Division 4 of Title 3 of the California Code of Regulations constitutes a violation subject to Food and Agricultural Code Section 15071.1. In applying Section 15071.1, the provisions of this section shall be used to determine the violation class.

(b) Violations meeting any of the following criteria shall be classified as major and subject to an administrative penalty.

(1) Violations deemed by the secretary to require immediate action to protect public or animal health and safety.

(2) Violations involving the unauthorized movement, distribution, or sale of all or part of any lot, parcel, or package of commercial feed that has been quarantined by the secretary, or denial of access for the purpose of inspection, sampling, or enforcement.

(3) Violations demonstrating severity, intent, and recurrence.

(A) Severity is demonstrated by the seriousness of the violation and the degree of noncompliance. Violations demonstrating severity may include, but are not limited to, risks to public or animal health and safety; involvement of drugs, food additives, harmful substances, unapproved ingredients, or any other substance in an amount specified as being unsafe; risk of consumer or competitive harm; or non-cooperation of the violator, such as failure to accept responsibility for assuring compliance, failure to cease noncompliant actions despite awareness of requirements, failure to implement requested corrections, failure to participate in requested meetings, or failure to provide requested records.

(B) Intent is demonstrated by the degree to which the violator failed to prevent noncompliance. Violations demonstrating intent may include, but are not limited to, events that did not occur accidentally, involuntarily, or in a manner beyond the control of the violator; voluntary or knowing concealment, misrepresentation, or fraud, such as refusing to provide production records or other evidence, providing false or conflicting records or statements, or refusing to correct a violation that financially benefits the violator; or negligence in attempting to prevent a violation, such as failure to implement requested corrections, failure to develop standard operating procedures or quality assurance plans, failure to maintain documentation showing procedures and plans are followed, or failure to create and maintain production records.

(C) Recurrence is demonstrated by repeated violations. Violations demonstrating recurrence may include, but are not limited to, multiple violations of the same code section within twelve months.

(c) Violations that do not meet the criteria specified in subparagraph (b) shall be classified as minor and receive a notice of warning in lieu of an administrative penalty.

Note: Authority cited: Sections 407, 14902, 15071, and 15071.4, Food and Agricultural Code. Reference: Section 15071.1, 15071.4, 15072, 15082, and 15092, Food and Agricultural Code.

§2766. Administrative Penalties.

(a) In applying Section 15071.1, the provisions of this section shall be used to determine the penalty amount for major violations. Administrative penalty amounts shall be determined based upon consideration of the following factors and shall be calculated by adding together the applicable amount from each subparagraph below:

(1) Nature of the violation, meaning the potential risk posed and the actions of the violator. Violations that pose a risk to public or animal health and safety; involve drugs, food additives, harmful substances, unapproved ingredients, or any other substance in an amount specified as being unsafe; involve voluntary or knowing concealment, misrepresentation, or fraud; or involve movement of quarantine or denial of access shall have $500 added toward the total penalty amount. Violations that do not meet the criteria specified in this subparagraph shall have $250 added toward the total penalty amount.

(2) Effect of the violation upon the effectuation of the purposes and provisions of this chapter, meaning how the violation impacted consumers. Violations that negatively impacted public or animal health and safety, defrauded consumers, or limited the ability of other companies to compete in the marketplace shall have $1,000 added toward the total penalty amount. Violations that do not meet the criteria specified in this subparagraph shall have $500 added toward the total penalty amount.

(3) Impact of the penalty on the violator, meaning the deterrent effect on future violations and deterrent effect on noncooperation. Violators that refuse to cooperate with the Department or that have been assessed an administrative penalty within the previous 36 months shall have $1,000 added toward the total penalty amount. Violations that do not meet the criteria specified in this subparagraph shall have $500 added toward the total penalty amount.

(b) Subsequent major violations of the same statutory or regulatory section of Chapter 6 (commencing with Section 14901) of Division 7 of the Food and Agricultural Code or Subchapter 2 (commencing with Section 2675) of Chapter 2 of Division 4 of Title 3 of the California Code of Regulations shall be subject to an administrative penalty in the amount of $5,000 per violation.

(c) Pursuant to Food and Agricultural Code Section 15071.3, the Department is entitled to reimbursement for reasonable attorney’s fees and other related costs, including, but not limited to, investigative costs. The amount to be reimbursed shall be added to the administrative penalty amount determined by subparagraph (a) or (b).

Note: Authority cited: Sections 407, 14902, and 15071.4, Food and Agricultural Code. Reference: Sections 15071.1, 15071.3, 15071.4, 15072, 15082, and 15092, Food and Agricultural Code.

§2767. Filing Deadlines and Procedures.

(a) A respondent may contest a notice of adverse determination, including a notice to deny a right, authority, license or privilege or the renewal thereof, for any violation within 30 calendar days from the date of the notice of proposed action by submitting a written request to the Legal Office of Hearings and Appeals of the Department of Food and Agriculture, 1220 N Street, Room 315, Sacramento, California 95814. Any objection to the Department's selection of the informal hearing procedure shall be made in writing to the Legal Office of Hearings and Appeals and shall be resolved by the Hearing Officer prior to the hearing.

(b) Failure to present a timely request for a hearing constitutes a waiver of the respondent's right to contest the notice of an adverse determination.

(c) If the notice of adverse determination places a hold on a commercial feed product, or requires a person to cease operations, the notice of adverse determination shall remain in effect pending the outcome of the hearing.

Note: Authority cited: Section 407, Food and Agricultural Code; and Section 11400.20, Government Code. Reference: Section 15071, 15071.1, Food and Agricultural Code; and Section 11445.30, Government Code.

§2768. Hearing Schedule and Notification.

(a) The Legal Office of Hearings and Appeals shall schedule an informal hearing within 30 days from the receipt of a written request from the respondent.

(b) Formal hearings shall be scheduled by the Department consistent with the provisions of Chapter 5 (commencing with Section 11500), Part 1, Division 3, Title 2 of the Government Code, and any applicable regulations enacted pursuant to these provisions.

(c) The Department shall provide a notice of the informal hearing to the respondent containing the following information:

(1) Date, location, and time of the informal hearing;

(2) Departmental contact information including applicable telephone and facsimile numbers;

(3) Subject matter of the adverse determination; and,

(4) Any other information or documentation relative to the adverse determination.

(d) The notice of hearing shall be sent to the address of the respondent, as provided on the license application, renewal or provided to the Department pursuant to Section 2751(f), whichever is most current.

(e) A notice that is sent pursuant to subsection (d) shall be considered effective, even if delivery is refused or if the notice is not accepted at that address.

Note: Authority cited: Section 407, Food and Agricultural Code; and Section 11400.20, Government Code. Reference: Sections 11445.30, 11501, 11502 and 11503, Government Code.

§2769. Hearing Procedures.

(a) Hearings shall be presided over and conducted by a Hearing Officer designated by the secretary.

(b) The standard of proof to be applied by the Hearing Officer shall be the preponderance of the evidence.

(c) Hearings may be conducted by telephone, at the discretion of the Hearing Officer.

(d) The decision of the Hearing Officer shall be in writing. It may be handwritten.

(e) The written decision shall be issued within 30 days after the conclusion of the hearing.

(f) The written decision shall be served on the respondent either by personal service, facsimile transmission, or email.

(g) The Hearing Officer's decision shall be effective immediately and shall be final and not appealable to the secretary or any other officer of the Department.

(h) The respondent may challenge the Hearing Officer's decision by filing a writ of administrative mandamus in the appropriate court pursuant to Code of Civil Procedure Section 1094.5 within 30 days of the date of the decision.

(i) Hearings shall be recorded.

Note: Authority cited: Sections 407, 14902, 15071, and 15071.1, Food and Agricultural Code; and Section 11400.20, Government Code. Reference: Sections 15071, 15071.1, and 15082, Food and Agricultural Code; and Sections 11425.50 and 11445.10, Government Code.

ARTICLE 14. RECOGNIZED OFFICIAL NAMES

§2770. General Provisions.

(a) The following abbreviations shall be used for the purposes of this Article:

(1) “3 CCR” means Title 3 of the California Code of Regulations.

(2) “21 CFR” means Title 21 of the Code of Federal Regulations.

(3) “AAFCO” means Association of American Feed Control Officials.

(4) “AOAC” means Association of Official Agricultural Chemists.

(5) “FDA” means Food and Drug Administration.

(6) “FD&C” means federal Food, Drug, and Cosmetic Act.

(7) “GRAS” means generally recognized as safe as defined in 21 CFR 570.3(k) and 21 CFR 570.30.

(8) “USDA” means United States Department of Agriculture.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2771. Alfalfa Products.

(a) General Provisions.

(1) Alfalfa products shall be prepared only from the processing of entire alfalfa hay without the addition of foreign materials, except as specifically permitted herein, and shall not contain more than 10 percent of other crops and weeds.

(2) Alfalfa products shall contain not less than 15 percent crude protein and not more than 30 percent crude fiber.

(3) If alfalfa products do not comply with the standards in every respect, the term “forage” must be substituted for the word “alfalfa” in the name of the product.

(4) A guarantee of the beta carotene content of alfalfa products expressed in milligrams per pound, and accompanied by an expiration date may be included on the label if the distributor so desires. Guarantees made on the label (including the invoice), on the delivery ticket, on a “certificate of analysis,” or other document associated with the distribution of an alfalfa product are to be in terms of milligrams per pound of beta carotene without reference to quantity of Vitamin A which may be derived therefrom by the animal. Example: Beta carotene 60 milligrams per pound (a source of Vitamin A).

(5) Brand names, such as “Doe’s [X]% Alfalfa Meal with Animal Fat or Vegetable Oil,” must be used on the label to show that the product is a mixture and not simply alfalfa meal. The chemical name of the antioxidant or antioxidants must be listed in the ingredient statement.

(b) Alfalfa Nutrient Concentrate is the product obtained from the extracted juice of freshly cut alfalfa by coagulation, separation from the alfalfa solubles, and subsequent dehydration. The product should express both protein and Xanthophyll guarantees.

(c) Concentrated Alfalfa Solubles is the product obtained by the concentration of the liquid remaining after the separation of Alfalfa Nutrient Concentrate from the juice of freshly cut alfalfa. The moisture level should not exceed 50 percent.

(d) Dehydrated Alfalfa Meal or Pellets is the aerial portion of the alfalfa plant, reasonably free of other crop plants, weeds, and mold, which has been finely ground and dried by thermal means under controlled conditions.

(e) Direct Dehydrated Alfalfa Meal or Pellet is the aerial portion of the alfalfa plant, reasonably free of other crop plants, weeds, and mold, that has not been stored in bales or in stacks as sun-cured alfalfa hay prior to being ground and dried by thermal means under controlled conditions.

(f) Suncured Alfalfa Meal, or Pellets or Ground Alfalfa Hay is the aerial portion of the alfalfa plant, reasonably free of other crop plants, weeds, and mold, which has been dried by solar means, stored as bales or stacks, and finely or coarsely ground. If it is chopped instead of ground, it must be designated as “Suncured Chopped Alfalfa” or “Chopped Alfalfa Hay.” If the ingredient is further dehydrated by thermal means after being ground, it must be designated as “Dehydrated Suncured Alfalfa Meal, or Pellets.”

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2772. Almond Hull Products.

(a) General Provisions.

(1) Almond Hull Products shall be processed in accordance with good manufacturing practices and free of foreign material, including plastic, glass, and metal except in such trace amounts as unavoidably occur in good manufacturing practices.

(2) If the ash exceeds nine (9.0) percent, the term “and dirt” shall be included in the product name.

(3) When the following Almond Hull Products are mixed with Almond Hulls or used in a mixed feed, the maximum percentage shall be stated.

(A) Almond Shell.

(B) Almond Products containing more than nine (9.0) percent ash.

(b) Almond Hulls are obtained by drying the pericarp which surrounds the nut. Almond Hulls shall contain not more than 13.0 percent moisture, 15.0 percent crude fiber and nine (9.0) percent ash.

(c) Almond Hull and Shell must not contain more than 29.0 percent crude fiber, nine (9.0) percent ash and 13.0 percent moisture. If the crude fiber exceeds 29.0 percent, the product shall be labeled Almond Shell.

(d) Almond Shell is that portion of the almond fruit which surrounds the nut. If ground, it must be reasonably free of the whole nutshell and labeled Ground Almond Shell.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2773. Amino Acids and Related Products.

(a) General Provisions.

(1) Guarantees for amino acids should be expressed as percent on feed labels.

(2) Unless indicated otherwise, the amino acids defined below can be added to animal feed for nutritional purposes in accord with good manufacturing or feeding practices.

(b) DL-Arginine (21 CFR 582.5145) is a product which contains a minimum of 98 percent racemic 2-amino- 5-guanidyl-valeric acid. The percentage of DL-Arginine must be guaranteed.

(c) DL-Methionine (21 CFR 582.5475) is a product containing a minimum of 99 percent racemic 2-amino- 4-(methylthio)butanoic acid. The percentage of DL-Methionine must be guaranteed.

(d) DL-Methionine Hydroxy Analogue (21 CFR 582.5477) is a product containing a minimum of 88 percent racemic 2-hydroxy-4-(methylthio)butanoic acid. The percentage of DL-Methionine Hydroxy Analogue must be guaranteed.

(e) DL-Methionine Hydroxy Analogue Calcium (21 CFR 582.5477) is a product that contains a minimum of 97 percent racemic 2-hydroxy-4-(methylthio)butanoic acid calcium salt. The percentage of DL-Methionine Hydroxy Analogue Calcium must be guaranteed.

(f) DL-Methionine Hydroxyl Analogue Isopropyl Ester is a product containing a minimum of 90 percent racemic 2-hydroxy-4(methylthio)butanoic acid isopropyl ester monomer for use as a source of methionine activity in cattle diets. The percentage of DL-methionine hydroxyl analogue isopropyl ester monomer must be guaranteed.

(g) DL-Methionine Sodium is a product containing a minimum of 45.9 percent racemic 2-amino-(methylthio)butanoic acid sodium salt. The percentage of DL-methionine must be guaranteed.

(h) DL-Tryptophan (21 CFR 582.5915) is a product which contains a minimum of 97 percent racemic 2-amino-3-(3-indolyl)-propionic acid. The percentage of DL-tryptophan must be guaranteed. Excessive tryptophan consumption in cattle (in excess of 0.17 grams tryptophan per 100 pounds bodyweight per day) is associated with bovine pulmonary emphysema.

(i) Glycine (21 CFR 582.5049) is a product which contains a minimum of 97 percent amino acetic acid. The percentage of glycine must be guaranteed.

(j) L-Arginine (21 CFR 582.5145) is a product which contains a minimum of 98 percent L-2-amino- 5-guanidyl-valeric acid. The percentage of L-Arginine must be guaranteed.

(k) L-Lysine (21 CFR 582.5411) is a product which contains a minimum of 95 percent L-2,6- diaminohexanoic acid. The percentage of L-lysine must be guaranteed.

(l) L-Lysine Liquid (21 CFR 582.5411) is a product that contains a minimum of 50 percent L-2, 6-diaminohexanoic acid by weight in a water solution. The L-lysine content must not be less than 85 percent on a moisture-free basis. The percentage of L-lysine must be guaranteed.

(m) L-Lysine Monohydrochloride is a product which contains a minimum of 95 percent L-2, 6-diaminohexanoic acid monohydrochloride. The percentage of L-lysine must be guaranteed.

(n) L-Methionine is a product containing a minimum of 98.5 percent L-isomer of 2-amino-4-(methylthio)butanoic acid. L-Methionine is produced by Escherichia coli K12 fermentation followed by enzymatic conversion to L-methionine. The percentage of L-methionine must be guaranteed.

(o) L-Threonine (21 CFR 582.5881) is a product which contains a minimum of 95 percent L-2-amino-3- hydroxybutanoic acid. The percentage of L-threonine must be guaranteed.

(p) L-Tryptophan (21 CFR 582.5915) is a product which contains a minimum of 97 percent L-2-amino- 3-(3'indolyl)-propionic acid. The percentage of L-tryptophan must be guaranteed. Excessive tryptophan consumption in cattle (in excess of 0.17 grams tryptophan per 100 pounds bodyweight per day) is associated with bovine pulmonary emphysema.

(q) L-Tyrosine (21 CFR 582.5920) is a product which contains a minimum of 98 percent L-2-amino-3-(4- hydroxyphenyl) propionic acid. The percentage of L-Tyrosine must be guaranteed.

(r) Taurine (21 CFR 573.980) is a product that contains a minimum of 97 percent 2-aminoethanesulfonic acid. The percentage of taurine must be guaranteed. It is used as a nutritional supplement in fish foods. Taurine may also be added to the feed of growing chickens; when added to complete chicken feed, the total taurine content shall not exceed 0.054 percent of the feed.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2774. Animal Products.

(a) General Provisions.

(1) Animals other than livestock shall be excluded from all Animal Products.

(2) All Animal Products must be produced by a commercial renderer operating in conformance with the standards of 3 CCR Section 1180.34. Any animal protein product sold as pure porcine shall be so labeled, pursuant to 21 CFR 589.2000.

(3) The animal product will be considered adulterated when Salmonella is present in one or more subsamples of the animal feed or feed ingredient; and the Salmonella is of a serotype that is pathogenic to the animal species for which the animal feed or feed ingredient is intended; and the animal feed or feed ingredient will not undergo a subsequent commercial heat step or other commercial process that will kill Salmonella.

(A) A Salmonella serotype that is considered pathogenic to the animal intended to consume the animal feed includes, but is not limited to:

(i) Poultry feed with Salmonella Pullorum, Salmonella Gallinarum, or Salmonella Enteritidis.

(ii) Swine feed with Salmonella Choleraesuis.

(iii) Sheep feed with Salmonella abortusovis.

(iv) Horse feed with Salmonella abortusequi.

(v) Dairy and beef feed(s) with Salmonella Newport or Salmonella Dublin.

(b) Air Dried Animal Blood Cells (Air Swept Tubular Drying) is obtained by drying red and white blood cells which have been separated from the plasma of clean, fresh, whole animal blood with only such amounts of plasma as might occur unavoidably in good manufacturing practices. The blood cells are dried by exposing the cells to a heated air stream and retaining them in the maximum moisture of 11 percent; and a minimum protein of 90 percent. If the product bears a name descriptive of its kind, origin, or composition it must correspond thereto.

(c) Animal By-Product Meal is the rendered product from animal tissues, exclusive of any added hair, hoof, horn, hide trimmings, manure, stomach and rumen contents, except in such amounts as may occur unavoidably in good manufacturing practices. It shall not contain added extraneous materials not provided for by this definition. This ingredient definition is intended to cover those individual rendered animal tissue products that cannot meet the criteria as set forth elsewhere in this section. This ingredient is not intended to be used to label a mixture of animal tissue products. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(d) Animal Digest is a material which results from chemical and/or enzymatic hydrolysis of clean and undecomposed animal tissue. The animal tissues used shall be exclusive of hair, horns, teeth, hooves and feathers, except in such trace amounts as might occur unavoidably in good manufacturing practices and shall be suitable for animal feed. If it bears a name descriptive of its kind or flavor(s), it must correspond thereto. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(e) Animal Liver if it bears a name descriptive of its kind, it must correspond thereto. Meal is obtained by drying and grinding liver from slaughtered animals. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(f) Animal Plasma is the product obtained by spray drying plasma which has been separated away from the cellular matter (red and white blood cells) of fresh whole blood by chemical and mechanical processing. The protein portion of this product is primarily albumin, globulin, and fibrinogen type proteins. The minimum percent crude protein and the maximum percent ash must be guaranteed on the label. If it bears a name descriptive of its kind, composition, or origin, it must correspond thereto.

(g) Animal Serum is the product obtained by removing the fibrin from liquid animal plasma by chemical and mechanical processes. The serum protein portion of this product is primarily albumin and globulin proteins. The minimum percent crude protein, maximum percent ash, minimum albumin content, and the minimum globulin content must be guaranteed on the label. The minimum albumin content is 42 percent (as a percent of total protein) determined by colorimetric assay and the minimum globulin content is 20 percent (as a percent of total protein) as measured by an assay method such as the Becker titer analysis. If the product bears a name descriptive of its kind, origin or composition, it must correspond thereto.

(h) Blood Meal [Specify] is produced from clean, fresh animal blood, exclusive of all extraneous materials such as hair, stomach belchings and urine, except as might occur unavoidably in good manufacturing practices. The process used must be listed on the label as a part of the product name, such as “Blood Meal (Conventional Cooker Dried, Steamed, Hydrolyzed).” The product usually has a dark black like color and is rather insoluble in water.

(i) Blood Meal, Flash Dried is produced from clean, fresh animal blood, exclusive of all extraneous material such as hair, stomach belchings and urine except as might occur unavoidably in good manufacturing practices. A large portion of the moisture (water) is usually removed by a mechanical dewatering process or by condensing by cooking to a semi-solid state. The semi-solid blood mass is then transferred to a rapid drying facility where the more tightly bound water is rapidly removed. The minimum biological activity of lysine shall be 80 percent.

(j) Blood Protein is produced by quick freezing and/or transporting in a chilled state, clean, fresh, whole or dewatered animal blood exclusive of all extraneous material such as hair, stomach belchings and urine except as might occur unavoidably in good manufacturing practices. If the product bears a name descriptive of its kind, composition or origin, it must correspond thereto.

(k) Cooked Bone Marrow is the soft material coming from the center of large bones, such as leg bones. This material, which is predominantly fat with some protein, must be separated from the bone material by cooking with steam. It shall not contain added extraneous materials not provided for by this definition except for small amount of tissue which may adhere to the bone unavoidably in good manufacturing practices. The labeling of this product shall include, but is not limited to, guarantees for minimum crude protein and minimum crude fat. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(l) Dried Meat Solubles is obtained by drying the defatted water extract of the clean, wholesome parts of slaughtered animals prepared by steaming or hot water extraction. It must be designated according to its crude protein content which shall be no less than 70 percent. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(m) Egg Product is product obtained from egg graders, egg breakers and/or hatchery operations that is dehydrated, handled as liquid, or frozen. These sources shall be labeled as per USDA regulations governing eggs and egg products (9 CFR 590). This product shall be free of shells or other non-egg materials except in such amounts which might occur unavoidably in good manufacturing practices and contain a maximum ash content of six (6) percent on a dry matter basis.

(n) Egg Shell Meal is a mixture of eggshells, shell membranes and egg content obtained by drying the residue from an egg breaking plant in a dehydrator to an end product

temperature of 180 degrees Fahrenheit. It must be designated according to its protein and calcium content.

(o) Ensiled Paunch is a product composed of the contents of rumen of cattle slaughtered at USDA inspected facilities. The moisture level is reduced to 50-68 percent. The product is then packed into an airtight environment, such as a silo, where it undergoes an acid fermentation that retards spoilage. The ensiled product will have a pH of four (4.0) or less.

(p) Fleshings Hydrolysate (21 CFR 573.200) is obtained by acid hydrolysis of the flesh from fresh or salted hides. It is defatted, strained, and neutralized. If evaporated to 50 percent solids, it shall be designated “Condensed Fleshings Hydrolysate.” It must have a minimum crude protein and maximum salt guarantee. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(q) Glandular Meal and Extracted Glandular Meal is obtained by drying liver and other glandular tissues from slaughtered mammals. When a significant portion of the water-soluble material has been removed, it may be called Extracted Glandular Meal. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(r) Hydrolyzed Hair is a product prepared from clean, undecomposed hair, by heat and pressure to produce a product suitable for animal feeding. Not less than 80 percent of its crude protein must be digestible by the pepsin digestibility method determined by AOAC method utilized by the AAFCO Proficiency Testing Program for Analytical Variations. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(s) Hydrolyzed Leather Meal is produced from leather scrap that is treated with steam for not less than 33 minutes at a pressure not less than 125 pounds per square inch and further processed to contain not more than 10 percent moisture, not less than 60 percent crude protein, not more than six (6) percent crude fiber, not more than 2.75 percent chromium, and with not less than 80 percent of its crude protein digestible by the pepsin digestibility method determined by AOAC method utilized by the AAFCO Proficiency Testing Program for Analytical Variations. Hydrolyzed leather meal may be utilized in livestock feeds as provided in food additive regulation 21 CFR 573.540. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(t) Hydrolyzed Poultry By-Products Aggregate is the product resulting from hydrolyzation, heat treatment, or a combination thereof, of all by-products of slaughter poultry, clean and undecomposed, including such parts as heads, feet, undeveloped eggs, intestines, feathers and blood. The parts may be fermented as a part of the manufacturing process. The product shall be processed in such a fashion as to make it

suitable for animal food, including heating (boiling at 212 degrees Fahrenheit, or 100 degrees Celsius at sea level for 30 minutes, or its equivalent, and agitated, except in steam cooking equipment). It may, if acid treated, be subsequently neutralized. If the product bears a name descriptive of its kind, the name must correspond thereto.

(u) Hydrolyzed Poultry Feathers is the product resulting from the treatment under pressure of clean, undecomposed feathers from slaughtered poultry, free of additives, and/or accelerators. Not less than 75 percent of its crude protein content must be digestible by the pepsin digestibility method determined by AOAC method utilized by the AAFCO Proficiency Testing Program for Analytical Variations.

(v) Leather Hydrolysate is obtained from chromium tanned unfinished leather shavings, trimmings, and/or lime fleshings that may or may not be pressure cooked with the addition of steam, sodium hydroxide, lime or magnesium oxide. Chromium is precipitated and separated so that only trivalent chromium at less than 1000 parts per million on a dry matter basis remains in the hydrolysate. This product is available as a liquid ingredient or as a spray dried powder. In either form, the analysis on a solids basis will not be less than 75 percent crude protein and not less than 85 percent of the protein shall be pepsin digestible determined by AOAC method utilized by the AAFCO Proficiency Testing Program for Analytical Variations.

(w) Meat is the clean flesh derived from slaughtered mammals and is limited to that part of the striate muscle which is skeletal or that which is found in the tongue, in the diaphragm, in the heart, or in the esophagus; with or without the accompanying and overlying fat and the portions of the skin, sinew, nerve, and blood vessels which normally accompany the flesh. It shall be suitable for use in animal food. If it bears a name descriptive of its kind, it must correspond thereto. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(x) Meat and Bone Meal is the rendered product from mammal tissues, including bone, exclusive of any added blood, hair, hoof, horn, hide trimmings, manure, stomach and rumen contents, except in such amounts as may occur unavoidably in good manufacturing practices. It shall not contain added extraneous materials not provided for in this definition. It shall contain a minimum of four (4.0) percent Phosphorus (P) and the Calcium (Ca) level shall not be more than 2.2 times the actual Phosphorus (P) level. It shall not contain more than 12 percent pepsin indigestible residue determined by AOAC method utilized by the AAFCO Proficiency Testing Program for Analytical Variations and not more than nine (9) percent of the crude protein in the product shall be pepsin indigestible determined by AOAC method utilized by the AAFCO Proficiency Testing Program for Analytical Variations. The label shall include guarantees for minimum crude protein, minimum crude fat, maximum crude fiber, minimum Phosphorus (P) and minimum and maximum Calcium (Ca). If it bears a name description of its kind, composition or origin it must correspond thereto. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(y) Meat and Bone Meal Tankage is the rendered product from mammal tissues, including bone, exclusive of any added hair, hoof, horn, hide trimmings, manure, stomach and rumen contents except in such amounts as may occur unavoidably in good manufacturing practices. It may contain added blood or blood meal, however, it shall not contain any added extraneous materials not provided for in this definition. It shall contain a minimum of four (4.0) percent Phosphorus (P) and the Calcium (Ca) level shall not be more than 2.2 times the actual Phosphorus (P) level. It shall not contain more than 12 percent pepsin indigestible residue determined by AOAC method utilized by the AAFCO Proficiency Testing Program for Analytical Variations and not more than nine (9) percent of the crude protein in the product shall be pepsin indigestible determined by AOAC method utilized by the AAFCO Proficiency Testing Program for Analytical Variations. The label shall include guarantees for minimum crude protein, minimum crude fat, maximum crude fiber, minimum Phosphorus (P) and minimum and maximum Calcium (Ca). If the product bears a name descriptive of its kind, composition or origin it must correspond thereto. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(z) Meat By-Products is the non-rendered, clean parts, other than meat, derived from slaughtered mammals. It includes, but is not limited to, lungs, spleen, kidneys, brain, livers, blood, bone, partially defatted low temperature fatty tissue, and stomachs and intestines freed of their contents. It does not include hair, horns, teeth and hoofs. It shall be suitable for use in animal food. If it bears name descriptive of its kind, it must correspond thereto. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(aa) Meat Meal is the rendered product from mammal tissues, exclusive of any added blood, hair, hoof, horn, hide trimmings, manure, stomach and rumen contents except in such amounts as may occur unavoidably in good manufacturing practices. It shall not contain added extraneous materials not provided for by this definition. The Calcium (Ca) level shall not exceed the actual level of Phosphorus (P) by more than 2.2 times. It shall not contain more than 12 percent Pepsin indigestible residue determined by AOAC method utilized by the AAFCO Proficiency Testing Program for Analytical Variations and not more than nine (9) percent of the crude protein in the product shall be pepsin indigestible determined by AOAC method utilized by the AAFCO Proficiency Testing Program for Analytical Variations. The label shall include guarantees for minimum crude protein, minimum crude fat, maximum crude fiber, minimum Phosphorus (P) and minimum and maximum Calcium (Ca). If the product bears a name descriptive of its kind, composition or origin, it must correspond thereto. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(bb) Meat Meal Tankage is the rendered product from mammal tissues, exclusive of any added hair, hoof, horn, hide trimmings, manure, stomach and rumen contents, except in such amounts as may occur unavoidably in good manufacturing practices. It may

contain added blood or blood meal, however, it shall not contain any other added extraneous materials not provided for by this definition. The Calcium (Ca) level shall not exceed the actual level of Phosphorus (P) by more than 2.2 times. It shall not contain more than 12 percent pepsin indigestible residue determined by AOAC method utilized by the AAFCO Proficiency Testing Program for Analytical Variations and not more than nine (9) percent of the crude protein in the product shall be pepsin indigestible determined by AOAC method utilized by the AAFCO Proficiency Testing Program for Analytical Variations. The label shall include guarantees for minimum crude protein, minimum crude fat, maximum crude fiber, minimum Phosphorus (P) and minimum and maximum Calcium (Ca). If the product bears a name descriptive of its kind, composition or origin it must correspond thereto. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(cc) Meat Protein Isolate is produced by separating meat protein from fresh, clean, unadulterated bones by heat processing followed by low temperature drying to preserve function and nutrition. This product is characterized by a fresh meaty aroma, a 90 percent minimum protein level, one (1) percent maximum fat and two (2) percent maximum ash. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(dd) Mechanically Separated Bone Marrow is the soft material coming from the center of large bones, such as leg bones. This material, which is predominantly fat with some protein, must be separated from the bone material by mechanical separation. It shall not contain added extraneous materials not provided for by this definition except for small amount of tissue which may adhere to the bone unavoidably in good manufacturing practices. The labeling of this product shall include, but is not limited to, guarantees for minimum crude protein and minimum crude fat. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(ee) Poultry is the clean combination of flesh and skin with or without accompanying bone, derived from the parts or whole carcasses of slaughtered poultry, or a combination thereof, exclusive of feathers (except as unavoidable in good manufacturing practices), heads, feet, and viscera. If it bears a name descriptive of its kind, it must correspond thereto. If the bone has been removed, the process may be so designated by use of the appropriate feed term. It shall be suitable for use in animal food.

(ff) Poultry By-Products consists of non-rendered clean parts of poultry, such as heads, feet, viscera, and whole carcasses, free from foreign matter except in such trace amounts as might occur unavoidably in good manufacturing practices. If the product bears a name descriptive of its kind, the name must correspond thereto. It shall be suitable for use in animal food.

(gg) Poultry By-Product Meal consists of the ground, rendered, clean parts of the carcass of poultry, such as necks, feet, undeveloped eggs, viscera, and whole carcasses, exclusive of added feathers, except in such amounts as might occur unavoidably in good manufacturing practices. The label shall include guarantees for minimum crude protein, minimum crude fat, maximum calcium (Ca), and minimum phosphorus (P). The calcium (Ca) level shall not exceed the actual level of phosphorus (P) by more than 2.2 times. If the product bears a name descriptive of its kind, the name must correspond thereto. It shall be suitable for use in animal food.

(hh) Poultry Hatchery By-Product is a mixture of eggshells, infertile and unhatched eggs, and culled chicks which have been cooked, dried, and ground, with or without removal of part of the fat.

(ii) Poultry Meal is the wet rendered or dry rendered product from a combination of clean flesh and skin with or without accompanying bone, derived from the parts of whole carcasses of slaughtered poultry, or a combination thereof, exclusive of feathers (except as unavoidable in good manufacturing practices), heads, feet, and viscera. The label shall include guarantees for minimum crude protein, minimum crude fat, maximum calcium (Ca), and minimum phosphorus (P). The calcium (Ca) level shall not exceed the actual level of phosphorus (P) by more than 2.2 times. If it bears a name descriptive of its kind, it must correspond thereto. It shall be suitable for use in animal food.

(jj) Serum Albumin is the product obtained by removing the fibrin and globulin proteins from liquid animal plasma by chemical and mechanical processes. The resultant product will be greater than 60 percent albumin (as a percent of total protein) as measured by colorimetric assay (Doumas, B. T., Watson, W. A., Biggs, H. G., Clin Chim Acta. 1971). The minimum percent crude protein and the maximum percent ash must be guaranteed on the label as well as the minimum albumin concentration. If the product bears a name descriptive of its kind, origin or composition, it must correspond thereto.

(kk) Serum Globulin is the product obtained by removing the fibrin and albumin proteins from liquid animal plasma by chemical and mechanical processes. The resultant product will be greater than 40 percent globulin (as a percent of total protein) as measured by an assay method such as the Becker titer analysis (Becker, W. 1969 Immunochemistry 6: 539-546). The minimum percent crude protein and the maximum percent ash must be guaranteed on the label as well as the minimum globulin concentration. If the product bears a name descriptive of its kind, origin or composition, it must correspond thereto.

(ll) Spray Dried Animal Blood is produced from clean, fresh animal blood, exclusive of all extraneous material such as hair, stomach belchings, urine, except in such traces as might occur unavoidably in good manufacturing practices. Moisture is removed from the blood by a low temperature, evaporator under vacuum until it contains approximately 30 percent solids. It is then dried by spraying into a draft of warm, dry air which reduces the blood to finely divided particles with a maximum moisture of eight (8) percent and a minimum crude protein of 85 percent. It must be designated according to its minimum water solubility.

(mm) Spray Dried Animal Blood Cells is the product obtained by spray drying red and white blood cells which have been separated from the plasma of clean, fresh, whole animal blood with only such amounts of plasma as might occur unavoidably in good manufacturing practices. The blood cells are dried by spraying into a draft of warm, dry air which reduces the blood to finely divided particles. The guaranteed analysis is: a maximum moisture of eight (8) percent; a minimum crude protein of 90 percent; and a minimum solubility in water of 75 percent. If the product bears a name descriptive of its kind, origin, or composition, it must correspond thereto.

(nn) [Specify] Stock/Broth is obtained by cooking mammalian or poultry bones, parts, and/or muscle tissue. The crude protein content of stock/broth must be no less than 90 percent on a dry matter basis. In order for the stock/broth to be labeled as such, the moisture to crude protein ratio must not exceed 135:1 (135 parts water to one (1) part crude protein). The product label must bear a name descriptive of its kind, composition or origin, such as, but not limited to, meat, beef, pork, poultry, chicken, turkey: and may be called either stock or broth; for example, “Beef Stock.” Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2775. Barley Products.

(a) Barley Hulls consist of the outer covering of the barley.

(b) Barley Mill By-Product is the entire residue from the milling of barley flour from clean barley and is composed of barley hulls and barley middlings.

(c) Barley Protein Concentrate is the dried protein fraction of barley prepared by enzymatic hydrolysis of starch, beta glucans, and fiber. The ingredient is prepared from barley that is dehulled or of a hulless variety. It must not contain less than 60 percent crude protein on a dry matter basis. The finished ingredient should not contain more than 10 percent moisture. It is to be used in the feed of fish as a source of protein.

(d) Ground Barley or Rolled Barley is the product obtained by grinding or rolling barley of such quality that the resulting processed material contains not more than seven (7.0) percent crude fiber.

(e) Ground or Rolled Pearl Barley is the product obtained by grinding or rolling barley from which the hull has been removed.

(f) Pearl Barley is barley from which the hull has been removed.

(g) Pearl Barley By-Product is the entire by-product resulting from the manufacture of pearl barley from clean barley.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2776. Brewers Products.

(a) Brewers Condensed Solubles is obtained by condensing liquids resulting as by-products from manufacturing beer or wort. It must contain not less than 20 percent total solids, 70 percent carbohydrates on a dry matter basis and the guaranteed analysis shall include maximum moisture.

(b) Brewers Dried Grains is the dried extracted residue of barley malt alone or in mixture with other cereal grain or grain products resulting from the manufacture of wort or beer and may contain pulverized dried spent hops in an amount not to exceed three (3) percent, evenly distributed.

(c) Brewers Wet Grains is the extracted residue resulting from the manufacture of wort from barley malt alone or in mixture with other cereal grains or grain products. The guaranteed analysis shall include the maximum moisture.

(d) Dried Spent Hops is obtained by drying the material filtered from hopped wort.

(e) Malt Cleanings is obtained from the cleaning of malted barley or from the recleaning of malt which does not meet the minimum crude protein standard of malt sprouts. It must be designated and sold according to its crude protein content.

(f) Malt Hulls consists almost entirely of hulls as obtained in the cleaning of malted barley.

(g) Malt Sprouts is obtained from malted barley by the removal of the rootlets and sprouts which may include some of the malt hulls, other parts of malt and foreign material unavoidably present. It must contain not less than 24 percent crude protein. The term malt sprouts when applied to a corresponding portion of other malted cereals must be used in qualified form: i.e., "Rye Malt Sprouts," "Wheat Malt Sprouts," etc.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2777. Citrus Products.

(a) Citrus Seed Meal, Mechanical Extracted, is the seed or seed meats of orange and grapefruit from which most of the oil has been removed by means of pressure. It is composed mostly of the kernel with such portions of the hull and pulp as cannot be avoided in the manufacture of Citrus Seed Oil. It may be designated and sold according to its crude protein content.

(b) Dried Citrus Meal is the finer particles obtained by screening dried citrus pulp.

(c) Dried Citrus Pulp is the ground peel, residue of the inside portions, and occasional cull fruits of the citrus family which have been dried, producing a coarse, flaky product. It may contain dried citrus meal or pellets and whole citrus seeds. If calcium oxide or calcium hydroxide is added as an aid in processing, the maximum percentage present, expressed as calcium (Ca), must be shown. If it bears a name descriptive of its kind or origin, it must correspond thereto.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2778. Collective Terms.

(a) Collective terms are not allowed in labeling of commercial feed, except for the terms listed below.

(b) Grain Products. May be used as an ingredient name. However, when one or more grains are named, no substitution shall be made. Any of the normal forms such as whole, ground, cracked, screen cracked, flaked, kibbled, toasted, or heat processed are acceptable. A statement of form is optional. Grain Products may include one or more of the following:

(1) Grain Sorghums: Ground Grain Sorghum, Rolled Grain Sorghum.

(2) Maize Products: Corn Feed Meal, Ground Corn, Cracked Corn, Screened Cracked Corn, Flaked Corn, Toasted Corn Flakes, Kibbled Corn.

(3) Oat Products: Mixed Feed Oats.

(4) Rice Products: Ground Brown Rice, Ground Rough Rice or Ground Paddy, Chipped Rice, Broken Rice, Brewers Rice.

(5) Whole Grains: Barley, Oats, Rye, Triticale, Wheat.

(c) Roughage Products. May be used as an ingredient name only in labeling medicated, mineral and vitamin premixes if the labeled recommended use level of the premix in the total ration is specified to be one percent or less of the total ration. Roughage Products may include one or more of the following:

(1) Almond Hull Products: Almond Hulls.

(2) Barley Products: Barley Hulls, Barley Mill By-Product.

(3) Brewers Products: Malt Hulls.

(4) Citrus Products: Dried Citrus Pulp, Dried Citrus Meal, Citrus Seed Meal.

(5) Corn Products: Corn Cob Fractions, Ground Corn Cob.

(6) Cottonseed Products: Cottonseed Hulls.

(7) Human Food By-Products: Dried Apple Pectin Pulp, Dried Apple Pomace, Dried Tomato Pomace.

(8) Miscellaneous Products: Buckwheat Hulls, Ground Straw, Psyllium Seed Husk.

(9) Molasses and Molasses Products: Bagasse, Beet Pulp, Dried, Plain.

(10) Oat Products: Oat Hulls, Clipped Oat By-Product, Oat Mill By-Product.

(11) Other Oilseed Products: Sunflower Hulls, Flax Straw By-Product, Peanut Hulls.

(12) Rice Products: Rice Hulls, Rice Mill By-Product.

(13) Rye Products: Rye Mill Run.

(14) Soybean Products: Soybean Hulls, Soybean Mill Feed, Soybean Mill Run.

Note: Authority cited: Sections 407, 14902 and 14992, Food and Agricultural Code. Reference: Section 14992(e), Food and Agricultural Code.

§2779. Corn Products.

(a) Condensed Fermented Corn Extractives is obtained by the partial removal of water from the liquid resulting from steeping corn in a water and sulphur dioxide solution which is allowed to ferment by the action of naturally occurring lactic acid producing microorganisms as practiced in the wet milling of corn.

(b) Corn Bran is the outer coating of the corn kernel, with little or none of the starchy part of germ.

(c) Corn Cob Fractions is obtained by the mechanical separation of one or more fractions of corn cobs. For identification purposes the name of the fraction must be included parenthetically following the name of the product: i.e., Corn Cob Fractions (Hard Woody Ring and Beeswings).

(d) Corn Feed Meal is the fine siftings obtained from screened cracked corn, with or without its aspiration products added.

(e) Corn Flour is the fine sized hard flinty portions of ground corn containing little or none of the bran or germ.

(f) Corn Germ Dehydrated consists of whole corn germ with other parts of the corn kernel from which the oil has not been removed, and is the product obtained in the dry and wet milling process of manufacture of corn meal, corn grits, hominy feed, corn starch, corn syrup or other corn products.

(g) Corn Germ Meal (Dry Milled) is ground corn germ which consists of corn germ with other parts of the corn kernel from which part of the oil has been removed and is the product obtained in the dry milling process of manufacture of corn meal, corn grits, hominy feed, and other corn products.

(h) Corn Germ Meal (Wet Milled) is ground corn germ from which most of the solubles have been removed by steeping and most of the oil removed by hydraulic, expeller, or solvent extraction processes, and is obtained in the wet milling process of manufacture of corn starch, corn syrup, or other corn products.

(i) Corn Grits is the medium sized hard flinty portions of ground corn containing little or none of the bran or germ. May also appear in the ingredient list of a mixed feed as Hominy Grits.

(j) Corn Protein Concentrate is the dried proteinaceous fraction of the corn primarily originating from the endosperm after removal of the majority of the non- protein components by enzymatic solubilization of the protein stream obtained from the wet-mill process. This proteinaceous fraction of the corn must contain not less than 80 percent protein on a moisture free basis and not more than one (1) percent starch on a moisture free basis. The product must be labeled on “as fed” basis. This fraction shall be free of fermented corn extractives, corn germ meal, and other non-protein components except in such amounts as might occur unavoidably in good manufacturing practices. Vegetable oils or other appropriate ingredients may be added in concentrations not to exceed three (3) percent to reduce dust during handling. The name of the conditioning dust control agent, if used, must be shown as an added ingredient.

(k) Corn Protein Feed is that part of the commercial shelled corn that remains after the extraction of the larger portion of the starch, protein, and germ by the processes employed in the wet milling manufacture of corn starch or syrup. It may or may not contain one or more of the following: fermented corn extractives, corn germ meal. Originally called Corn Gluten Feed.

(l) Corn Protein Meal is the dried residue from corn after the removal of the larger part of the starch and germ, and the separation of the bran by the process employed in the wet milling manufacture of corn starch or syrup, or by enzymatic treatment of the endosperm. It may contain fermented corn extractives and/or corn germ meal. Originally called Corn Gluten Meal.

(m) Corn Refinery Concentrate is the concentration of sweetwaters, by filtration and evaporation, which are by-products in the production of corn syrup. The total sugars expressed as invert and the moisture level shall be guaranteed.

(n) Cracked Corn is the entire corn kernel ground or chopped. It must contain not more than four (4) percent foreign material.

(o) Dehydrated Corn Plant is the entire corn plant consisting of the ear, leaves, and stalk, which has been artificially dried and ground.

(p) Dried Corn Syrup is a dried product from corn syrup, a purified concentrated aqueous solution of nutritive saccharides obtained from starch having a dextrose equivalent of 20 or more.

(q) Flaked Corn is obtained by running cracked corn which has been aspirated and properly tempered, over smooth flaking rolls and subsequently dried and cooled.

(r) Gelatinized Corn Flour is obtained from endosperm of corn which has been gelatinized and reduced to a finely ground meal and must contain not more than one (1) percent crude fiber.

(s) Ground Corn is the entire corn kernel ground or chopped. It must contain not more than four (4) percent foreign material. May also appear in the ingredient list of a mixed feed as Corn Meal or Corn Chop.

(t) Ground Corn Cob is the product resulting from grinding the entire cob. If it is designated as “Fine Ground,” the entire grind must pass through a number 10 sieve and 33 percent of the total material must pass through a number 20 sieve. If it is designated “Coarse Ground,” the entire grind must pass through a number four sieve and 50 percent must pass through a number 10 sieve. If it is designated as “Dehydrated,” it must contain not more than 10 percent moisture.

(u) Ground Ear Corn is the entire ear of corn ground, without husks, with no greater portion of cob than occurs in the ear corn in its natural state. May also appear in the ingredient list of a mixed feed as Corn and Cob Meal or Ear Corn Chop.

(v) Ground Ear Corn with Husks is the entire ear of corn with husks ground or chopped, with not greater proportion of cob than occurs in the ear corn in its natural state. May also appear in the ingredient list of a mixed feed as Corn and Cob Meal with Husks, or Ear Corn Chop with Husks.

(w) Hominy Feed is a mixture of corn bran, corn germ, and part of the starchy portion of either white or yellow corn kernels or mixture thereof, as produced in the manufacture of pearl hominy, hominy grits, or table meal, and must contain not less than four (4) percent crude fat. If prefixed with the words "white" or "yellow," the product must correspond thereto.

(x) Hydrolyzed Corn Protein is the product resulting from complete hydrolysis of isolated corn protein, and after partial removal of the glutamic acid.

(y) Kibbled Corn is obtained by cooking cracked corn under steam pressure and extruding from an expeller or other mechanical pressure device.

(z) Liquified Corn Product is the product resulting from pressure hydrolysis of corn (steam cooking) and enzymatic treatment of the corn without removing any of the component parts. It shall contain not less than 30 percent solid.

(aa) Maltodextrins is a purified concentrated aqueous solution of nutritive saccharides, or a dried product derived from said solution, derived from starch having a dextrose equivalent of less than 20.

(bb) Screened Cracked Corn is the coarse portion of cracked corn from which most of the fine particles have been removed and may be fine, medium, or coarse. It must contain not more than four (4) percent foreign material.

(cc) Solvent Extracted Hominy Feed is hominy feed from which the fat has been extracted by the solvent process.

(dd) Toasted Corn Flakes is obtained by running cracked corn which has been aspirated and properly tempered, over smooth flaking rolls, and subsequently dried, cooled, and toasted.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2780. Cottonseed Products.

(a) Ammoniated Cottonseed Meal (21 CFR 573.140) is obtained by the treatment of cottonseed meal with anhydrous ammonia until a pressure of 50 pounds per square inch gauge is reached. It is to be used in the feed of ruminants as a source of protein and/or as the sole source of non-protein nitrogen in an amount not to exceed 20 percent of the total ration. The label of the additive and of any feed additive supplement, feed additive concentrate, or feed additive premix prepared therefrom, must contain the following information in addition to any other required information:

(1) The name of the additive.

(2) The maximum percentage of equivalent crude protein from non-protein nitrogen.

(3) Directions for use to provide not more than 20 percent of the additive in the total ration and a prominent statement: “Warning - This feed should be used only in accordance with the directions furnished on the label.”

(b) Cotton Plant By-Product is the residue from the ginning of cotton. It consists of cotton burrs, leaves, stems, lint, immature seeds, and sand and/or dirt. It shall not contain more than 38 percent crude fiber, nor more than 15 percent ash. It must be labeled with minimum guarantees for crude protein and crude fat, and maximum guarantees for crude fiber and ash. If it contains more than 15.0 percent ash, the words "sand and/or dirt" must appear in the product name.

(c) Cottonseed Cake, Mechanical Extracted, is the unground product composed of the kernel and such portions of the lint, hull, and oil as remain after removal of most of the oil from cottonseed by a mechanical process. It must contain not less than 36 percent crude protein. The words “Mechanical Extracted” are not required when listing as an ingredient in a manufactured feed.

(d) Cottonseed Flakes, Mechanical Extracted, is the unground product, composed of the kernel and such portions of the lint, hull, and oil as remain after removal of the oil from cottonseed by a mechanical extraction process. It must contain not less than 36 percent crude protein. The words “Mechanical Extracted” are not required when listing as an ingredient in a manufactured feed.

(e) Cottonseed Flakes, Solvent Extracted, is the unground product, composed of the kernel and such portions of the lint, hull, and oil as remain after removal of the oil from cottonseed by a solvent extraction process. It must contain not less than 36 percent crude protein. The words “Solvent Extracted” are not required when listing as an ingredient in a manufactured feed.

(f) Cottonseed Hulls consist primarily of the outer covering of the cottonseed.

(g) Cottonseed Meal, Mechanical Extracted, is the product obtained by finely grinding the cake, which remains after removal of most of the oil from cottonseed by a mechanical extraction process. It must contain not less than 36 percent crude protein. It may contain an inert, non-toxic conditioning agent either nutritive or non-nutritive or any combination thereof, to reduce caking and improve flowability in an amount not to exceed that necessary to accomplish its intended effect and in no case exceed 0.5 percent. The name of the conditioning agent must be shown as an added ingredient. The words “Mechanical Extracted” are not required when listing as an ingredient in a manufactured feed.

(h) Cottonseed Meal, Solvent Extracted, is the product obtained by finely grinding the flakes, which remain after removal of most of the oil from cottonseed by a solvent extraction process. It must contain not less than 36 percent crude protein. It may contain an inert, non-toxic conditioning agent either nutritive or non-nutritive or any combination thereof, to reduce caking and improve flowability in an amount not to exceed that necessary to accomplish its intended effect and in no case exceed 0.5 percent. The name of the conditioning agent must be shown as an added ingredient. The words “Solvent Extracted” are not required when listing as an ingredient in a manufactured feed.

(i) Cottonseed Screenings is obtained in the commercial delinting and processing of cottonseeds for planting purposes. It consists of lint, stems, leaves, small and immature seeds, sand and/or dirt. It must contain a minimum of 12 percent crude protein and not

more than 30 percent crude fiber. It must be labeled with minimum guarantees for crude protein and crude fat, and maximum guarantees for crude fiber and ash. If it contains more than 6.5 percent ash, the words “sand” and/or “dirt” must appear in the product name.

(j) Cracked or Ground Pima is pima cottonseed that has been processed but from which the oil has not been extracted. It shall be labeled to include the maximum percent ash. It shall contain not more than three (3.0) percent free fatty acids in the oil. It shall contain not more than 13.0 percent moisture and not more than two (2.0) percent foreign material. It shall be labeled to include the maximum percent ash.

(k) Low Gossypol Cottonseed Meal, Mechanical Extracted, is a meal in which the gossypol is not more than 0.04 percent free gossypol. The words “Mechanical Extracted” are not required when listing as an ingredient in a manufactured feed.

(l) Low Gossypol Cottonseed Meal, Solvent Extracted, is a meal in which the gossypol is not more than 0.04 percent free gossypol. The words “solvent extracted” are not required when listing as an ingredient in a manufactured feed.

(m) Prime Whole Cottonseed is seed remaining after the removal of fiber in the ginning process. It shall contain not more than three (3.0) percent free fatty acids in the oil. It shall contain not more than 13.0 percent moisture and not more than two (2.0) percent foreign material. It shall be labeled to include the maximum percent ash.

(n) Whole Cottonseed is seed remaining after removal of fiber in the ginning process. It shall contain not more than 15.0 percent free fatty acids in the oil. It shall contain not more than 13.0 percent moisture and not more than two (2.0) percent foreign material. It shall be labeled to include the maximum percent ash.

(o) Whole-Pressed Cottonseed, Mechanical Extracted, is composed of sound, mature, clean, delinted, and unhulled cottonseed, from which most of the oil has been removed by mechanical pressure. It must be designated and sold by its crude protein content. If ground, it must be so designated. The words “Mechanical Extracted” are not required when listing as an ingredient in a manufactured feed.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2781. Distillers Products.

(a) [Specify] Condensed Distillers Solubles is obtained after the removal of ethyl alcohol by distillation from the yeast fermentation of a grain or a grain mixture by condensing the thin stillage fraction to a semi-solid. The predominating grain must be declared as the first word in the name on the label; for example, “Corn Condensed Distillers Solubles.”

(b) Deoiled Corn Distillers Dried Grains with Solubles, Solvent Extracted, is the product resulting from the solvent extraction of oil from corn distillers dried grains with solubles (DDGS) to result in a crude fat content of less than three (3) percent on an as fed basis. It is intended as a source of protein. The label shall include a guarantee for minimum crude protein and maximum sulfur. The words “Solvent Extracted” are not required when listing as an ingredient in a manufactured feed.

(c) [Specify] Distillers Dried Grains is obtained after the removal of ethyl alcohol by distillation from the yeast fermentation of a grain or a grain mixture by separating the resultant coarse grain fraction of the whole stillage and drying it by methods employed in the grain distilling industry. The predominating grain shall be declared as the first word in the name on the label; for example, “Corn Distillers Dried Grains.”

(d) [Specify] Distillers Dried Grains with Solubles is the product obtained after the removal of ethyl alcohol by distillation from the yeast fermentation of a grain or a grain mixture by condensing and drying at least 3/4 of the solids of the resultant whole stillage by methods employed in the grain distilling industry. The predominating grain shall be declared as the first word in the name on the label; for example, “Corn Distillers Dried Grains with Solubles.”

(e) [Specify] Distillers Dried Solubles is obtained after the removal of ethyl alcohol by distillation from the yeast fermentation of a grain or a grain mixture by condensing the thin stillage fraction and drying it by methods employed in the grain distilling industry. The predominating grain must be declared as the first word in the name on the label; for example, “Corn Distillers Dried Solubles.”

(f) [Specify] Distillers Wet Grains is the product obtained after the removal of ethyl alcohol by distillation from the yeast fermentation of a grain or a grain mixture. The guaranteed analysis shall include the maximum moisture. The predominating grain must be declared as the first word in the name on the label; for example, “Corn Distillers Wet Grains.”

(g) Molasses Distillers Condensed Solubles is obtained by condensing to a syrupy consistency the residue from the yeast fermentation of molasses after the removal of the alcohol by distillation.

(h) Molasses Distillers Dried Solubles is obtained by drying the residue from the yeast fermentation of molasses after the removal of the alcohol by distillation.

(i) Potato Distillers Dried Residue is the dried product obtained after the manufacture of alcohol and distilled liquors from potatoes or from a mixture in which potatoes predominate.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2782. Enzymes.

(a) General Provisions.

(1) “Typical Substrates” are listed to provide guidance and are not all-inclusive.

(2) “Supported Use” references additional enzyme functionality beyond that listed under “Function” and does not limit the enzyme functionality statement to specific animal species.

(3) The purpose statement of a product label shall include the statement “Contains a source of (enzymatic activity) which can (“Function” and/or “Supported Use” as stated in this section)” if enzymatic activity is represented in any manner. For enzymes obtained from microorganisms, ingredient names shall use one of the

applicable definitions (Dried [Specify] Fermentation Extract, Dried [Specify] Fermentation Solubles, Dried [Specify] Fermentation Product, or Liquid [Specify] Fermentation Product) using the source organism that produced the specific enzyme. For example, the name Dried Aspergillus niger Fermentation Extract may be used for a dry alpha-amylase enzyme product because Aspergillus niger is an accepted source organism for alpha-amylase. Enzymes obtained from plants or animals shall use an appropriate common or usual name that accurately describes the ingredient obtained from the source organism, such as dried pineapple stem for bromelain, fig extract for ficin, or dried pork stomach mucosa powder for pepsin. In the case of microbial enzymes, it is understood that they are produced from nonpathogenic and nontoxigenic strains.

(b) Fumonisin Esterase (21 CFR 573.485). The food additive fumonisin esterase may be safely used to degrade fumonisins in swine and poultry feed in accordance with the following prescribed conditions:

(1) Fumonisin esterase, a carboxylesterase, is produced by a nontoxigenic and nonpathogenic yeast, Komagataella phaffii, genetically engineered to express the fumonisin esterase gene from the bacterium Sphingopyxis sp. Hydrolyzed fumonisin and two tricarballylic acid molecules are the reaction products of fumonisin hydrolysis by this 493 amino acid fumonisin esterase enzyme.

(2) The additive shall meet the following specifications: The fermentation media for the Komagataella phaffii shall not contain methanol. Viable genetically engineered Komagataella phaffii shall not be present. One unit of fumonisin esterase activity is defined as the amount of enzymatic activity required to release one micromole of tricarballylic acid (CAS 99-14-9) per minute from 100 micromolar fumonisin B1 in 20 millimolar Tris- hydrochloride buffer (pH 8.0) containing 0.1 milligram per milliliter of bovine serum albumin at 30 degrees Celsius.

(3) The additive is incorporated at a minimum of 15 units of fumonisin esterase activity per kilogram of complete feed: Complete swine feeds cannot contain more than 10 parts per million of total fumonisins. Complete feed for poultry being raised for slaughter cannot contain more than 50 parts per million of total fumonisins. Complete feed for breeding poultry and hens laying eggs for human consumption cannot contain more than 15 parts per million of total fumonisins.

(4) To assure safe use of the additive, in addition to the other information required by the FD&C: The label and labeling of the additive, any feed premix, and complete feed shall contain the common or usual name of the additive’s source, dried Komagataella phaffii fermentation product. The label and labeling of the additive and any feed premix shall also contain: adequate directions for use including a statement that the additive must be uniformly applied and thoroughly mixed into complete feeds; a guarantee for the minimum amount of fumonisin esterase activity, expressed in accordance with this section, and the unit of weight being consistent with the inclusion rate stated in the directions for use; appropriate warning and safety precaution statements concerning the additive as a respiratory sensitizer; and a cautionary statement concerning the maximum fumonisin content as established in this section.

(c) Carbohydrases.

(1) alpha-Amylase.

(A) Source Organism: Animal pancreatic tissue, Aspergillus niger, var., Aspergillus oryzae, var., Bacillus amyloliquefaciens, Bacillus lentus, Bacillus licheniformis, Bacillus licheniformis containing a Bacillus stearothermophilus gene for alpha-amylase Bacillus stearothermophilus Bacillus subtilis containing a Bacillus megaterium gene for alpha-amylase, Bacillus subtilis containing a Bacillus stearothermophilus gene for alpha- amylase, Bacillus subtilis, var., Barley malt, Paenibacillus lentus, Rhizopus niveus, Rhizopus oryzae, var.

(B) Typical Substrate: Corn silage, corn, corn feed meal, corn protein feed, soybean meal, wheat, wheat middlings, barley, grain sorghum, pea, oat, tapioca, millet, rice.

(C) Function: Hydrolyzes starch.

(2) Maltogenic alpha-amylase.

(A) Source Organism: Bacillus subtilis containing a Bacillus stearothermophilus gene for maltogenic alpha-amylase.

(B) Typical Substrate: See alpha- amylase.

(C) Function: Hydrolyzes starch with production of maltose.

(3) beta-Amylase.

(A) Source Organism: Barley malt.

(B) Typical Substrate: See alpha- amylase.

(C) Function: Hydrolyzes starch with production of maltose.

(4) Cellulase.

(A) Source Organism: Aspergillus niger, var., Humicola insolens, Trichoderma longibrachiatum (also known as T. reesei or T. viride).

(B) Typical Substrate: Corn, barley, wheat, wheat, bran, rye, grain sorghum.

(C) Function: Breaks down cellulose.

(5) alpha-Galactosidase.

(A) Source Organism: Aspergillus niger, var., Morteirella vinaceae var. raffinoseutilizer, Saccharomyces sp.

(B) Typical Substrate: Sweet lupin, soybean meal.

(C) Function: Hydrolyzes oligosaccharides.

(6) beta-Glucanase.

(A) Source Organism: Aspergillus niger, var., Aspergillus aculeatus, Bacillus lentus, Bacillus subtilis, var., Humicola insolens, Paenibacillus lentus,

Talaromyces funiculosus, Talaromyces versatilis overexpressing glucanase, Trichoderma longibrachiatum (also known as T. reesei or T. viride).

(B) Typical Substrate: Wheat, barley, canola meal, wheat by-product, oat groats, rye, triticale, grain sorghum.

(C) Function: Hydrolyzes beta-glucans, a type of non-starch polysaccharide.

(D) Supported Use: Reduction of digesta viscosity with barley-based poultry diets, reduces soluble non-starch polysaccharides in digesta.

(7) beta-Glucosidase.

(A) Source Organism: Aspergillus niger, var.

(B) Typical Substrate: Plant cell wall constituents.

(C) Function: Hydrolyzes cellulose degradation products to glucose.

(8) Glucoamylase (amyloglucosidase).

(A) Source Organism: Aspergillus niger, var., Aspergillus oryzae, var., Rhizopus niveus, Rhizopus oryzae, var.

(B) Typical Substrate: See alpha- amylase.

(C) Function: Hydrolyzes starch with production of glucose.

(9) Hemicellulase.

(A) Source Organism: Aspergillus aculeatus, Aspergillus niger, var., Bacillus lentus, Bacillus subtilis, var., Humicola insolens, Paenibacillus lentus, Trichoderma longibrachiatum (also known as T. reesei or T. viride).

(B) Typical Substrate: Corn, soybean meal, guar meal, barley, rye, grain sorghum, wheat, oats, peas, lentils.

(C) Function: Breaks down hemicellulose.

(D) Supported Use: Reduction in stickiness of excreta in poultry fed guar meal.

(10) Invertase.

(A) Source Organism: Aspergillus niger, var., Saccharomyces sp.

(B) Typical Substrate: Sucrose containing products and by-products.

(C) Function: Hydrolyzes sucrose to glucose and fructose.

(11) Lactase.

(A) Source Organism: Aspergillus niger, var., Aspergillus oryzae, var., Candida pseudotropicalis, Kluyveromyces marxianis var. lactis (formerly Saccharomyces sp.).

(B) Typical Substrate: Lactose containing products and by-products.

(C) Function: Hydrolyzes lactose to glucose and galactose.

(12) beta-Mannanase.

(A) Source Organism: Aspergillus niger, var., Bacillus lentus, Paenibacillus lentus, Trichoderma longibrachiatum (also known as T. reesei or T. viride).

(i) Typical Substrate: Corn, soybean meal, guar meal, copra meal.

(ii) Function: Hydrolyzes beta- mannans, a component of hemicellulose.

(iii) Supported Use: Reduction in stickiness of excreta in poultry fed guar meal.

(B) Source Organism: Bacillus subtilis, var.

(i) Typical Substrate: Distillers dried grains with solubles.

(ii) Function: Hydrolyzes beta- mannans, a component of hemicellulose.

(iii) Supported Use: Reduction of digesta viscosity with swine diets.

(13) Pectinase.

(A) Source Organism: Aspergillus aculeatus, Aspergillus niger, var., Rhizopus oryzae.

(B) Typical Substrate: Corn, wheat.

(C) Function: Breaks down pectin.

(14) Pullulanase.

(A) Source Organism: Bacillus acidopullulyticus, Bacillus licheniformis containing a Bacillus deramificans gene for pullulanase.

(B) Typical Substrate: See alpha- amylase.

(C) Function: Hydrolyzes starch.

(15) Xylanase.

(A) Source Organism: Aspergillus niger, var., Aspergillus oryzae expressing a Thermomyces lanuginosus xylanase gene, Bacillus lentus, Bacillus subtilis, var., Humicola insolens, Paenibacillus lentus, Talaromyces funiculosus, Talaromyces versatilis overexpressing xylanase Trichoderma longibrachiatum (also known as T. reesei or T. viride).

(B) Typical Substrate: Corn, barley, rye, wheat, grain sorghum, triticale, oats.

(C) Function: Hydrolyzes xylans, a component of hemicellulose.

(D) Supported Use: Reduction of digesta viscosity with poultry diets.

(d) Lipases.

(1) Lipase.

(A) Source Organism: Animal pancreatic tissue, Aspergillus niger, var., Aspergillus oryzae, var., Candida rugosa (formerly cylindracea), Edible

forestomach of calves, kids, and lambs, Rhizomucor (Mucor-)miehei, Rhizopus oryzae.

(B) Typical Substrate: Plant and animal sources of fats and oils.

(C) Function: Hydrolyzes triglycerides.

(e) Proteases.

(1) Bromelain.

(A) Source Organism: Pineapples-stem, fruit.

(B) Typical Substrate: Plant and animal proteins.

(C) Function: Hydrolyzes proteins.

(2) Ficin.

(A) Source Organism: Figs.

(B) Typical Substrate: Plant and animal proteins.

(C) Function: Hydrolyzes proteins.

(3) Keratinase.

(A) Source Organism: Bacillus licheniformis.

(B) Typical Substrate: Plant and animal proteins.

(C) Function: Hydrolyzes proteins.

(4) Papain.

(A) Source Organism: Papaya.

(B) Typical Substrate: Plant and animal proteins.

(C) Function: Hydrolyzes proteins.

(5) Pepsin.

(A) Source Organism: Porcine or other animal stomachs.

(B) Typical Substrate: Plant and animal proteins.

(C) Function: Hydrolyzes proteins.

(6) Protease (general).

(A) Source Organism: Aspergillus niger, var., Aspergillus oryzae, var., Bacillus amyloliquefaciens Bacillus licheniformis Bacillus subtilis, var.

(i) Typical Substrate: Plant and animal proteins.

(ii) Function: Hydrolyzes proteins.

(B) Source Organism: Bacillus licheniformis expressing serine protease genes from Nocardiopsis prasine.

(i) Typical Substrate: Plant proteins.

(ii) Function: Hydrolyzes proteins.

(iii) Supported Use: Increases the digestibility of protein in corn-soybean meal based diets.

(C) Source Organism: Bacillus subtilis containing a Bacillus amyloliquefaciens gene for protease.

(i) Typical Substrate: Plant proteins.

(ii) Function: Hydrolyzes proteins.

(7) Trypsin.

(A) Source Organism: Animal pancreas.

(B) Typical Substrate: Plant and animal proteins.

(C) Function: Hydrolyzes proteins.

(f) Oxidoreductases.

(1) Catalase.

(A) Source Organism: Aspergillus niger, var., Micrococcus lysodeikticus.

(B) Typical Substrate: Hydrogen peroxide.

(C) Function: Produces water and oxygen from hydrogen peroxide.

(2) Glucose oxidase.

(A) Source Organism: Aspergillus niger, var.

(B) Typical Substrate: Glucose.

(C) Function: Degrades glucose to hydrogen peroxide and gluconic acid.

(g) Phosphatases.

(1) Phytase.

(A) Source Organism: Aspergillus niger, var., Aspergillus oryzae, var., Aspergillus oryzae expressing the Peniophora lycii phytase gene, Phytase canola (Brassica napus expressing the Aspergillus niger phytase gene), Komagataella pastoris expressing a phytase gene from a Risk Group 1 Escherichia coli, Schizosaccharomyces pombe expressing an Excherichia coli strain B phytase gene, Trichoderma reesei expressing an altered phytase gene from a Risk Group 1 Escherichia coli, Trichoderma reesei expressing an altered phytase gene from a Buttiauxella sp.

(i) Typical Substrate: Corn, soybean meal, sunflower meal, hominy, tapioca, plant by-products.

(ii) Function: Hydrolyzes phytate.

(iii) Supported Use: Increases the digestibility of phytin-bound phosphorus in poultry and swine diets.

(B) Source Organism: Talaromyces funiculosus.

(i) Function: Hydrolyzes phytate.

(ii) Supported Use: Increases the digestibility of phytin-bound phosphorus in poultry diets.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2783. Fats and Oils.

(a) General Provisions.

(1) The use of the term "feed grade" requires that the specific type of product be adequately tested to prove its safety for feeding purposes. In mixed feeds containing fats or fat derivatives the term “feed grade” may be omitted in the ingredient declaration.

(2) Any mixture of two or more fats or fat derivatives defined below is to be identified by listing each component: e.g., "animal fat and hydrolyzed vegetable oil."

(3) Fats or fat derivatives must come from acceptable animal feed sources. Waste water sludge that contains sanitary sewer water is not an acceptable source of animal feed. FDA should be contacted regarding the safe use in animal feed of all other sludge material that does not contain sanitary waste water. (Sludge: The suspended or dissolved solid matter resulting from the processing of animal or plant tissue for human food. Waste Water Sludge: The sanitary sewer water and suspended or dissolved solid matter resulting from the processing of animal or plant tissues for human food.)

(b) Animal Fat is obtained from the tissues of mammals and/or poultry in commercial processes of rendering or extracting. It consists predominately of glyceride esters of fatty acids and contains no additions of free fatty acids or other materials obtained from fats. It must contain, and be guaranteed for, not less than 90 percent total fatty acids, not more than 2.5 percent unsaponifiable matter, and not more than one (1) percent insoluble impurities. Maximum free fatty acids and moisture must also be guaranteed. If the product bears a name descriptive of its kind or origin, e.g., “beef,” “pork,” “poultry,” it must correspond thereto. Rendered animal fat derived from only pork raw materials can be labeled as white grease. Rendered animal fat derived from only cattle raw materials can be labeled as beef tallow. Tallow containing greater than 0.15 percent insoluble impurities must be labeled with the BSE caution statement “do not feed to cattle or other ruminants.” If an antioxidant(s) is used, the common name or names must be indicated, followed by the words “used as a preservative.”

(c) Black Soldier Fly Larvae Oil is the product obtained by mechanically extracting the oil from dried larvae of Black Soldier Fly, Hermetia illucens, that have been raised on a feedstock composed exclusively of feed grade materials. It is intended for use in swine, finfish feed as a source of energy consistent with good feeding practices. It consists predominantly of glyceride esters of fatty acids and contains no additions of free fatty acids or other materials obtained from fats. It must contain, and be guaranteed for, not less than 90 percent total fatty acids, not more than two (2) percent unsaponifiable matter and not more than one (1) percent insoluble impurities. Maximum free fatty acids and moisture must also be guaranteed. If an antioxidant(s) is used, the common name or names must be indicated, followed by the words “used as a preservative.”

(d) Calcium Salts of Long-Chain Fatty Acids are the reaction products between calcium and long-chain fatty acids of vegetable and/or animal origin. They shall contain a maximum of 20 percent lipid not bound in the calcium salt form and the percent total fat shall be indicated. The unsaponifiable matter (exclusive of calcium salts) shall not exceed four (4) percent and moisture shall not exceed five (5) percent. If an antioxidant(s) is used, its common name(s) must be indicated on the label. Prior to conducting an assay for total fats, hydrolysis of the calcium salts should be performed to liberate the lipid fraction.

(e) Corn Syrup Refinery Insolubles, Feed Grade, is obtained in the refining of a corn syrup. It consists predominantly of the fatty fraction of corn starch together with protein and residual carbohydrate. It may contain water and not more than seven (7) percent ash nor less than 50 percent fat on a water-free basis.

(f) [Specify] Distillers Oil, Feed Grade, is obtained after the removal of ethyl alcohol by distillation from the yeast fermentation of a grain or a grain mixture and mechanical or solvent extraction of oil by methods employed in the ethanol production industry. It consists predominantly of glyceride esters of fatty acids and contains no additions of free fatty acids or other materials obtained from fats. It must contain, and be guaranteed for, not less than 85 percent total fatty acids, not more than 2.5 percent unsaponifiable matter, and not more than one (1) percent insoluble impurities. Maximum free fatty acids and moisture must be guaranteed. If an antioxidant(s) is used, the common or usual name must be indicated, followed by the words “used as a preservative.” If the product bears a name descriptive of its kind or origin, e.g., “corn, sorghum, barley, rye,” it must correspond thereto with the predominating grain declared as the first word in the name on the label; for example, “Corn Distillers Oil, Feed Grade.”

(g) [Specify] Ester [Specify], Feed Grade (21 CFR 573.640), is the product consisting of methyl, ethyl, or other non-glyceride ester of fatty acids derived from animal and/or vegetable fats. It consists predominantly of the ester and must contain not less than 85 percent total fatty acids, not more than 10 percent free fatty acids, not more than six (6) percent unsaponifiable matter (two (2) percent for methyl esters) and not more than one (1) percent insoluble matter. Its source must be stated in the product name on the label; e.g., “methyl ester of animal fatty acids,” “ethyl ester of vegetable oil fatty acids.” Methyl esters must contain not more than 150 parts per million (0.015 percent) free methyl alcohol. If an antioxidant(s) is used, the common name or names must be indicated, followed by the word “preservative(s).”

(h) Gamma-Linolenic Acid Safflower Oil (21 CFR 573.492). The food additive gamma-linolenic acid safflower oil may be safely used in animal food as a source of gamma-linolenic acid and other omega-6 fatty acids in accordance with the following conditions:

(1) The additive is the oil obtained from whole seeds and/or partially dehulled seeds of a Carthamus tinctorius L. safflower Centennial variety genetically engineered to express the delta-6-desaturase gene from Saprolegnia diclina Humphrey. The 453 amino acid, delta-6-desaturase enzyme converts the fatty acid linoleic acid to gamma-linolenic acid (all-cis-6,9,12-octadecatrienoic acid) during seed development.

(A) The additive obtained from the seeds of the genetically engineered safflower Centennial variety may be blended with oil obtained from seeds of non-engineered oleic acid safflower varieties in order to meet the specifications required for the additive or the blend in this section.

(B) The additive or a safflower oil blend containing the additive for use in animal food meets the following specifications: Crude fat content of the additive or the safflower oil blend is not less than 99.5 percent. Gamma-linolenic acid content is between 350 and 450 milligrams gamma-linolenic acid per gram of the additive or the safflower oil blend. Total content of stearidonic acid and cis, cis-6,9-octadecadienoic acid in the additive or the safflower oil blend must not exceed a total of 0.3 percent.

(2) To assure safe use of the additive, in addition to other information required by the FD&C, the label and labeling of the additive shall bear the following: The name of the additive, gamma-linolenic acid safflower oil, or GLA safflower oil; a guarantee for the minimum content of gamma-linolenic acid; and adequate directions for use such that the finished animal food complies with the provisions of this section.

(i) Hydrolyzed [Specify] Fat, or Oil, Feed Grade, is obtained in the fat processing procedures commonly used in edible fat processing or soap making. It consists predominately of fatty acids and must contain, and be guaranteed for, not less than 85 percent total fatty acids, not more than six (6) percent unsaponifiable matter, and not more than one (1) percent insoluble impurities. Maximum moisture must also be guaranteed. Its source must be stated in the product name on the label; e.g., “hydrolyzed animal fat,” “hydrolyzed vegetable fat,” or “hydrolyzed animal and vegetable fat.” If an antioxidant(s) is used, the common name or names must be indicated, followed by the words “used as a preservative.”

(j) Hydrolyzed [Specify] Sucrose Polyesters, Feed Grade, is the product resulting from the acid hydrolysis of sucrose polyesters, such as olestra, to make them digestible. It shall consist predominantly of fatty acids and contain, and be guaranteed for, not less than 85 percent total fatty acids, not more than two (2) percent Sucrose Polyesters (hex ester and above), not more than two (2) percent unsaponifiable matter, and not more than two (2) percent insoluble impurities. Maximum moisture must also be guaranteed. Its source must be stated in the product name on the label; e.g., “Hydrolyzed animal sucrose polyesters,” “Hydrolyzed vegetable sucrose polyesters,” or “Hydrolyzed animal and vegetable sucrose polyesters.” If an antioxidant(s) is used, the common name or names must be indicated, followed by the words “used as a preservative.”

(k) Methyl Esters of Conjugated Linoleic Acid (cis-9, trans-11 and trans-10, cis-12-octadecadienoic acids) (21 CFR 573.637) may be safely used in swine feed and feed for early lactation dairy cows (less than 100 days-in-milk) in accordance with the prescribed conditions:

(1) The food additive is manufactured by the reaction of refined sunflower oil with methanol to produce fatty acid methyl esters, which then undergo conjugation to yield methyl esters of octadecadienoic acid. The additive consists of not less than 28 percent methyl ester of cis-9, trans-11-octadecadienoic acid, and not less than 28 percent methyl ester of trans-10, cis-12-octadecadienoic acid with the sum of the other methyl esters of octadecadienoic acid not to exceed four (4) percent. The additive shall contain not less than 35 percent of other fatty acid esters composed of oleic acid, palmitic acid, stearic acid, linoleic acid, and other associated acid esters.

(2) The additive is used or intended for use in the feed of growing and finishing swine as a source of fatty acids at levels not to exceed 0.6 percent in the finished feed.

(3) The additive meets the following specifications:

(A) Free methyl alcohol not to exceed 0.015 percent.

(B) Insoluble impurities not to exceed 0.1 percent.

(C) Moisture not to exceed 0.5 percent.

(D) Unsaponifiable matter not to exceed one (1.0) percent.

(4) To assure safe use of the additive, in addition to the other information required by the FD&C: The label and labeling of the additive and any feed premix shall bear the following: The name of the additive. A statement to indicate that methyl esters of conjugated linoleic acid (cis-9, trans-11 and trans-10, cis-12- octadecadienoic acids) must not be added to vitamin or mineral premixes. The label and labeling of the additive, any feed premix, or complete feed prepared therefrom shall bear adequate directions for use.

(l) Palmitic Acid is a waxy solid derived from the hydrolysis of vegetable oils and/or animal fats. It is used as an energy source in growing and adult ruminant diets up to a maximum inclusion of two (2) percent (weight/weight) in the finished feed. It cannot be used in pre- ruminant animal feed or in milk replacers. The final ingredient is produced by fractional distillation of the hydrolyzed fats and oils. It contains predominantly palmitic acid, with lesser amounts of myristic acid. It must contain, and be guaranteed for, minimum 98 percent palmitic acid, maximum 0.8 percent myristic acid, minimum 99 percent total free fatty acids, maximum one (1) percent sulfated ash, and maximum five (5) parts per million lead. Maximum moisture must also be guaranteed. Animal fats and vegetable oils used in the hydrolysis reaction to produce palmitic acid must meet the specifications stated in the respective definitions for Animal Fat and Vegetable Fat or Oil. If tallow is used, the starting material must comply with the BSE feed regulation under 21 CFR 589.2000 and 589.2001.

(m) Stearic Acid is a waxy solid derived from the hydrolysis of vegetable oils and/or animal fats. It is used as an energy source in growing and adult ruminant diets up to a

maximum inclusion of three (3) percent (weight/weight) in the finished feed. It cannot be used in pre- ruminant animal feed or in milk replacers. The final ingredient is produced by fractional distillation of the hydrolyzed fats and oils. It contains predominantly stearic acid, with lesser amounts of palmitic acid. It must contain, and be guaranteed for, minimum 92 percent stearic acid, maximum five (5) percent palmitic acid, minimum 99 percent total free fatty acids, maximum one (1) percent sulfated ash, and maximum five (5) parts per million lead. Maximum moisture must also be guaranteed. Animal fats and vegetable oils used in the hydrolysis reaction to produce stearic acid must meet the specifications stated in the respective definitions for Animal Fat and Vegetable Fat or Oil. If tallow is used, the starting material must comply with the BSE feed regulation under 21 CFR 589.2000 and 589.2001.

(n) Used Cooking Oil, Feed Grade, is the product of used cooking or frying oil from human food preparation, consisting of animal and/or vegetable fats or oils, collected from commercial human food facilities and then heated to reduce moisture. It must contain, and be guaranteed for, not less than 90 percent total fatty acids, not more than one (1) percent unsaponifiable matter, not more than 0.5 percent insoluble impurities, and not more than one (1) percent moisture. Maximum free fatty acids must also be guaranteed. This product may not include recovered trap grease or material recovered from sanitary sewer sources. If an antioxidant(s) is used, the common name or names must be indicated, followed by the words “used as a preservative.”

(o) Vegetable Fat, or Oil is the product of vegetable origin obtained by extracting the oil from seeds or fruits which are commonly processed for edible purposes. It consists predominantly of glyceride esters of fatty acids and contains no additions of free fatty acids or other materials obtained from fats. It must contain, and be guaranteed for, not less than 90 percent total fatty acids, not more than two (2) percent unsaponifiable matter and not more than one (1) percent insoluble impurities. Maximum free fatty acids and moisture must also be guaranteed. If the product bears a name descriptive of its kind or origin; e.g., “soybean oil,” “cottonseed oil,” it must correspond thereto. If an antioxidant(s) is used, the common name or names must be indicated, followed by the words “used as a preservative.”

(p) Vegetable Oil Refinery Lipid, Feed Grade, is obtained in the alkaline refining of a vegetable oil for edible use. It consists predominantly of the salts of fatty acids, glycerides, and phosphates. It may contain water and not more than 22 percent ash on a water-free basis. It may or may not be acidulated before using in commercial feeds, but if acidulated, it should be neutralized.

(q) Yellow Grease, Feed Grade, is the rendered product from the tissues of mammals and/or poultry blended with used cooking or frying oil from human food preparation, consisting of animal and/or vegetable fats or oils. It must contain, and be guaranteed for, not less than 90 percent total fatty acids, not more than 2.5 percent unsaponifiable matter, not more than 0.5 percent insoluble impurities, and not more than one (1) percent moisture. Maximum free fatty acids must also be guaranteed. This product may not include recovered trap grease or material recovered from sanitary sewer sources. If an antioxidant(s) is used, the common name or names must be indicated, followed by the words “used as a preservative.” If the product contains tallow (from cattle)

containing greater than 0.15 percent insoluble impurities, then it must be labeled with the BSE caution statement “do not feed to cattle or other ruminants.”

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2784. Fermentation Products.

(a) Condensed, Extracted Glutamic Acid Fermentation Product (21 CFR 573.500) is a concentrated mixture of the liquor remaining from the extraction of glutamic acid, combined with the cells of Corynebacterium lilium or Corynebacterium glutamicum used to produce the glutamic acid. It is used or intended for use as follows: in poultry feed as a source of protein in an amount not to exceed five (5) percent of the total ration; and in cattle feed as a source of protein in an amount not to exceed 10 percent of the feed. In order to assure safe use, the label and labeling of the additive shall bear the following:

(1) The name of the additive.

(2) A statement of the concentration of the additive contained in any mixture.

(3) Adequate directions for use.

(4) Non-protein nitrogen content must be guaranteed when present.

(b) Condensed [Specify] Fermentation Solubles is the product resulting from the removal of a considerable portion of the liquid by-product resulting from the action of the ferment on the basic medium of grain, molasses, whey, or other media. Non-protein nitrogen content (when present) must be guaranteed. For label identification, the source must be indicated as “Condensed (Whey, Grain, or Molasses) Fermentation Solubles.”

(c) Direct-Fed Microorganisms. The following microorganisms were reviewed by the Food and Drug Administration, Center for Veterinary Medicine, and found to present no safety concerns when used in direct-fed microbial products. These microorganisms must be nontoxigenic.

(1) Aspergillus niger, Aspergillus oryzae, Bacillus amyloliquefaciens, Bacillus coagulans, Bacillus lentus, Bacillus licheniformis, Bacillus pumilus, Bacillus subtilis, Bacteroides amylophilus, Bacteroides capillosus, Bacteroides ruminocola, Bacteroides suis, Bifidobacterium adolescentis, Bifidobacterium animalis, Bifidobacterium bifidum, Bifidobacterium infantis, Bifidobacterium longum, Bifidobacterium thermophilum, Lactococcus cremoris, Lactococcus lactis, Enterococcus faecium, Lactococcus lactis, Lactobacillus acidophilus, Lactobacillus animalis, Lactobacillus brevis, Lactobacillus buchneri (cattle only), Lactobacillus casei, Lactobacillus curvatus, Lactobacillus delbrueckii, Lactobacillus farciminis (swine only), Lactobacillus fermentum, Lactobacillus helveticus, Lactobacillus plantarum, Lactobacillus reuteri, Lactococcus cremoris, Lactococcus lactis, Leuconostoc mesenteroides, Megasphaera elsdenii (cattle only), Pediococcus acidilactici, Pediococcus damnosus, Pediococcus pentosaceus, Propionibacterium acidipropionici (cattle only), Propionibacterium freudenreichii, Rhodopseudomonas palustris (broiler chickens only), Saccharomyces cerevisiae, Streptococcus intermedius, Streptococcus thermophilus, Weissella confusa, Yeast (as defined elsewhere).

(d) Dried Extracted [Specify] Fermentation Solubles is the dried extracted broth obtained from a specified source of fermentation. For label identification the source must be indicated such as Penicillium, Streptomyces, or citric acid, or as permitted by FDA.

(e) Dried Fermentation Biomass is a nonviable biomass product resulting from the production of the amino acids by the fermentation of nonpathogenic, nontoxigenic, risk group 1 Escherichia coli. The product must contain a minimum of 75 percent crude protein on a dry matter basis. The product is intended as a source of protein. Non-protein nitrogen content must be guaranteed when present.

(f) Dried [Specify] Fermentation Extract is the dried product resulting from extracting and precipitating by means of non-aqueous solvents or other suitable means, the water soluble materials from a fermentation conducted for maximum production of enzymes using a nonpathogenic strain of the microorganism specified in accordance with good manufacturing practices. For label identification the source must be indicated such as Bacillus subtilis, Aspergillus oryzae, Aspergillus niger, or as permitted by FDA.

(g) Dried [Specify] Fermentation Product is the product derived by culturing on appropriate nutrient media for the production of one or more of the following: enzymes, fermentation substances, or other microbial metabolites, and dried in accordance with approved methods and good manufacturing practices. Protein, amino acids, fat, fiber, cell count, enzyme activity or nutrient metabolite level shall be guaranteed where applicable. Use of Lactobacillus buchneri, Lactobacillus diolivorans, and Lentilactobacillus hilgardii is limited to silage and high moisture corn grain in plant inoculant products. For label identification the source must be indicated such as Bacillus subtilis, Aspergillus oryzae, Aspergillus niger, Lactobacillus acidophilus, Lactobacillus buchneri, Lactobacillus diolivorans, Lentilactobacillus hilgardii, Lactobacillus delbrueckii, or Enterococcus faecium, or as permitted by FDA.

(h) Dried [Specify] Fermentation Solubles is the dried material resulting from drying the water soluble materials after separation of suspended solids from a fermentation conducted for maximum production of enzymes using a nonpathogenic strain of the microorganism specified in accordance with good manufacturing practices. For label identification the source must be indicated such as Bacillus subtilis, Aspergillus oryzae, Aspergillus niger, or as permitted by FDA.

(i) Dried L-Lysine Fermentation Product is the dry biomass product from the fermentation of Corynebacterium glutamicum on an appropriate nutrient media and stabilized in accordance with good manufacturing practices. The product is intended as a source of lysine in livestock, poultry and aquaculture feeds. The L-lysine content must not be less than 50 percent on a dry matter basis. The label shall include guarantees for minimum L-lysine and maximum sulfur.

(j) Extracted [Specify] [Specify] is the filtered and dried mycelium obtained from a specified source of fermentation. For label identification the source must be indicated as Penicillium, Streptomyces, or citric acid and must be stated as that in the second word of the name. The third word of the name is for the form of the ingredient, i.e., presscake, meal, or pellets.

(k) Extracted [Specify] Presscake is the filtered and dried mycelium obtained from a specified source of fermentation. For label identification the source must be indicated as Penicillium, Streptomyces, citric acid, etc.

(l) Extracted [Specify] Meal is the ground specified fermentation source presscake. For label identification the source must be indicated as Penicillium, Streptomyces, citric acid, etc.

(m) Liquid [Specify] Fermentation Product is the liquid product derived by culturing or fermenting a specified fermentation source on appropriate liquid nutrient media for the production of one or more of the following: enzymes, fermentation substances, or other microbial metabolites, and stabilized by approved methods in accordance with good manufacturing practices. Percent solids, cell count, enzyme activity or nutrient metabolite level shall be guaranteed where applicable. For label identification the source must be indicated such as Bacillus subtilis, Aspergillus oryzae, Aspergillus niger, Lactobacillus acidophilus, Lactobacillus delbrueckii or Enterococcus faecium, or as permitted by FDA. For Dried Cultured Skimmed Milk, refer to Milk Products Section. For Condensed Cultured Skimmed Milk, refer to Milk Products Section.

(n) Liquid L-Lysine Fermentation Product is the liquid biomass product from the fermentation of Corynebacterium glutamicum on appropriate nutrient media and stabilized in accordance with good manufacturing practices. The product is intended as a source of lysine in livestock and poultry feeds. The L-lysine content must not be less than 50 percent on a dry matter basis. The label shall include guarantees for minimum L-lysine and maximum sulfur.

(o) Undried Extracted [Specify] Solids and Fermentation Solubles is undried mycelium and extracted broth or the extracted and undried mycelium and broth obtained from a specified source of fermentation. For label identification the source must be indicated such as Penicillium, Streptomyces, citric acid, or as permitted by FDA.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2785. Grain Sorghums (Milo, Hegari, Kaffir, or Feterita).

(a) General Provisions.

(1) Any of the types shown parenthetically in the heading for this section may be substituted for the words "Grain Sorghums" in the definitions below. If the name of the type is given it must correspond thereto.

(b) Gelatinized Sorghum Grain Flour is obtained from the endosperm of sorghum grain which has been gelatinized and reduced to a finely ground meal and must contain not more than one (1) percent crude fiber.

(c) Grain Sorghum Germ Cake or Grain Sorghum Germ Meal consists of the germ of grain sorghum grains from which part of the oil has been pressed and is the product obtained in the wet milling process of manufacture of starch, syrup, and other grain sorghum products.

(d) Grain Sorghum Grits consists of the hard flinty portions of sorghums containing little or no bran or germ.

(e) Grain Sorghum Mill Feed is a mixture of grain sorghum bran, grain sorghum germ, part of the starchy portion of grain sorghum kernels, or mixture thereof as produced in the manufacture of grain sorghum grits and refined meal and flour and must contain not less than five (5) percent crude fat and not more than six (6) percent crude fiber.

(f) Grain Sorghum Protein Feed is that part of the grain of grain sorghums that remains after the extraction of the larger part of the starch and germ, by the processes employed in the wet milling manufacture of starch or syrup. Originally called Grain Sorghum Gluten Feed.

(g) Grain Sorghum Protein Meal is the part of the grain of grain sorghums that remains after the extraction of the larger part of the starch and germ, and the separation of the bran by the processes employed in the wet milling manufacture of starch or syrup. Originally called Grain Sorghum Gluten Meal.

(h) Ground Grain Sorghum is the entire product made by grinding the grains of grain sorghum. The word “cracked” must be substituted for the word “ground” in the above definition when the product is cracked instead of ground.

(i) Partially Aspirated Sorghum Grain Flour is obtained from whole sorghum grain which has been partially aspirated and has been gelatinized and reduced to a finely ground meal and must contain not more than 2.5 percent crude fiber.

(j) Rolled Grain Sorghum is obtained by running whole grain sorghum over smooth flaking rolls, after properly tempering, removing most of the fine particles and subsequently dried and cooled.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2786. Human Food By-Products.

(a) General Provisions.

(1) All ingredients must be feed grade. Firms should perform a safety assessment of materials that may be included in the offered feed ingredient, at the maximum use level (including cocoa products and non-nutritive sweeteners), to determine safety for the intended animal species and the safety of milk, meat, or eggs from animals consuming the ingredient. The safety assessment should be archived in the firm's files and provided to state or federal regulators upon request.

(b) Cereal Food Fines consists of particles of breakfast cereals obtained as a by-product of their processing.

(c) Cull Fruit or Vegetables means material rejected as inferior during the process of grading or separating. This includes any fruits or vegetables that are left in the field after harvest. The label for these products shall include the word “cull,” the name of the product, and a statement to the effect of “not for human consumption” or “for livestock feed only.”

(d) Dried Apple Pectin Pulp is the sound, dried residue obtained by the removal of pectin from apple products.

(e) Dried Apple Pomace is the sound, dried residue obtained by the removal of cider from apples.

(f) Dried Bakery Product is a mixture of bread, cookies, cake, crackers, flours, and doughs which has been mechanically separated from non-edible material, artificially dried and ground. If the product contains more than 3.5 percent salt, the maximum percentage of salt must be a part of the name on the label; i.e. Dried Bakery Product with [X]% Salt.

(g) [Specify] Dried Beans are the residue of the normal packaging and processing of a specified variety of dried beans for human consumption. This residue shall consist of the broken, small, shriveled, and cull specified variety of beans. They shall be identified by variety such as navy, Northern, pinto, kidney, et al. Where further processing, such as grinding, roasting, etc., has occurred, ground, roasted, or other acceptable description may be part of the name on the label, i.e., ground roasted pinto dried beans.

(h) Dried Potato Products is the dried residue of potato pieces, peeling, culls, etc., obtained from the manufacture of processed potato products for human consumption. The residue may contain up to three (3) percent hydrate of lime which may be added to aid in processing.

(i) Dried Tomato Pomace is the dried mixture of tomato skins, pulp, and crushed seeds. If the pomace contains spices used in the production of the tomato product, this must be shown in the name as “Dried Spiced Tomato Pomace.”

(j) Food Processing Waste is composed of any and all animal and vegetable products from basic food processing. This may include manufacturing or processing waste, cannery residue, production over-run, and otherwise unsaleable material. The guaranteed analysis shall include the maximum moisture, unless the product is dried by artificial means to less than 12 percent moisture and designated as “Dehydrated Food Processing Waste.” If part of the grease and fat is removed, it must be designated as “Degreased.” Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.” This ingredient may contain materials subject to the Swine Health Protection Act and may require additional processing controls, if fed to swine. Prior to the use of this ingredient for the feeding of swine or its use in the manufacturing of an ingredient or feed intended for swine, manufacturers and/or feeders should adhere to the provisions of the Swine Health Protection Act where appropriate (9 CFR 166).

(k) Gelatin By-Products is the dried residue from the various process streams from the manufacture of edible gelatin. The total crude protein content will contain a minimum of 85 percent digestible protein as determined by the AOAC pepsin method 22.025-22.031. A 25 percent maximum of diatomaceous earth will not be exceeded. This product is for use in poultry feeds not to exceed five (5) percent of the total rations.

(l) Mixed Feed Nuts are the residue of the normal packaging and processing for human consumption of shelled tree nut and peanut products. This residue shall consist of

broken, small, shriveled and cull edible tree nuts or peanuts of two or more kinds and shall be suitable for animal consumption. If salt has been added during processing, a guarantee must be made for maximum sodium.

(m) Pasta Product is a mixture of dry, whole and broken particles of noodles, macaroni, spaghetti, etc., or a mixture of these resulting from the manufacturing and packaging of edible pasta products and which has been mechanically separated from any non-edible materials.

(n) [Specify] Pomace is the sound residue from the normal processing of fruits for human consumption. This residue shall be suitable for animal feed usage and may contain the skin, peel, seed, and pulp, exclusive of stems except in accordance with good manufacturing practices. It must contain a maximum guarantee for moisture percentage and acid detergent fiber. The source must be declared as the first word in the ingredient name, i.e., apple pomace, grape pomace, etc. Moisture may be removed by an acceptable method and the term “dried” included in the name on the label, i.e., dried apple pomace, etc.

(o) Recovered Retail Food is composed of edible human food products safe and suitable for livestock feed that are collected from retail food establishments, domestic holding facilities, and domestic packing facilities. Permitted recovered retail foods are products from overstocks, lacking consumer acceptance, or beyond their sell-by date that include items such as bruised, cut, or overly ripe produce (fruit and vegetables), bakery goods, eggs, and dairy products. It shall be safe and appropriately labeled for its intended use and shall be free of material harmful to animals. Materials excluded from this definition include pet foods and products containing beef, lamb, pork, poultry, fish, or shellfish. It must not contain packaging materials (e.g., plastics, glass, metal, string, Styrofoam, cardboard, and similar materials), flowers, potted plants, or potting soil. The recovered foods shall be collected and intermixed in secure holding containers to exclude unauthorized addition of trash, materials harmful to animals, or infestation and adulteration by pests. Egg and dairy products (and other products ordinarily held at refrigerator temperatures) must be kept in cold storage until the scheduled pick-up. To minimize spoilage, the recovered retail food shall be collected at least weekly, or more frequently if necessary. The establishment should have a sanitation plan in place, and the containers should be cleaned and sanitized as necessary. The collected material may be further processed or delivered as is to an animal feeding facility. The product must be handled to preserve its safety and nutritional value.

(p) Restaurant Food Waste is composed of edible food waste collected from restaurants, cafeterias, and other institutes of food preparation. Processing and/or handling must remove any and all undesirable constituents including crockery, glass, metal, string, and similar materials. The guaranteed analysis shall include maximum moisture, unless the product is dried by artificial means to less than 12 percent moisture and designated as “Dehydrated Restaurant Food Waste.” If part of the grease and fat is removed it must be designated as “Degreased.” Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.” This ingredient may contain materials subject to the Swine Health Protection Act and may require additional processing controls, if fed

to swine. Prior to the use of this ingredient for the feeding of swine or its use in the manufacturing of an ingredient or feed intended for swine, manufacturers and/or feeders should adhere to the provisions of the Swine Health Protection Act where appropriate (9 CFR 166).

(q) Sugar Foods By-Product is the product resulting from the grinding and mixing of the inedible portions derived from the preparation and packaging of sugar based food products such as candy, dry packaged drinks, dried gelatin mixes, and similar food products which are largely sugar. It shall contain not less than 80 percent total sugar expressed as invert. It shall be free from foreign materials harmful to animals.

(r) Wet Food Processing Waste is composed of any and all animal and vegetable products from basic food processing. This may include manufacturing or processing waste, cannery residue, production over-run, and otherwise unsaleable material and is 70 percent moisture or higher. The guaranteed analysis shall include the maximum moisture. If part of the grease and fat is removed, it must be designated as "Degreased." If wet food processing waste is comprised of a single ingredient the label shall additionally specify what the product is, e.g. Wet Food Processing Waste - Potato Peels. Other examples of Wet Food Processing Waste may include, but are not limited to, tomato pomace, citrus pulp, beet pulp, and apple pomace. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: "Do not feed to cattle or other ruminants." This ingredient may contain materials subject to the Swine Health Protection Act and may require additional processing controls, if fed to swine. Prior to the use of this ingredient for the feeding of swine or its use in the manufacturing of an ingredient or feed intended for swine, manufacturers and/or feeders should adhere to the provisions of the Swine Health Protection Act where appropriate (9 CFR 166).

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2787. Lespedeza Products.

(a) Lespedeza Meal is obtained by grinding lespedeza hay which is reasonably free of other crop plants, weeds, and mold. It must not contain more than 28 percent crude fiber.

(b) Lespedeza Stem Meal is the ground product remaining after the separation of the leafy material from lespedeza hay or meal. It must be reasonably free from other crop plants and weeds.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2788. Marine Products.

(a) Condensed Fish Protein Digest is the condensed enzymatic digest of clean undecomposed whole fish or fish cuttings using the enzyme hydrolysis process. The product must be free of bones, scales, and undigested solids with or without the extraction of part of the oil. It must contain not less than 30 percent protein.

(b) Condensed Fish Solubles is obtained by evaporating excess moisture from the stickwater, aqueous liquids, resulting from the wet rendering of fish into fish meal, with or without removal of part of the oil. Minimum percentage of solids, minimum percentage of crude protein, and minimum percentage of crude fat must be guaranteed.

(c) Crab Meal is the undecomposed ground dried waste of the crab and contains the shell, viscera, and part or all of the flesh. It must contain not less than 25 percent crude protein. If it contains more than three (3) percent salt (NaCl), the amount of salt must constitute a part of the product name, provided that in no case must the salt content of this product exceed seven (7) percent.

(d) Dried Fish Protein Digest is the dried enzymatic digest of clean undecomposed whole fish or fish cuttings using the enzyme hydrolysis process. The product must be free of bones, scales and undigested solids with or without the extraction of part of the oil. It must contain not less than 80 percent protein and not more than 10 percent moisture. If the degree of fineness is stated, it must conform thereto. If the product bears a name descriptive of its kind, composition or origin, it must correspond thereto.

(e) Dried Fish Solubles is obtained by dehydrating the stickwater. It must contain not less than 60 percent crude protein.

(f) Dried Shellfish Digest is the dried enzymatic digest of clean undecomposed shellfish (crustaceans and/or mollusks), using the enzyme hydrolysis process. The product may contain shells, viscera, and part or all of the flesh, and must be free of undigested solids with or without the extraction of part of the oil. It must contain not less than 50 percent crude protein with not more than 10 percent moisture. If the degree of fineness is stated, it must conform thereto. If the product bears a name descriptive of its kind, composition or origin, it must correspond thereto.

(g) Fish By-Products must consist of non-rendered, clean undecomposed portions of fish (such as, but not limited to, heads, fins, tails, ends, skin, bone and viscera) which result from the fish processing industry. If it bears a name descriptive of its kind, it must correspond thereto. Any single constituent used as such may be labeled according to the common or usual name of the particular portion used (such as fish heads, fish tails, etc).

(h) Fish Digest Residue is the clean, dried, undecomposed residue (bones-scales-undigested solids) of the enzymatic digest resulting from the enzyme hydrolysis process of producing fish protein digest. It must be designated according to its protein, calcium and phosphorus content.

(i) Fish Liver and Glandular Meal is obtained by drying the complete viscera of the fish. At least 50 percent of the dry weight of the product must be derived from fish liver and must contain at least 18 milligrams of riboflavin per pound.

(j) Fish Meal is the clean, dried, ground tissue of undecomposed whole fish or fish cuttings, either or both, with or without the extraction of part of the oil. If it contains more than three (3) percent salt (NaCl), the amount of salt must constitute a part of the product name, provided that in no case must the salt content of this product exceed seven (7) percent. The label shall include guarantees for minimum crude protein, minimum crude fat, maximum crude fiber, minimum phosphorus (P) and minimum and

maximum calcium (Ca). If it bears a name descriptive of its kind, it must correspond thereto.

(k) Fish Oil is the oil from rendering whole fish or cannery waste.

(l) Fish Protein Concentrate, Feed Grade, is prepared from clean, undecomposed whole fish or fish cuttings using the solvent extraction process developed for the production of edible whole fish protein concentrate. It must contain not less than 70 percent protein and not more than 10 percent moisture. If the degree of fineness is stated, it must conform thereto. Solvent residues are not to exceed those established in Food Additive Regulations.

(m) Fish Residue Meal is the clean, dried, undecomposed residue from the manufacture of glue from non-oily fish. If it contains more than three (3) percent salt (NaCl), the amount of salt must constitute a part of the product name, provided that in no case must the salt content of this product exceed seven (7) percent.

(n) Fish Stock/Broth is obtained by cooking fish and/or other marine animal products, including bones, shells, parts, and/or muscle, but not including fish solubles. The crude protein content of the stock/broth base material must be no less than 80 percent on a dry matter basis. In order for the stock/broth to be labeled as such, the moisture-to-crude protein ration must not exceed 135:1 (135 parts water to one (1) part crude protein). If the product bears a name descriptive of its kind, composition or origin, it must correspond thereto; and may be called either stock or broth.

(o) Shrimp Meal is the undecomposed ground dried waste of shrimp and contains parts and/or whole shrimp. If it contains more than three (3) percent salt (NaCl), the amount of salt must constitute a part of the product name, provided that in no case must the salt content of this product exceed seven (7) percent.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2789. Milk Products.

(a) Bovine Colostrum is lacteal secretions obtained within 48 hours after parturition. It contains three (3) percent maximum lactose, 15 percent minimum total solids, and 60 percent minimum of the solids must be protein. The minimum specific gravity is 1.04 grams per milliliter.

(b) Cheese Rind is obtained by cooking cheese trimming devoid of fat other than milk fat.

(c) Condensed Buttermilk is the residue obtained by evaporating buttermilk. It contains 27 percent minimum total solids, 0.055 percent minimum milk fat for each percent of total solids, and 0.14 percent maximum ash for each percent of total solids.

(d) Condensed Cultured Skim Milk is the residue obtained by evaporating lactic acid bacteria cultured defatted milk. It contains 27 percent minimum total solids.

(e) Condensed Cultured Whey is the product obtained by partially removing water from whey which has been cultured. The minimum percent of solids must be prominently declared on the label.

(f) Condensed Delactosed Whey Permeate is the product resulting from the removal of lactose from whey permeate. It shall be labeled to show the minimum percent total whey product solids, lactose, crude protein and crude fat and the maximum percent ash and equivalent crude protein from non-protein nitrogen. (p) Casein is the solid residue obtained by acid or rennet coagulation of defatted milk. It contains 80 percent minimum crude protein.

(g) Condensed Hydrolyzed Whey is the residue obtained by evaporating lactase enzyme hydrolyzed whey. It contains 50 percent minimum total solids and 0.3 percent minimum total glucose and galactose for each percent total solids.

(h) Condensed Modified Whey Solubles is the product obtained by concentrating the whey residue after removal of whey protein and partial removal of lactose, and modifying the sugar content so that there is a minimum of 0.3 percent nonlactose carbohydrate for each percent solids. The minimum percent of solids and the maximum percent ash must be prominently declared on the label.

(i) Condensed Skimmed Milk is the residue obtained by evaporating defatted milk. It contains 27 percent minimum total solids.

(j) Condensed Whey is the product obtained by partially removing water from whey. Minimum percentage of solids must be prominently declared on the label.

(k) Condensed Whey Permeate is the product resulting from the removal of proteins from whey permeate. It shall be labeled to show the minimum percent total whey product solids, crude protein and lactose and the maximum percent ash and equivalent crude protein from non-protein nitrogen.

(l) Condensed Whey Product is the product obtained by partially removing water from whey from which a portion of the lactose, protein and/or minerals have been removed. The minimum percent of solids, crude protein, and lactose and the maximum percent ash must be prominently declared on the label. May also be labeled “condensed reduced minerals whey” or “condensed reduced lactose whey,” if appropriate.

(m) Condensed Whey Solubles is the product obtained by concentrating the whey residue after removal of whey protein, with or without partial removal of lactose. Minimum percentage of solids, crude protein and lactose and maximum percentage of ash must be prominently declared on the label.

(n) Dairy Food By-Products are the products resulting from the collection of solids contained in the wash water from the normal processing and packaging of various foods manufacturing plants. Dairy products are the primary source but non-dairy products may occasionally constitute a minor amount of the total volume. No sanitary sewer wastes may be included. This product is to be fed at levels less than 25 percent of the animal’s total dry matter intake. Minimum percent of solids, crude protein and crude fat and maximum percent ash must be prominently declared on the label.

(o) Dried Bovine Colostrum is the product obtained by removing water from bovine colostrum. It contains eight (8) percent maximum moisture, 20 percent maximum lactose, and 50 percent minimum of the solids must be protein.

(p) Dried Buttermilk, Feed Grade, is the residue obtained by drying buttermilk. It contains eight (8) percent maximum moisture, 13 percent maximum ash, and five (5) percent minimum milk fat (Roese-Gottlieb method). The words “Feed Grade” are not required when listed as an ingredient in a manufactured feed.

(q) Dried Cheese is the product obtained by dehydrating cheeses as defined in 21 CFR 133. No more than 10 percent of the fat may be other than milk fat.

(r) Dried Cheese Product is the product obtained by processing various cheese products from the food industry, including dried cheese, cheese rind, processed cheese foods, and cheese-flavored powders. The product shall have characteristic cheese color and aroma. The crude protein, crude fat, and crude fiber shall be guaranteed.

(s) Dried Chocolate Milk is the residue obtained by drying chocolate milk originally intended for human consumption.

(t) Dried Cultured Skim Milk is the residue obtained by drying lactic acid bacteria cultured in defatted milk. It contains eight (8) percent maximum moisture.

(u) Dried Cultured Whey is the product obtained by drying whey which has been cultured. The label shall include a guarantee for the minimum amount of lysine and methionine. This is the dried version of Condensed, Cultured Whey. AOAC High Performance Liquid Chromatography methods are recommended to be used to quantitate the amino acids.

(v) Dried Cultured Whey Product is that product obtained by drying whey from which a portion of the lactose, protein and/or minerals has been removed and which has been cultured.

(w) Dried (Dry) Whey is the product obtained by removing water from whey. It contains not less than 11 percent protein nor less than 61 percent lactose.

(x) Dried (Dry) Whey Product is the product obtained by drying whey from which a portion of the lactose, protein and/or minerals have been removed. The minimum percent of crude protein and lactose and maximum percent ash must be prominently declared on the label. May also be labeled as “dried reduced minerals whey” or “dried reduced lactose whey” if appropriate.

(y) Dried (Dry) Whey Protein Concentrate is the product obtained by removal or separation of water, lactose and/or minerals from whey by ultrafiltration, dehydration or other process. It shall contain 25 percent minimum crude protein. The minimum percent of crude protein and lactose and the maximum percent ash must be prominently declared on the label.

(z) Dried (Dry) Whey Solubles is obtained by drying the whey residue after removal of whey protein, with or without partial removal of lactose. Minimum percentage of crude protein and lactose and maximum percentage ash must be prominently declared on the label.

(aa) Dried Hydrolyzed Casein is the residue obtained by drying the water-soluble product resulting from the enzymatic digestion of casein. It contains 74 percent minimum crude protein.

(bb) Dried Hydrolyzed Whey is the residue obtained by drying lactase enzyme hydrolyzed whey. It contains 30 percent minimum total glucose and galactose.

(cc) Dried Lactalbumin is the dried coagulated protein residue from whey. It contains 80 percent minimum crude protein on a moisture free basis.

(dd) Dried Milk, Feed Grade, is the residue obtained by drying whole milk or milk of intermediate fat levels other than defatted milk. If the product qualifies as dried whole milk by containing a minimum of 26 percent milk fat, that term may be used as the ingredient name. The label must contain a guarantee for minimum crude protein and for minimum crude fat (Roese-Gottlieb method). The words “Feed Grade” are not required when listed as an ingredient in a manufactured feed.

(ee) Dried Milk Protein is obtained by drying the coagulated protein residue resulting from the controlled co-precipitation of casein, lactalbumin, and minor milk proteins from defatted milk.

(ff) Dried Skimmed Milk, Feed Grade, is the residue obtained by drying defatted milk. It contains eight (8) percent maximum moisture. The words “Feed Grade” are not required when listed as an ingredient in a manufactured feed.

(gg) Whey is the product obtained as a fluid by separating the coagulum from milk, cream, or skimmed milk and from which a portion of the milk fat may have been removed.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2790. Mineral Products.

(a) General Provisions.

(1) The mineral products section includes ingredients that come from mined and processed rock and ore deposits, chemically manufactured salts, recovered natural salts, residue or remains of living organisms, and organic salts or organically bound elements as well as other similar ingredients. Minerals from animal and plant sources can be found in other sections.

(b) Ammonium Chloride is the product resulting from the neutralization of hydrochloric acid with ammonia generally expressed as NH_4Cl. It must contain not less than 25.6 percent nitrogen (equivalent to 160 percent crude protein). It must contain not more than 0.1 percent moisture, 0.4 percent salt (NaCl), 15 parts per million iron (Fe), three (3) parts per million arsenic (As), and 10 parts per million heavy metals reported as lead. It may be treated with not more than one (1.0) percent tricalcium phosphate to prevent caking. It shall not be made from by-product ammonia recovered from coke oven gas. It is to be used only in feeds for cattle, sheep, and goats as a source of both non-protein nitrogen and chloride at a level not to exceed one (1.0) percent ammonium chloride in the total daily ration to provide not more than 1.6 percent equivalent crude protein. Labels for feed containing ammonium chloride include premixes, concentrates, and supplements shall contain adequate directions for use and the following prominent statements: “CAUTION: Use only as directed. For ruminants (cattle, sheep, and goats) only.”

(c) Ammonium Sulfate is the product resulting from the neutralization of sulfuric acid with ammonia. It shall contain not less than 21 percent nitrogen (N) and not less than 24 percent sulfur (S). It shall contain not more than 75 parts per million arsenic (As) and 30 parts per million heavy metals reported as lead. This does not include ammonium sulfate made from by-product ammonia recovered from coke-oven gas. It shall be used only in ruminant feeds as a source of sulfur and nitrogen in an amount that supplies not more than two (2) percent of equivalent crude protein in the total daily ration. If a premix, concentrate, or supplement contains more than two (2) percent of equivalent crude protein from ammonium sulfate, the label shall have adequate directions for use and a prominent statement, “Caution - This feed shall be used only in accordance with directions furnished on the label.”

(d) Basic Copper Chloride is the copper salt of hydrochloric acid and hydrated form of copper oxide generally expressed as $Cu_2(OH)_3Cl$ and its hydrated forms. Minimum copper (Cu) must be specified.

(e) Bone Ash is the ash obtained by burning bones with free access to air, and containing a minimum of 15.3 percent phosphorus (P). The label must show a guarantee for calcium (Ca) and phosphorus (P).

(f) Bone Charcoal is obtained by charring bones in closed retorts. It must contain a minimum of 14 percent phosphorus (P). It must be labeled with guarantees for calcium (Ca) and phosphorus (P). (This product is sometimes referred to as “Bone Black,” however, bone charcoal must be used in all labeling.)

(g) Bone Charcoal, Spent, is the product resulting from the repeated charring of bone charcoal after use in clarifying sugar solutions. It must contain a minimum of 11.5 percent phosphorus (P). It must be labeled with guarantees for phosphorus (P) and calcium (Ca). (This product is sometimes referred to as “Spent Bone Black,” however, spent bone charcoal must be used in all labeling.)

(h) Bone Meal, Cooked, is the dried and ground sterilized product resulting from wet cooking without steam pressure of undecomposed bones. Fat, gelatin, and meat fiber may or may not be removed. When labeled as a commercial feed ingredient, it shall carry guarantees for protein, phosphorus (P), and calcium (Ca). Cooked bone meal shall be used in all labeling. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(i) Bone Meal, Steamed, is the dried and ground product sterilized by cooking undecomposed bones with steam under pressure. Grease, gelatin, and meat fiber may or may not be removed. It must be labeled with guarantees for phosphorus (P) and calcium (Ca). Steamed bone meal must be used in all labeling. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(j) Bone Phosphate is the residue of bones that have been treated first in a hydrochloric acid solution and thereafter precipitated with lime and dried. It must contain a minimum

of 17 percent phosphorus (P). It must be labeled with guarantees for calcium (Ca) and phosphorus (P).

(k) Calcite is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33 percent calcium (Ca).

(l) Calcium Carbonate (21 CFR 582.5191) is a product true to name which contains a minimum of 38 percent calcium (Ca).

(m) Calcium Carbonate, Precipitated, is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33 percent calcium (Ca). Precipitated calcium carbonate must be used in all labeling.

(n) Calcium Carbonate, Precipitated $CaCO_3$ Calcium Chloride is the calcium salt of hydrochloric acid generally expressed as $CaCl_2$ and its hydrated forms. Minimum calcium (Ca) and chlorine (Cl) must be specified.

(o) Calcium Gluconate is the calcium salt of gluconic acid generally expressed as $Ca(C_6H_{11}O_7)_2$ and its hydrated forms. Minimum Calcium (Ca) must be specified.

(p) Calcium Hydroxide is the hydrated form of calcium oxide generally expressed as $Ca(OH)_2$. Minimum calcium (Ca) must be specified.

(q) Calcium Iodate is the calcium salt of iodic acid generally expressed as $Ca(IO_3)_2$ and the monohydrate form. Minimum calcium (Ca) and iodine (I) must be specified.

(r) Calcium Iodobehenate is the calcium salt of iodobehenic acid generally expressed as Ca(C21H42ICO2)2 and its hydrated forms. Minimum calcium (Ca) and minimum iodine (I) must be specified.

(s) Calcium Oxide is the oxide form of calcium generally expressed as CaO (commonly called quicklime). The product of calcining limestone. A strong alkali requiring caution in its use. Minimum calcium (Ca) must be specified.

(t) Calcium Periodate (21 CFR 573.240) is an acceptable source of iodine. It is produced by reacting calcium iodate with calcium hydroxide or calcium oxide to form a substance consisting of not less than 60 percent by weight of penta calcium orthoperiodate containing 28 to 31 percent by weight of iodine. It is used or intended for use in salt for livestock as a source of iodine.

(u) Calcium Sulfate is the calcium salt of sulfuric acid generally expressed as $CaSO_4$ and its hydrated forms. Minimum calcium (Ca) and minimum sulfur (S) must be specified.

(v) Seaweed-Derived Calcium is the dried ground product resulting from the harvest of skeletal remains of the marine algae species Lithothamnium corallioides and Phymatolithon calcareum. It is composed of mixtures of calcium carbonate ($CaCO_3$) and magnesium carbonate ($MgCO_3$) and is intended as a supplemental source of calcium and magnesium for animals. It contains not less than 32 percent calcium as calcium carbonate and 2.3 percent magnesium as magnesium carbonate. It shall not contain more than 40 parts per million fluorine, 40 parts per million iodine, five (5) parts per million lead, and five (5) parts per million arsenic.

(w) Chalk, Precipitated, is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33 percent calcium (Ca). Precipitated chalk must be used in all labeling.

(x) Chromium Tripicolinate. Chromium tripicolinate is the product resulting from reaction of chromium chloride with picolinic acid. It is to be used as a source of supplemental chromium in swine diets, not to supply more than 200 parts per billion of chromium to the complete diet. Chromium from all sources of supplemental chromium cannot exceed this limit. Minimum chromium from chromium tripicolinate must be specified.

(y) Chalk Rock is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33 percent of calcium (Ca).

(z) Clam Shells, Ground, is an acceptable source of calcium carbonate. It must be true to name and contain not less than 35 percent calcium (Ca).

(aa) Cobalt Acetate is the cobalt salt of acetic acid generally expressed as $Co(C_2H_3O_2)_2$, and its hydrated forms. Minimum cobalt (Co) must be specified.

(bb) Cobalt Carbonate is the cobalt salt of carbonic acid generally expressed as $CoCO_3$ and its hydrated forms. Minimum cobalt (Co) must be specified.

(cc) Cobalt Chloride is the cobalt salt of hydrochloric acid generally expressed as $CoCl_2$, and its hydrated forms. Minimum cobalt (Co) must be specified.

(dd) Cobalt Choline Citrate Complex is the product resulting from the complexing of the soluble cobalt salt with choline dihydrogen citrate. Minimum cobalt (Co) must be specified. When used as a commercial feed ingredient, it must be declared as “cobalt choline citrate.”

(ee) Cobalt Glucoheptonate is the cobalt salt of glucoheptonic acid generally expressed as $C_{14}H_{26}O_{16}Co \cdot H_2O$. Minimum cobalt (Co) must be specified.

(ff) Cobalt Gluconate is the cobalt salt of gluconic acid, generally expressed as $Co(C_6H_{11}O_7)_2$, and its hydrated forms. Minimum cobalt (Co) must be specified.

(gg) Cobalt Oxide is the oxide form of cobalt generally expressed as CoO. Minimum cobalt (Co) must be specified.

(hh) Cobalt Sulfate is the cobalt salt of sulfuric acid generally expressed as $CoSO_4$ and its hydrated forms. Minimum cobalt (Co) must be specified.

(ii) Copper Acetate Monohydrate is the copper salt of acetic acid generally expressed as $Cu(C_2H_3O_2)_2 \cdot H_2O$ and its hydrated forms. Minimum copper must be specified.

(jj) Copper Carbonate is the copper salt of carbonic acid generally expressed as $CuCO_3$. Minimum copper (Cu) must be specified.

(kk) Copper Chloride is the copper salt of hydrochloric acid generally expressed as CuCl or $CuCl_2$ and their hydrated forms. Minimum copper (Cu) must be specified.

(ll) Copper Choline Citrate Complex is the product resulting from the complexing of the soluble copper salt with choline dihydrogen citrate. Minimum copper (Cu) must be

specified. When used as a commercial feed ingredient, it must be declared as “copper choline citrate.”

(mm) Copper Citrate is the copper salt of citric acid generally expressed as $C_6H_4Cu_2O_7$. It is to be used as a source of copper in broiler feeds at levels not exceeding 185 parts per million of total dietary copper. Minimum copper (Cu) must be specified.

(nn) Copper Gluconate is the copper salt of gluconic acid generally expressed as $Cu(C_6H_{11}C_7)_2$ and its hydrated forms. Minimum copper (Cu) must be specified.

(oo) Copper Hydroxide is the hydrated form of copper oxide generally expressed as $Cu(OH)_2$. Minimum copper (Cu) must be specified.

(pp) Copper Orthophosphate is the copper salt of phosphoric acid generally expressed as $Cu_3(PO_4)_2$ and its hydrated forms. Minimum copper (Cu) must be specified.

(qq) Copper Oxide is the oxide form of copper generally expressed as CuO or Cu_2O. Minimum copper (Cu) must be specified.

(rr) Copper Sulfate is the copper salt of sulfuric acid generally expressed as $CuSO_4$ and its hydrated forms. Minimum copper (Cu) must be specified.

(ss) Cuprous Iodide is the copper salt of hydriodic acid generally expressed as CuI. Minimum copper (Cu) must be specified.

(tt) Diiodosalicylic Acid is an iodine compound of salicylic acid generally expressed as $C_7H_4I_2O_3$. Minimum iodine (I) must be specified.

(uu) Ethylenediamine Dihydroiodide is an organic compound of iodine generally expressed as $C_2H_8N_2 \cdot 2HI$. Minimum iodine (I) must be specified.

(vv) Ferric Ammonium Citrate is an ammoniacally complexed iron salt of citric acid of indefinite composition sometimes expressed as $Fe(NH_4)C_6H_5O_7$ and its hydrated forms. Minimum iron (Fe) must be specified.

(ww) Ferric Chloride is the iron salt of hydrochloric acid generally expressed as $FeCl_3$ and its hydrated forms. Minimum iron (Fe) must be specified.

(xx) Ferric Choline Citrate Complex is the product resulting from the complexing of the soluble iron salt with choline dihydrogen citrate. Minimum iron (Fe) must be specified. When used as a commercial feed ingredient it must be declared as “ferric choline citrate.”

(yy) Ferric Formate is an iron salt of formic acid generally expressed as $Fe(HCO_2)_3$.

(zz) Ferric Phosphate is the iron salt of phosphoric acid generally expressed as $FePO_4$ and its hydrated forms. Minimum iron (Fe) must be specified.

(aaa) Ferric Pyrophosphate is the iron salt of pyrophosphoric acid generally expressed as $Fe_4(P_2O_7)_3$ and its hydrated forms. Minimum iron (Fe) must be specified.

(bbb) Ferric Sulfate is the iron salt of sulfuric acid generally expressed as $Fe_2(SO_4)_3$ and its hydrated forms. Minimum iron (Fe) must be specified.

(ccc) Ferrous Carbonate is the iron salt of carbonic acid generally expressed as $FeCO_3$. Minimum iron (Fe) must be specified.

(ddd) Ferrous Chloride is the iron salt of hydrochloric acid generally expressed as $FeCl_2$ and its hydrated forms. Minimum iron (Fe) must be specified.

(eee) Ferrous Fumarate is an iron salt of fumaric acid generally expressed as $FeC_4H_2O_4$. Minimum iron (Fe) must be specified.

(fff) Ferrous Gluconate is the iron salt of gluconic acid generally expressed as $Fe(C_6H_{11}O_7)_2$ and its hydrated forms. Minimum iron (Fe) must be specified.

(ggg) Ferrous Glycine Complex is the reaction product of one molecular equivalent of ferrous iron salt and two or more molecular equivalents of glycine, generally expressed as $FeC_4N_2H_8O_4$. Minimum iron (Fe) must be specified. When used as a commercial feed ingredient it must be declared as Ferrous Glycine.

(hhh) Ferrous Sulfate is the iron salt of sulfuric acid generally expressed as $FeSO_4$ and its hydrated forms. Minimum iron (Fe) must be specified.

(iii) Gypsiferrous Shale is a natural occurring shale type rock containing native calcium sulfate ($CaSO_4$). It must carry guarantees of calcium (Ca) and sulfur (S).

(jjj) Iron Oxide is the oxide form of iron occurring both naturally and synthetically in various chemical valence compositions and colors - sometimes expressed as Fe_2O_3. Minimum iron (Fe) must be specified.

(kkk) Iron, Reduced, is a metallic form of iron obtained by reducing ferric oxide with hydrogen. Minimum iron (Fe) must be specified.

(lll) Limestone, Ground, is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33 percent calcium (Ca). Ground limestone must be used in all labeling.

(mmm) Limestone, Magnesium or Dolomitic, is an acceptable source of magnesium and calcium carbonate. The terms are synonymous and designate a native mineral composed of mixtures of magnesium carbonate ($MgCO_3$), and calcium carbonate ($CaCO_3$). It must contain not less than 10 percent magnesium (Mg) and must be declared as an ingredient as magnesium limestone or dolomitic limestone.

(nnn) Magnesium Carbonate is a magnesium salt of carbonic acid generally expressed as $MgCO_3 \cdot Mg(OH)_2$ and its hydrated forms. Minimum magnesium (Mg) must be specified.

(ooo) Magnesium Chloride is the magnesium salt of hydrochloric acid generally expressed as $MgCl_2$ and its hydrated forms. Minimum magnesium (Mg) must be specified.

(ppp) Magnesium Gluconate is the magnesium salt of gluconic acid generally expressed as $Mg(C_6H_{11}O_7)_2$ and its hydrated forms. Minimum magnesium (Mg) must be specified. For use in animal feeds, excluding aquatic species.

(qqq) Magnesium Hydroxide is the hydrated form of magnesium generally expressed as $Mg(OH)_2$. Minimum magnesium (Mg) must be specified.

(rrr) Magnesium Phosphate is the magnesium salt of phosphoric acid, generally expressed as $MgHPO_4$ and its hydrated forms. Minimum magnesium (Mg) and phosphorus (P) and maximum fluorine (F) must be specified. It must contain not more than one part fluorine (F) to 100 parts phosphorus.

(sss) Magnesium Oxide is the oxide of magnesium generally expressed as MgO. Minimum magnesium (Mg) must be specified.

(ttt) Magnesium-Mica is a natural occurring magnesium, iron, and potassium layer silicate. It must be labeled with guarantees for magnesium (Mg), iron (Fe), and potassium (K).

(uuu) Magnesium Sulfate is the magnesium salt of sulfuric acid generally expressed as $MgSO_4$ and its hydrated forms. Minimum magnesium (Mg) must be specified.

(vvv) Manganese Acetate is the manganese salt of acetic acid generally expressed as $Mn(C_2H_3O_2)_2$ and its hydrated forms. Minimum manganese (Mn) must be specified.

(www) Manganese Carbonate is the manganese salt of carbonic acid generally expressed as $MnCO_3$ and its hydrated forms. Minimum Manganese (Mn) must be specified.

(xxx) Manganese Chloride is the manganese salt of hydrochloric acid generally expressed as $MnCl_2$ and its hydrated forms. Minimum manganese (Mn) must be specified.

(yyy) Manganese Citrate (Soluble) is the manganese salt of citric acid generally expressed as $Mn_3(C_6H_5O_7)_2$ and its hydrated forms. Minimum manganese (Mn) must be specified.

(zzz) Manganese Gluconate is the manganese salt of gluconic acid generally expressed as $Mn(C_6H_{11}O_7)_2$. Minimum manganese (Mn) must be specified.

(aaaa) Manganese Orthophosphate is the manganese salt of phosphoric acid generally expressed as $Mn_3(PO_4)_2$ and its hydrated forms. Minimum manganese (Mn) must be specified.

(bbbb) Manganese Phosphate (dibasic) is the manganese salt of phosphoric acid generally expressed as $MnHPO_4$ and its hydrated forms. Minimum manganese (Mn) must be specified.

(cccc) Manganese Sulfate is the manganese salt of sulfuric acid generally expressed as $MnSO_4$ and its hydrated forms. Minimum manganese (Mn) must be specified.

(dddd) Manganous Oxide is an oxide form of manganese generally expressed as MnO. Minimum manganese (Mn) must be specified.

(eeee) Metal Amino Acid Complex is the product resulting from complexing of a soluble metal salt (such as potassium or manganese) with an amino acid(s). Minimum metal content must be declared. When used as a commercial feed ingredient, it must be

declared as a specific metal amino acid complex, i.e., potassium amino acid complex, copper amino acid complex, zinc amino acid complex, magnesium amino acid complex, iron amino acid complex, cobalt amino acid complex, calcium amino acid complex, and manganese amino acid complex.

(ffff) Metal (specific amino acid) Complex is the product resulting from complexing a soluble metal salt with a specific amino acid. Minimum metal content must be declared. When used as a commercial feed ingredient, it must be declared as a specific metal, specific amino acid, i.e., copper lysine complex, zinc lysine complex, ferric methionine complex, manganese methionine complex and zinc methionine complex.

(gggg) Metal Amino Acid Chelate is the product resulting from the reaction of a metal ion from a soluble metal salt with amino acids with a mole ratio of one mole of metal to one to three (preferably two) moles of amino acid to form coordinate covalent bonds. The chelating ligand(s) are a mixture of hydrolyzed amino acids with an average molecular weight of approximately 150, or are specific amino acid(s). The resulting molecular weight of the chelate must not exceed 800. The minimum metal content must be declared. When used as a commercial feed ingredient it must be declared as a specific metal amino acid chelate; i.e., Calcium Amino Acid Chelate, Cobalt Amino Acid Chelate, Copper Amino Acid Chelate, Iron Amino Acid Chelate, Magnesium Amino Acid Chelate, Manganese Amino Acid Chelate or Zinc Amino Acid Chelate.

(hhhh) Metal Methionine Hydroxy Analogue Chelate is the product resulting from the reaction of a metal salt with 2-hydroxy-4-methylthiobutanoic acid (HMTBa), having a chelated molar ratio of one mole of metal to two moles of HMTBa to form coordinate covalent bonds. This ingredient is intended to be used as a source of trace minerals. The specific metal chelate must be declared as a metal methionine hydroxyl analogue chelate; i.e. copper methionine hydroxy analogue chelate, manganese methionine hydroxy analogue chelate, or zinc methionine hydroxy analogue chelate. The minimum metal content must be declared, and must be at least 15 percent for copper, 13 percent for manganese and 16 percent for zinc.

(iiii) Metal Polysaccharide Complex is the product resulting from complexing of a soluble salt with a polysaccharide solution declared as an ingredient as the specific metal complex i.e., copper polysaccharide complex, zinc polysaccharide complex, iron polysaccharide complex, cobalt polysaccharide complex, magnesium polysaccharide complex and manganese polysaccharide complex.

(jjjj) Zinc Propionate is the product resulting from reaction of a zinc salt with propionic acid. Zinc propionate is prepared with an excess of propionic acid, at an appropriate stoichiometric ratio. Minimum zinc content must be declared.

(kkkk) Chromium Propionate (21 CFR 573.304). The food additive chromium propionate may be safely used in animal feed as a source of supplemental chromium in accordance with the following prescribed conditions:

(1) The additive is manufactured by the reaction of a chromium salt with propionic acid, at an appropriate stoichiometric ratio, to produce triaqua-(mu_3-oxo) hexakis (mu_2-propionato-O,O′) trichromium propionate with the empirical formula, $[Cr_3(O)(CH_3CH_2CO_2)_6(H_2O)_3]CH_3CH_2CO_2$.

(2) It is added to feed as follows:

(A) In the complete feed for broiler chickens and swine at a level not to exceed 0.2 milligrams of chromium from chromium propionate per kilogram of feed.

(B) In cattle diets at a level not to exceed 0.5 milligrams of chromium from chromium propionate per kilogram of the complete feed. Chromium propionate must be premixed with dry ingredients prior to adding to high moisture ingredients or forages.

(C) In feed for horses at a level not to exceed an intake of four (4) milligrams of chromium from chromium propionate per horse per day.

(3) The additive meets the following specifications:

(A) Total chromium content, eight (8) to 10 percent.

(B) Hexavalent chromium content, less than two (2) parts per million.

(C) Arsenic, less than one (1) parts per million.

(D) Cadmium, less than one (1) parts per million.

(E) Lead, less than 0.5 parts per million.

(F) Mercury, less than 0.5 parts per million.

(G) Viscosity, not more than 2,000 centipoise.

(4) The additive shall be incorporated into feed as follows:

(A) It shall be incorporated into each ton of complete feed by adding no less than one pound of a premix containing no more than 181.4 milligrams of added chromium from chromium propionate per pound.

(B) The premix manufacturer shall follow good manufacturing practices in the production of chromium propionate premixes. Inventory, production, and distribution records must provide a complete and accurate history of product production.

(C) Chromium from all sources of supplemental chromium cannot exceed:

(i) A level of 0.2 parts per million of the complete feeds for broiler chickens and swine;

(ii) A level of 0.5 parts per million of the complete feed for cattle; and

(iii) An intake of four (4) milligrams per horse per day.

(5) To assure safe use of the additive in addition to the other information required by the FD&C:

(A) The label and labeling of the additive, any feed premix, and complete feed shall contain the name of the additive.

(B) The label and labeling of the additive and any feed premix shall also contain: A guarantee for added chromium content. Adequate directions for use and cautions for use including these statements: "Caution: Follow label directions" and consistent with the directions for use, the following: “Chromium from all sources of supplemental chromium cannot exceed 0.2 parts per million of the complete feed for broiler chickens and swine and 0.5 parts per million of the complete feed for cattle.” “Chromium from all sources of supplemental chromium cannot exceed four (4) milligrams per horse per day.”

(llll) Metal Proteinate is the product resulting from the chelation of a soluble salt with amino acids and/or partially hydrolyzed protein. It must be declared as an ingredient as the specific metal proteinate: i.e., Copper Proteinate, Zinc Proteinate, Magnesium Proteinate, Iron Proteinate, Cobalt Proteinate, Manganese Proteinate or Calcium Proteinate.

(mmmm) Oyster Shell Flour is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33 percent calcium (Ca).

(nnnn) Ammonium Polyphosphate Solution is the product resulting from the neutralization of superphosphoric acid. It must contain not less than nine (9) percent nitrogen (N) and 13 percent phosphorus (P). It must contain not more than one (1) part fluorine (F) to 100 parts phosphorus (P), 75 parts per million of arsenic (As), and 30 parts per million of heavy metals reported as lead. It may be used in ruminant feeds as a source of both phosphorus and nitrogen in an amount that supplies not more than two (2) percent of equivalent crude protein in the total daily ration. It may be used in non-ruminant feeds as a source of phosphorus only. The maximum equivalent crude protein from this source shall not exceed 1.25 percent of the total daily ration. When incorporated into a feed for non-ruminants the label will carry a statement that the equivalent crude protein is nutritionally unavailable to the non-ruminant. It shall be labeled as follows: (example) BLUE BIRD HOG FINISHER, Crude Protein (Minimum) 16% (This includes not more than [X]% equivalent crude protein which is not nutritionally available to swine.). If a premix, concentrate or supplement for ruminants contains more than two (2) percent equivalent crude protein from ammonium polyphosphate or if a premix concentrate or supplement for non-ruminants contains more than 1.25 percent equivalent crude protein from ammonium polyphosphate, then the label must contain adequate directions for use, and a prominent statement: “Warning - This feed must be used only in accordance with directions furnished on the label.”

(oooo) Calcium Phosphate is a calcium phosphate product either calcined, fused, precipitated or reacted. It must contain not more than one part fluorine (F) to 100 parts of phosphorus (P). The minimum percent of calcium (Ca) and phosphorus (P) and maximum percent of fluorine (F) must be stated on the label.

(pppp) Diammonium Phosphate is the product resulting from neutralization of phosphoric acid, feed grade, or defluorinated wet-process phosphoric acid which contains not less than 17 percent nitrogen (N) and 20 percent phosphorus (P). It must contain not more than one (1) part fluorine (F) to 100 parts phosphorus (P), 75 parts per million of arsenic (As), and 30 parts per million of heavy metals reported as lead. This does not include diammonium phosphate made from by-product ammonia absorbed

from coke-oven gas. It may be used in ruminant feeds as a source of both phosphorus and nitrogen in an amount that supplies not more than two (2) percent of equivalent crude protein in the total daily ration. It may be used in non-ruminant feeds as a source of phosphorus only. The maximum equivalent crude protein from diammonium phosphate must be guaranteed and the equivalent crude protein from this source shall not exceed 1.25 percent of the total daily ration. When incorporated into a feed for non-ruminants, the label will carry a statement that the equivalent crude protein is nutritionally unavailable to the non-ruminant. It shall be labeled as follows: (example) BLUE BIRD HOG FINISHER. Crude protein (minimum) 16% (This includes not more than [X]% equivalent crude protein which is not nutritionally available to swine.). If a premix, concentrate or supplement for ruminants contains more than two (2) percent equivalent crude protein from diammonium phosphate or if a premix concentrate or supplement for non-ruminants contains more than 1.25 percent equivalent crude protein from diammonium phosphate, then the label must contain adequate directions for use, and a prominent statement: “Warning - This feed must be used only in accordance with directions furnished on the label.”

(qqqq) Dicalcium Phosphate is a calcium salt of phosphoric acid generally expressed as CaHPO4 and its hydrated forms. Minimum phosphorus (P), minimum calcium (Ca) and maximum fluorine (F) must be specified. It must not contain more than one (1) part of fluorine (F) to 100 parts phosphorus (P).

(rrrr) Disodium Phosphate is a sodium salt of phosphoric acid generally expressed as Na_2HPO_4 and its hydrated forms. Minimum phosphorus (P), minimum sodium (Na) and maximum fluorine (F) must be specified. It must not contain more than one (1) part fluorine (F) to 100 parts phosphorus (P).

(ssss) Monoammonium Phosphate (21 CFR 582.1141) is the product resulting from the neutralization of phosphoric acid, feed grade, or defluorinated wet-process phosphoric acid which contains not less than nine (9) percent nitrogen (N) and 23 percent phosphorus (P). It must contain not more than one (1) part fluorine (F) to 100 parts phosphorus (P), 75 parts per million of arsenic (As) and 30 parts per million of heavy metals reported as lead (Pb). It may be used in ruminant feeds as a source of both phosphorus and nitrogen in an amount that supplies not more than two (2) percent of equivalent crude protein in the total daily ration. It may be used in non-ruminant feeds as a source of phosphorus only. The maximum equivalent crude protein from mono-ammonium phosphate must be guaranteed and the equivalent crude protein from this source shall not exceed 1.25 percent of the total daily ration. When incorporated into a feed for non-ruminants the label will carry a statement that the equivalent crude protein is nutritionally unavailable to the non-ruminant. It shall be labeled as follows: (example) BLUE BIRD HOG FINISHER, Crude Protein (Minimum) 16% (This includes not more than [X]% equivalent crude protein which is not nutritionally available to swine.). If a premix, concentrate or supplement for ruminants contains more than three (3) percent equivalent crude protein from mono-ammonium phosphate or if a premix concentrate or supplement for non-ruminants contains more than 1.25 percent equivalent crude protein from mono-ammonium phosphate, then the label must contain adequate directions for use, and a prominent statement: “Warning - This feed must be used only in accordance with directions furnished on the label.”

(tttt) Monocalcium Phosphate is a calcium salt of phosphoric acid generally expressed as $CaH_4(PO_4)_2$ and its hydrated forms. Minimum phosphorus (P), minimum calcium (Ca) and maximum fluorine (F) must be specified. It must contain not more than one (1) part fluorine (F) to 100 parts phosphorus (P).

(uuuu) Monosodium Phosphate is a sodium salt of phosphoric acid generally expressed as NaH_2PO_4 and its hydrated forms. Minimum phosphorus (P), minimum sodium (Na) and maximum fluorine (F) must be specified. It must contain not more than one (1) part fluorine (F) to 100 parts phosphorus (P). (Published 1975) IFN 6-04-288 Sodium phosphate monobasic monohydrate $NaH_2PO_4 \cdot H_2O$ Phosphoric Acid, [X]%, is a solution of phosphoric acid in water generally expressed as H_3PO_4. Minimum phosphorus (P) must be specified. It must not contain more than 100 parts per million fluorine (F) and 3.2 parts per million Arsenic (As) for each percentage of phosphorus present. When this ingredient is used as a constituent in mixed feeds, it must be indicated in the ingredient list as “phosphoric acid.”

(vvvv) Phosphate, Defluorinated, includes either calcined, fused, precipitated or reacted calcium phosphate. It must contain not more than one part of fluorine (F) to 100 parts of phosphorus (P). The minimum percent of calcium (Ca) and phosphorus (P) and the maximum percent of fluorine (F) must be stated on the label. The term "defluorinated" must not be used as a part of the name of any product containing more than one part of fluorine (F) to 100 parts of phosphorus (P). The term "defluorinated phosphate” must be used, where appropriate, in labeling ingredient listings.

(wwww) Rock Phosphate, Soft, is the very finely divided by-product (washings) obtained from mining Florida rock phosphate by the hydraulic process. It must contain a minimum of nine (9) percent phosphorus (P) and 15 percent calcium (Ca), and not more than 30 percent clay and 1.5 percent fluorine (F). The term soft rock phosphate must be used in all labeling.

(xxxx) Rock Phosphate, Ground, is ground phosphate rock. It must be labeled with guarantees for calcium (Ca) and phosphorus (P) and a maximum guarantee for fluorine (F). Ground rock phosphate must be used in all labeling.

(yyyy) Rock Phosphate, Ground, Low Fluorine is ground phosphate rock that contains not more than 0.5 percent fluorine (F). Low fluorine ground rock phosphate must be used in all labeling. It must be labeled with guarantees for minimum percentages of calcium (Ca) and phosphorus (P) and for a maximum percentage of fluorine (F).

(zzzz) Sodium Hexametaphosphate is the sodium salt of Phosphoric Acid generally expressed as $(NaPO_3)x \cdot H_2O$ (x=6-20) Minimum sodium and maximum fluorine must be specified. It must not contain more than one part fluorine (F) to 100 parts phosphorus (P), 75 parts per million of arsenic (As) and 30 parts per million of heavy metals reported as lead.

(aaaaa) Sodium Tripolyphosphate, is a sodium salt of phosphoric acid generally expressed as $Na_5P_3O_{10}$. Minimum sodium (Na) and maximum fluorine (F) must be specified. It must contain not more than one (1) part fluorine (F) to 100 parts phosphorus (P).

(bbbbb) Tribasic Sodium Phosphate is the sodium salt of phosphoric acid generally expressed as Na_3PO_4 and its hydrated forms. Minimum phosphorus (P), minimum sodium (Na) and maximum fluorine (F) must be specified. It must contain not more than one (1) part fluorine (F) to 100 parts of phosphorus (P).

(ccccc) Tricalcium Phosphate is a calcium salt of phosphoric acid generally expressed as $Ca_3(PO_4)_2$. Minimum phosphorus (P), minimum calcium (Ca) and maximum fluorine (F) must be specified. It must contain not more than one (1) part fluorine (F) to 100 parts phosphorus (P).

(ddddd) Potassium Bicarbonate is a potassium salt of carbonic acid generally expressed as $KHCO_3$. Minimum potassium (K) must be specified.

(eeeee) Potassium Carbonate is a potassium salt of carbonic acid generally expressed as K_2CO_3 and its hydrated forms. Minimum potassium (K) must be specified.

(fffff) Potassium Citrate is a potassium salt of citric acid generally expressed as $K_3C_6H_5O_7 \cdot H_2O$ and its hydrated forms. Minimum potassium (K) must be specified.

(ggggg) Potassium Chloride, is the potassium salt of hydrochloric acid generally expressed as KCl. Minimum potassium (K) must be specified.

(hhhhh) Potassium Gluconate is the potassium salt of gluconic acid generally expressed as $KC_6H_{11}O_7$ and its hydrated forms. Minimum potassium must be specified. For use in animal feeds, excluding aquatic species.

(iiiii) Potassium Hydroxide (21 CFR 582.1631) is the hydroxyl form of potassium generally expressed as KOH. Minimum potassium (K) must be specified.

(jjjjj) Potassium Iodate is the potassium salt of iodic acid generally expressed as KIO_3. Minimum potassium (K) and minimum iodine (I) must be specified.

(kkkkk) Potassium Iodide is the potassium salt of hydriodic acid generally expressed as KI. Minimum potassium (K) and iodine (I) must be specified.

(lllll) Potassium Sulfate is the potassium salt of sulfuric acid generally expressed as K_2SO_4. Minimum potassium (K) and sulfur (S) must be specified.

(mmmmm) Salt is an acceptable source of sodium chloride. It must be true to name and contain not less than 95 percent sodium chloride.

(nnnnn) Iodized Salt, is a common salt (NaCl) containing not less than 0.007 percent iodine, uniformly distributed.

(ooooo) Shell Flour is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33 percent calcium (Ca).

(ppppp) Sodium Acid Pyrophosphate is the disodium salt of pyrophosphoric acid, generally expressed as $Na_2HP_2O_7 \cdot 6H_2O$ and other hydrated forms. Minimum phosphorus; (P), minimum sodium (Na), and maximum fluorine (F), must be specified. It must contain not more than one (1) part fluorine (F) to 100 parts phosphorus (P).

(qqqqq) Sodium, Pyrophosphate, Hexahydrate Sodium Bicarbonate is the sodium salt of carbonic acid generally expressed as $NaHCO_3$. Minimum sodium (Na) must be specified.

(rrrrr) Sodium Carbonate is the sodium salt of carbonic acid generally expressed as Na_2CO_3 and its hydrated forms. Minimum sodium (Na) must be specified.

(sssss) Sodium Iodate is the sodium salt of iodic acid generally expressed as $NaIO_3$. Minimum iodine (I) must be specified.

(ttttt) Sodium Iodide is the sodium salt of hydriodic acid generally expressed as NaI. Minimum sodium (Na) and minimum iodine (I) must be specified.

(uuuuu) Sodium Molybdate is the sodium salt of molybdenum, generally expressed as Na_2MoO_4, and its hydrated forms. Minimum molybdenum must be specified.

(vvvvv) Sodium Selenate (21 CFR 573.920) is a sodium salt of selenic acid generally expressed as Na_2SeO_4 and its hydrated forms. Minimum selenium (Se) must be specified. All premixes shall bear adequate directions and cautions for use including this statement “Caution. Follow label directions. The addition to feed of higher levels of this premix containing selenium is not permitted.”

(wwwww) Sodium Selenite (21 CFR 573.920) is a sodium salt of selenious acid generally expressed as Na_2SeO_3 and its hydrated forms. Minimum selenium (Se) must be specified. All premixes shall bear adequate directions and cautions for use including this statement “Caution. Follow label directions. The addition to feed of higher levels of this premix containing selenium is not permitted.”

(xxxxx) Sodium Sesquicarbonate is the mixed sodium salt of carbonic acid, generally expressed as $Na_2CO_3 \cdot NaHCO_3 \cdot 2H_2O$, providing not less than 90 percent of the hydrated double salt with 42 percent minimum sodium carbonate, 33 percent minimum sodium bicarbonate, and providing not less than 27.5 percent sodium.

(yyyyy) Sodium Sulfate is the sodium salt of sulfuric acid generally expressed as Na_2SO_4 and its hydrated forms. The minimum sodium (Na) and minimum sulfur (S) must be specified.

(zzzzz) Sulfur is elemental sulfur generally expressed as sulfur (S). Minimum sulfur (S) must be specified.

(aaaaaa) Thymol Iodide is a mixture of iodine derivatives of thymol generally expressed as $C_{20}H_{24}I_2O_2$. Minimum iodine (I) must be specified.

(bbbbbb) Zinc Acetate, is the zinc salt of acetic acid generally expressed as $Zn(C_2H_3O_2)_2$ and its hydrated forms. Minimum zinc (Zn) must be specified.

(cccccc) Zinc Carbonate is the zinc salt of carbonic acid generally expressed as $ZnCO_3$ and its hydrated forms. Minimum zinc (Zn) must be specified.

(dddddd) Zinc Chloride is the zinc salt of hydrochloric acid generally expressed as $ZnCl_2$ and its hydrated forms. Minimum zinc (Zn) must be specified.

(eeeeee) Zinc Chloride Diammine Complex is the product resulting from the complexing of zinc with ammonium chloride and is generally expressed as $[Zn(NH_3)_2]$ Cl_2. Minimum zinc (Zn) must be specified.

(ffffff) Zinc Oxide is the oxide form of zinc generally expressed as ZnO. Minimum zinc (Zn) must be specified.

(gggggg) Zinc Sulfate is the zinc salt of sulfuric acid generally expressed as $ZnSO_4$ and its hydrated forms. Minimum zinc (Zn) must be specified.

(hhhhhh) Selenium Yeast (21 CFR 573.920) is a dried non-viable yeast, Saccharomyces cerevisiae, cultivated in a fed-batch fermentation that provides incremental amounts of cane molasses and selenium salts in a manner that minimizes the detrimental effects of selenium salts on the growth rate of the yeast and allows for optimal incorporation of inorganic selenium into cellular organic material. Residual inorganic selenium is eliminated in a rigorous washing process and must not exceed two (2) percent of the total selenium content in the final selenium yeast product. Guaranteed organic selenium content must be declared on the product label. The additive selenium yeast may be added to:

(1) Complete feeds for chickens, turkeys, swine, beef cattle, dairy cattle, bison, sheep, goats, llamas, alpacas, and horses at a level not to exceed 0.3 part per million of selenium.

(2) Feed supplements for limit feeding for beef cattle, bison, and horses at a level not to exceed an intake of three (3) milligrams per head per day.

(3) Feed supplements for limit feeding for goats, llamas, and alpacas at a level not to exceed an intake of 0.7 milligrams per head per day.

(4) Salt-mineral mixtures for free-choice feeding of beef cattle, bison, and horses up to 120 parts per million in a mixture for free-choice feeding at a rate not to exceed an intake of three (3) milligrams per head per day.

(5) Salt-mineral mixtures for free-choice feeding for goats, llamas, and alpacas up to 90 parts per million in a mixture for free-choice feeding at a rate not to exceed an intake of 0.7 milligrams per head per day.

(6) Selenium yeast shall be incorporated into each ton of complete feed by adding no less than one (1) pound of a premix containing no more than 272.4 milligrams of added selenium per pound. The label or labeling of any selenium premix shall bear adequate directions and cautions for use including this statement: “Caution: Follow label directions. The addition to feed of higher levels of this premix containing selenium is not permitted.”

(iiiiii) Zinc Hydroxychloride is the hydrolysis product of zinc chloride having the empirical formula $Zn_5(OH)_8Cl_2 \cdot (H_2O)$. The particle size must not exceed 100 microns. It must contain not less than 54 percent zinc and is intended to be a source of zinc for use in livestock, poultry, and companion animal diets. It must not contain more than 20 percent chloride, 90 parts per million lead, 15 parts per million chromium, 10 parts per million arsenic, 10 parts per million cadmium, and 0.2 parts per million mercury.

(jjjjjj) Manganese Hydroxychloride is the reaction product of manganese oxide and hydrochloric acid at the appropriate stoichiometric ratio, having the empirical formula $Mn_2(OH)_3Cl$. The particle size must not exceed 100 microns. It must contain not less than 44 percent manganese and is intended to be a source of manganese for use in livestock, poultry, and companion animal diets. It must not contain more than 20 percent chloride, 50 parts per million lead, 50 parts per million arsenic, 10 parts per million cadmium, and 0.5 parts per million mercury.

(kkkkkk) Selenomethionine Hydroxy Analogue [R,S-2-hydroxy-4- methylselenobutanoic acid (CAS 873660-49-2)] (21 CFR 573.920) is manufactured by the reaction of elemental selenium with methyllithium to form a methylseleno salt, which is then reacted with R,S-2-hydroxybutyrolactone to form a salt of 2-hydroxy-4-methylselenobutanoic acid. After acidification and purification, the additive consists of not less than 39.5 percent total selenium by weight with a selenomethionine hydroxy analogue content of not less than 98 percent of total selenium. The total organic selenium content of the additive is not less than 99 percent of total selenium.

(1) The selenomethionine hydroxy analogue meets the following specifications:

(A) Arsenic, not more than two (2) parts per million;

(B) Cadmium, not more than one (1) parts per million;

(C) Lead, not more than one (1) parts per million; and

(D) Mercury, not more than one (1) parts per million.

(2) Selenium, as selenomethionine hydroxy analogue, is added to feed as follows:

(A) In complete feed for chickens, turkeys, swine, beef cattle, and dairy cattle at a level not to exceed 0.3 parts per million.

(B) In feed supplements for limit feeding for beef cattle at a level not to exceed an intake of three (3) milligrams per head per day.

(C) In salt-mineral mixtures for free-choice feeding for beef cattle up to 120 parts per million in a mixture for free-choice feeding at a rate not to exceed an intake of three (3) milligrams per head per day.

(3) To ensure safe use of the additive, in addition to the other information required by the FD&C, the label and labeling of selenomethionine hydroxy analogue in its packaged form shall contain:

(A) The name, selenomethionine hydroxy analogue;

(B) Minimum and maximum guarantees for a total selenium content of not less than 2.08 percent (weight/weight) and not more than 2.24 percent;

(C) Minimum guarantee for selenomethionine hydroxy analogue content of not less than 5.2 percent;

(D) The following statement, “Storage Conditions: Selenomethionine hydroxy analogue must be stored in a closed package at temperatures not higher than 20 degrees Celsius (68 degrees Fahrenheit).”; and

(E) An expiration date not to exceed one (1) year from the date of manufacture.

(4) Selenomethionine hydroxy analogue, shall be incorporated into each ton of complete feed by adding no less than one (1) pound of a premix containing no more than 272.4 milligrams of added selenium per pound.

(5) The premix manufacturer shall follow good manufacturing practices in the production of selenium premixes. Inventory, production, and distribution records must provide a complete and accurate history of product production. Production controls must assure products to be what they are purported and labeled. Production controls shall include analysis sufficient to adequately monitor quality.

(6) The label or labeling of any selenium premix shall bear adequate directions and cautions for use including this statement: “Caution: Follow label directions. The addition to feed of higher levels of this premix containing selenium is not permitted.”

(llllll) Iron-Choline Citrate Complex (21 CFR 573.580) made by reacting approximately equimolecular quantities of ferric hydroxide, choline, and citric acid may be safely used as a source of iron in animal feed. Minimum iron (Fe) must be specified.

(mmmmmm) Descriptions of Salts, Complexes and Chelates.

(1) Metal (Mineral) Salt. an ionic substance containing a metal cation and either an inorganic or an organic anion. The water soluble portion of a Metal (Mineral) Salt dissociates in water to give the hydrated metal cation and the free anion (or its hydrolysis product) in solution.

(2) Metal (Mineral) Complex. a substance in which a metal cation (electron pair acceptor) accepts an electron pair from one or more anionic or neutral bonding partners (ligands, electron pair donors) to form chemical bonds. The water soluble portion of the complex remains as the intact complex in aqueous solution.

(3) Metal (Mineral) Chelate. a metal complex (see preceding term) in which at least one ligand (electron pair donor) forms two or more bonds to the central metal ion through different atoms of the ligand. A distinctive feature of a metal chelate is the presence of a heterocyclic ring(s) in which the metal is a member of the ring. In the water soluble portion of the chelate, the heterocyclic ring(s) remains intact.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2791. Miscellaneous Products.

(a) Aspirated Grain Fractions are obtained during the normal aspiration of cereal grains and/or oil seeds for the purpose of environmental control and safety within a grain handling facility. It shall consist primarily of seed parts and may not contain more than 15 percent ash. It shall not contain aspirations from medicated feeds.

(b) Biodiesel-Derived Glycerin is a liquid co-product of biodiesel production by a base catalyzed transesterification process. It must be derived from processes utilizing sources of fatty acids compliant with the term “feed grade” and if animal fat of ruminant origin is utilized, sources must not contain more than 0.15 percent insoluble impurities. It is intended as a source of energy in livestock diets. It must contain not less than 80

percent glycerin, not more than 15 percent water, not more than 0.5 percent methanol, and not more than five (5) parts per million heavy metals. It may contain up to eight (8) percent salt. It must be labeled with guarantees for minimum percentage glycerin, maximum percentage moisture, maximum percentage sulfur, maximum percentage ash, and maximum percentage methanol as well as the statement “For further mixing into livestock feed.” It is for use in an amount not to exceed 15 percent of the complete feed for ruminants and ten (10) percent of the complete feed for all other livestock species, including poultry.

(c) Buckwheat Hulls is the product consisting primarily of the outer covering of the buckwheat obtained in the milling of buckwheat flour.

(d) Buckwheat Middlings is that portion of the buckwheat grain immediately under the hull after separation of the flour. It must contain no more hulls than is obtained in the usual process of buckwheat milling, and must contain not more than 10 percent crude fiber.

(e) 1, 3-Butylene Glycol (1, 3-Butanediol) (21 CFR 573.225 and 21 CFR 173.220) is a viscous, colorless liquid of 99 percent purity, with a specific gravity at 20 degrees centigrade:1.004 to 1.006, and has a distillation range of 200-215 degrees centigrade. It is to be used as a source of energy in swine feed at a level not to exceed nine (9) percent of the dry matter of the total ration. It should be thoroughly mixed in feed, not less than five (5) minutes after its addition, with equipment adapted for the addition of liquids.

(f) Charcoal (vegetable) is charred hard or soft wood, nut shells, or fruit pits. If it is wood charcoal, it shall bear a designation indicating whether it is hard wood charcoal or soft wood charcoal. Charcoal from nut shells or fruit pits shall be designated as shell charcoal. When used in a mixed feed the maximum percent shall be stated on the label.

(g) Chia Seed consists of cleaned, sound, dry, whole seed of the chia plant (Salvia hispanica). Typically it contains 18 percent crude protein, 32 percent crude fat and 32 percent crude fiber.

(h) Coastal Bermudagrass Hay is the dried aerial portion of the perennial hybrid grass, Coastal bermuda (Cynodon dactylon) (L.)a (Pers.), reasonably free of other crop plants, weeds and mold, which has been cultivated as a crop and harvested during an period of active growth. If it is fully ground, it must be designated as “Coastal Bermudagrass Meal.” If it is dried by thermal means, it should be designated as “Dehydrated Coastal Bermudagrass Hay” or “Dehydrated Coastal Bermudagrass Meal.”

(i) Cocoa Bean Shells or Cocoa Bean Hulls is the hard outside coating of the cocoa bean.

(j) Dehydrated Silage (ensilage) Pellets are pellets made from wholesome silage (ensilage) which has been dried by thermal means and formed into pellets by compacting and forcing through die openings by a mechanical process. The product should bear a name descriptive of the type of silage (ensilage) pelleted, such as “Dehydrated Alfalfa Silage (ensilage) Pellets,” etc.

(k) Distressed Pet Food is a product resulting from pet food distribution, but which is no longer available for retail sale. This product may be pet food in, but not limited to, dented cans, torn bags, product past its sell-by date, or returned product that is suitable for use in feed. It may consist of a single formula, still in the original packaging, or a variety of formulas commingled into one bulk container and containing none of the original packaging or labeling. It if contains, or may contain, any material identified by 21 CFR 589.2000 as prohibited from use in the feed of ruminant animals, or if it is no longer accompanied by a detailed label listing all of the ingredients in the distressed product, the label must contain the precautionary statement “Do not feed to cattle or other ruminants.” It shall be free of foreign materials harmful to animals, suitable for the purpose for which it is being marketed, and properly labeled for its intended use. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.”

(l) Dried Black Soldier Fly Larvae is the dried larvae of the Black Soldier Fly, Hermetia illucens, with or without mechanical extraction of part of the oil, that has been raised on feedstock composed exclusively of feed grade materials. The ingredient must be labeled with guarantees for minimum crude protein and minimum crude fat on an as-fed basis. If oil is mechanically extracted, maximum crude fat must also be guaranteed on the ingredient label. The ingredient is dried by artificial means to no more than 10 percent moisture. It is for use in salmonid, poultry, and swine feed as a source of protein and fat consistent with good feeding practices. This ingredient may contain materials subject to the Swine Health Protection Act and may require additional processing controls, if fed to swine. Prior to the use of this ingredient for the feeding of swine or its use in the manufacturing of an ingredient or feed intended for swine, manufacturers and/or feeders should adhere to the provisions of the Swine Health Protection Act where appropriate (9 CFR 166).

(m) Dried Chicory Root is the dried, non-roasted root Cichorium intybus L., intended as a source of inulin, a soluble, fermentable fiber. It shall contain no less than 50 percent inulin and no more than 13 percent moisture.

(n) Dried Kelp is dried seaweed of the families Laminariaceae and Fucaceae. The maximum percentage of salt (NaCl) and the minimum percentage of potassium (K) must be declared. If the kelp is sold as a source of iodine (I), the minimum percentage of iodine must be declared. If the product is prepared by artificial drying, it may be called “Dehydrated Kelp.”

(o) Dried Seaweed Meal is the product resulting from drying and grinding non-toxic macroscopic marine algae (marine plants) of the following botanical divisions: Division RHODOPHYTA (Red Algae); Division PHAEOPHYTA (Brown Algae); Division CHLOROPHYTA (Green Algae). The maximum percentage of salt (NaCl) (determined by sodium content), the minimum percentage of potassium (K), and the percentage of iodine (I) shall be guaranteed. If the product is prepared by artificial drying it must be labeled as: Dehydrated Seaweed Meal. The family(ies) shall be identified on the label. The following families are accepted for use under the definition Dried Seaweed Meal: RHODOPHYTA (Red Algae): Gelidiaceae, Endocladiaceae, Gigartinaceae, Gracilariaceae, Phyllophoraceae, Solieriaceae, Hypneaceae, Palmariaceae,

Bangiaceae; PHAEOPHYTA (Brown Algae): Chordaceae, Laminariaceae, Lessoniaceae, Alariaceae, Fucaceae, Sargassaceae, Durvillaeaceae; CHLOROPHYTA (Green Algae): Monostromataceae, Ulvaceae.

(p) Ethyl Alcohol Containing Ethyl Acetate (21 CFR 584.200) is a product containing not less than 92.5 percent ethyl alcohol, each 100 gallons having had added the equivalent of 4.25 gallons of 100 percent ethyl acetate. It is used in ruminant feed supplements as a source of added energy.

(q) Fructooligosaccharide is a carbohydrate product composed of short chain fructose units bound by B-(2-1) linkages attached to a terminal glucose unit. The final product must contain a minimum of 80 percent fructooligosaccharide on a dry weight basis.

(r) Ground Grass is obtained by drying and grinding grass which has been cut before formation of the seed. If a specie name is used, the produce must correspond thereto.

(s) Ground Juniper is a roughage consisting of the entire aerial portion of the juniper plant (trunk, bark, branches, leaves, and berries), obtained only from Juniperus pinchotii and/or Juniperus ashei. Any plant part below ground level is excluded to avoid contamination with soil and/or rocks. It is ground to pass a screen no larger than 5/8 inches (15.875 mm). The ingredient must be guaranteed for crude protein and acid detergent fiber. Ground juniper is to be fed as a dietary roughage for cattle, sheep, or goats in accordance with good feeding practices.

(t) Ground Pecan Shells is obtained by grinding the hard outer shell. It must be reasonably free of the nut meat and other foreign material. It is to be used as a source of dietary fiber. A minimum crude fiber level must be guaranteed on the label.

(u) Ground Straw is the ground product remaining after separation of the seed from mature forage plants. The source of the material shall constitute a part of the name of the product; i.e., “Ground Blue Grass Straw,” “Ground Alfalfa Straw.”

(v) Ground Whole Aspen and/or Parts is generally recognized as a feed ingredient in cattle diets when used in accordance with good feeding practices. Ground whole aspen (Populus tremuloides Michiz and Populus gradidentata) is composed of the entire tree including leaves, branches, trunk, and bark. Ground aspen parts may also include leaves, branches, trunk, and bark. Roots and stumps are excluded to avoid contamination of dirt and rocks in the product. The particle size of the product shall not exceed 3/8 inches.

(w) Guar Meal is obtained from whole guar beans after removal of most of the endosperm. If the product is heat treated, it may be designated as “heat treated” or “toasted.”

(x) Hydrolyzed Roughage is the residue from the acid hydrolysis and steam stripping of roughage products. The product will contain a minimum of 50 percent acid detergent fiber and a maximum of five (5) percent ash. The product is used as a carrier for oils, fats, and molasses and as a source of acid detergent fiber for ruminants.

(y) Inulin is a polysaccharide product obtained from plant sources such as chicory (Cichorium intybus L.), agave (Agave azul tequilana), and Jerusalem artichoke (Helianthus tuberosus) by hot water extraction. It is intended as a source of soluble,

fermentable fiber. It must contain not less than 90 percent inulin on a dry matter basis. It may contain products of partially hydrolyzed inulin.

(z) Lablab (Lablab purpureus or Dolichos lablab) also known as hyacinth bean, is an annual legume that produces forage as either hay or pasture for ruminants. Leaves and/or stems can be used as a feed ingredient if it is free of mature seed.

(aa) L-Carnitine is a nutritional supplement with a minimum content of 97.0 percent L-Carnitine and a maximum of 0.5 percent D-isomer. L-Carnitine is for use in swine feeds at levels not to exceed 0.1 percent (1000 parts per million) of complete feed, for use in chicken and turkey feeds at levels not to exceed 0.02 percent (200 parts per million) of complete feed, for use in fish feed at levels not to exceed 0.25 percent (2500 parts per million) of complete feed, for use in milk replacers for ruminant animals at levels not to exceed 0.075 percent (750 parts per million) of milk replacer powder. L-Carnitine is a fatty acid carrier that plays a role in fat oxidation in the body.

(bb) Oil Cake is the product obtained after the extraction of part of the oil by crushing, cooking, and pressing, or by crushing, heating, and the use of solvents, from vegetable seeds which have been screened and cleaned of weed seed, hulls, and other foreign materials by a commercial process. A name indicative of the source shall be prefixed to the words “oil cake.”

(cc) Oil Meal is oil cake ground to a meal. A name indicative of the source shall be prefixed to the words “oil meal.”

(dd) Paunch Product, Dehydrated is a product composed of the contents of the rumen of slaughtered cattle, dehydrated at temperatures over 100 degrees Celsius to a moisture content of 12 percent or less, such dehydration designed to destroy any pathogenic bacteria. It shall be dehydrated promptly after removal from the rumen to prevent decomposition.

(ee) Potato Protein is derived from de-starched potato juice from which the proteinaceous fraction has been precipitated by thermal coagulation followed by dehydration.

(ff) Psyllium Seed Husk is the cleaned, dried seed coat separated by winnowing and thrashing of psyllium seeds. It is to be used as a source of dietary fiber and the crude fiber level must be declared on the label.

(gg) Pulse Fiber consists primarily of the outer coverings or hull of pulse crops derived from pulse dry milling. Pulse crops include the edible seeds of legumes (excluding oil seeds). Acceptable pulse crops are listed below. The product must contain not less than 23 percent crude fiber on a dry matter basis. If a conditioning agent is used, the name of the conditioning agent must be shown as an added ingredient. If the ingredient bears a name descriptive of its kind or origin, it must correspond thereto (e.g., pea fiber). Accepted pulse crops: Lentil (Lens culinaris).

(hh) Pulse Flour is the fraction remaining after removal of fiber from pulse seeds. It is obtained from mechanically dehulled and dry milled pulse seeds. This flour fraction must be free of fiber and seed hull/pod, except in such amounts as might occur unavoidably in good manufacturing practices. Pulse crops include the edible seeds of

legumes (excluding oil seeds). Acceptable pulse crops are listed below. The ingredient must contain not less than 20 percent crude protein and not more than three (3) percent crude fiber on a dry matter basis. If a conditioning agent is used, the name of the conditioning agent must be shown on the product label as an added ingredient. If the ingredient bears a name descriptive of its kind or origin, it must correspond thereto (e.g., pea flour). Accepted pulse crops: Lentil (Lens culinaris).

(ii) Pulse Protein is the protein fraction of pulse seeds. It is obtained from mechanically dehulled, dry milled pulse seeds that are further separated through air classification or the addition of water, acid, and alkali. The ingredient may be obtained from pulse seed separated by dry separation, wet separation, or both. Pulse crops include the edible seeds of legumes (excluding oil seeds). Acceptable pulse crops are listed below. The ingredient must contain not less than 53 percent crude protein on a dry matter basis, and a label shall include a guarantee for minimum crude protein. If a conditioning agent is used, the name of the conditioning agent must be shown as an added ingredient. If the ingredient bears a name descriptive of its kind or origin, it must correspond thereto. Accepted pulse crops: Lentil (Lens culinaris).

(jj) Pulse Starch is the fraction remaining after removal of protein and fiber from pulse seeds. It is obtained from mechanically dehulled, dry milled pulse seeds that are further separated through air classification or through the addition of water. The ingredient may be obtained from pulse seed separated by dry separation, wet separation, or both. Pulse crops include the edible seeds of legumes (excluding oil seeds). Acceptable pulse crops are listed below. The product must contain not less than 65 percent dietary starch on a dry matter basis, and the label shall include a guarantee for minimum dietary starch. If a conditioning agent is used, the name of the conditioning agent must be shown on the product label as an added ingredient. If the ingredient bears a name descriptive of its kind or origin, it must correspond thereto. Accepted pulse crops: Lentil (Lens culinaris).

(kk) Quinoa Seed consists of cleaned, sound, whole seed of the quinoa plant (Chenopodium quinoa) from which the saponin contained in the seed’s outer layer has been removed.

(ll) Salts of Volatile Fatty Acids (21 CFR 573.914) is a blend containing the ammonium or calcium salt of isobutyric acid and the ammonium or calcium salts of a mixture of 5-carbon acids/ isovaleric, 2-methylbutyric, and n-valeric. The contained ammonium or calcium salts of volatile fatty acids shall conform to the specifications in 21 CFR 573.914. It is used as a source of energy in dairy cattle feed. The label of the product shall bear adequate directions for use including statements expressing maximum use levels: for ammonium salts of volatile fatty acids - not to exceed 160 grams per head per day thoroughly mixed in dairy cattle feed as a source of energy; for calcium salts of volatile fatty acids - not to exceed 135 grams per head per day thoroughly mixed in dairy cattle feed as a source of energy.

(mm) Salvage Pet Food is a product resulting from pet food manufacturing. This product may consist of, but is not limited to, start-up and over-run product, unfinished pet food, pet food fines and other product not suitable for packaging for retail sale. If it contains, or may contain, any material identified by 21 CFR 589.2000 as prohibited from use in the feed of ruminant animals, or if it is no longer accompanied by a detailed label listing

all of the ingredients in the salvage pet food, the label must contain the precautionary statement “Do not feed to cattle or other ruminants.” It shall be free of foreign materials harmful to animals, suitable for the purpose for which it is being marketed, and properly labeled for its intended use. Use of this ingredient, from mammalian origins, is restricted to non-ruminant feeds unless specifically exempted by 21 CFR 589.2000. Feeds containing prohibited material must bear the following label statement: “Do not feed to cattle or other ruminants.” This ingredient may contain materials subject to the Swine Health Protection Act and may require additional processing controls, if fed to swine. Prior to the use of this ingredient for the feeding of swine or its use in the manufacturing of an ingredient or feed intended for swine, manufacturers and/or feeders should adhere to the provisions of the Swine Health Protection Act where appropriate (9 CFR 166).

(nn) Silage is green fodder that has been preserved with or without additives by ensiling. Normally the material is finely cut and blown into a chamber such as a pit or bag where it is pressed to exclude air and where it undergoes an acid fermentation that retards spoilage. The materials shall be labeled to show the kind of silage, for example, corn silage, oat silage, hay silage. When the product is sold in a formula or mixed feed, all ingredients shall be stated on the label. The label shall state the following guarantees: minimum percent crude protein, minimum percent crude fat, maximum percent crude fiber, maximum percent ash and maximum and minimum percent moisture.

(oo) Sweet Lupin Meal is the product resulting from the grinding of the entire seed of the species of Lupinus albus (white), L. augustifolius (blue), or L. luteus (yellow) which contain less than 0.03 percent alkaloids.

(pp) Sweet Lupin Meal Dehulled is the product resulting from the grinding of seeds after mechanical removal of the hulls from the species of Lupinus albus (white), L. augustifolius (blue), or L. luteus (yellow) which contain less than 0.03 percent alkaloids.

(qq) Sweet Lupin Meal Solvent Extracted is the product obtained by grinding of the flakes after the removal of most of the oil by a solvent extraction process from the seeds of the species of Lupinus albus (white), L. augustifolius (blue), or L. luteus (yellow) which contain less than 0.03 percent alkaloids. It must contain not more than seven (7) percent crude fiber. The sweet lupin species defined above are of Mediterranean origin and are quite distinct from the Lupine's of North America. The two differ evolutionarily and genetically in their origin and thus the sweet lupin cannot be “contaminated” by outcrossing with the North American lupine.

(rr) Tapioca/Manioca and Cassava Root is the whole root chipped mechanically into small pieces and sun dried on concrete surfaces for two (2) to three (3) days and then the chips are pelleted.

(ss) Yeast Dried Grains is the properly dried residue from the mixture of cereals, malt, and malt sprouts (sometimes cottonseed meal) obtained in the manufacture of yeast or vinegar, and consists of corn or corn and rye from which most of the starch has been extracted, together with malt added during the manufacturing process to change the starch to sugar, and malt sprouts (sometimes cottonseed meal) added during the manufacturing process to aid in filtering the residue from the wort and to serve as a

source of food supply for the yeast. If residue is from manufacture of vinegar, may also be listed as “Vinegar Dried Grains.”

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2792. Molasses and Molasses Products.

(a) Bagasse is that portion of the stalk of sugar cane, after removal of leaves and tops, remaining after extraction of the juice.

(b) Beet Fiber, Dried, Plain is the refined plant material derived from sugar beet pulp after sugar extraction which has been further refined by washing, drying and milling. It shall contain a total dietary fiber (crude fiber) content of not less than 80 percent and an ash content of not more than three (3) percent.

(c) Beet Pulp, Dried, Molasses is the dried residue from sugar beets which has been cleaned and freed from crowns, leaves, and sand, and which has been extracted in the process of manufacturing sugar to which has been added (beet) molasses obtained in the extraction of sugar.

(d) Beet Pulp, Dried, Plain is the dried residue from sugar beets which has been cleaned and freed from crowns, leaves, and sand, and which has been extracted in the process of manufacturing sugar.

(e) Beet Pulp, Dried Product CSF, RNS, is the dried residue from sugar beets which has been cleaned and freed from crowns, leaves, and sand, and which has been extracted in the process of manufacturing sugar to which has been added the concentrated Steffen's filtrate obtained in the extraction of the sugar from the beets.

(f) Beet Molasses is a by-product of the manufacture of sucrose from sugar beets. It must contain not less than 48 percent total sugars expressed as invert.

(g) Beet Molasses, Dried Product, is the properly dried mixture of molasses and molasses dried beet pulp containing not less than 45 percent total sugar expressed as invert.

(h) Cane Molasses is a by-product of the manufacture of sucrose from sugar cane. It must contain not less than 43 percent total sugars expressed as invert and not less than 73 percent total solids.

(i) Citrus Molasses is the partially dehydrated juices obtained from the manufacture of dried citrus pulp. It must contain not less than 45 percent total sugars expressed as invert.

(j) Concentrated Separator By-Product (CSB) is obtained as a by-product of the recovery of sucrose from beet molasses by utilization of molecular exclusion chromatography.

(k) Concentrated Steffen Filtrate (CSF) is obtained as a by-product of the recovery of sucrose from beet molasses by utilization of the Steffen process (precipitation with calcium oxide).

(l) Hemicellulose Extract (21 CFR 573.520) is a by-product of the manufacture of pressed wood. It is the concentrated soluble material obtained from the treatment of wood at elevated temperature and pressure without use of acids, alkalis, or salts. It contains pentose and hextose sugars, and has a total carbohydrate content of not less than 55 percent.

(m) Starch Molasses is a by-product of the manufacture of dextrose from starch derived from corn or grain sorghums in which the starch is hydrolized by use of enzymes and/or acid. It must contain not less than 43 percent reducing sugars expressed as dextrose and not less than 50 percent total sugars expressed as dextrose. It shall contain not less than 73 percent total solids.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2793. Non-Protein Nitrogen.

(a) Feed Grade Biuret (21 CFR 573.220) is predominantly composed of biuret (55 percent minimum) together with related non-toxic nitrogenous compounds resulting from the controlled pyrolysis of urea and subsequent processing. It must contain not less than 35 percent nitrogen (equivalent to 218.7 percent crude protein) with not more than 15 percent nitrogen (equivalent to 93.75 percent crude protein) being from urea. It shall not contain more than 0.5 percent mineral oil. The label of the additive and of any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom, must contain the following information in addition to any other required information:

(1) The name of the additives.

(2) The maximum percentage of equivalent crude protein from non-protein nitrogen.

(3) Directions for use to provide: The diet be balanced to provide adequate nutrients when equivalent crude protein from all forms of non-protein nitrogen exceed one-third of the total crude protein in the total daily ration. Use only in mixed feeds for ruminants (cattle, sheep and goats).

(4) This feed should be used only in accordance with directions furnished on the label.

(b) Fermented Ammoniated Condensed Whey (21 CFR 573.450) is the product produced by the Lactobacillus bulgaricus or Lactobacillus delbrueckii fermentation of whey with the addition of ammonia. It must contain 35 percent to 55 percent crude protein and not more than 42 percent equivalent crude protein from non-protein nitrogen. It is to be used as a source of crude protein and non-protein nitrogen for cattle. The label of the additive and of any feed additive supplement, feed additive concentrate or feed additive premix prepared therefrom must contain the following information in addition to any other required information:

(1) The name of the additive.

(2) The maximum percentage of equivalent crude protein from non-protein nitrogen.

(3) Directions for storage and use: Store in closed vented tank equipped for agitation. Agitate five (5) minutes before using. Do not store at temperatures above 110 degrees Fahrenheit (43 degrees Celsius). Mix with grain, roughage, or grain and roughage prior to feeding or as a component of free choice liquid feeds, used to supplement the diets of cattle fed other sources of nutrients. Fermented ammoniated condensed whey shall not exceed 80 percent of free choice liquid feed. The maximum equivalent crude protein from fermented ammoniated condensed whey and equivalent crude protein from all other added forms of non-protein nitrogen shall not exceed 30 percent of the dietary crude protein.

(4) A prominent statement: “CAUTION - This feed should be used only in accordance with the directions furnished on the label.”

(c) Gelatinized Starch-Urea Product is obtained by processing a mixture of finely ground grains or other carbohydrate containing materials with urea under regulated conditions of temperature (250 to 250 degrees Fahrenheit), moisture (15 to 30 percent) and pressure (400 to 500 p.s.i.). It is to be used in the feed of ruminants as a source of protein and/or as the sole source of non-protein nitrogen in an amount not to exceed 25 percent of the total ration. The label of the additive and of any feed additive supplement, feed additive concentrate, or feed additive premix prepared therefrom, must contain the following information in addition to any other required information:

(1) The name of the additive.

(2) The maximum percentage of equivalent crude protein from non-protein nitrogen.

(3) Directions for use to provide not more than 25 percent of the additive in the total ration and a prominent statement: “Warning - This feed should be used in accordance with the directions furnished on the label.”

(d) Liquid Starch-Controlled Urea Product is obtained by processing a slurry of finely ground grains or other carbohydrate-containing materials with urea in a hydroheater under regulated conditions of temperature (250 to 350 degrees Fahrenheit), moisture (50 to 70 percent) and pressure (15 to 150 p.s.i.). It is to be used in the feed of ruminants as a source of protein and/or as the sole source of non-protein nitrogen in an amount not to exceed 25 percent of the total ration. The label of the additive and of any feed additive supplement, feed additive concentrate or feed additive premix prepared therefrom, must contain the following information in addition to any other required information:

(1) The name of the additive.

(2) The maximum percentage of equivalent crude protein from non-protein nitrogen.

(3) Directions for use to provide not more than 25 percent of the additive in the total ration and a prominent statement: “WARNING - This feed should be used only in accordance with the directions furnished on the label.”

(e) Urea is predominantly urea but may contain other non-toxic nitrogenous compounds which are present as by-products from the commercial synthesis and processing of Urea. It must contain not less than 45 percent nitrogen (equivalent to 281.25 percent crude protein). If it contains less than 45 percent N but 41 percent or more N, it must be

designated as “Urea and Conditioner(s).” If the name of the conditioner(s) does not appear in the product name, the ingredient listing must contain the specific name of the conditioner(s). If the Urea and Conditioner(s) contribute more than 0.5 percent conditioner(s) to the mixed feed, the conditioner(s) must be named in the mixed ingredient list.

(f) Non-Protein Nitrogen Products defined in other sections of this Article include:

(1) Special Purpose Products: Ammoniated Cottonseed Meal, Ammoniated Rice Hulls, Anhydrous Ammonia.

(2) Mineral Products: Ammonium Chloride, Ammonium Polyphosphate, Ammonium Sulfate, Diammonium Phosphate, Monoammonium Phosphate.

(3) Fermentation Products: Condensed, Extracted Glutamic Acid Fermentation Product, Condensed [Specify] Fermentation Solubles, Dried Fermentation Biomass.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2794. Oat Products.

(a) Clipped Oat By-Product is obtained in the manufacture of clipped oats. It may contain the light chaffy material broken from the end of the hulls, empty hulls, light immature oats, and dust. It must not contain an excessive amount of oat hulls.

(b) Feeding Oat Meal is obtained in the manufacture of rolled oat groats or rolled oats and consists of broken oat groats, oat groat chips, and floury portions of the oat groats, with only such quantity of finely ground oat hulls as is unavoidable in the usual process of commercial milling. It must not contain more than four (4) percent crude fiber.

(c) Ground Oats, Pulverized Oats, Crushed Oats and Crimped Oats consist of the entire product made by grinding, cutting, crushing, or crimping whole oats. They shall contain not more than 10.0 percent of other grains, weed seeds, and other foreign material containing not more than 15.0 percent crude fiber.

(d) Mixed Feed Oats consists of a mixture of grain containing at least 30 percent of cultivated oats provided that the mixture consists of either (a) not less than 65 percent of cultivated and wild oats combined or (b) not less than 65 percent of wild oats. It must contain more than 25 percent of other grains, not more than six (6) percent heat damaged kernels of oats, wild oats, and other grains, and not more than 10 percent foreign material which may include four (4) percent fine seeds. Foreign material must be all matter except wild oats and grains for which standards have been established under the United States Grain Standards Act.

(e) Oat Fiber is obtained from oat hulls that have been processed through a continuous wet and dry process to modify soluble and insoluble fractions of the fiber, and to reduce the content of lignin. The ingredient must be guaranteed for neutral detergent fiber, acid detergent fiber, and acid insoluble lignin. Oat fiber is to be used as a source of insoluble fiber in animal feed.

(f) Oat Groats are cleaned oats with the hulls removed.

(g) Oat Hulls consists primarily of the outer covering of oats, obtained in the milling of table cereals or in the groating of oats from clean oats.

(h) Oat Mill By-Product is the by-product obtained in the manufacture of oat groats, consisting of oat hulls, and particles of the groat, and containing not more than 25 percent crude fiber.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2795. Other Oilseed Products.

(a) Brassica carinata Meal, Solvent Extracted, is the meal obtained after the removal of most of the oil by solvent extraction of Brassica carinata seeds. The meal shall contain less than two (2.0) percent erucic acid and less than 30 micromoles of total glucosinolates per gram. It is a source of protein for beef cattle in an amount not to exceed 10 percent of the total diet. The maximum sulfur content must be guaranteed. The words “Solvent Extracted” are not required when listed as an ingredient in a manufactured feed.

(b) Camelina Meal, Extracted, is the product obtained from high-pressure crushing of seed, or from a pre-press solvent extraction process, which removes the oil from the whole seed of the species Camelina sativa. The meal may be heated. The meal is the material which remains after most of the oil has been removed. It must not contain less than 30 percent crude protein, and a maximum of 12 percent crude fiber. It may contain up to 15 percent residual oil. The meal contains less than 30 micromoles of any mixture of 9-Methylsulfinylnonyl glucosinolate, 10-Methylsulfinyldecyl glucosinolate, and 11-Methylsulfinylundecyl glucosinolate per gram of dry oil free solid. It is used in the diets of broiler chickens, cattle fed in confinement for slaughter, and laying hen chickens at an inclusion of no more than 10 percent of the diet.

(c) Canola Meal is the low erucic acid, low glucosinolate meal obtained after the removal of most of the oil by mechanical extraction, or by direct solvent or prepress solvent extraction of whole seeds obtained from the genus Brassica (Brassica napus, Brassica rapa, or Brassica juncea) from which the oil shall contain less than two (2) percent erucic acid and the solid component shall contain less than 30 micromoles of any one or any mixture of 3-butenyl glucosinolate, 4-pentenyl glucosinolate, 2-hydroxy-3 butenyl glucosinolate, 2-hydroxy-4-pentenyl glucosinolate, and allyl glucosinolate per gram of air dry, oil free solid. When produced from Brassica juncea it must also contain less than five (5) micromoles of allyl glucosinolates per gram of air dry, oil free solid. It must contain a maximum of 12 percent crude fiber and a maximum of 30 micromoles of glucosinolates per gram. It is used in the diets of animals as a source of protein, in accordance with good feeding practices.

(d) Coconut Meal, Mechanical Extracted, is the ground residue which remains after removal of most of the oil from dried meat of coconuts by a mechanical extraction process. May also be called “Copra Meal.” The words “Mechanical Extracted” or are not required when listed as an ingredient in a manufactured feed.

(e) Coconut Meal, Solvent Extracted, is the ground residue which remains after removal of most of the oil from dried meat of coconuts by a solvent extraction process. May also

be called “Copra Meal.” The words “Solvent Extracted” are not required when listed as an ingredient in a manufactured feed.

(f) Crambe Meal, Heat Toasted (21 CFR 573.310), is the seed meal of Crambe abyssinica after the removal of oil from the seed and hull by pre-press solvent extraction or by solvent extraction alone. The resulting seed meal is heat toasted. It shall conform to the restriction of glucosinolate, goitrin, and nitrogen soluble as set forth in 21 CFR 573.310. It shall have a crude protein, crude fat, and a crude fiber guarantee. Myrosinase enzyme activity shall be absent. It is used or intended for use in the feed of feedlot cattle as a source of protein in an amount not to exceed 4.2 percent of the total ration.

(g) Flaxseed Screenings Meal, Solvent Extracted, is the ground product obtained after solvent extraction of part of the oil from the smaller imperfect flaxseeds, weed seeds, other oilseeds and other foreign material having feeding value, separated in cleaning flaxseed. The words “Solvent Extracted” are not required when listed as an ingredient in a manufactured feed.

(h) Flax Plant Product is that portion of the flax plant having feeding value remaining after harvesting the seed and separation of the base fibers and flax shives. It consists of the leaves, corticle tissues, flax seed bolls, broken and immature flax seeds. It must contain a minimum of nine (9) percent crude protein and a maximum of 35 percent crude fiber.

(i) Flax Straw By-Product is the ground product remaining after the removal of the longer fiber material from flax straw by mechanical processing. It must contain not less than two (2) percent crude protein and not more than 70 percent crude fiber.

(j) Ground Peanut Hay is composed of ground peanut leaves and stems from which the peanuts have been removed.

(k) Linseed Meal, Mechanical Extracted, is the product obtained by grinding the cake or chips which remain after removal of most of the oil from flaxseed by a mechanical extraction process. It must contain no more than 10 percent fiber. The words “Mechanical Extracted” are not required when listed as an ingredient in a manufactured feed.

(l) Linseed Meal, Solvent Extracted, is the product obtained by grinding the flakes which remain after removal of most of the oil from flaxseed by a solvent extraction process. It must contain no more than 10 percent fiber. The words “Solvent Extracted” are not required when listed as an ingredient in a manufactured feed.

(m) Low Glucosinolate High Erucic Acid Rapeseed Meal, Mechanically Extracted, is the meal obtained after the removal of most of the oil by mechanical extraction of whole seeds obtained from the genus Brassica (Brassica napus, Brassica rapa, or Brassica juncea) from which the oil shall contain more than two (2) percent erucic acid and the solid component shall contain less than 30 micromoles of any one or any mixture of 3-butenyl glucosinolate, 4-pentenyl glucosinolate, 2-hydroxy-3-butenyl glucosinolate, 2-hydroxy-4-pentenyl glucosinolate, and allyl glucosinolate per gram of air dry, oil free solid. When produced from Brassica juncea, it must also contain less than five (5) micromoles of allyl glucosinolates per gram of air dry, oil free solid. It must contain a

maximum of six (6) percent erucic acid, a maximum of 12 percent crude fiber, and a maximum of 30 micromoles of glucosinolates per gram. It is used in the diets of animals as a source of protein, not to exceed a five (5) percent inclusion rate. The words “Mechanical Extracted” are not required when listed as an ingredient in a manufactured feed.

(n) Low Glucosinolate High Erucic Acid Rapeseed Meal, Solvent Extracted, is the meal obtained after the removal of most of the oil by the prepress solvent extraction of whole seeds obtained from the genus Brassica [Brassica napus, Brassica rapa, or Brassica juncea] from which the oil shall contain more than two (2) percent erucic acid and the solid component shall contain less than 30 micromoles of any one or any mixture of 3-butenyl glucosinolate, 4-pentenyl glucosinolate, 2-hydroxy-3-butenyl glucosinolate and 2-hydroxy-4-pentenyl glucosinolate, and allyl glucosinolate per gram of air dry, oil free solid. When produced from Brassica juncea it must also contain less than five (5) micromoles of allyl glucosinolates per gram of air dry, oil free solid. It must contain a maximum of two (2) percent erucic acid, a maximum of 12 percent crude fiber, and a maximum of 30 micromoles of glucosinolates per gram. It is used in the diets of animals as a source of protein, in accordance with good feeding practices. The words “Solvent Extracted” are not required when listed as an ingredient in a manufactured feed.

(o) Mustard Meal, Solvent Extracted, is the product obtained by grinding the cake that remains after removal of some of the oil by mechanical extraction, and removing most of the remaining oil by solvent extraction. It is obtained from the seed of the cultivated mustard plants Brassica juncea, Brassica nigra, and Sinapis alba (formerly Brassica alba). Use should be restricted to cattle and sheep and at no more than 10 percent of the ration. It should not be fed to lactating dairy cows if milk production is for human consumption because of objectionable taste and/or odor. The words “Solvent Extracted” are not required when listed as an ingredient in a manufactured feed.

(p) Peanut Hulls consists of the outer hull of the peanut shell.

(q) Peanut Meal and Hulls, Mechanical Extracted and Solvent Extracted, is a product of shelled peanuts, composed principally of the kernels and hulls, with such portion of the oil, as may be left in the ordinary course of manufacture. The words “Mechanical Extracted” or “Solvent Extracted” are not required when listed as an ingredient in a manufactured feed.

(r) Peanut Meal, Mechanical Extracted and Solvent Extracted, is a ground product of the shelled peanuts, composed principally of the kernels, with such portion of the hull, or fiber, and oil as may be left in the ordinary course of manufacture. It must contain no more than seven (7) percent crude fiber. The words “Mechanical Extracted” or “Solvent Extracted” are not required when listed as an ingredient in a manufactured feed.

(s) Peanut Skins is the outer covering of the peanut kernel, exclusive of hulls, as obtained in ordinary commercial processing. The product may contain broken peanut kernels.

(t) Safflower Meal, Mechanical Extracted, is the ground residue obtained after extracting the oil from whole safflower seed by a mechanical extraction process. The words

“Mechanical Extracted” are not required when listed as an ingredient in a manufactured feed.

(u) Safflower Meal, Solvent Extracted, is the ground residue obtained after extracting the oil from whole safflower seed by a solvent extraction process. The words “Solvent Extracted” are not required when listed as an ingredient in a manufactured feed.

(v) Sunflower Hulls consists of the outer covering of sunflower seed.

(w) Sunflower Meal, Dehulled, Mechanical Extracted, is obtained by grinding the residue remaining after the extraction process. The words “Mechanical Extracted” or are not required when listed as an ingredient in a manufactured feed.

(x) Sunflower Meal, Dehulled, Solvent Extracted, is obtained by grinding the residue remaining after extraction of most of the oil from dehulled sunflower seed by a solvent extraction process. The words “Solvent Extracted” are not required when listed as an ingredient in a manufactured feed.

(y) Sunflower Meal, Mechanical Extracted, is obtained by grinding the residue remaining after extraction of the oil from whole sunflower seed by a mechanical extraction process. The words “Mechanical Extracted” are not required when listed as an ingredient in a manufactured feed.

(z) Sunflower Meal, Solvent Extracted, is obtained by grinding the residue remaining after extraction of most of the oil from whole sunflower seed by a solvent extraction process. The words “Solvent Extracted” are not required when listed as an ingredient in a manufactured feed.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2796. Preservatives.

(a) General Provisions.

(1) When using any of these materials, a statement of the fact that a preservative has been added must be shown. Examples: BHA (a preservative), or preserved with BHT, or sorbic acid added to retard mold growth.

(b) Ascorbic acid (21 CFR 582.3013). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: No quantitative restrictions, although use must conform to good manufacturing practices.

(c) Ascorbyl palmitate (21 CFR 582.3149). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: No quantitative restrictions, although use must conform to good manufacturing practices.

(d) Benzoic acid (21 CFR 582.3021). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: Not to exceed 0.1 percent.

(e) Butylated hydroxy anisole (BHA) (21 CFR 582.3169). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: Total content

of preservatives not more than 0.02 percent of fat or oil content including essential (volatile) oil content of food. Either the name or the abbreviation may be used.

(f) Butylated hydroxytoluene (BHT) (21 CFR 582.3173). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: Total content of preservatives not more than 0.02 percent of fat or oil content including essential (volatile) oil content of food. Either the name or the abbreviation may be used.

(g) Calcium ascorbate (21 CFR 582.3189). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: No quantitative restrictions, although use must conform to good manufacturing practices.

(h) Calcium propionate (21 CFR 582.3221). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: No quantitative restrictions, although use must conform to good manufacturing practices.

(i) Calcium sorbate (21 CFR 582.3225). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: No quantitative restrictions, although use must conform to good manufacturing practices.

(j) Citric acid (21 CFR 582.6033, 21 CFR 582.1033). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: No quantitative restrictions, although use must conform to good manufacturing practices.

(k) Dilauryl thiodipropionate (21 CFR 582.3280). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: Total content of preservatives not more than 0.02 percent of fat or oil content including essential (volatile) oil content of food.

(l) Distearyl thiodipropionate. Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: Total content of preservatives not more than 0.02 percent of fat or oil content including essential (volatile) oil content of food.

(m) Erythorbic acid (21 CFR 582.3041). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: No quantitative restrictions, although use must conform to good manufacturing practices.

(n) Ethoxyquin (21 CFR 573.380). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: 0.015 percent in or on feed (a) it is intended for use only: (1) as a chemical preservative for retarding oxidation of carotene, xanthophylls, and vitamins A and E in animal feed and fish feed.

(o) Gum guaiac (21 CFR 582.3336). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: 0.1 percent (equivalent preservative activity 0.01 percent) only in edible fats or oils.

(p) Methylparaben (21 CFR 582.3490). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: 0.1 percent.

(q) Potassium bisulfite (21 CFR 582.3616). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: Not for use in meats or vitamin B_1 sources.

(r) Potassium metabisulfite (21 CFR 582.3637). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: Not for use in meats or vitamin B_1 sources.

(s) Potassium sorbate (21 CFR 582.3640). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: No quantitative restrictions, although use must conform to good manufacturing practices.

(t) Propionic acid (21 CFR 582.3081). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: No quantitative restrictions, although use must conform to good manufacturing practices.

(u) Propyl gallate (21 CFR 582.3660). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: Total content of preservatives not more than 0.02 percent of fat or oil content including essential (volatile) oil content of food.

(v) Propylparaben (21 CFR 582.3670). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: 0.1 percent.

(w) Sodium ascorbate (21 CFR 582.3731). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: No quantitative restrictions, although use must conform to good manufacturing practices.

(x) Sodium benzoate (21 CFR 582.3733). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: 0.1 percent.

(y) Sodium bisulfite (21 CFR 582.3739). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: Not for use in meats or vitamin B_1 sources.

(z) Sodium metabisulfite (21 CFR 582.3766). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: Not for use in meats or vitamin B_1 sources.

(aa) Sodium propionate (21 CFR 582.3784). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: No quantitative restrictions, although use must conform to good manufacturing practices.

(bb) Sodium sorbate (21 CFR 582.3795). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: No quantitative restrictions, although use must conform to good manufacturing practices.

(cc) Sodium sulfite (21 CFR 582.3798). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: Not for use in meats or vitamin B_1 sources.

(dd) Sorbic acid (21 CFR 582.3089). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: No quantitative restrictions, although use must conform to good manufacturing practices.

(ee) Stannous chloride (21 CFR 582.3845). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: Not to exceed 0.0015 percent as tin.

(ff) Sulfur dioxide (21 CFR 582.3862). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: Not for use in meats or vitamin B_1 sources.

(gg) Tertiary butyl hydroquinone (TBHQ) (Informal Review Process). Classification Under Food Additives Amendment: Chemical Preservative. Limitations or Restrictions: Total content of preservatives not more than 0.02 percent of fat or oil content including essential (volatile) oil content of food.

(hh) Thiodipropionic acid (21 CFR 582.3109). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: Total content of preservatives not more than 0.02 percent of fat or oil content including essential (volatile) oil content of food.

(ii) Tocopherols (21 CFR 582.3890). Classification Under Food Additives Amendment: Chemical preservative. Limitations or Restrictions: No quantitative restrictions, although use must conform to good manufacturing practices.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2798. Processed Animal Waste Products.

(a) General Provisions.

(1) Processed Animal Waste Products shall not contain:

(A) Any levels of medically important antimicrobial drug residue, as defined in Food and Agricultural Code Section 14400(a).

(B) Levels of non-medically important antimicrobial drug residue, pesticide residue, or other toxic or deleterious substances that could be harmful to animals or result in harmful or unlawful residue levels in their tissues or by-products.

(2) It shall not be used in feed for female dairy animals over 20 months of age and laying hens.

(3) When used in a mixed feed, the maximum percentage shall be stated.

(4) The processed animal waste product will be considered adulterated when Salmonella is present in one or more subsamples of the animal feed or feed ingredient; and the Salmonella is of a serotype that is pathogenic to the animal species for which the animal feed or feed ingredient is intended; and the animal feed or feed ingredient will not undergo a subsequent commercial heat step or other commercial process that will kill Salmonella.

(A) A Salmonella serotype that is considered pathogenic to the animal intended to consume the animal feed including, but not limited to; Poultry feed with Salmonella Pullorum, Salmonella Gallinarum, or Salmonella Enteritidis; Swine

feed with Salmonella Choleraesuis; Sheep feed with Salmonella Abortusovis; Horse feed with Salmonella Abortusequi; Dairy and beef feed(s) with Salmonella Newport or Salmonella Dublin.

(5) Processed animal waste products and formula feeds or mixed feeds containing processed animal waste products must be manufactured, processed, stored, and distributed in accordance with a written food safety plan as outlined in 21 CFR 507.31. At minimum, the written food safety plan must address the hazard of Salmonella sp.

(b) Dried Poultry Litter (DPL) means a processed animal waste product composed of a processed combination of feces from commercial poultry together with litter that was present in the floor production of poultry, which has been artificially dehydrated to a moisture content not in excess of 15.0 percent. It shall contain not less than 18.0 percent crude protein, and not more than 25.0 percent crude fiber, 20.0 percent ash, and four (4.0) percent feathers.

(c) Dried Poultry Waste (DPW) means a processed animal waste product composed primarily of feces from commercial poultry, which has been thermally dehydrated to a moisture content not in excess of 15.0 percent. It shall contain not less than 18.0 percent crude protein, and not more than 15.0 percent crude fiber, 30.0 percent ash, and one (1.0) percent feathers.

(d) Dried Poultry Waste - NPN Extracted means a processed animal waste product composed primarily of feces from commercial poultry which has been processed to remove part or all of the equivalent crude protein, NPN as urea and/or uric acid and which has been thermally dehydrated to a moisture content not in excess of 15.0 percent. It shall contain not less than 11.0 percent crude protein, and not more than 15.0 percent crude fiber, 30.0 percent ash, and one (1.0) percent feathers.

(e) High Moisture Processed Animal Waste Products are processed animal waste products in excess of 15.0 percent moisture including silages and other semidry products. If sold for feeding purposes, these products shall be labeled as "High Moisture Processed Animal Waste" and the label shall show type of process, the specific name of each component material in the product, maximum moisture, minimum crude protein, maximum equivalent crude protein from non-protein nitrogen, minimum crude fat, maximum crude fiber, lignin and ash, and maximum sodium (Na).

(f) Processed Animal Waste Derivative means a product resulting from the chemical, physical or microbiological alteration of an animal waste. Examples of processed animal waste derivatives are composts, yeasts, algae or other organisms produced from non-human animal wastes, or wastes treated with ammonia, formaldehyde, or other chemicals. The specific name of each such animal waste derivative product must be descriptive, and efficacy and safety data must be submitted and approved before the product is registered or offered for sale.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2799. Rice Products.

(a) Chipped Rice, Broken Rice, or Brewers Rice is the small fragments of rice kernels that have been separated from the larger kernels of milled rice.

(b) Ground Brown Rice is the entire product obtained in grinding the rice kernels after the hulls have been removed.

(c) Ground Rough Rice or Ground Paddy is the entire product obtained in grinding the whole rice grain including the hulls.

(d) Parboiled Rice Bran is about five (5) to seven (7) percent by weight of Parboiled Rough Rice and is a mixture made up of a combination of several botanical tissues: pericarp, seed coat, nucleus, and the outermost portion of the endosperm (the aleurone layer). It may contain hull fragments, broken grains and traces of added calcium carbonate as is unavoidable in the milling of parboiled rice.

(e) Rice Bran is the pericarp or bran layer and germ of the rice, with only such quantity of hull fragments, chipped, broken, or brewers' rice, and calcium carbonate as is unavoidable in the regular milling of edible rice. It must contain not more than 13 percent crude fiber. When the calcium carbonate exceeds three (3) percent (Ca.-1.2 percent), the percentage must be declared in the brand name; i.e., Rice Bran with Calcium Carbonate not exceeding [X]%.

(f) Rice Bran, Solvent Extracted is obtained by removing part of the oil from rice bran by the use of solvents and must contain not less than 14 percent crude protein and not more than 14 percent crude fiber.

(g) Rice Hulls consists primarily of the outer covering of the rice.

(h) Rice Mill By-Product is the total offal obtained in the milling of rice. It consists of rice hulls, rice bran, rice polishings and broken rice grains. Its crude fiber content must not exceed 32 percent.

(i) Rice Polishings is a by-product of rice obtained in the milling operation of brushing the grain to polish the kernel.

(j) [Specify] Stabilized Rice Bran is rice bran that has been treated soon after milling by heat or other means that will substantially reduce the lipase activity. Free fatty acid content of the crude fat extracted shall not exceed four (4) percent. (AOAC 940.28) Stabilization process must be specified on the label (i.e., Heat Stabilized Rice Bran).

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2800. Rye Products.

(a) Rye Middlings consist of rye feed and rye red dog combined in the proportions obtained in the usual process of milling rye flour, and must not contain more than 8.5 percent crude fiber.

(b) Rye Mill Run is obtained in the usual process of the milling of rye flour from cleaned and scoured rye, consisting principally of the mill-run of the outer covering of the rye kernel and the rye germ with small quantities of rye flour and aleurone, and must not contain more than 9.5 percent crude fiber.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2801. Screenings.

(a) General Provisions.

(1) Screenings are obtained in the cleaning of grains which are included in the United States Grain Standard Act and other agricultural seeds. It may include light and broken grains and agricultural seeds, weed seeds, hulls, chaff, joints, straw, elevator or mill dust, sand, and dirt. It must be designated as Grain Screenings, Mixed Screenings and Chaff and/or Dust.

(2) No grade of screenings may contain any seeds or other material in amount that is either injurious to animals or will impart an objectionable odor or flavor to their milk or flesh. The screenings must contain not more than four whole prohibited noxious weed seeds per pound and must contain not more than 100 whole restricted noxious weed seeds per pound. The prohibited and restricted noxious weed seeds are those named as such by the following: 3 CCR Section 3854 Prohibited Noxious Weed Seed, 3 CCR Section 3855 Restricted Noxious Weed Seed, and 3 CCR Section 4500 Noxious Weed Species.

(3) All screenings must be processed by grinding or otherwise to render the seed of any pest incapable of reproduction.

(b) Chaff and/or Dust is material that is separated from grains or seeds in the usual commercial cleaning processes. It may include hulls, joints, straw, mill or elevator dust, sweepings, sand, dirt, grains, seeds. It must be labeled, "chaff and/or dust." If it contains more than 15 percent ash the words “sand” and “dirt” must appear on the label.

(c) Ground Bean Screenings or Ground Pea Screenings is the ground, broken and culled beans or peas removed from field run beans or peas in the process of recleaning. They shall be free from dirt, pods, and straw.

(d) Ground Nut Meat Screenings is the ground fragments, immature, and culled nut meats obtained in the cleaning and grading of nut meats. They shall be free of shells, hulls, dirt, and other foreign material.

(e) Ground Paddy Rice Screenings is the product resulting from the cleaning of paddy rice and consists of immature rice kernels, water grass seed, rice hulls, straw, dirt and sand. It shall be free of unpalatable or injurious weed seeds. When used in a mixture, the maximum percentage shall be stated.

(f) Grain Screenings are those screenings containing 70 percent or more grains, including light and broken grains. It may contain wild buckwheat and wild oats. The term "Grain Screenings" may be used for unspecified kinds of grain, or the predominating kind of grain (if in excess of 50 percent) may be declared as the first word or words in the name. It may contain no more than 6.5 percent ash.

(g) Mixed Screenings are screenings excluded from the preceding definition. It must contain not more than 27 percent crude fiber and not more than 15 percent ash.

(h) Seed Screenings shall consist of 70.0 percent or more seed, light and broken and contain not more than 6.5 percent ash. The name of the seed shall be a part of the name.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2802. Sesame Products.

(a) Sesame Oil Cake is the product obtained by removing most of the oil from sesame seed by crushing, cooking, and the use of pressure or solvents. The process used in the production (expeller or solvent) shall be a part of the brand name.

(b) Sesame Oil Meal is ground sesame oil cake. The process used in the production (expeller or solvent) shall be a part of the brand name.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2803. Soybean Products.

(a) Ground Extruded Whole Soybeans is the meal product resulting from extrusion by friction heat and/or steam, whole soybeans without removing any of the component parts. It must be sold according to its crude protein, fat, and fiber content.

(b) Ground Soybeans is obtained by grinding whole soybeans without cooking or removing any of the oil.

(c) Ground Soybean Hay is the ground soybean plant including the leaves and beans. It must be reasonably free of other crop plants and weeds and must contain not more than 33 percent crude fiber.

(d) Heat Processed Soybeans is the product resulting from heating whole soybeans without removing any of the component parts. It may be ground, pelleted, flaked, or powdered. The maximum pH rise using standard urease testing procedure should not exceed 0.10 pH units. It must be sold according to its crude protein, crude fat and crude fiber content.

(e) Hydrolyzed Soy Protein is made from soybean flours, concentrates or isolates, treated with an acid or a base or an enzyme and then dried.

(f) Kibbled Soybean Meal is the product obtained by cooking ground solvent extracted soybean meal, under pressure and extruding from an expeller or other mechanical pressure device. It must be designated and sold according to its protein content and shall contain not more than seven (7) percent crude fiber.

(g) [Specify] Protein Modified is a Soybean Product that has been processed to primarily modify the natural protein structure by utilizing heat or elevated temperatures, acids, alkalies or other chemicals and without removing significant amounts of any nutrient constituent. The defined name of the applicable soybean product so modified shall be declared in the product name on the label.

(h) Soy Flour is the finely powdered material resulting from the screened and graded product after removal of most of the oil from selected, sound, cleaned and dehulled soybeans by a mechanical or solvent extraction process. It must contain not more than four (4.0) percent crude fiber.

(i) Soy Grits is the granular material resulting from the screened and graded product after removal of most of the oil from selected, sound, clean and dehulled soybeans by a mechanical or solvent extraction process. It must contain not more than four (4.0) percent crude fiber.

(j) Soy Phosphate or Soy Lecithin is the mixed phosphatide product obtained from soybean oil by a degumming process. It contains lecithin, cephalin, and inositol phosphatides, together with glycerides of soybean oil and traces of tocopherols, glucosides, and pigments. It must be designated and sold according to conventional descriptive grades with respect to consistency and bleaching.

(k) Soy Protein Concentrate is prepared from high quality sound, clean, dehulled soybean seeds by removing most of the oil and water soluble non-protein constituents and must contain not less than 65 percent protein on a moisture-free basis.

(l) Soy Protein Isolate is the major proteinaceous fraction of soybeans prepared from dehulled soybeans by removing the majority of non-protein components and must contain not less than 90 percent protein on a moisture-free basis.

(m) Soybean Feed, Solvent Extracted, is the product remaining after the partial removal of protein and nitrogen free extract from dehulled solvent extracted soybean flakes. The words "Solvent Extracted" are not required when listing as an ingredient in a manufactured feed.

(n) Soybean Hulls consist primarily of the outer covering of the soybean.

(o) Soybean Meal, Dehulled, Mechanical Extracted is the product obtained by grinding of cakes that remain after removal of most of the oil from dehulled soybean seeds by mechanical extraction process. It must contain not more than 3.5 percent crude fiber and not less than 46.5 percent crude protein. It may contain calcium carbonate or an anti-caking agent not to exceed 0.5 percent as defined in Special Purpose Products to reduce caking and improve flowability. The name of the conditioning agent must be shown as an added ingredient. When listed as an ingredient in a manufactured feed it may be identified as “Dehulled Soybean Meal.” The words “Mechanical Extracted” are not required when listing as an ingredient in a manufactured feed.

(p) Soybean Meal, Dehulled, Solvent Extracted is obtained by grinding the flakes remaining after removal of most of the oil from dehulled soybeans by a solvent extraction process. It must contain not more than 3.5 percent crude fiber. It may contain calcium carbonate or an anti-caking agent not to exceed 0.5 percent as defined in Special Purpose Products) to reduce caking and improve flowability. The name of the conditioning agent must be shown as an added ingredient. When listed as an ingredient in a manufactured feed it may be identified as "Dehulled Soybean Meal." The words “Solvent Extracted” are not required when listing as an ingredient in a manufactured feed.

(q) Soybean Meal, Mechanical Extracted is the product obtained by grinding the cake or chips which remain after removal of most of the oil from soybeans by a mechanical extraction process. It must contain not more than seven (7.0) percent crude fiber. It may contain calcium carbonate or an anti-caking agent not to exceed 0.5 percent as defined in Special Purpose Products to reduce caking and improve flowability. The name of the conditioning agent must be shown as an added ingredient. The words “Mechanical Extracted” are not required when listing as an ingredient in a manufactured feed.

(r) Soybean Meal, Solvent Extracted is the product obtained by grinding the flakes which remain after removal of most of the oil from soybeans by a solvent extraction process. It must contain not more than seven (7.0) percent crude fiber. It may contain calcium carbonate or an anti-caking agent not to exceed 0.5 percent as defined in Special Purpose Products to reduce caking and improve flowability. The name of the conditioning agent must be shown as an added ingredient. The words “Solvent Extracted” are not required when listing as an ingredient in a manufactured feed.

(s) Soybean Mill Feed is composed of soybean hulls and the offal from the tail of the mill which results from the manufacture of soy grits or flour. It must contain not less than 13 percent crude protein and not more than 32 percent crude fiber.

(t) Soybean Mill Run is composed of soybean hulls and such bean meats that adhere to the hulls which result from normal milling operations in the production of dehulled soybean meal. It must contain not less than 11 percent crude protein and not more than 35 percent crude fiber.

(u) Soybean Solubles, Condensed, is the product resulting from the washing of soy flour or soybean flakes with water and acid; water, alkali and acid; or water and alcohol. The wash water is then concentrated to a solids content of not less than 50 percent.

(v) Soybean Solubles, Dried, is the product resulting from the washing of soy flour or soybean flakes with water and acid; water, alkali and acid; or water and alcohol. The wash water is then dried.

(w) Textured Soy Protein Product is made from defatted soy flour mixed with water and/or steam, extruded and then dried.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2804. Special Purpose Products.

(a) Aloe vera gel concentrate. Classification Under Food Additives Amendment: Flavoring agent. Limitations or Restrictions: Not to exceed 125 parts per million (0.0125 percent) in finished feed.

(b) Ammoniated Cottonseed Meal (21 CFR 573.140) is obtained by the treatment of cottonseed meal with anhydrous ammonia until a pressure of 50 pounds per square inch gauge is reached. It is to be used in the feed of ruminants as a source of protein and/or as the sole source of non-protein nitrogen in an amount not to exceed 20 percent of the total ration. The label of the additive and of any feed additive supplement, feed additive concentrate, or feed additive premix prepared therefrom, must contain the following information in addition to any other required information:

(1) The name of the additive.

(2) The maximum percentage of equivalent crude protein from non-protein nitrogen.

(3) Directions for use to provide not more than 20 percent of the additive in the total ration and a prominent statement: “Warning - This feed should be used only in accordance with the directions furnished on the label.”

(c) Ammoniated Rice Hulls (21 CFR 573.160) is obtained by the treatment of ground rice hulls with monocalcium phosphate and anhydrous ammonia at a temperature of 350 degrees Fahrenheit and a pressure of 175 pounds per square inch. It is to be used in beef cattle feeds at a level not to exceed 20 percent of the total rations as a source of crude fiber and as the sole source of non-protein nitrogen. The label of the additive and of any feed additive supplement, feed additive concentrate, or feed additive premix prepared therefrom, must contain the following information in addition to any other required information:

(1) The name of the additive.

(2) The maximum percentage of equivalent crude protein from non-protein nitrogen.

(3) Directions for use to provide not more than 20 percent of the additive in the total ration and a prominent statement: “Warning - This feed should be used only in accordance with the directions furnished on the label.”

(d) Anhydrous Ammonia (21 CFR 573.180) is applied to corn plant material prior to ensiling as a source of non-protein nitrogen in accordance with any one of the following methods:

(1) As a component of an aqueous premix containing 16 to 17 percent ammonia, with molasses, minerals, and not less than 83 percent crude protein. The labeling must bear the following statements: an expiration date of not less than 10 weeks after date of manufacture, additional protein should not be fed to lactating dairy cows producing less than 32 pounds of milk per day or beef cattle consuming less than one (1) percent of their body weight daily in shelled corn, and do not use additional trace mineral supplementation with treated silage;

(2) After being diluted to a 15 to 30 percent aqueous ammonia solution (by weight) and: does not exceed anhydrous ammonia equivalent to 0.3 percent of the corn plant material, the corn plant material contains 28 to 38 percent dry matter, and the treated silage is fed to dairy cattle only; and

(3) Directly, and does not exceed anhydrous ammonia equivalent to 0.35 percent of the corn plant material, the corn plant material contains 30 to 35 percent dry matter, 75 to 85 percent of the anhydrous ammonia is liquid at ambient pressure during the direct application, and the treated material is used in dairy or beef cattle rations.

(4) The labeling of the article must contain the following information in addition to any other required information: the name of the article, the concentration of ammonia, the maximum percentage of equivalent crude protein from non-protein nitrogen, directions for use consistent with the above, and a prominent: “Warning -

This feed should be used only in accordance with the directions furnished on the label."

(e) Anise seed (21 CFR 582.10). Classification Under Food Additives Amendment: Spices, seasonings, essential oils, oleo resins, and natural extractives. Limitations or Restrictions: In accordance with good manufacturing practices.

(f) Annatto Extract (21 CFR 73.30). The color additive, annatto extract, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive annatto extract is an extract prepared from annatto seed, Bixa orellana L., using any one or an appropriate combination of the food-grade extractants listed in this definition: Alkaline aqueous solution, alkaline propylene glycol, ethyl alcohol or alkaline solutions thereof, edible vegetable oils or fats, mono- and diglycerides from the glycerolysis of edible vegetable oils or fats. The alkaline alcohol or aqueous extracts may be treated with food-grade acids to precipitate annatto pigments, which are separated from the liquid and dried, with or without intermediate recrystallization, using the solvents listed under this definition. Food-grade alkalis or carbonates may be added to adjust alkalinity. Acetone, ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, trichloroethylene. Color additive mixtures for food use made with annatto extract may contain only diluents that are suitable and that are listed in 21 CFR 73.1 as safe in color additive mixtures for coloring foods.

(2) Specifications. Annatto extract, including pigments precipitated therefrom, shall conform to the following specifications: Arsenic (as As), not more than three (3) parts per million; lead (as Pb), not more than 10 parts per million. When solvents listed under this definition are used, annatto extract shall contain no more solvent residue than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in 21 CFR 170 through 189.

(3) Uses and restrictions. Annatto extract may be safely used for coloring foods generally, in amounts consistent with good manufacturing practices, except that it may not be used to color foods for which standards of identity have been promulgated under FD&C 401 unless added color is authorized by such standards.

(4) Labeling. The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25. Labels shall bear information showing that the color is derived from annatto seed. The requirements of 21 CFR 70.25(a) that all ingredients shall be listed by name shall not be construed as requiring the declaration of residues of solvents listed in this definition.

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(g) Astaxanthin (21 CFR 73.35). The color additive, astaxanthin, may be safely used in the manufacture of salmonid fish feed in accordance with the following prescribed conditions:

(1) Identity. The color additive astaxanthin is 3, 3'-dihydroxy-B, B-carotene-4, 4'-dione. Astaxanthin may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with astaxanthin may contain only those diluents that are suitable and are listed in 21 CFR 73.1 as safe for use in color additive mixtures for coloring foods.

(2) Specifications. Astaxanthin shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practices:

(A) Physical state, solid.

(B) 0.05 percent Solution in chloroform, complete and clear.

(C) Absorption maximum wavelength 484 to 493 nanometers (in chloroform). Residue on ignition, not more than 0.1 percent.

(D) Total carotenoids other than astaxanthin, not more than four (4) percent.

(E) Lead, not more than five (5) parts per million.

(F) Arsenic, not more than two (2) parts per million.

(G) Mercury, not more than one (1) part per million.

(H) Heavy metals, not more than 10 parts per million.

(I) Assay, minimum 96 percent.

(3) Uses and restrictions. Astaxanthin may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions: The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish. The quantity of color additive in feed is such that the color additive shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(4) Labeling requirements. The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required 21 CFR 70.25, and adequate directions to prepare a final product complying with the limitations prescribed in this definition. The presence of the color additive in finished fish feed prepared according to this definition shall be declared in accordance with 21 CFR 501.4. The presence of the color additive in salmonid fish that have been fed feeds containing astaxanthin shall be declared in accordance with 21 CFR 101.22(k)(2) and 21 CFR 101.100(a)(2).

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(h) Astaxanthin Dimethyldisuccinate. The color additive, astaxanthin dimethyldisuccinate, may be safely used in the manufacture of salmonid fish feed in accordance with the following prescribed conditions:

(1) Identity. The color additive astaxanthin dimethyldisuccinate is 3,3'-bis(4-methoxy-1,4-dioxobutoxy)-B,B-carotene-4,4'-dione. Astaxanthin dimethyldisuccinate may be added to the fish feed only as a component of a stabilized mixture. Color additive mixtures for fish feed use made with astaxanthin dimethyldisuccinate may contain only those diluents that are suitable and are listed in 21 CFR 73.1 as safe for use in color additive mixtures for coloring foods.

(2) Specifications. Astaxanthin dimethyldisuccinate shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practices:

(A) Physical state, solid.

(B) 0.05 percent Solution in chloroform, complete and clear.

(C) Absorption maximum wavelength 484 to 493 nanometers (in chloroform).

(D) Residue on ignition, not more than 0.1 percent.

(E) Total carotenoids other than astaxanthin dimethyldisuccinate, not more than four (4) percent.

(F) Lead, not more than five (5) milligrams per kilogram (5 parts per million).

(G) Arsenic, not more than two (2) milligrams per kilogram (2 parts per million).

(H) Mercury, not more than one (1) milligrams per kilogram (1 part per million).

(I) Heavy metals, not more than 10 milligrams per kilogram (10 parts per million).

(J) Assay including astaxanthin dimethyldisuccinate, astaxanthin monomethylsuccinate, and astaxanthin, minimum 96 percent.

(3) Uses and restrictions. Astaxanthin dimethyldisuccinate may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions: The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish. The quantity of astaxanthin dimethyldisuccinate in the finished feed, when used alone or in combination with other astaxanthin color additive sources listed in 21 CFR 73, shall not exceed 110 milligrams per kilogram, which is equivalent to 80 milligrams per kilogram astaxanthin (72 grams per ton).

(4) Labeling requirements. The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by 21 CFR 70.25, and adequate directions to prepare a final product complying with the limitations prescribed in this definition. The presence of the color additive in finished fish feed prepared according to this definition shall be declared in accordance with 21 CFR 501.4.

(i) Canthaxanthin (21 CFR 73.75). The color additive canthaxanthin may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive canthaxanthin is B-carotene-4,4'-dione. Color additive mixtures for food use made with canthaxanthin may contain only those diluents that are suitable and that are listed in 21 CFR 73.1 as safe for use in color additive mixtures for coloring foods.

(2) Specifications. Canthaxanthin shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practices:

(A) Physical state, solid.

(B) One (1) percent solution in chloroform, complete and clear.

(C) Melting range (decomposition), 207 to 212 degrees Celsius (corrected).

(D) Loss on drying, not more than 0.2 percent.

(E) Residue on ignition, not more than 0.2 percent.

(F) Total carotenoids other than trans-canthaxanthin, not more than five (5) percent.

(G) Lead, not more than 10 parts per million.

(H) Arsenic, not more than three (3) parts per million.

(I) Mercury, not more than one (1) part per million.

(J) Assay, 96 to 101 percent.

(3) Use and restrictions. The color additive canthaxanthin may be safely used for coloring foods generally subject to the following restrictions: the quantity of canthaxanthin does not exceed 30 milligrams per pound of solid or semisolid food or per pint of liquid food; and it may not be used to color foods for which standards of identity have been promulgated under FD&C 401 unless added color is authorized by such standards. Canthaxanthin may be safely used in broiler chicken feed to enhance the yellow color of broiler chicken skin in accordance with the following conditions: The quantity of canthaxanthin incorporated in the feed shall not exceed 4.41 milligrams per kilogram (4 grams per ton) of complete feed to supplement other known sources of xanthophyll and associated carotenoids to accomplish the intended effect. Canthaxanthin may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions: Canthaxanthin may be added to the fish feed only in the form of a stabilized color additive mixture; the color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish; and the quantity of color additive in feed shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(4) Labeling requirements. The labeling of the color additive and any mixture prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25. For purposes of coloring fish, the labeling of the color additive and any premixes prepared therefrom shall bear expiration dates (established through generally accepted stability testing methods) for the sealed and open container, other information required by 21 CFR 70.25, and adequate

directions to prepare a final product complying with the limitations prescribed in this definition. The presence of the color additive in feed prepared according to this definition shall be declared in accordance with 21 CFR 501.4. The presence of the color additive in salmonid fish that have been fed feeds containing canthaxanthin shall be declared in accordance with 21 CFR 101.22(b), (c), and (k)(2), and 101.100(a)(2).

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(j) Capsicum; red pepper (21 CFR 582.10). Classification Under Food Additives Amendment: Spices, seasonings, etc. Limitations or Restrictions: In accordance with good manufacturing practices.

(k) Caramel (21 CFR 73.85). The color additive, caramel, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive caramel is the dark-brown liquid or solid material resulting from the carefully controlled heat treatment of the following food-grade carbohydrates: dextrose, invert sugar, lactose, malt syrup, molasses, starch hydrolysates and fractions thereof, and sucrose.

(A) The food-grade acids, alkalis, and salts listed in this subparagraph may be employed to assist caramelization, in amounts consistent with good manufacturing practices.

(i) Acids: acetic acid, citric acid, phosphoric acid, sulfuric acid, and sulfurous acid.

(ii) Alkalis: ammonium hydroxide, calcium hydroxide U.S.P., potassium hydroxide, and sodium hydroxide.

(iii) Salts: ammonium, sodium, or potassium carbonate, bicarbonate, phosphate (including dibasic phosphate and monobasic phosphate), sulfate, and sulfite.

(B) Polyglycerol esters of fatty acids, identified in 21 CFR 172.854, may be used as antifoaming agents in amounts not greater than that required to produce the intended effect.

(C) Color additive mixtures for food use made with caramel may contain only diluents that are suitable and that are listed in 21 CFR 73.1 as safe in color additive mixtures for coloring foods.

(2) Specifications. Caramel shall conform to the following specifications:

(A) Lead (as Pb), not more than 10 parts per million.

(B) Arsenic (as As), not more than three (3) parts per million.

(C) Mercury (as Hg), not more than 0.1 part per million.

(3) Uses and restrictions. Caramel may be safely used for coloring foods generally, in amounts consistent with good manufacturing practices, except that it may not be used to color foods for which standards of identity have been promulgated under FD&C 401 unless added color is authorized by such standards.

(4) Labeling. The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(l) Carmine (21 CFR 73.100). The color additive, carmine, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive carmine is the aluminum or calcium-aluminum lake on an aluminum hydroxide substrate of the coloring principles, chiefly carminic acid, obtained by an aqueous extraction of cochineal [Dactylopius coccus costa (Coccus cacti L.)]. Color additive mixtures for food use made with carmine may contain only diluents that are suitable and that are listed in 21 CFR 73.1 as safe in color additive mixtures for coloring foods.

(2) Specifications. Carmine shall conform to the following specifications:

(A) Volatile matter (at 135 degrees Celsius for three (3) hours), not more than 20.0 percent.

(B) Ash, not more than 12.0 percent.

(C) Lead (as Pb), not more than 10 parts per million.

(D) Arsenic (as As), not more than one (1) part per million.

(E) Carminic acid, not less than 50.0 percent.

(F) Carmine shall be pasteurized or otherwise treated to destroy all viable Salmonella microorganisms. Pasteurization or such other treatment is deemed to permit the adding of safe and suitable substances (other than chemical preservatives) that are essential to the method of pasteurization or other treatment used. For the purposes of this definition, safe and suitable substances are those substances that perform a useful function in the pasteurization or other treatment to render the carmine free of viable Salmonella microorganisms, which substances are not food additives as defined in FD&C 201(s) or, if they are food additives as so defined, are used in conformity with regulations established pursuant to FD&C 409.

(3) Uses and restrictions. Carmine may be safely used for coloring foods generally in amounts consistent with good manufacturing practices, except that they may not be used to color foods for which standards of identity have been promulgated under FD&C 401 unless added color is authorized by such standards.

(4) Labeling requirements. The label of the color additives and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of 21 CFR 70.25.

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(m) Carrot Oil (21 CFR 73.300). The color additive, carrot oil, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive carrot oil is the liquid or the solid portion of the mixture or the mixture itself obtained by the hexane extraction of edible carrots (Daucus carota L.) with subsequent removal of the hexane by vacuum distillation. The resultant mixture of solid and liquid extractives consists chiefly of oils, fats, waxes, and carrotenoids naturally occurring in carrots. The definition of "carrot oil" in this paragraph is for the purpose of identity as a color additive only and shall not be construed as setting forth an official standard for carrot oil or carrot oleoresin under FD&C 401. Color additive mixtures for food use made with carrot oil may contain only those diluents listed in 21 CFR 73.1 as safe and suitable in color additive mixtures for coloring foods.

(2) Specifications. Carrot oil shall contain no more than 25 parts per million of hexane.

(3) Uses and restrictions. Carrot oil may be safely used for coloring foods generally, in amounts consistent with good manufacturing practices, except that it may not be used to color foods for which standards of identity have been promulgated under FD&C 401 unless the use of added color is authorized by such standards.

(4) Labeling requirements. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(n) Cashew Nut Shell Extract is the mechanical cold-pressed liquid from cashew nut shells to be used as a flavor additive in cattle feeds in amounts not to exceed 500 parts per million in complete feed. The liquid ingredient must contain not less than 59 percent anacardic acid, not less than 18 percent cardol, and not more than three (3) percent moisture. Minimum percent anacardic acid must be guaranteed.

(o) Cochineal Extract (21 CFR 73.100). The color additive, cochineal extract, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive cochineal extract is the concentrated solution obtained after removing the alcohol from an aqueous-alcoholic extract of cochineal [Dactylopius coccus costa (Coccus cacti L.)]. The coloring principle is chiefly carminic acid. Color additive mixtures for food use made with cochineal extract may

contain only diluents that are suitable and that are listed in 21 CFR 73.1 as safe in color additive mixtures for coloring foods.

(2) Specifications. Cochineal extract shall conform to the following specifications:

(A) pH, not less than 5.0 and not more than 5.5 at 25 degrees Celsius.

(B) Protein (N x 6.25), not more than 2.2 percent.

(C) Total solids, not less than 5.7 percent and not more than 6.3 percent.

(D) Methyl alcohol, not more than 150 parts per million.

(E) Lead (as Pb), not more than 10 parts per million.

(F) Arsenic (as As), not more than one (1) part per million.

(G) Carminic acid, not less than 1.8 percent.

(H) Cochineal extract shall be pasteurized or otherwise treated to destroy all viable Salmonella microorganisms. Pasteurization or such other treatment is deemed to permit the adding of safe and suitable substances (other than chemical preservatives) that are essential to the method of pasteurization or other treatment used. For the purposes of this definition, safe and suitable substances are those substances that perform a useful function in the pasteurization or other treatment to render the cochineal extract free of viable Salmonella microorganisms, which substances are not food additives as defined in FD&C 201(s) or, if they are food additives as so defined, are used in conformity with regulations established pursuant to FD&C 409.

(3) Uses and restrictions. Cochineal extract may be safely used for coloring foods generally in amounts consistent with good manufacturing practices, except that they may not be used to color foods for which standards of identity have been promulgated under FD&C 401 unless added color is authorized by such standards.

(4) Labeling requirements. The label of the color additives and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of 21 CFR 70.25.

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(p) Corn Endosperm Oil (21 CFR 73.315). The color additive, corn endosperm oil, may be safely used in the manufacture of chicken feed in accordance with the following prescribed conditions:

(1) Identity. The color additive corn endosperm oil is a reddish-brown liquid composed chiefly of glycerides, fatty acids, sitosterols, and carotenoid pigments obtained by isopropyl alcohol and hexane extraction from the gluten fraction of yellow corn grain. The definition of corn endosperm oil in this paragraph is for the purpose of a color additive only and shall not be construed as a food standard of identity under FD&C 401. Color additive mixtures for food use made with corn

endosperm oil may contain only those diluents listed in 21 CFR 73.1 as safe and suitable in color additive mixtures for coloring foods.

(2) Specifications. Corn endosperm oil shall conform to the following specifications:

(A) Total fatty acids, not less than 85 percent.

(B) Iodine value, 118 to 134.

(C) Saponification value, 165 to 185.

(D) Unsaponifiable matter, not more than 14 percent.

(E) Hexane, not more than 25 parts per million.

(F) Isopropyl alcohol, not more than 100 parts per million.

(3) Uses and restrictions. The color additive corn endosperm oil may be safely used in chicken feed in accordance with the following prescribed conditions: The color additive is used to enhance the yellow color of chicken skin and eggs. The quantity of the color additive incorporated in the feed is such that the finished feed is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in this definition.

(4) Labeling requirements. The label of the color additive and any premixes prepared therefrom shall bear, in addition to the information required by 21 CFR 70.25, a statement of the concentration of xanthophyll contained therein.

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(q) Dehydrated Beets (21 CFR 73.40). The color additive, dehydrated beets, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive dehydrated beets is a dark red powder prepared by dehydrating sound, mature, good quality, edible beets. Color additive mixtures made with dehydrated beets may contain as diluents only those substances listed in 21 CFR 73.1 as safe and suitable for use in color additive mixtures for coloring foods.

(2) Specifications. The color additive shall conform to the following specifications:

(A) Volatile matter, not more than four (4) percent.

(B) Acid insoluble ash, not more than 0.5 percent.

(C) Lead (as Pb), not more than 10 parts per million.

(D) Arsenic (as As), not more than one (1) part per million.

(E) Mercury (as Hg), not more than one (1) part per million.

(3) Uses and restrictions. Dehydrated beets may be safely used for the coloring of foods generally in amounts consistent with good manufacturing practices, except

that it may not be used to color foods for which standards of identity have been promulgated under FD&C 401, unless the use of added color is authorized by such standards.

(4) Labeling. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(r) Dried Algae Meal (21 CFR 73.275). The color additive, dried algae meal, may be safely used in the manufacture of chicken feed in accordance with the following prescribed conditions:

(1) Identity. The color additive dried algae meal is a dried mixture of algae cells (genus Spongiococcum, separated from its culture broth), molasses, cornsteep liquor, and a maximum of 0.3 percent ethoxyquin. The algae cells are produced by suitable fermentation, under controlled conditions, from a pure culture of the genus Spongiococcum.

(2) Uses and restrictions. The color additive dried algae meal may be safely used in chicken feed in accordance with the following prescribed conditions: The color additive is used to enhance the yellow color of chicken skin and eggs. The quantity of the color additive incorporated in the feed is such that the finished feed: is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in this definition; and meets the tolerance limitation for ethoxyquin in animal feed prescribed in 21 CFR 573.380.

(3) Labeling. The label of the color additives and any premixes prepared therefrom shall bear in addition to the information required by 21 CFR 70.25: a statement of the concentrations of xanthophyll and ethoxyquin contained therein; and adequate directions to provide a final product complying with the limitations prescribed in this definition.

(4) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(s) FD&C Blue No. 1 (21 CFR 74.101). The color additive, FD&C Blue No. 1, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive FD&C Blue No. 1 is principally the disodium salt of ethyl [4-[p-[ethyl (m-sulfobenzyl) amino]-a-(o-sulfophenyl) benzylidene]- 2,5-cyclohexadien-1-ylidene] (m-sulfobenzyl) ammonium hydroxide inner salt with smaller amounts of the isomeric disodium salts of ethyl [4-[p-[ethyl(p-sulfobenzyl) amino]-a-(o-sulfophenyl) benzylidene]-2,5- cyclohexadien-1-ylidene] (p-sulfobenzyl) ammonium hydroxide inner salt and ethyl [4-[p-[ethyl (o-sulfobenzyl) amino]-a-(o-sulfophenyl) benzylidene]-2,5-cyclohexadien-1-ylidene] (o-sulfobenzyl) ammonium

hydroxide inner salt. Color additive mixtures for food use made with FD&C Blue No. 1 may contain only those diluents that are suitable and that are listed in 21 CFR 73.1 as safe for use in color additive mixtures for coloring foods.

(2) Specifications. FD&C Blue No. 1 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practices:

(A) Sum of volatile matter (at 135 degrees Celcius) and chlorides and sulfates (calculated as sodium salts), not more than 15.0 percent.

(B) Water-insoluble matter, not more than 0.2 percent.

(C) Leuco base, not more than five (5) percent.

(D) Sum of o-, m-, and p-sulfobenzaldehydes, not more than 1.5 percent.

(E) N-Ethyl,N-(m-sulfobenzyl)sulfanilic acid, not more than 0.3 percent.

(F) Subsidiary colors, not more than six (6.0) percent.

(G) Chromium (as Cr), not more than 50 parts per million.

(H) Manganese (as Mn), not more than 100 parts per million.

(I) Arsenic (as As), not more than three (3) parts per million.

(J) Lead (as Pb), not more than 10 parts per million.

(K) Total color, not less than 85.0 percent.

(3) Uses and restrictions. FD&C Blue No. 1 may be safely used for coloring foods generally in amounts consistent with good manufacturing practices except that it may not be used to color foods for which standards of identity have been promulgated under FD&C 401 unless added color is authorized by such standards.

(4) Labeling. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(5) Certification. All batches of FD&C Blue No. 1 shall be certified in accordance with regulations in 21 CFR 80.

(t) FD&C Blue No. 2 (21 CFR 74.102). The color additive, FD&C Blue No. 2, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive FD&C Blue No. 2 is principally the disodium salt of 2-(1,3-dihydro-3-oxo-5-sulfo-2H-indol-2-ylidene)-2,3-dihydro-3-oxo-1H- indole-5-sulfonic acid (CAS Reg. No. 860-22-0) with smaller amounts of the disodium salt of 2-(1,3-dihydro-3-oxo-7-sulfo-2H-indol-2-ylidene)- 2,3-dihydro-3-oxo-1H-indole-5-sulfonic acid (CAS Reg. No. 54947-75-0) and the sodium salt of 2-(1,3-dihydro-3-oxo-2H-indol-2-ylidene)-2,3- dihydro-3-oxo-1H-indole-5-sulfonic acid (CAS Reg. No. 605-18-5). Additionally, FD&C Blue No. 2 is obtained by heating indigo (or indigo paste) in the presence of sulfuric acid. The color additive is isolated and subjected to

purification procedures. The indigo (or indigo paste) used above is manufactured by the fusion of N-phenylglycine (prepared from aniline and formaldehyde) in a molten mixture of sodamide and sodium and potassium hydroxides under ammonia pressure. The indigo is isolated and subjected to purification procedures prior to sulfonation. Color additive mixtures for food use made with FD&C Blue No. 2 may contain only those diluents that are suitable and that are listed in 21 CFR 73.1 as safe for use in color additive mixtures for coloring foods.

(2) Specifications. The color additive FD&C Blue No. 2 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practices:

(A) Sum of volatile matter at 135 degrees Celsius (275 degrees Fahrenheit) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

(B) Water-insoluble matter, not more than 0.4 percent.

(C) Isatin-5-sulfonic acid, not more than 0.4 percent.

(D) 5-Sulfoanthranilic acid, not more than 0.2 percent.

(E) Disodium salt of 2-(1,3-dihydro-3-oxo-7-sulfo-2H-indol-2-ylidene)-2,3-dihydro-3-oxo-1H-indole-5-sulfonic acid, not more than 18 percent.

(F) Sodium salt of 2-(1,3-dihydro-3-oxo-2H-indol-2-ylidene)-2,3-dihydro-3- oxo-1H-indole-5-sulfonic acid, not more than two (2) percent.

(G) Lead (as Pb), not more than 10 parts per million.

(H) Arsenic (as As), not more than three (3) parts per million.

(I) Mercury (as Hg), not more than one (1) part per million.

(J) Total color, not less than 85 percent.

(3) Uses and restrictions. The color additive FD&C Blue No. 2 may be safely used for coloring foods generally in amounts consistent with current good manufacturing practices except that it may not be used to color foods for which standards of identity have been promulgated under FD&C 401 unless added color is authorized by such standards.

(4) Labeling. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(5) Certification. All batches of FD&C Blue No. 2 shall be certified in accordance with regulations in 21 CFR 80.

(u) FD&C Green No. 3 (21 CFR 74.203). The color additive, FD&C Green No. 3, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive FD&C Green No. 3 is principally the inner salt disodium salt of N-ethyl-N-[4-[[4-[ethyl[(3-sulfophenyl)methyl]amino] phenyl](4-

hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1- ylidene]-3-sulfobenzenemethanaminium hydroxide (CAS Reg. No. 2353-45-9); with smaller amounts of the isomeric inner salt disodium salt of N-ethyl-N-[4-[[4-[ethyl[(3-sulfophenyl)methyl]amino]phenyl] (4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-sulfobenzenemethanaminium hydroxide; of N-ethyl-N-[4-[[4- [ethyl[(4-sulfophenyl)methyl]amino]phenyl](4-hydroxy-2-sulfophenyl) methylene]-2,5-cyclohexadien-1-ylidene]-4-sulfobenzenemethanaminium hydroxide and of N-ethyl-N-[4-[[4-[ethyl[(2-sulfophenyl)methyl]amino] phenyl](4-hydroxy-2-sulfophenyl)methylene]-2,5-cyclohexadien-1- ylidene]-3-sulfobenzenemethanaminium hydroxide. Additionally, FD&C Green No. 3 is manufactured by the acid catalyzed condensation of one molecule of 2-formyl-5-hydroxybenzenesulfonic acid with two (2) molecules from a mixture consisting principally of 3-[(ethylphenylamino)methyl] benzensulfonic acid, and smaller amounts of 4-[(ethylphenylamino) methyl] benzenesulfonic acid and 2-[(ethylphenylamino)methyl] benzenesulfonic acid to form the leuco base. The leuco base is then oxidized with lead dioxide and acid or with dichromate and acid to form the dye. The intermediate 2-formyl-5-hydroxybenzenesulfonic acid is prepared by the potassium permanganate oxidation of 2,2'-(1,2-ethenediyl)-bis(5-aminobenzenesulfonic acid) to sodium amino-2-formylbenzenesulfonate. This amine is diazotized, and the resulting diazonium salt is hydrolyzed to the desired 2-formyl-5- hydroxybenzenesulfonic acid. Color additive mixtures for food use made with FD&C Green No. 3 may contain only those diluents that are suitable and that are listed in 21 CFR 73.1 as safe for use in color additive mixtures for coloring food.

(2) Specifications. The color additive FD&C Green No. 3 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practices:

(A) Sum of volatile matter at 135 degrees Celsius (275 degrees Fahrenheit) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

(B) Water-insoluble matter, not more than 0.2 percent.

(C) Leuco base, not more than five (5) percent.

(D) Sum of 2-, 3-, 4-formylbenzenesulfonic acids, sodium salts, not more than 0.5 percent.

(E) Sum of 3- and 4-[[ethyl(4-sulfophenyl)amino]methyl] benzenesulfonic acid, disodium salts, not more than 0.3 percent.

(F) 2-Formyl-5-hydroxybenzenesulfonic acid, sodium salt, not more than 0.5 percent.

(G) Subsidiary colors, not more than six (6) percent.

(H) Chromium (as Cr), not more than 50 parts per million.

(I) Arsenic (as As), not more than three (3) parts per million.

(J) Lead (as Pb), not more than 10 parts per million.

(K) Mercury (as Hg), not more than one (1) part per million.

(L) Total color, not less than 85 percent.

(3) Uses and restrictions. The color additive FD&C Green No. 3 may be safely used for coloring foods generally in amounts consistent with current good manufacturing practices except that it may not be used to color foods for which standards of identity have been promulgated under FD&C 401 unless added color is authorized by such standards.

(4) Labeling. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(5) Certification. All batches of FD&C Green No. 3 shall be certified in accordance with regulations in 21 CFR 80.

(v) FD&C Red No. 3 (21 CFR 74.303). The color additive, FD&C Red No. 3, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive FD&C Red No. 3 is principally the monohydrate of 9 (o- carboxyphenyl)-6-hydroxy-2,4,5,7-tetraiodo-3H-xanthen-3-one, disodium salt, with smaller amounts of lower imdinated fluoresceins. Color additive mixtures for food use made with FD&C Red No. 3 may contain only those diluents that are suitable and that are listed in 21 CFR 73.1 as safe for use in color additive mixtures for coloring foods.

(2) Specifications. FD&C Red No. 3 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practices:

(A) Volatile matter (at 135 degrees Celcius) and chlorides and sulfates (calculated as the sodium salts), total not more than 13 percent.

(B) Water-insoluble matter, not more than 0.2 percent.

(C) Unhalogenated intermediates, total not more than 0.1 percent.

(D) Sodium iodide, not more than 0.4 percent.

(E) Triiodoresorcinol, not more than 0.2 percent.

(F) 2(2',4'-Dihydroxy-3', 5'-diiodobenzoyl) benzoic acid, not more than 0.2 percent.

(G) Monoiodofluoresceins not more than one (1.0) percent.

(H) Other lower iodinated fluoresceins, not more than nine (9.0) percent.

(I) Lead (as Pb), not more than 10 parts per million.

(J) Arsenic (as As), not more than three (3) parts per million.

(K) Total color, not less than 87.0 percent.

(3) Uses and restrictions. FD&C Red No. 3 may be safely used for coloring foods generally in amounts consistent with good manufacturing practices except that it may not be used to color foods for which standards of identity have been promulgated under FD&C 401 unless added color is authorized by such standards.

(4) Labeling. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(5) Certification. All batches of FD&C Red No. 3 shall be certified in accordance with regulations in 21 CFR 80.

(w) FD&C Red No. 40 (21 CFR 74.340). The color additive, FD&C Red No. 40, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive FD&C Red No. 40 is principally the disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-2- naphthalenesulfonic acid. Color additive mixtures for food use (including dietary supplements) made with FD&C Red No. 40 may contain only those diluents that are suitable and that are listed in 21 CFR 73.1 as safe for use in color additive mixtures for coloring foods. The listing of this color additive includes lakes prepared as described in 21 CFR 82.51, except that the color additive used is FD&C Red No. 40 and the resultant lakes meet the specification and labeling requirements prescribed by 21 CFR 82.51.

(2) Specifications. FD&C Red No. 40 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practices:

(A) Sum of volatile matter (at 135 degrees Celsius) and chlorides and sulfates (calculated as sodium salts), not more than 14.0 percent.

(B) Water-insoluble matter, not more than 0.2 percent.

(C) Higher sulfonated subsidiary colors (as sodium salts), not more than one (1.0) percent.

(D) Lower sulfonated subsidiary colors (as sodium salts), not more than one (1.0) percent.

(E) Disodium salt of 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl) azo]- 8-(2-methoxy-5-methyl-4-sulfophenoxy)-2-naphthalenesulfonic acid, not more than one (1.0) percent.

(F) Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid (Schaeffer's salt), not more than 0.3 percent.

(G) 4-Amino-5-methoxy-o-toluenesulfonic acid, not more than 0.2 percent.

(H) Disodium salt of 6,6'-oxybis (2-naphthalene-sulfonic acid), not more than one (1.0) percent.

(I) Lead (as Pb), not more than 10 parts per million.

(J) Arsenic (as As), not more than three (3) parts per million.

(K) Total color, not less than 85.0 percent.

(3) Uses and restrictions. FD&C Red No. 40 may be safely used for coloring foods generally in amounts consistent with good manufacturing practices except that it may not be used to color foods for which standards of identity have been promulgated under FD&C 401 unless added color is authorized by such standards.

(4) Labeling. The label of the color additive and any lakes or mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(5) Certification. All batches of FD&C Red No. 40 and lakes thereof shall be certified in accordance with regulations in 21 CFR 80.

(x) FD&C Yellow No. 6 (21 CFR 74.706). The color additive, FD&C Yellow No. 6, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive FD&C Yellow No. 6 is principally the disodium salt of 6-hydroxy-5-[(4-sulfophenyl)azo]-2-naphthalenesulfonic acid (CAS Reg. No. 2783-94-0). The trisodium salt of 3-hydroxy-4-[(4-sulfophenyl) azo]-2,7-naphthalenedisulfonic acid (CAS Reg. No. 50880-65-4) may be added in small amounts. The color additive is manufactured by diazotizing 4-aminobenzenesulfonic acid using hydrochloric acid and sodium nitrite or sulfuric acid and sodium nitrite. The diazo compound is coupled with 6-hydroxy-2-naphthalene-sulfonic acid. The dye is isolated as the sodium salt and dried. The trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7- naphthalenedisulfonic acid which may be blended with the principal color is prepared in the same manner except the diazo benzenesulfonic acid is coupled with 3-hydroxy-2,7-naphthalenedisulfonic acid. Color additive mixtures for food use made with FD&C Yellow No. 6 may contain only those diluents that are suitable and that are listed in 21 CFR 73.1 as safe for use in color additive mixtures for coloring foods.

(2) Specifications. The color additive FD&C Yellow No. 6 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by current good manufacturing practices:

(A) Sum of volatile matter (at 135 degrees Celsius) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.

(B) Water-insoluble matter, not more than 0.2 percent.

(C) Sodium salt of 4-aminobenzenesulfonic acid, not more than 0.2 percent.

(D) Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid, not more than 0.3 percent.

(E) Disodium salt of 6,6'-oxybis[2-naphthalenesulfonic acid], not more than one (1) percent.

(F) Disodium salt of 4,4'-(1-triazene-1,3-diyl)bis[benzenesulfonic acid], not more than 0.1 percent.

(G) Sum of the sodium salt of 6-hydroxy-5-(phenylazo)-2-naphthalenesulfonic acid and the sodium salt of 4-[(2-hydroxy-1-naphthalenyl)azo] benzenesulfonic acid, not more than one (1) percent.

(H) Sum of the trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid and other higher sulfonated subsidiaries, not more than five (5) percent.

(I) 4-Aminoazobenzene, not more than 50 parts per billion.

(J) 4-Aminobiphenyl, not more than 15 parts per billion.

(K) Aniline, not more than 250 parts per billion.

(L) Azobenzene, not more than 200 parts per billion.

(M) Benzidine, not more than one (1) part per billion.

(N) 1,3-Diphenyltriazene, not more than 40 parts per billion.

(O) 1-(Phenylazo)-2-naphthalenol, not more than 10 parts per million.

(P) Lead (as Pb), not more than 10 parts per million.

(Q) Arsenic (as As), not more than three (3) parts per million.

(R) Mercury (as Hg), not more than one (1) part per million.

(S) Total color, not less than 87 percent.

(3) Uses and restrictions. The color additive FD&C Yellow No. 6 may be safely used for coloring foods generally in amounts consistent with current good manufacturing practices, except that it may not be used to color foods for which standards of identity have been promulgated under FD&C 401 unless added color is authorized by such standards.

(4) Labeling requirements. The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of 21 CFR 70.25.

(5) Certification. All batches of FD&C Yellow No. 6 shall be certified in accordance with regulations in 21 CFR 80.

(y) FD&C Yellow No. 5 (21 CFR 74.705). The color additive, FD&C Yellow No. 5, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive FD&C Yellow No. 5 is principally the trisodium salt of 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[4-sulfophenyl-azo]-1H-pyrazole- 3-carboxylic acid (CAS Reg. No. 1934-21-0). To manufacture the additive, 4-amino-benzenesulfonic acid is diazotized using hydrochloric acid and sodium nitrite. The diazo compound is coupled with 4,5-dihydro- 5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-

carboxylic acid or with the methyl ester, the ethyl ester, or a salt of this carboxylic acid. The resulting dye is purified and isolated as the sodium salt. Color additive mixtures for food use made with FD&C Yellow No. 5 may contain only those diluents that are suitable and that are listed in 21 CFR 73.1 as safe for use in color additive mixtures for coloring foods.

(2) Specifications. FD&C Yellow No. 5 shall conform to the following specifications and shall be free from impurities other than those named to the extent that such other impurities may be avoided by good manufacturing practices:

(A) Sum of volatile matter at 135 degrees Celsius (275 degrees Fahrenheit) and chlorides and sulfates (calculated as sodium salts), not more than 13 percent.

(B) Water-insoluble matter, not more than 0.2 percent.

(C) 4,4'-[4,5-Dihydro-5-oxo-4-[(4-sulfophenyl)hydrazono]-1H-pyrazol-1,3-diyl]bis[benzenesulfonic acid], trisodium salt, not more than one (1) percent.

(D) 4-[(4',5-Disulfo[1,1'-biphenyl]-2-yl)hydrazono]-4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylic acid, tetrasodium salt, not more than one (1) percent.

(E) Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl) hydrazono]-1H-pyrazole-3-carboxylate, disodium salt, not more than one (1) percent.

(F) Sum of 4,5-dihydro-5-oxo-1-phenyl-4-[(4-sulfophenyl)azo]-1H-pyrazole- 3-carboxylic acid, disodium salt, and 4,5-dihydro-5-oxo-4-(phenylazo)-1- (4-sulfophenyl)-1H-pyrazole-3-carboxylic acid, disodium salt, not more than 0.5 percent.

(G) 4-Aminobenzenesulfonic acid, sodium salt, not more than 0.2 percent.

(H) 4,5-Dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylic acid, disodium salt, not more than 0.2 percent.

(I) Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylate, sodium salt, not more than 0.1 percent.

(J) 4,4'-(1-Triazene-1,3-diyl)bis[benzenesulfonic acid], disodium salt, not more than 0.05 percent.

(K) 4-Aminoazobenzene, not more than 75 parts per billion.

(L) 4-Aminobiphenyl, not more than five (5) parts per billion.

(M) Aniline, not more than 100 parts per billion.

(N) Azobenzene, not more than 40 parts per billion.

(O) Benzidine, not more than one (1) part per billion.

(P) 1,3-Diphenyltriazene, not more than 40 parts per billion.

(Q) Lead (as Pb), not more than 10 parts per million.

(R) Arsenic (as As), not more than three (3) parts per million.

(S) Mercury (as Hg), not more than one (1) part per million.

(T) Total color, not less than 87 percent.

(3) Uses and restrictions. FD&C Yellow No. 5 may be safely used for coloring foods generally in amounts consistent with good manufacturing practices, except that it may not be used to color foods for which standards of identity have been promulgated under FD&C 401 unless added color is authorized by such standards.

(4) Labeling requirements. The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of 21 CFR 70.25.

(5) Certification. All batches of FD&C Yellow No. 5 shall be certified in accordance with regulations in 21 CFR 80.

(z) Fennel (21 CFR 582.10). Classification Under Food Additives Amendment: Spices, seasonings, essential oils, etc. Limitations or Restrictions: In accordance with good manufacturing practices.

(aa) Fenugreek seed (21 CFR 582.10). Classification Under Food Additives Amendment: Spices, seasonings, essential oils, etc. Limitations or Restrictions: In accordance with good manufacturing practices.

(bb) Flavoring Agents. Flavoring substances and adjuvants may be safely used in animal food in accordance with the following conditions. They are used in the minimum quantity required to produce their intended technical effect and in accordance with all the principles of good manufacturing practices. In the appropriate forms (plant parts, fluid and solid extracts, concentrates, absolutes, oils, gums, balsams, resins, oleoresins, waxes, and distillates) consisting of one or more of the following:

(1) Aloe. Botanical Name of Plant Source: Aloe perryi Baker, Aloe barbadensis Mill., Aloe ferox Mill., and hybrids of this sp. with Aloe Africana Mill. and Aloe spicata Baker.

(2) Althea root and flowers. Botanical Name of Plant Source: Althea officinalis L.

(3) Amyris (West Indian sandalwood). Botanical Name of Plant Source: Amyris balsamifera L.

(4) Artemisia (wormwood). Botanical Name of Plant Source: Artemisia spp. Limitations: Finished food thujone free as determined by using the method (or, in other than alcoholic beverages, a suitable adaptation thereof) in section 9.129 of the Official Methods of Analysis of the Association of Official Analytical Chemists, 13th edition (1980), which is incorporated by reference.

(5) Benzoin resin. Botanical Name of Plant Source: Styrax benzoin Dryander, Styrax paralleloneurus Perkins, Styrax tonkinensis (Pierre) Craib ex Hartwich, or other spp. of the Section Anthostyrax of the genus Styrax.

(6) Blackberry bark. Botanical Name of Plant Source: Rubus, Section Eubatus.

(7) Boronia flowers. Botanical Name of Plant Source: Boronia megastigma Nees.

(8) Buchu leaves. Botanical Name of Plant Source: Barosma betulina Bartl. et Wendl., Barosma crenulata (L.) Hook. or Barosma serratifolia Willd.

(9) Cajeput. Botanical Name of Plant Source: Melaleuca leucadendron L. and other Melaleuca spp.

(10) Camphor tree. Botanical Name of Plant Source: Cinnamomum camphora (L.) Nees et Eberm. Limitations: Safrole free.

(11) Cascara sagrada. Botanical Name of Plant Source: Rhamnus purshiana DC.

(12) Cassie flowers. Botanical Name of Plant Source: Acacia farnesiana (L.) Willd.

(13) Castor oil. Botanical Name of Plant Source: Ricinus communis L.

(14) Catechu, black. Botanical Name of Plant Source: Acacia catechu Willd.

(15) Cedar, white (aborvitae), leaves and twigs. Botanical Name of Plant Source: Thuja occidentalis L. Limitations: Finished food thujone free as determined by using the method (or, in other than alcoholic beverages, a suitable adaptation thereof) in section 9.129 of the Official Methods of Analysis of the Association of Official Analytical Chemists, 13th edition (1980), which is incorporated by reference.

(16) Cherry pits. Botanical Name of Plant Source: Prunus avium L. or Prunus cerasus L. Limitations: Not to exceed 25 parts per million prussic acid.

(17) Cherry-laurel leaves. Botanical Name of Plant Source: Prunus laurocerasus L. Limitations: Not to exceed 25 parts per million prussic acid.

(18) Chestnut leaves. Botanical Name of Plant Source: Castanea dentate (Marsh.) Borkh.

(19) Copaiba. Botanical Name of Plant Source: South American spp. of Copaifera L.

(20) Costus root. Botanical Name of Plant Source: Saussurea lappa Clarke.

(21) Cubeb. Botanical Name of Plant Source: Piper cubeba L.

(22) Currant, black, buds and leaves. Botanical Name of Plant Source: Ribes nigrum L.

(23) Damiana leaves. Botanical Name of Plant Source: Turnera diffusa Willd.

(24) Davana. Botanical Name of Plant Source: Artemisia pallens Wall.

(25) Dill, Indian. Botanical Name of Plant Source: Anethum sowa Roxb. (Peucedanum graveolens Benth et Hook., Anethum graveolens L.

(26) Dittany of Crete. Botanical Name of Plant Source: Origanum dictamnus L.

(27) Dragon's blood (dracorubin). Botanical Name of Plant Source: Daemonorops spp.

(28) Elemi. Botanical Name of Plant Source: Canarium commune L. or Canarium Luzonicum Miq.

(29) Erigeron. Botanical Name of Plant Source: Erigeron canadensis L.

(30) Eucalyptus globulus leaves. Botanical Name of Plant Source: Eucalyptus globulus Labill.

(31) Fir ("pine") needles and twigs. Botanical Name of Plant Source: Abies sibirica Ledeb., Abies alba Mill., Abies sachalinesis Masters, or Abies mayriana Miyabe et Kudo.

(32) Fir, balsam, needles and twigs. Botanical Name of Plant Source: Abies balsamea (L.) Mill.

(33) Galbanum. Botanical Name of Plant Source: Ferula galbaniflua Boiss. et Buhse and other Ferula spp.

(34) Gambir (catechu, pale). Botanical Name of Plant Source: Uncaria gambir Roxb.

(35) Genet flowers. Botanical Name of Plant Source: Spartium junceum L.

(36) Gentian rhizome and roots. Botanical Name of Plant Source: Gentiana lutea L.

(37) Guaiac. Botanical Name of Plant Source: Guaiacum officinale L., Guaiacum sanctum L., Bulnesia sarmienti Lor.

(38) Guarana. Botanical Name of Plant Source: Paullinia cupana HBK.

(39) Haw, black, bark. Botanical Name of Plant Source: Viburnum prunifolium L.

(40)Hemlock needles and twigs. Botanical Name of Plant Source: Tsuga canadensis (L.) Carr. or Tsuga heterophylla (Raf.) Sarg.

(41) Hyacinth flowers. Botanical Name of Plant Source: Hyacinthus orientalis L.

(42) Imperatoria. Botanical Name of Plant Source: Peucedanum ostruthium (L.) Koch (Imperatoria ostruthium L.).

(43) Labdanum. Botanical Name of Plant Source: Cistus spp.

(44) Linaloe wood. Botanical Name of Plant Source: Bursera delpechiana Poiss. and other Bursera spp.

(45) Lovage. Botanical Name of Plant Source: Levisticum officinale Koch.

(46) Lungmoss (lungwort). Botanical Name of Plant Source: Sticta pulmonacea Ach.

(47) Maple, mountain. Botanical Name of Plant Source: Acer spicatum Lam.

(48) Mimosa (black wattle) flowers. Botanical Name of Plant Source: Acacia decurrens Willd. var. dealbata.

(49) Myrrh. Botanical Name of Plant Source: Commiphora molmol Engl., Commiphora abyssinica (Berg) Engl., or other Commiphora spp.

(50) Oak, white, chips. Botanical Name of Plant Source: Quercus alba L.

(51) Oak moss.Botanical Name of Plant Source: Evernia prunastri (L.) Ach., Evernia furfuracea (L.) Mann, and other lichens. Limitations: Finished food thujone free as determined by using the method (or, in other than alcoholic beverages, a suitable adaptation thereof) in section 9.129 of the Official Methods of Analysis of the Association of Official Analytical Chemists, 13th edition (1980), which is incorporated by reference.

(52) Olibanum. Botanical Name of Plant Source: Boswellia carteri Birdw. and other Boswellia spp.

(53) Opopanax (bisabolmyrrh). Botanical Name of Plant Source: Opopanax chironium Koch (true opopanax) of Commiphora erythraea Engl. var. Llabrescens.

(54) Orris root. Botanical Name of Plant Source: Iris germanica L. (including its variety florentina Dykes) and Iris pallida Lam.

(55) Passion flower. Botanical Name of Plant Source: Passiflora incarnate L.

(56) Patchouli. Botanical Name of Plant Source: Pogostemon cablin Benth. And Pogostemon heyneanus Benth.

(57) Pine, dwarf, needles and twigs. Botanical Name of Plant Source: Pinus mugo Turra var. pumilio (Haenke) Zenari.

(58) Pine, Scotch, needles and twigs. Botanical Name of Plant Source: Pinus sylvestris L.

(59) Pine, white oil. Botanical Name of Plant Source: Pinus palustris Mill. and other Pinus spp.

(60) Quassia. Botanical Name of Plant Source: Picrasma excelsa (Sw.) Planch, or Quassia amara L.

(61) Quebracho bark. Botanical Name of Plant Source: Aspidosperma quebracho-blanco Schlecht, Schinopsis lorentzii (Griseb.) Engl., or Quebrachia lorentzii (Griseb.).

(62) Quillaia (soapbark). Botanical Name of Plant Source: Quillaja saponaria Mol.

(63) Rhatany root. Botanical Name of Plant Source: Krameria triandra Ruiz et Pav. Or Krameria argentea Mart.

(64) Rhubarb root. Botanical Name of Plant Source: Rheum officinale Baill., Rheum palmatum L., or other spp. (excepting Rheum rhaponticum L. or hybrids of Rheum grown in China).

(65) Sandalwood, white (yellow, or East Indian). Botanical Name of Plant Source: Santalum album L.

(66) Sarsaparilla. Botanical Name of Plant Source: Smilax aristolochiaefolia Mill., (Mexican sarsaparilla), Smilax regelii Killip et Morton (Honduras sarsaparilla), Smilax febrifuga Kunth (Ecuadorean sarsaparilla), or undetermined Smilax spp. (Ecuadorean or Central American sarsaparilla).

(67) Sassafras leaves. Botanical Name of Plant Source: Sassafras albidum (Nutt.) Nees. Limitations: Safrole free.

(68) Senna, Alexandria. Botanical Name of Plant Source: Cassia acutifolia Delile.

(69) Snakeroot, Canadian (wild ginger). Botanical Name of Plant Source: Asarum canadense L.

(70) Spruce needles and twigs. Botanical Name of Plant Source: Picea glauca (Moench) Voss or Picea mariana (Mill.) BSP.

(71) Storax (styrax). Botanical Name of Plant Source: Liquidambar orientalis Mill. or. Liquidambar styraciflua L.

(72) Tagetes (marigold). Botanical Name of Plant Source: Tagetes patula L., Tagetes erecta L., or Tagetes minuta L. (Tagetes glandulifera Schrank). Limitations: As oil only.

(73) Thymus capitatus (Spanish "origanum"). Botanical Name of Plant Source: Thymus capitatus Hoffmg. et Link.

(74) Tolu. Botanical Name of Plant Source: Myroxylon balsamum (L.) Harms.

(75) Turpentine. Botanical Name of Plant Source: Pinus palustris Mill. and other Pinus spp. that yield terpene oils exclusively.

(76) Valerian rhizome and roots. Botanical Name of Plant Source: Valeriana officinalis L.

(77) Violet, Swiss. Botanical Name of Plant Source: Viola calcarata L.

(78) Walnut husks (hulls), leaves, and green nuts. Botanical Name of Plant Source: Juglans nigra L. or Juglans regia L.

(79) Yerba santa. Botanical Name of Plant Source: Eriodictyon californicum (Hook et Arn.) Torr.

(80) Yucca, Joshua-tree. Botanical Name of Plant Source: Yucca brevifolia Engelm.

(81) Yucca, Mohave. Botanical Name of Plant Source: Yucca schidigera Roezl ex Ortgies (Yucca mohavensis Sarg.).

(cc) Fruit Juice (21 CFR 73.250). The color additive, fruit juice, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive fruit juice is prepared either by expressing the juice from mature varieties of fresh, edible fruits, or by the water infusion of the dried fruit. The color additive may be concentrated or dried. The definition of fruit juice in this paragraph is for the purpose of identity as a color additive only and shall not be construed as a standard of identity under FD&C 401. However, where a standard of identity for a particular fruit juice has been promulgated under FD&C 401, it shall conform to such standard. Color additive mixtures made with fruit juice may contain as diluents only those substances listed in 21 CFR 73.1 as safe and suitable in color additive mixtures for coloring foods.

(2) Uses and restrictions. Fruit juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practices, except that it may not be used to color foods for which standards of identity have been promulgated under FD&C 401, unless the use of added color is authorized by such standards.

(3) Labeling. The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the FD&C, labeling in accordance with the provisions of 21 CFR 70.25.

(4) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(dd) Fumaric acid. Classification Under Food Additives Amendment: pH adjuster, preservative, or flavoring agent. Limitations or Restrictions: Not to exceed 0.5 percent of the diet.

(ee) Ginger (21 CFR 582.10). Classification Under Food Additives Amendment: Spices, seasonings, essential oils, etc. Limitations or Restrictions: In accordance with good manufacturing practices.

(ff) Glucose Syrup (21 CFR 168.120) is the purified, concentrated, aqueous solution of nutritive saccharides obtained from edible starch. It shall meet the following specifications: total solids content not less than 70.0 percent mass/mass and reducing sugar content (dextrose equivalent), expressed as D-glucose, not less than 20.0 percent mass/mass calculated on a dry basis. The sulfated ash content is not more than one (1.0) percent mass/mass (calculated on a dry basis), and the sulfur dioxide content is not more than 40 milligrams per kilogram. If the product bears a name descriptive of its kind or origin, e.g., “corn syrup,” “grain sorghum syrup,” it must correspond thereto.

(gg) Glutamic acid. Classification Under Food Additives Amendment: Flavoring agent. Limitations or Restrictions: Up to 400 parts per million in finished feed.

(hh) Glycyrrhizin ammoniated (21 CFR 582.20). Classification Under Food Additives Amendment: Spices, seasonings, essential oils, etc. Limitations or Restrictions: In accordance with good manufacturing practices.

(ii) Guanidinoacetic acid (21 CFR 573.496). The food additive guanidinoacetic acid may be safely used in poultry feeds in accordance with the following prescribed conditions:

(1) The additive is manufactured by reacting glycine with cyanamide in an aqueous solution.

(2) The additive is used or intended for use at levels not to exceed 0.12 percent of the complete feed: to spare arginine in broiler chicken and turkey feeds, or as a precursor of creatine in poultry feeds.

(3) The additive consists of not less than 97 percent guanidinoacetic acid [N-(aminoiminomethyl)-glycine] (CAS 352-97-6) by weight.

(4) The additive meets the following specifications: Dicyandiamide not to exceed 0.5 percent; Cyanamide not to exceed 0.01 percent; Melamine not to exceed 15 parts

per million; sum of ammeline, ammelide, and cyanuric acid not to exceed 35 parts per million; and water not to exceed one (1) percent.

(5) To ensure safe use of the additive in addition to the other information required by the FD&C: The label and labeling of the additive, any feed premix, and complete feed shall contain the name of the additive. The label and labeling of the additive and any feed premix shall also contain: a statement to indicate that the maximum use level of guanidinoacetic acid must not exceed 0.12 percent of the complete feed for poultry; and adequate directions for use.

(jj) Haematococcus Algae Meal (21 CFR 73.185). The color additive, Haematococcus algae meal, may be safely used in the manufacture of salmonid fish feed in accordance with the following prescribed conditions:

(1) Identity. The color additive haematococcus algae meal consists of the comminuted and dried cells of the alga Haematococcus pluvialis. Haematococcus algae meal may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with haematococcus algae meal may contain only those diluents that are suitable and are listed in 21 CFR 73.1 as safe for use in color additive mixtures for coloring foods.

(2) Specifications. Haematococcus algae meal shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practices:

(A) Physical state, solid.

(B) Lead (as Pb), not more than five (5) parts per million.

(C) Arsenic (as As), not more than two (2) parts per million.

(D) Mercury (as Hg), not more than one (1) part per million.

(E) Heavy metals, not more than 10 parts per million.

(F) Astaxanthin, not less than 1.5 percent.

(3) Uses and restrictions. Haematococcus algae meal may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions: The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish. The quantity of astaxanthin in finished feed, from haematococcus algae meal when used alone or in combination with other astaxanthin color additive sources listed in 21 CFR 73, shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(4) Labeling requirements. The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by 21 CFR 70.25, and adequate directions to prepare a final product complying with the limitations prescribed in this definition. The presence of the color additive in finished fish feed prepared according to this definition shall be declared in accordance with 21 CFR 501.4. The presence of the color additive in salmonid fish

that have been fed feeds containing haematococcus algae meal shall be declared in accordance with 21 CFR 101.22(b), (c), and (k)(2), and 101.100(a)(2).

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(kk) Microcrystalline Cellulose is purified, partially depolymerized cellulose prepared by processing alpha cellulose obtained as a pulp from fibrous plant material by treating with mineral acids.

(ll) Monosodium glutamate (21 CFR 582.1). Classification Under Food Additives Amendment: Spices, seasonings, etc. Limitations or Restrictions: In accordance with good manufacturing practices.

(mm) Neohesperidin Dihydrochalcone is the product resulting from hydrogenation of neohesperidin, a flavonoid extracted from bitter orange (Citrus aurantium), under alkaline conditions in the presence of a palladium-on-charcoal catalyst. It is to be used as a flavoring agent in weanling pig diets at levels not to exceed 15 parts per million of complete feed.

(nn) Paprika (21 CFR 73.340). The color additive, paprika, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive paprika is the ground dried pod of mild capsicum (Capsicum annuum L.). The definition of paprika in this paragraph is for the purpose of identity as a color additive only and shall not be construed as setting forth an official standard for paprika under FD&C 401. Color additive mixtures made with paprika may contain as diluents only those substances listed in 21 CFR 73.1 as safe and suitable in color additive mixtures for coloring foods.

(2) Uses and restrictions. Paprika may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practices, except that it may not be used to color foods for which standards of identity have been promulgated under FD&C 401, unless the use of added color is authorized by such standards.

(3) Labeling. The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the FD&C, labeling in accordance with the provisions of 21 CFR 70.25 of this chapter.

(4) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(oo) Paprika Oleoresin (21 CFR 73.345). The color additive, paprika oleoresin, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive paprika oleoresin is the combination of flavor and color principles obtained from paprika (Capsicum annuum L.) by extraction, using

any one or a combination of the following solvents: acetone, isopropyl alcohol, ethyl alcohol, methyl alcohol, ethylene dichloride, methylene chloride, hexane, and trichloroethylene. The definition of paprika oleoresin in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for paprika oleoresin under FD&C 401. Color additive mixtures made with paprika oleoresin may contain as diluents only those substances listed in 21 CFR 73.1 as safe and suitable in color additive mixtures for coloring foods.

(2) Specifications. Paprika oleoresin shall contain no more residue of the solvents listed in this definition than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in 21 CFR 170 through 189.

(3) Uses and restrictions. Paprika oleoresin may be safely used for the coloring of foods generally in amounts consistent with good manufacturing practices, except that it may not be used to color foods for which standards of identity have been promulgated under FD&C 401, unless the use of added color is authorized by such standards.

(4) Labeling. The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the FD&C, labeling in accordance with the provisions of 21 CFR 70.25.

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(pp) Paracoccus Pigment (21 CFR 73.352). The color additive, paracoccus pigment, may be safely used in the manufacture of salmonid fish feed in accordance with the following prescribed conditions:

(1) Identity. The color additive paracoccus pigment consists of the heat-killed, dried cells of a nonpathogenic and nontoxicogenic strain of the bacterium Paracoccus carotinifaciens and may contain added calcium carbonate to adjust the astaxanthin level. Color additive mixtures for fish feed use made with paracoccus pigment may contain only those diluents that are suitable and are listed in 21 CFR 73.1 as safe for use in color additive mixtures for coloring foods.

(2) Specifications. Paracoccus pigment shall conform to the following specifications and shall be free from impurities, other than those named, to the extent that such impurities may be avoided by good manufacturing practices:

(A) Physical state, solid.

(B) Lead (as Pb), not more than five (5) milligrams per kilogram (5 parts per million).

(C) Arsenic (as As), not more than two (2) milligrams per kilogram (2 parts per million).

(D) Mercury (as Hg), not more than one (1) milligrams per kilogram (1 parts per million).

(E) Heavy metals, not more than 10 milligrams per kilogram (10 parts per million).

(F) Astaxanthin, not less than 1.75 percent.

(3) Uses and restrictions. Paracoccus pigment may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions: The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish. The quantity of astaxanthin in finished feed, from paracoccus pigment when used alone or in combination with other astaxanthin color additive sources listed in 21 CFR 73, shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(4) Labeling requirements. The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by 21 CFR 70.25, and adequate directions to prepare a final product complying with the limitations prescribed in this definition. The presence of the color additive in finished fish feed prepared according to this definition shall be declared in accordance with 21 CFR 501.4. The presence of the color additive in salmonid fish that have been fed feeds containing paracoccus pigment shall be declared in accordance with 21 CFR 101.22(b), (c), and (k)(2), and 101.100(a)(2).

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(qq) Phaffia Yeast (21 CFR 73.355). The color additive, phaffia yeast, may be safely used in the manufacture of salmonid fish feed in accordance with the following prescribed conditions:

(1) Identity. The color additive phaffia yeast consists of the killed, dried cells of a nonpathogenic and nontoxicogenic strain of the yeast Phaffia rhodozyma. Phaffia yeast may be added to the fish feed only as a component of a stabilized color additive mixture. Color additive mixtures for fish feed use made with phaffia yeast may contain only those diluents that are suitable and are listed in 21 CFR 73.1 as safe for use in color additive mixtures for coloring foods.

(2) Specifications. Phaffia yeast shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practices:

(A) Physical state, solid.

(B) Lead (as Pb), not more than five (5) parts per million.

(C) Arsenic (as As), not more than two (2) parts per million.

(D) Mercury (as Hg), not more than one (1) part per million.

(E) Heavy metals, not more than 10 parts per million.

(F) Astaxanthin, not less than 0.4 percent.

(3) Uses and restrictions. Phaffia yeast may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions: The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish. The quantity of astaxanthin in finished feed, from phaffia yeast when used alone or in combination with other astaxanthin color additive sources listed in 21 CFR 73, shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(4) Labeling requirements. The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by 21 CFR 70.25, and adequate directions to prepare a final product complying with the limitations prescribed in this definition. The presence of the color additive in finished fish feed prepared according to this definition shall be declared in accordance with 21 CFR 501.4. The presence of the color additive in salmonid fish that have been fed feeds containing phaffia yeast shall be declared in accordance with 21 CFR 101.22(b), (c), and (k)(2) and 21 CFR 101.100(a)(2).

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(rr) Phosphoric acid (21 CFR 582.1073). Classification Under Food Additives Amendment: Misc. and/or general purpose. Limitations or Restrictions: In accordance with good manufacturing practices.

(ss) Polyethylene Roughage Replacement (21 CFR 573.780) consists of basic polymers manufactured by the catalytic polymerization of ethylene, is designed in a pellet form in a configuration presenting maximum angular surface having the following dimensions in centimeters. 0.9 + 0.1 x 0.8 + 0.1 x 1.2 + 0.1. It is used as a replacement for roughage in feedlot rations for finishing slaughter cattle. The labels and labeling shall bear the name of the additive “Polyethylene Roughage Replacement,” and adequate directions for use which shall provide for the administration of one-half pound of polyethylene pellets per day for six (6) successive days. All natural roughage should be removed for a minimum of 12 hours prior to administration of polyethylene roughage replacement. Roughage replacement must be adequately mixed in the ration for uniform distribution.

(tt) Powdered Cellulose is purified, mechanically disintegrated cellulose prepared by processing alpha cellulose obtained as a pulp from fibrous plant materials.

(uu) Riboflavin (21 CFR 73.450). The color additive, riboflavin, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive riboflavin is the riboflavin defined in the Food Chemicals Codex, third edition (1981), pp. 262 to 263, which is incorporated by reference. Color additive mixtures made with riboflavin may contain as diluents only those substances listed in 21 CFR 73.1 as safe and suitable for use in color additive mixtures for coloring foods.

(2) Specifications. Riboflavin shall meet the specifications given in the Food Chemicals Codex, third edition (1981), which is incorporated by reference.

(3) Uses and restrictions. Riboflavin may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practices, except that it may not be used to color foods for which standards of identity have been promulgated under FD&C 401, unless the use of added color is authorized by such standards.

(4) Labeling. The label of the color additive shall conform to the requirements of 21 CFR 70.25.

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(vv) Rice By-Products Fractions is obtained by screening and aspirating Ground Rice Hulls. It is used primarily as a pelleting aid and is composed of such fine particles of Ground Rice Hulls, Spongy Parenchyma, and minute amounts of Rice Flour, Rice Germ, Pericarp, and Rice Starch as will pass an 80 mesh screen and contain not less than five (5) percent crude protein, 1.5 percent crude fat, and not more than 25 percent crude fiber.

(ww) Saccharin sodium (GRAS). Classification Under Food Additives Amendment: Non-nutritive sweeteners. Limitations or Restrictions: In accordance with good manufacturing practices.

(xx) Saffron (21 CFR 73.500). The color additive, saffron, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive saffron is the dried stigma of Crocus sativus L. The definition of saffron in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for saffron under FD&C 401. Color additive mixtures made with saffron may contain as diluents only those substances listed in 21 CFR 73.1 as safe and suitable in color additive mixtures for coloring foods.

(2) Uses and restrictions. Saffron may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practices, except that it may not be used to color foods for which standards of identity have been promulgated under FD&C 401, unless the use of added color is authorized by such standards.

(3) Labeling. The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the FD&C, labeling in accordance with the provisions of 21 CFR 70.25.

(4) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(yy) Sodium bisulfate. Classification Under Food Additives Amendment: General purpose feed additive.

(zz) Tagetes (Aztec Marigold) Extract (21 CFR 73.295). The color additive, tagetes (Aztec marigold) extract, may be safely used in the manufacture of chicken feed in accordance with the following prescribed conditions:

(1) Identity. The color additive tagetes (Aztec marigold) extract is a hexane extract of the flower petals of the Aztec marigold (Tagetes erecta L.). It is mixed with an edible vegetable oil, or with an edible vegetable oil and a hydrogenated edible vegetable oil, and not more than 0.3 percent ethoxyquin. It may also be mixed with soy flour or corn meal as a carrier.

(2) Specifications. Tagetes (Aztec marigold) extract shall be prepared from tagetes (Aztec marigold) petals free from admixture with other plant material from Tagetes erecta L. or from plant material or flowers of any other species of plants and shall conform to the following additional specifications:

(A) Melting point, 53.5–55.0 degrees Celsius.

(B) Iodine value, 132–145.

(C) Saponification value, 175-200.

(D) Acid value, 0.60–1.20.

(E) Titer, 35.5–37.0 degrees Celsius.

(F) Unsaponifiable matter, 23-27 percent.

(G) Hexane residue, not more than 25 parts per million.

(H) All determinations, except the hexane residue, shall be made on the initial extract of the flower petals (after drying in a vacuum oven at 60 degrees Celsius for 24 hours) prior to the addition of the oils and ethoxyquin. The hexane determination shall be made on the color additive after the addition of the vegetable oils, hydrogenated vegetable oils, and ethoxyquin.

(3) Uses and restrictions. The color additive tagetes (Aztec marigold) extract may be safely used in chicken feed in accordance with the following prescribed conditions: The color additive is used to enhance the yellow color of chicken skin and eggs. The quantity of the color additive incorporated in the feed is such that the finished feed is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in this definition; and meets the tolerance limitation for ethoxyquin in animal feed prescribed in 21 CFR 573.380.

(4) Labeling requirements. The label of the color additive and any premixes prepared therefrom shall bear, in addition to the information required in 21 CFR 70.25: A statement of the concentrations of xanthophyll and ethoxyquin contained therein. Adequate directions to provide a final product complying with the limitations prescribed in this definition.

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(aaa) Tagetes (Aztec Marigold) Meal (21 CFR 73.295). The color additive, tagetes (Aztec marigold) meal, may be safely used in the manufacture of chicken feed in accordance with the following prescribed conditions:

(1) Identity. The color additive tagetes (Aztec marigold) meal is the dried, ground flower petals of the Aztec marigold (Tagetes erecta L.) mixed with not more than 0.3 percent ethoxyquin.

(2) Specifications. Tagetes (Aztec marigold) meal is free from admixture with other plant material from Tagetes erecta L. or from plant material or flowers of any other species of plants.

(3) Uses and restrictions. The color additive tagetes (Aztec marigold) meal may be safely used in chicken feed in accordance with the following prescribed conditions: The color additive is used to enhance the yellow color of chicken skin and eggs. The quantity of the color additive incorporated in the feed is such that the finished feed is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in this definition; and meets the tolerance limitation for ethoxyquin in animal feed prescribed in 21 CFR 573.380.

(4) Labeling requirements. The label of the color additive and any premixes prepared therefrom shall bear, in addition to the information required in 21 CFR 70.25: A statement of the concentrations of xanthophyll and ethoxyquin contained therein. Adequate directions to provide a final product complying with the limitations prescribed in this definition.

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(bbb) Titanium Dioxide (21 CFR 73.575). The color additive, titanium dioxide, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. (A) The color additive titanium dioxide is synthetically prepared TiO_2, free from admixture with other substances. Color additive mixtures for food use made with titanium dioxide may contain only those diluents that are suitable and that are listed in 21 CFR 73.1 as safe in color additive mixtures for coloring foods, and the following: silicon dioxide, SiO_2, and/or aluminum oxide, Al_2O_3, as dispersing aids - not more than two (2) percent total.

(2) Specifications. Titanium dioxide shall conform to the following specifications:

(A) Lead (as Pb), not more than 10 parts per million.

(B) Arsenic (as As), not more than one (1) part per million.

(C) Antimony (as Sb), not more than two (2) parts per million.

(D) Mercury (as Hg), not more than one (1) part per million.

(E) Loss on ignition at 800 degrees Celsius (after drying for three (3) hours at 105 degrees Celsius), not more than 0.5 percent.

(F) Water-soluble substances, not more than 0.3 percent.

(G) Acid-soluble substances, not more than 0.5 percent.

(H) TiO_2, not less than 99.0 percent after drying for three (3) hours at 105 degrees Celsius.

(I) Lead, arsenic, and antimony shall be determined in the solution obtained by boiling 10 grams of the titanium dioxide for 15 minutes in 50 milliliters of 0.5N hydrochloric acid.

(3) Uses and restrictions. The color additive titanium dioxide may be safely used for coloring foods generally, subject to the following restrictions: The quantity of titanium dioxide does not exceed one (1) percent by weight of the food. It may not be used to color foods for which standards of identity have been promulgated under FD&C 401 unless added color is authorized by such standards.

(4) Labeling. The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of 21 CFR 70.25.

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(ccc) Toasted Partially Defatted Cooked Cottonseed Flour (21 CFR 73.140). The color additive, toasted partially defatted cooked cottonseed flour, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive toasted partially defatted cooked cottonseed flour is a product prepared as follows: Food quality cottonseed is delinted and decorticated; the meats are screened, aspirated, and rolled; moisture is adjusted, the meats heated, and the oil expressed; the cooked meats are cooled, ground, and reheated to obtain a product varying in shade from light to dark brown. Color additive mixtures for food use made with toasted partially defatted cooked cottonseed flour may contain only diluents that are suitable and that are listed in 21 CFR 73.1 as safe in color additive mixtures for coloring foods.

(2) Specifications. Toasted partially defatted cooked cottonseed flour shall conform to the following specifications:

(A) Arsenic (as As): It contains no added arsenic compound and therefore may not exceed a maximum natural background level of 0.2 part per million total arsenic, calculated as As.

(B) Lead (as Pb), not more than 10 parts per million.

(C) Free gossypol content, not more than 450 parts per million.

(3) Uses and restrictions. The color additive toasted partially defatted cooked cottonseed flour may be safely used for coloring foods generally, in amounts consistent with good manufacturing practices, except that it may not be used to color

foods for which standards of identity have been promulgated under FD&C 401, unless added color is authorized by such standards.

(4) Labeling. The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(ddd) Tomato Lycopene Concentrate (21 CFR 73.585). The color additive, tomato lycopene concentrate, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive tomato lycopene concentrate is a powder prepared from tomato lycopene extract by removing most of the tomato lipids with ethyl acetate and then evaporating off the solvent. Color additive mixtures made with tomato lycopene concentrate may contain only those diluents listed in 21 CFR 73.1 as safe and suitable for use in color additive mixtures for coloring food.

(2) Specifications. Tomato lycopene concentrate shall conform to the following specifications: Lycopene, not less than 60 percent of oleoresin.

(3) Uses and restrictions. Tomato lycopene concentrate may be safely used for coloring foods generally in amounts consistent with good manufacturing practices, except that they may not be used to color foods for which standards of identity have been issued under FD&C 401, unless the use of added color is authorized by such standards.

(4) Labeling. The label of the color additive shall conform to the requirements of 21 CFR 70.25.

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(eee) Tomato Lycopene Extract (21 CFR 73.585). The color additive, tomato lycopene extract, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive tomato lycopene extract is a red to dark brown viscous oleoresin extracted with ethyl acetate from tomato pulp followed by removal of the solvent by evaporation. The pulp is produced from fresh, edible varieties of the tomato by removing the liquid. The main coloring component is lycopene. Color additive mixtures made with tomato lycopene extract may contain only those diluents listed in 21 CFR 73.1 as safe and suitable for use in color additive mixtures for coloring food.

(2) Specifications. Tomato lycopene extract shall conform to the following specification: Lycopene, not less than 5.5 percent of oleoresin.

(3) Uses and restrictions. Tomato lycopene extract may be safely used for coloring foods generally in amounts consistent with good manufacturing practices, except that they may not be used to color foods for which standards of identity have been issued under FD&C 401, unless the use of added color is authorized by such standards.

(4) Labeling. The label of the color additive shall conform to the requirements of 21 CFR 70.25.

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(fff) Turmeric Oleoresin (21 CFR 73.615). The color additive, turmeric oleoresin, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive turmeric oleoresin is the combination of flavor and color principles obtained from turmeric (Curcuma longa L.) by extraction using any one or a combination of the following solvents: acetone, isopropyl alcohol, ethyl alcohol methyl alcohol, ethylene dichloride, methylene chloride, hexane, and trichloroethylene. The definition of turmeric oleoresin in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for turmeric oleoresin under FD&C 401. Color additive mixtures made with turmeric oleoresin may contain as diluents only those substances listed in 21 CFR 73.1 as safe and suitable in color additive mixtures for coloring foods.

(2) Specifications. Turmeric oleoresin shall contain no more residue of the solvents listed under this definition than is permitted for the corresponding solvents in spice oleoresins under applicable food additive regulation in 21 CFR 170 through 189.

(3) Uses and restrictions. Turmeric oleoresin may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practices, except that it may not be used to color foods for which standards of identity have been promulgated under FD&C 401, unless the use of added color is authorized by such standards.

(4) Labeling. The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the FD&C, labeling in accordance with the provisions of 21 CFR 70.25.

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(ggg) Turmeric (21 CFR 73.600). The color additive, turmeric, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive turmeric is the ground rhizome of Curcuma longa L. The definition of turmeric in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as setting forth an official standard for

turmeric under FD&C 401. Color additive mixtures made with turmeric may contain as diluents only those substances listed in 21 CFR 73.1 as safe and suitable in color additive mixtures for coloring foods.

(2) Uses and restrictions. Turmeric may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practices, except that it may not be used to color foods for which standards of identity have been promulgated under FD&C 401, unless the use of added color is authorized by such standards.

(3) Labeling. The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the FD&C, labeling in accordance with the provisions of 21 CFR 70.25.

(4) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(hhh) Ultramarine Blue (21 CFR 73.50). The color additive, ultramarine blue, may be safely used to color salt intended for animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive ultramarine blue is a blue pigment obtained by calcining a mixture of kaolin, sulfur, sodium carbonate, and carbon at temperatures above 700 degrees Celsius. Sodium sulfate and silica may also be incorporated in the mixture in order to vary the shade. The pigment is a complex sodium aluminum sulfo- silicate having the approximate formula $Na_7Ai_6Si_6O_{24}S_3$.

(2) Specifications. Ultramarine blue shall conform to the following specifications:

(A) Lead (as Pb), not more than 10 parts per million.

(B) Arsenic (as As), not more than one (1) part per million.

(C) Mercury (as Hg), not more than one (1) part per million.

(3) Uses and restrictions. The color additive ultramarine blue may be safely used for coloring salt intended for animal feed subject to the restriction that the quantity of ultramarine blue does not exceed 0.5 percent by weight of the salt.

(4) Labeling requirements. The color additive shall be labeled in accordance with the requirements of 21 CFR 70.25.

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(iii) Vegetable Juice (21 CFR 73.260). The color additive, vegetable juice, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive vegetable juice is prepared either by expressing the juice from mature varieties of fresh, edible vegetables, or by the water infusion of the

dried vegetable. The color additive may be concentrated or dried. The definition of vegetable juice in this paragraph is for the purpose of identity as a color additive only, and shall not be construed as a standard of identity under FD&C 401. However, where a standard of identity for a particular vegetable juice has been promulgated under FD&C 401, it shall conform to such standard. Color additive mixtures made with vegetable juice may contain as diluents only those substances listed in 21 CFR 73.1 as safe and suitable in color additive mixtures for coloring foods.

(2) Uses and restrictions. Vegetable juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practices, except that it may not be used to color foods for which standards of identity have been promulgated under FD&C 401, unless the use of added color is authorized by such standards.

(3) Labeling. The color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall bear, in addition to the other information required by the FD&C, labeling in accordance with the provisions of 21 CFR 70.25.

(4) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(jjj) Yucca schidigera Extract (21 CFR 172.510) may be used as a flavoring agent in all animal foods. It is also an aid in the control of manure odor (post-excretion) when added to finished feeds of poultry and livestock. The inclusion rate shall be the minimum quantity necessary to produce the intended effect, but not exceeding 125 parts per million in the finished feed.

(kkk) β-Apo-8′-Carotenal (21 CFR 73.90). The color additive, B-apo-8'-carotenal, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive is B-apo-8'-carotenal. Color additive mixtures for food use made with B-apo-8'-carotenal may contain only diluents that are suitable and that are listed in 21 CFR 73.1 as safe in color additive mixtures for coloring foods.

(2) Specifications. B-Apo-8'-carotenal shall conform to the following specifications:

(A) Physical state, solid.

(B) one (1) percent solution in chloroform, clear.

(C) Melting point (decomposition), 136–140 degrees Celsius (corrected).

(D) Loss of weight on drying, not more than 0.2 percent.

(E) Residue on ignition, not more than 0.2 percent.

(F) Lead (as Pb), not more than 10 parts per million.

(G) Arsenic (as As), not more than one (1) part per million.

(H) Assay (spectrophotometric), 96–101 percent.

(3) Uses and restrictions. The color additive B-apo-8'-carotenal may be safely used for coloring foods generally, subject to the following restrictions: The quantity of B-apo-8'-carotenal does not exceed 15 milligrams per pound of solid or semisolid food or 15 milligrams per pint of liquid food. It may not be used to color foods for which standards of identity have been promulgated under FD&C 401 unless added color is authorized by such standards.

(4) Labeling. The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

(lll) β-Carotene (21 CFR 73.95). The color additive, B-carotene, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(1) Identity. The color additive is B-carotene prepared synthetically or obtained from natural sources. Color additive mixtures for food use made with B-carotene may contain only diluents that are suitable and that are listed in 21 CFR 73.1 as safe in color additive mixtures for coloring foods.

(2) Specifications. B-Carotene shall conform to the following specifications:

(A) Physical state, solid.

(B) One (1) percent solution in chloroform, clear.

(C) Loss of weight on drying, not more than 0.2 percent.

(D) Residue on ignition, not more than 0.2 percent.

(E) Lead (as Pb), not more than 10 parts per million.

(F) Arsenic (as As), not more than three (3) parts per million.

(G) Assay (spectrophotometric), 96–101 percent.

(3) Uses and restrictions. The color additive B-carotene may be safely used for coloring foods generally, in amounts consistent with good manufacturing practices, except that it may not be used to color those foods for which standards of identity have been promulgated under FD&C 401 unless added color is authorized by such standards.

(4) Labeling. The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of 21 CFR 70.25.

(5) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of FD&C 721(c).

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2805. Technical Additives.

(a) General Provisions.

(1) Technical Additives are substances added to feed during manufacturing that assist in the production of feed. Examples include, but are not limited to: acidifying agent, additives for biofuel processes that generate co-products used for feed, anticaking agents, anti-gel, antioxidant, binding agent, bioengineered yeast (biofuel), carrier, clear grease, diluent, dispersant, dust control, emulsifiers, flocculating agents, lubricant, pelleting aids, pH modulation, precipitating agent, preservative, processing aid, recover proteinaceous material, sequestrants, solubilizer, stabilizers, surfactant, suspension aid, and thickener.

(b) Aluminum sulfate (21 CFR 582.1125). Classification Under Food Additives Amendment: Anti-gelling agent for molasses, dewater of beetpulp. Limitations or Restrictions: In accordance with good manufacturing practices.

(c) Attapulgite clay. Classification Under Food Additives Amendment: Anti-caking agent and pelleting aid. Suspension aid in liquid feed supplement. Limitations or Restrictions: Not to exceed 2.0 percent. Not to exceed 2.5 percent in supplement. GRAS in non-medicated feeds as binder or pelleting aid when used in accordance with good manufacturing practices and do not exceed the limitations listed. Not prohibited in medicated feeds for the same purpose and at the same level when it can be demonstrated that it does not interfere with the analysis of the drug by acceptable methods.

(d) Calcium aluminates. Classification Under Food Additives Amendment: Pellet binder. Limitations or Restrictions: Maximum of two (2) percent in poultry, swine, and rodent feeds, and a maximum of one (1) percent in feed for all other species.

(e) Calcium silicate (21 CFR 573.260). Classification Under Food Additives Amendment: Anti-caking agent. Limitations or Restrictions: Not to exceed two (2) percent.

(f) Calcium stearate (21 CFR 573.280 (feed grade)). Classification Under Food Additives Amendment: Anti-caking agent. Limitations or Restrictions: In accordance with good manufacturing practices.

(g) Chondrus extract (21 CFR 582.7255). Classification Under Food Additives Amendment: Stabilizer. Limitations or Restrictions: In accordance with good manufacturing practices.

(h) Diacetyl tartaric acid esters of mono and diglycerides of edible fats or oils, or edible fat-forming fatty acids (21 CFR 582.4101). Classification Under Food Additives Amendment: Emulsifying agent. Limitations or Restrictions: In accordance with good manufacturing practices.

(i) Diatomaceous earth (21 CFR 573.340). Classification Under Food Additives Amendment: Inert carrier and anti-caking agent. Limitations or Restrictions: Not to exceed two (2) percent of total ration.

(j) Disodium EDTA (21 CFR 573.360). Classification Under Food Additives Amendment: To solubilize trace minerals in aqueous solutions. Limitations or Restrictions: Not to exceed 0.024 percent (240 parts per million) in finished feed.

(k) Ethoxylated mono and diglycerides (21 CFR 172.834). Classification Under Food Additives Amendment: Emulsifier. Limitations or Restrictions: Not to exceed 0.5 percent in dry milk replacers.

(l) Ethyl cellulose (21 CFR 573.420). Classification Under Food Additives Amendment: Binder or filler in dry vitamin preparations.

(m) Fumaric acid. Classification Under Food Additives Amendment: pH adjuster, preservative, or flavoring agent. Limitations or Restrictions: Not to exceed 0.5 percent of the diet.

(n) Guar gum (mucilage) (21 CFR 582.7339). Classification Under Food Additives Amendment: Stabilizer. Limitations or Restrictions: In accordance with good manufacturing practices.

(o) Hydrophobic silica (21 CFR 584.700). Classification Under Food Additives Amendment: Anti-caking free flow agent. Limitations or Restrictions: Not to exceed five (5) percent in vitamin preparations.

(p) Iron ammonium citrate (21 CFR 573.560). Classification Under Food Additives Amendment: Anti-caking agent in salt. Limitations or Restrictions: Not to exceed 0.0025 percent (25 parts per million) in the finished salt.

(q) Kaolin. Classification Under Food Additives Amendment: Anti-caking agent (in non-medicated feeds). Limitations or Restrictions: Not to exceed 2.5 percent in finished feed. GRAS in non-medicated feeds as binder or pelleting aid when used in accordance with good manufacturing practices and do not exceed the limitations listed. Not prohibited in medicated feeds for the same purpose and at the same level when it can be demonstrated that it does not interfere with the analysis of the drug by acceptable methods.

(r) Lecithin (21 CFR 582.1400). Classification Under Food Additives Amendment: Stabilizer. Limitations or Restrictions: In accordance with good manufacturing practices.

(s) Locust bean gum (Carob bean gum) (21 CFR 582.7343). Classification Under Food Additives Amendment: Stabilizer. Limitations or Restrictions: In accordance with good manufacturing practices.

(t) Magnesium stearate. Classification Under Food Additives Amendment: Die lubricating and release agent in the tableting process. Limitations or Restrictions: In accordance with good manufacturing practices.

(u) Methyl glucoside Coconut oil ester (21 CFR 573.660). Classification Under Food Additives Amendment: Surfactant in molasses. Limitations or Restrictions: Not to exceed 0.032 percent (320 parts per million) in the molasses.

(v) Mineral oil (21 CFR 573.680). Classification Under Food Additives Amendment: To reduce dustiness of feed or mineral supplements, to serve as a lubricant in the preparation of pellets, cubes, and blocks, to improve resistance to moisture of such pellets, cubes, and blocks, and to prevent segregation of trace minerals in mineralized salt. Limitations or Restrictions: Not to exceed three (3) percent in mineral supplements. Not to exceed 0.06 percent of the total ration. To serve as a diluent carrier in the manufacture of feed grade biuret.

(w) Mono and diglycerides of edible fats or oils, or edible fat-forming acids. (21 CFR 582.4505). Classification Under Food Additives Amendment: Emulsifying agent. Limitations or Restrictions: In accordance with good manufacturing practices.

(x) Monosodium phosphate derivatives of mono and diglycerides of edible fats or oils, or edible fat-forming fatty acids (21 CFR 582.4521). Classification Under Food Additives Amendment: Emulsifying agent. Limitations or Restrictions: In accordance with good manufacturing practices.

(y) Montmorillonite clays. Classification Under Food Additives Amendment: Anti-caking aid, pelleting aid, and non-nutritive carrier. Limitations or Restrictions: Not to exceed two (2) percent of the finished material. GRAS in non-medicated feeds as binder or pelleting aid when used in accordance with good manufacturing practices and do not exceed the limitations listed. Not prohibited in medicated feeds for the same purpose and at the same level when it can be demonstrated that it does not interfere with the analysis of the drug by acceptable methods.

(z) Paraffin. Classification Under Food Additives Amendment: Dust control agent. Limitations or Restrictions: Not to exceed three (3) percent in mineral supplements. Not to exceed 0.06 percent of the total ration.

(aa) Petrolatum or a combination of mineral oil and petrolatum (21 CFR 573.720). Classification Under Food Additives Amendment: To reduce dustiness of feed or mineral supplements; to serve as a lubricant in the preparation of pellets, cubes, and blocks; to improve resistance to moisture of such pellets, cubes, and blocks. Limitations or Restrictions: Not to exceed three (3) percent in mineral supplements. Not to exceed 0.06 percent of the total ration.

(bb) Petroleum jelly (21 CFR 573.720). Classification Under Food Additives Amendment: Dust control agent in mineral mixes. Limitations or Restrictions: Not to exceed three (3) percent in mineral supplements. Not to exceed 0.06 percent of the total ration.

(cc) Polyethylene glycol (400) mono and dioleate (21 CFR 573.800). Classification Under Food Additives Amendment: Processing aid when present as a result of its additions to molasses. Limitations or Restrictions: Not to exceed 0.025 percent (250 parts per million) in the molasses.

(dd) Polyoxyethylene glycol (400) mono and dioleates (21 CFR 573.820). Classification Under Food Additives Amendment: Emulsifier. Limitations or Restrictions: Calf milk replacers.

(ee) Polysorbate 80 (21 CFR 573.860). Classification Under Food Additives Amendment: Emulsifier. Limitations or Restrictions: Calf milk replacers. Vitamin and mineral premixes.

(ff) Polysorbate 60 (Polyoxy ethylene (20) sorbitan monostearate) (21 CFR 573.840). Classification Under Food Additives Amendment: Emulsifier. Limitations or Restrictions: Calf milk replacers and mineral premixes.

(gg) Polyvinyl alcohol. Classification Under Food Additives Amendment: Processing aid for dry granular feed enzymes. Limitations or Restrictions: Not to exceed 200 milligrams per kilogram in finished feed.

(hh) Propylene glycol (21 CFR 582.1666). Classification Under Food Additives Amendment: Emulsifying agent. Limitations or Restrictions: GRAS.

(ii) Sodium carboxymethyl-cellulose (21 CFR 582.1745). Classification Under Food Additives Amendment: Stabilizer. Limitations or Restrictions: Not to exceed two (2) percent in finished feed.

(jj) Sorbitan mono- stearate with or without polysorbate 60 (21 CFR 573.960). Classification Under Food Additives Amendment: Emulsifier in mineral premixes and dietary supplement for animal feed. Limitations or Restrictions: In accordance with good manufacturing practices.

(kk) Stearic acid (21 CFR 172.860). Classification Under Food Additives Amendment: Lubricant/binder in tablets and pellets. Limitations or Restrictions: Not to exceed three (3) percent (weight/weight) in finished feed.

(ll) Talc. Classification Under Food Additives Amendment: Die lubricant, finishing agent, and anti-caking agent. Limitations or Restrictions: Not to exceed two (2) percent in the finished feed. Not to exceed 10 percent as a carrier in animal feed premixes.

(mm) Tara gum. Classification Under Food Additives Amendment: Thickener, stabilizer in dry powdered and reconstituted liquid calf milk replacers. Limitations or Restrictions: Up to 0.25 percent in dry powdered calf milk replacer, or 0.04 percent in reconstituted liquid calf milk replacer.

(nn) Tetra sodium pyrophosphate. (21 CFR 582.6789). Classification Under Food Additives Amendment: Dispersant. Limitations or Restrictions: In accordance with good manufacturing practices.

(oo) Yellow prussiate of soda (21 CFR 573.1020). Classification Under Food Additives Amendment: Anti-caking agent in salt. Limitations or Restrictions: Not to exceed 0.0013 percent (13 parts per million).

(pp) Acidifiers.

(1) Ammonium Formate (21 CFR 573.170). The food additive ammonium formate may be safely used in the manufacture of complete swine feeds in accordance with the following prescribed conditions:

(A) The additive is manufactured by the reaction of 99.5 percent ammonia gas and 99 percent formic acid in a continuous loop reactor to produce a solution made up of 37 percent ammonium salt of formic acid and 62 percent formic acid.

(B) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine feeds at levels not to exceed 1.2 percent of the complete feed.

(C) To ensure safe use of the additive, formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(D) To assure safe use of the additive, in addition to the other information required by the FD&C, the label and labeling shall contain: The name of the additive. Adequate directions for use including a statement that ammonium formate must be uniformly applied and thoroughly mixed into complete swine feeds and that the complete swine feeds so treated shall be labeled as containing ammonium formate. Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(E) To assure safe use of the additive, in addition to the other information required by the FD&C and this section, the label and labeling shall contain: Appropriate warnings and safety precautions concerning ammonium formate (37 percent ammonium salt of formic acid and 62 percent formic acid). Statements identifying ammonium formate in formic acid (37 percent ammonium salt of formic acid and 62 percent formic acid) as a corrosive and possible severe irritant. Information about emergency aid in case of accidental exposure as follows: Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration’s (OSHA) human safety guidance regulations. Contact address and telephone number for reporting adverse reactions or to request a copy of the Safety Data Sheet (SDS).

(2) Benzoic Acid (21 CFR 573.210). The food additive benzoic acid may be safely used in the manufacture of complete swine feeds in accordance with the following prescribed conditions:

(A) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine feeds at levels not to exceed 0.5 percent of the complete feed.

(B) The additive consists of not less than 99.5 percent benzoic acid (CAS 65-85-0) by weight with the sum of 2-methylbiphenyl, 3-methylbiphenyl, 4-methylbiphenyl, benzyl benzoate, and isomers of dimethylbiphenyl not to exceed 0.01 percent by weight.

(C) To assure safe use of the additive, in addition to the other information required by the FD&C and this section, the label and labeling shall contain: The name of the additive; Adequate directions for use, including a statement that

benzoic acid must be uniformly applied and thoroughly mixed into complete swine feeds and that the complete swine feeds so treated shall be labeled as containing benzoic acid; Appropriate warnings and safety precautions concerning benzoic acid; A warning statement identifying benzoic acid as a possible irritant; Information about emergency aid in case of accidental exposure; and Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS).

(3) Formic Acid (21 CFR 573.480) is manufactured by heating carbon dioxide and NaOH under pressure and decomposing the resulting sodium formate with H_2SO_4; the resulting formic acid, CH_2O_2, has a molecular weight of 46.02. The food additive formic acid may be safely used in accordance with the following conditions:

(A) The additive is used as a preservative in hay crop silage in an amount not to exceed 2.25 percent of the silage on a dry weight basis or 0.45 percent when direct cut, as follows: The top foot of silage stored should not contain formic acid and Silage should not be fed to livestock within four (4) weeks of treatment.

(B) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine and poultry feeds at levels not to exceed 1.2 percent of the complete feed. The additive consists of not less than 85 percent formic acid (CAS 64-18-6).

(i) The additive meets the following specifications:

(a) Free methyl alcohol not to exceed 1,000 parts per million;

(b) Methyl formate not to exceed 1,000 parts per million; and

(c) Moisture not to exceed 15 percent.

(ii) To assure safe use of the additive, formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(C) To assure safe use of the additive, in addition to the other information required by the FD&C, the label and labeling shall contain: The name of the additive. Adequate directions for use including a statement that formic acid must be uniformly applied and thoroughly mixed into complete feeds and that the complete feeds so treated shall be labeled as containing formic acid. Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(D) To ensure safe use of the additive, in addition to the other information required by the FD&C and this section, the label and labeling shall contain: Appropriate warnings and safety precautions concerning formic acid (85 percent formic acid). Statements identifying formic acid (85 percent formic acid) as a corrosive and possible severe irritant. Information about emergency aid in case of accidental exposure. Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance

regulations. Contact address and telephone number for reporting adverse reactions or to request a copy of the Safety Data Sheet (SDS).

(4) Feed Grade Sodium Formate (21 CFR 573.696). The food additive feed grade sodium formate may be safely used in the manufacture of complete swine and poultry feeds in accordance with the following prescribed conditions:

(A) The additive is manufactured by the reaction of 99 percent formic acid and 50 percent sodium hydroxide in water to produce a solution made up of at least 20.5 percent sodium salt of formic acid and not more than 61 percent formic acid.

(B) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine and poultry feeds at levels not to exceed 1.2 percent of the complete feed.

(C) To assure safe use of the additive, formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(D) To assure safe use of the additive, in addition to the other information required by the FD&C, the label and labeling shall contain: The name of the additive. Adequate directions for use, including a statement that feed grade sodium formate must be uniformly applied and thoroughly mixed into complete feeds and that the complete feeds so treated shall be labeled as containing feed grade sodium formate. Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2 percent of complete feed when multiple sources of formic acid and its salts are used in combination.

(E) To assure safe use of the additive, in addition to the other information required by the FD&C and this section, the label and labeling shall contain: Appropriate warnings and safety precautions concerning feed grade sodium formate. Statements identifying feed grade sodium formate as a corrosive and possible severe irritant. Information about emergency aid in case of accidental exposure as follows: Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration (OSHA) human safety guidance regulations. Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS).

(qq) Antimicrobial Agents.

(1) Formaldehyde (21 CFR 573.460). The food additive formaldehyde may be safely used in the manufacture of animal feeds in accordance with the following conditions:

(A) The additive is used, or intended for use, to improve the handling characteristics of animal fat in combination with certain oilseed meals by producing them from a dry, free-flowing product as follows:

(i) For animal fat in combination with certain oilseed meals, as a component of dry, nonpelleted feeds for beef and non-lactating dairy cattle.

(a) For aqueous blend of soybean and sunflower meals in a ratio of 3:1, respectively, is mixed with animal fat such that the oilseed meals and animal fat are in a ratio of 3:2.

(b) Formaldehyde (37 percent solution) is added to the mixture at a level of four (4) percent of the dry matter weight of the oilseed meals and animal fat. This mixture, upon drying, contains not more than one (1) percent formaldehyde and not more than 12 percent moisture.

(c) To assure the safe use of the additive, in addition to the other information required by the FD&C, the label and labeling of the dried mixture shall bear: The name of the additive. Adequate directions for use providing that the feed as consumed does not contain more than 25 percent of the mixture.

(ii) For soybean and canola seeds and/or meals to which there may be added vegetable oil as a component of dry, nonpelleted feeds for beef and dairy cattle, including lactating dairy cattle.

(a) An aqueous blend of oilseed and/or meals, with or without added vegetable oil, in a ratio such that, on a dry matter basis, the final protein level will be 25 to 35 percent and the fat content will be 20 to 45 percent.

(b) Formaldehyde (37 percent solution) is added to the mixture at a level of 2.7 percent of the dry matter weight basis of the oilseeds and/or meals and the vegetable oil. This mixture, upon drying, contains not more than 0.5 percent formaldehyde and not more than 12 percent moisture.

(c) To assure the safe use of the additive, in addition to the other information required by the FD&C, the label and labeling of the dried mixture shall bear: The name of the additive. The statement, “This supplement is not to exceed 12.5 percent of the total ration. Dietary calcium and magnesium levels should be considered when supplementing the diet with fat.” The minimum and maximum levels of crude fat must be guaranteed and must be between -5 percent and +5 percent of the analyzed fat content for each batch.

(B) The food additive is formaldehyde (CAS No. 50-00-0; 37 percent aqueous solution). It is used at a rate of 5.4 pounds (2.5 kilograms) per ton of animal feed or feed ingredient. It is an antimicrobial agent used to maintain complete animal feeds or feed ingredients Salmonella negative for up to 21 days.

(i) To assure safe use of the additive, in addition to the other information required by the FD&C, the label and labeling shall contain: The name of the additive. A statement that formaldehyde solution which has been stored below 40 degrees Fahrenheit or allowed to freeze should not be applied to complete animal feeds or feed ingredients. Adequate directions for use including a statement that formaldehyde should be uniformly sprayed on and thoroughly mixed into the complete animal feeds or feed ingredients and that the complete animal feeds or feed ingredients so treated shall be labeled as containing formaldehyde. The label must prominently display the statement:

"Treated with formaldehyde to maintain feed Salmonella negative. Use within 21 days." The labeling for feed or feed ingredients to which formaldehyde has been added under the provisions of this section is required to carry the following statement: "Treated with formaldehyde to maintain feed Salmonella negative. Use within 21 days."

(ii) To assure safe use of the additive, in addition to the other information required by the FD&C, the label and labeling shall contain: Appropriate warnings and safety precautions concerning formaldehyde. Statements identifying formaldehyde as a poison with potentials for adverse respiratory effects. Information about emergency aid in case of accidental inhalation. Statements reflecting requirements of applicable sections of the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations. Contact address and phone number for reporting adverse reactions or to request a copy of the Materials Safety Data Sheet (MSDS).

(rr) Anticaking Agents.

(1) Bentonite (21 CFR 582.1155) is a naturally occurring mineral consisting primarily of the tri- layered aluminum silicate, montmorillonite. It may contain calcium or sodium as the predominant available or exchange ion. It is used or intended for use in non-medicated animal feed as an anti-caking agent and pelleting aid in an amount not to exceed two (2) percent in total ration. It is not prohibited in medicated animal feed for the same purposes and at the same levels when it can be demonstrated that it does not interfere with the bioavailability of the medicament to animals and the analysis of the feed for the medicament by acceptable methods. It is the manufacturer's responsibility to determine and submit adequate data to support the conclusion that interference does not occur before using it in a feed containing medicaments. Medicaments with which it may currently be used are listed in General Provisions.

(2) Castor oil is a triglyceride obtained by the extraction of oil from seeds of the castor bean plant, Ricinus communis. It consists predominately of triglyceride ester of fatty acids. It must meet the specifications in the Food Chemical Codex, 5th Edition, 2004, and be guaranteed for not less than 87 percent ricinoleic acid. Castor oil may be safely used as an anticaking agent, a releasing agent, and as diluent in animal feeds at levels not to exceed 250 parts per million in complete feed.

(3) Perlite is the expanded, powdered form of a glassy volcanic rock, consisting essentially of fused sodium potassium aluminum silicate. It meets the specifications of current edition and supplements of the Food Chemicals Codex. It is used as a filter aid or pressing aid in the processing of foods and feed ingredients and also may be used as an anti-caking agent. It may not exceed four (4) percent by weight of the product in which it is present as a processing aid.

(4) Pyrophyllite (aluminum silicate monohydrate) (21 CFR 573.900) may be safely used as the sole anticaking aid, blending agent, pelleting aid, or carrier in animal feed when incorporated therein in an amount not to exceed two (2) percent in complete animal feed.

(5) Silicon Dioxide. The food additive silicon dioxide may be safely used in animal feed in accordance with the following conditions: The food additive is manufactured by vapor phase hydrolysis or by other means whereby the particle size is such as to accomplish the intended effect. It is used or intended for use as an anticaking agent, antifoaming agent, carrier, and/or grinding aid in animal feed, including ingredients, intermediate premixes, premixes, supplements, concentrates, and complete feed. To ensure safe use of the additive, silicon dioxide is to be used in an amount not to exceed that reasonably required to accomplish its intended effect, and silicon dioxide from all sources cannot exceed two (2) percent by weight of the complete feed. To ensure safe use of the additive, the label and labeling of the additive and ingredients, intermediate premixes, premixes, supplements, concentrates, and complete feed containing the additive shall meet the requirements of the FD&C, including 21 CFR 501. To ensure safe use of the additive, in addition to the other information required by the FD&C, the label and labeling of the additive and ingredients, intermediate premixes, premixes, supplements, and concentrates containing the additive shall have: A statement of the concentration of the additive. A statement that silicon dioxide from all sources cannot exceed two (2) percent by weight of the complete feed.

(6) Sodium Bentonite (21 CFR 582.1155) is a naturally occurring mineral consisting primarily of the tri-layered hydrous aluminum silicate, montmorillonite characterized by a sodium exchange or available ion content of not less than one (1) percent and not more than two (2) percent of the air dried material. It is used or intended for use in non-medicated animal feed as an anti- caking agent and pelleting aid in an amount not to exceed two (2) percent in total ration. To reduce seepage in silage, the amount added would not exceed one (1) percent sodium bentonite. It is not prohibited in medicated animal feed for the same purposes and the same levels when it can be demonstrated that it does not interfere with the bioavailability of the medicament to animals and the analysis of the feed for the medicament by acceptable methods. It is the manufacturer’s responsibility to determine and submit adequate data to support the conclusion that interference does not occur before using it in a feed containing medicaments. Medicaments with which it may currently be used are listed in General Provisions.

(7) Verxite (exfoliated hydrobiotite) (21 CFR 573.1000), an additive, is a magnesium-aluminum- iron silicate conforming to one of the following:

(A) Verxite Granules contain a minimum of 98 percent Hydrobiotite, is thermally expanded and has a bulk density of five (5) to nine (9) pounds per cubic foot. It is used or intended for use in poultry feed at a level not to exceed five (5) percent of the weight of the finished feed as a non-nutritive bulking agent for restricting calorie intake in pullet replacement feeds, or as anticaking or blending agent, pelleting aid, or non- nutritive carrier for the incorporation of nutrients in poultry, swine, or ruminant feeds, in an amount not to exceed that necessary to accomplish its intended effect and in no case to exceed five (5) percent of the final feed.

(B) Verxite Flakes contain a minimum of 98 percent Hydrobiotite and has a bulk density of 20 to 30 pounds per cubic foot. It is used or intended for use as an

anticaking or blending agent in ruminant feeds in an amount not to exceed that necessary to accomplish its intended effect and in no case to exceed one (1) percent by weight of the final feed for ruminants.

(C) Verxite Grits contains a minimum of 80 percent Hydrobiotite. It has a bulk density of from 40 to 50 pounds per cubic foot. It is used or intended for use as a partial roughage replacement in ruminant feeds in an amount not to exceed that necessary to accomplish its intended effect and is in no case to exceed one (1) percent by weight of the final feed. To ensure safe use of the additive, the label of any feed additive supplement, feed additive concentrate, feed additive premix, or complete feed prepared therefrom shall bear, in addition to the other information required by the FD&C, the name of the additive (verxite granules or verxite flakes or verxite grits) and when the additive is present in excess of one (1) percent, a statement of the quantity of the additive contained therein and the term “non-nutritive” in juxtaposition therewith.

(8) Iron Tartrates is the reaction product of sodium tartrates [D-, L-, and meso-tartrates] and iron(III) chloride for use as an anticaking agent in salt. The molar ratio of iron(III) to meso-tartrate must be 1:1. It must contain no less than eight (8) percent iron(III) on a dry weight basis. It must contain no more than 1.5 percent oxalic acid, three (3) parts per million arsenic, two (2) parts per million lead, and one (1) parts per million mercury on a dry weight basis. The maximum iron tartrates inclusion rate (calculated as iron) is not more than 12 parts per million.

(9) Sodium Aluminosilicate is hydrated sodium aluminum silicate having Na_2O:Al_2O_3:SiO_2 in molar ratios of approximately 1:1:13, respectively. It can be naturally occurring or synthetic. It consists of 66.0 to 76.0 percent silicon dioxide; nine (9.0) to 13.0 percent aluminum oxide; and four (4.0) to seven (7.0) percent sodium oxide, on a dry basis. It is used as an anticaking agent not to exceed two (2) percent in finished feed.

(ss) Binders.

(1) Lignin Sulfonate (21 CFR 573.600) is either one, or a combination of, the ammonium, calcium, magnesium, or sodium salts of the extract of spent sulfite liquor derived from the sulfite digestion of wood or of abaca (Musa textilis) or of Sisal (Agave sisalana) in either a liquid form (moisture not to exceed 50 percent by weight) or dry form (moisture not to exceed six (6) percent by weight). It may be used in animal feed in amounts calculated on a dry weight basis, as:

(A) A pelleting aid, in the liquid or dry form, in an amount not to exceed four (4) percent of the finished pellets.

(B) A binding aid, in the liquid form, in the flaking of feed grains in an amount not to exceed four (4) percent of the flaked grain.

(C) A surfactant in molasses used in feeds, as liquid lignin sulfonate, in an amount not to exceed 11 percent of the molasses.

(D) A source of metabolizable energy, in the liquid or dry form, in an amount not to exceed four (4) percent of the finished feed.

(2) Sodium Salts of Fatty Acids are obtained by the neutralization of feed grade vegetable origin free fatty acids, or saponification of vegetable oil, or a combination thereof. The specifications of the starting materials must meet the requirements stated in the definitions for Hydrolyzed Vegetable Fats, or Oils, Feed Grade and Vegetable Fat, or Oil, respectively. Sodium hydroxide is used in the neutralization or saponification reactions. The resulting sodium salts are used as a binder and/or lubricant in the pelleted and flaked feed. The source of the fatty acids or vegetable oil shall be indicated on the label. Sodium salts are in dry form with the maximum moisture not to exceed eight (8) percent by weight. It may be used in animal feed in amounts calculated on an “as-is” basis not to exceed 5.5 pounds per ton. Sodium Salts of Fatty Acids shall be labeled with guarantees on an “as-is” basis for no more than 0.5 percent free fatty acids, no more than 12 percent glycerin, not less than 67 percent total sodium salts of fatty acids, and no more than one (1) percent unsaponifiable matter.

(3) Potassium Salts of Fatty Acids are obtained by the neutralization of feed grade vegetable origin free fatty acids, or saponification of vegetable oil or a combination thereof. The specifications of the starting materials must meet the requirements stated in the definitions for Hydrolyzed Vegetable Fats, or Oils, Feed Grade and Vegetable Fat, or Oil, respectively. Potassium hydroxide is used in the neutralization or saponification reactions. The resulting potassium salts are used as a binder and/or lubricant in the pelleted and flaked feed. The source of the fatty acids or vegetable oil shall be indicated on the label. Potassium salts are in liquid form with the maximum moisture not to exceed 68 percent by weight. It may be used in animal feed in amounts calculated on an “as-is” basis not to exceed 15.5 pounds per ton. Potassium Salts of Fatty Acids shall be labeled with guarantees on an “as-is” basis for no more than 0.5 percent free fatty acids, no more than 10 percent glycerin, not less than 24 percent total potassium salts of fatty acids, and no more than one (1) percent unsaponifiable matter.

(tt) Biofuel Production.

(1) Yeast for Production of Distillers Products. The ingredients list of the yeast marketed to the ethanol manufacturer should declare the genus species of the yeast and the enzyme(s) expressed.

(A) Saccharomyces cerevisiae expressing glucoamylase from Saccharomycopsis fibuligera for use in dry grind corn fuel ethanol production of distillers coproducts for animal feed. Distillers products for use in animal feed contain no live bioengineered yeast.

(B) Saccharomyces cerevisiae expressing pyruvate formate lyase activating enzyme, pyruvate formate lyase, and bifunctional acetaldehyde-CoA/alcohol dehydrogenase from Bifidobacterium adolescentis and a glucoamylase from Saccharomycopsis fibuligera for use in dry grind corn fuel ethanol production of distillers products for animal feed. Distillers products for use in animal feed contain no live bioengineered yeast.

(uu) Emulsifiers.

(1) Xanthan Gum as per 21 CFR 573.1010 is classified as a food additive as a stabilizer, emulsifier, thickener, suspending agent, or bodying agent in calf milk replacer and liquid feed supplements. Also per informal review processes, it can be used as a suspending agent in plant inoculant products. Maximum inclusion levels are 0.1 percent in calf milk replacers (as fed), and 0.25 percent in liquid feed supplements, and two (2) percent in plant inoculant products.

(vv) Floculants.

(1) Chitosan is a cationic carbohydrate polymer intended for use as a precipitating agent of proteinaceous material from food processing plants. It is chemically derived by deacetylation of the naturally occurring chitin in crab and shrimp shells. It may be used in an amount not to exceed that necessary to accomplish its intended effect. Chitosan when fed as a component of feed to livestock shall be present at no more than 0.1 percent of the feed. Proteinaceous material coagulated with chitosan must have safety and efficacy data approved before it can be registered or offered for sale.

(2) Kraft Lignin and its salts (ammonium, calcium, magnesium or sodium) is obtained from the acid precipitation of lignin from spent black liquor produced in the sulfate digestion process of wood and is dehydrated to less than eight (8) percent moisture by weight. It is used; as an aid in recovering proteinaceous material during the rendering process, limited to 0.1 percent of the crax, in the clarification of spent grease, and as a coating agent for fat soluble vitamins limited to 50 percent of the vitamin premix matrix and three (3) percent of the finished feed.

(ww) Nutritional Diluents.

(1) Reed-Sedge Peat is a natural, partially decomposed plant material, formed from a mixture of reeds, sedges, grasses and some hypnum mosses occurring in wetlands and containing one third to two thirds peat fibers. It should be dehydrated to a moisture content of not more than 15 percent and be in a state free from all harmful micro-organisms. It is intended for use in animal feed as a carrier for liquid products and premixes or as a nutritional diluent for lowered energy diets at a level not to exceed five (5) percent of the total daily ration.

(xx) Pelleting Aids.

(1) Hide Glue (Technical Gelatin) is a collagen-based product manufactured only from cattle hide pieces. Maximum moisture is 13.5 percent, maximum ash is four (4) percent and minimum protein is 90 percent. The product is used as a processing aid, pelleting aid, or feed binder, not to exceed two (2) percent of the feed by weight. (Either term, “hide glue” or “technical gelatin,” may be used in the ingredient statement.)

(2) Rice By-Products Fractions is obtained by screening and aspirating Ground Rice Hulls. It is used primarily as a pelleting aid and is composed of such fine particles of Ground Rice Hulls, Spongy Parenchyma, and minute amounts of Rice Flour, Rice Germ, Pericarp, and Rice Starch as will pass an 80 mesh screen and contain not less than five (5) percent crude protein, 1.5 percent crude fat, and not more than 25 percent crude fiber.

(3) Urea Formaldehyde Condensation Polymer is an amino resin that may be used in animal feeds: (a) as a pelleting aid, excluding feed for aquatic species. The free formaldehyde must not exceed 0.1 parts per million in the finished pelleted feed, and (b) as an agent to reduce the solubility and fermentation of soybean meal intended for ruminant feed. It must not exceed one (1) percent of the treated soybean meal.

(4) Sodium Hydroxide Lignin Dehydrated is obtained from the acid precipitation of lignin from spent black liquor produced in the sodium hydroxide and steam digestion of wheat straw without a bleaching process. The final product is dried to a powder with less than four (4) percent moisture by weight. It must contain, and be guaranteed for, not less than 83 percent total lignin (including acid insoluble and acid soluble lignins) and not more than 3.5 percent of ash. It is used as a pelleting aid in livestock and poultry feeds in an amount calculated on a dry weight basis not to exceed four (4) percent of the finished pellets.

(5) Hydrogenated Glycerides are obtained by hydrogenation of animal fats or vegetable oils and are used as a coating agent for ingredients or a binder and lubricant in pelleting of feed (pelleting aid) of all animal species. The maximum use rate of hydrogenated glycerides is four (4) pounds per ton of complete feed. Specifications of animal fats or vegetable oils used to produce the hydrogenated glycerides must meet the requirements stated in the definitions for Animal Fat and Vegetable Fat, or Oil, respectively. The specification for tallow must specify insoluble impurities not more than 0.15 percent to be consistent with BSE feed regulation 21 CFR 589.2000 and 589.2001, and a guaranteed titer above 40 degrees Celsius. The source of the hydrogenated glycerides must be indicated on the label. The hydrogenated glycerides must contain, and be guaranteed for, not less than 90 percent total ester content, not more than 0.8 percent unsaponifiable matter, not more than 0.001 percent heavy metals, and not more than five (5) of iodine value. The maximum moisture, maximum insoluble matter, maximum free fatty acids, saponification value, and melting range must also be guaranteed on the label. If an antioxidant is used, the common name or names must be indicated on the label, followed by the words “used as a preservative.”

(yy) Surfactants.

(1) Poloxalene (21 CFR 573.760) consists of polyoxypropylene-polyoxyethylene glycol non-ionic block polymer. It may be used as a surfactant for the flaking of feed grain, when added to liquid grain conditioner in an amount not to exceed one (1) percent of the conditioner, and the conditioner is added to the feed grain at a rate of one (1) quart per ton of feed grain.

(zz) Tracers.

(1) Iron Nickel Tracer the particles resulting from water atomization of high purity iron and nickel. The nickel content of the particles is between 35 percent and 51 percent with the remainder being iron. The particle size of the iron nickel alloy must range between 150 and 300 microns. This ingredient may be used in animal foods as a tracer for other ingredients or premixes present in a finished animal food. The inclusion level of the ingredient must not exceed 10 parts per million in the finished

food. The label shall include a maximum nickel guarantee and a caution statement indicating the maximum permitted inclusion level.

(2) Colored Graphite Tracer are the particles resulting from the milling of naturally occurring graphite coated with a color additive(s) approved for use in animal food. The graphite must be of feed grade material and may be used in animal food as a colored tracer for other ingredients or premixes present in a finished animal food. The inclusion level of the tracer must not exceed 50 parts per million in the finished food. The label shall include a caution statement indicating the maximum permitted inclusion level.

(aaa) Antioxidants.

(1) Cashew Nut Shell Liquid is the heat extracted liquid from cashew nut shells to be used as an antioxidant in fats and oils (excluding highly unsaturated oils with iodine value higher than 150) that are suitable for use in animal food. Cashew nut shell liquid can be used at levels up to 6000 milligrams per kilogram in fats and oils. The level of cashew nut shell liquid in complete feed must not exceed 600 milligrams per kilogram. The liquid ingredient must contain, and be guaranteed for, not less than 10 percent cardol, not less than 55 percent cardanol, and not more than one (1) percent moisture.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2806. Vitamins.

(a) Betaine (hydrochloride or anhydrous) is the crystalline chloride of betaine or anhydrous betaine; a partial replacement for choline.

(b) Cholecalciferol (D-Activated Animal Sterol) is obtained by activation of a sterol fraction of animal origin with ultra-violet light or other means. For label identification it may be followed with the parenthetical phrase (Source of Vitamin D_3).

(c) Cod Liver Oil is the oil obtained from the livers of gadus morrhuae or other species of the family gadidae, either or both. It must contain not less than 385,900 International Units of vitamin A per pound (850 units per gram) and not less than 29,510 International Chick Units of vitamin D per pound (65 units per gram).

(d) Cod Liver Oil with Added Vitamins A and D is the product consisting of cod liver oil to which has been added vitamins A and D. The product must contain not less than 136,000 International Chick Units of vitamin D per pound (300 per gram).

(e) Ergocalciferol (D-Activated Plant Sterol) is obtained by activation of a sterol fraction of plant origin with ultra-violet light or other means. For label identification it may be followed with the parenthetical phrase (Source of Vitamin D_2).

(f) Vitamin A and D Oil is an oil of animal or vegetable origin with or without vitamins A and D supplementation for which vitamin potencies are claimed.

(g) Vitamin A Oil is an oil of animal or vegetable origin with or without vitamin A supplementation for which vitamin A potency is claimed.

(h) Vitamin A Supplement is a feeding material used for its vitamin A content. It must contain a minimum of two million International Units of vitamin A per pound. The label must bear a statement of the source of vitamin A and a minimum guarantee of International Units of vitamin A per pound with additional permissive International Units of vitamin A per gram.

(i) Vitamin B_{12} Supplement is a feeding material used for its vitamin B_{12} activity. It must contain a minimum vitamin B_{12} activity of 1.5 milligrams per pound. The term must not be applied to products for which there are accepted names and definitions.

(j) Vitamin D Oil is an oil of animal or vegetable origin with or without vitamin D supplementation for which vitamin D potency is claimed.

(k) Vitamin D_2 Supplement is a feeding material used for its vitamin D_2 activity. It must contain a minimum of 100,000 International Units of vitamin D_2 per pound.

(l) Vitamin D_3 Supplement is a feeding material used for its vitamin D_3 activity. It must contain a minimum of 100,000 International Chick Units of vitamin D_3 per pound.

(m) Vitamin E Supplement is a feeding material used for its vitamin E activity. It must contain a minimum vitamin E activity equal to 10,000 International Units of vitamin E per pound.

(n) Niacin Supplement is a term that may be used in the ingredient list on a feed label of a mixed feed to indicate the addition of either Niacin or Niacinamide. Sources containing only Niacin or Niacinamide must state the source of Niacin on their label.

(o) Riboflavin Supplement is a feeding material used chiefly for its riboflavin content, and must contain not less than 1,000 milligrams of riboflavin per pound. The label must bear a parenthetical statement of origin immediately following this declaration.

(p) 25-hydroxyvitamin D_3 (21 CFR 573.550, 584.725). The food additive 25-hydroxyvitamin D_3 may be safely used in accordance with the following prescribed conditions:

(1) The additive is used or intended for use as a source of vitamin D_3 activity in animal feed or drinking water in accordance with good manufacturing and feeding practices as follows:

(A) In feed or drinking water of chickens not to exceed 69 parts per billion in feed or 34.5 parts per billion in drinking water.

(B) In feed or drinking water of turkeys not to exceed: 92 parts per billion in feed; or in drinking water, 25 parts per billion for turkeys up to three (3) weeks of age, 36 parts per billion for turkeys from four (4) to 11 weeks of age, or 45 parts per billion for turkeys over 11 weeks of age.

(2) The additive consists of not less than 94 percent 25-hydroxyvitamin D_3 (9,10-secocholesta-5,7,10(19)-triene-3B, 25-diol).

(3) The additive meets the following specifications:

(A) Not more than one (1) percent of any individual sterol.

(B) Not more than five (5) percent water.

(C) Not more than 20 parts per million lead.

(D) Not more than 20 parts per million aluminum.

(E) Not more than one (1.0) percent solvents and non-detectable levels of 2', 4', 5', 7' tetraiodofluorescin.

(F) Not more than one (1) parts per billion 1,25-dihydroxycholecalciferol.

(4) To assure safe use of the additive, in addition to the other information required by the FD&C, the label and labeling shall contain: The name of the additive. A statement to indicate the maximum use level of 25-hydroxyvitamin D3 must not exceed 69 parts per billion in feed or 34.5 parts per billion in drinking water for chickens. A statement to indicate for turkeys the maximum use level of 25-hydroxyvitamin D3 must not exceed 92 parts per billion in feed; or in drinking water, 25 parts per billion for turkeys up to three (3) weeks of age, 36 parts per billion for turkeys from four (4) to 11 weeks of age, or 45 parts per billion for turkeys over 11 weeks of age. Adequate use directions to ensure that 25-hydroxyvitamin D3 (and all premixes) is uniformly blended throughout the feed or drinking water. An expiration date on all premix labeling. A statement on all premix labeling (feed and drinking water forms) that 25-hydroxyvitamin D3 cannot be used simultaneously in both feed and water.

(q) Additional Officially Recognized Vitamin Ingredients for Animal Feed Use at Nutritional Levels and in Conformity with Current Good Manufacturing Practices.

(1) Ascorbic acid (21 CFR 582.5013). Article or Substance Indicated: Crystalline ascorbic acid commercial feed grade. Status Under Food Additive Amendments: GRAS.

(2) L-Ascorbyl-2-polyphosphate. Article or Substance Indicated: Stabilized ascorbic acid feed grade.

(3) L-Ascorbyl-2-sulfate. Article or Substance Indicated: Stabilized ascorbic acid feed grade. Status Under Food Additive Amendments 21 CFR: Aquatic species (salmon, trout, catfish, shrimp, and tilapia).

(4) Biotin (21 CFR 582.5159). Article or Substance Indicated: Biotin - commercial feed grade. Status Under Food Additive Amendments: GRAS.

(5) Calcium ascorbate. Article or Substance Indicated: Commercial grade. Status Under Food Additive Amendments: Vitamin C activity in dry feeds (<13 percent moisture) only.

(6) Calcium L-ascorbyl-2- monophosphate. Article or Substance Indicated: Stabilized ascorbic acid feed grade, may be used in the feed of any species provided that it is not promoted for species that do not have a dietary requirement for vitamin C.

(7) Calcium pantothenate (21 CFR 582.5212). Article or Substance Indicated: Crystalline calcium pantothenate - commercial feed grade. Status Under Food Additive Amendments: GRAS.

(8) Carotene (21 CFR 582.5245). Article or Substance Indicated: The refined crystalline carotene fraction of plants. Status Under Food Additive Amendments: GRAS.

(9) Choline chloride (21 CFR 582.5252). Article or Substance Indicated: Choline chloride - commercial feed grade. Status Under Food Additive Amendments: GRAS.

(10) Choline pantothenate. Article or Substance Indicated: Crystalline choline pantothenate - commercial feed grade.

(11) Choline xanthate (21 CFR 573.300). Article or Substance Indicated: Choline xanthate - commercial feed grade.

(12) Erythorbic acid (Iso ascorbic acid) (21 CFR 582.3041). Article or Substance Indicated: Either the acid or the sodium salt.

(13) Folic acid. Article or Substance Indicated: Crystalline folic acid - commercial feed grade.

(14) Herring oil. Article or Substance Indicated: The oil extracted from whole parts of herring.

(15) Inositol (21 CFR 582.5370). Article or Substance Indicated: Vitamin B complex vitamin; lipotropic, chemical name - cyclohexanehexol. Also referred to as i-inostol or meso-inositol. Status Under Food Additive Amendments: GRAS.

(16) Magnesium L-ascorbyl-2- phosphate. Article or Substance Indicated: Stablized ascorbic acid. Status Under Food Additive Amendments: Fish feeds only.

(17) Menadione. Article or Substance Indicated: Crystalline menadione - commercial feed grade. Status Under Food Additive Amendments: Poultry two (2) to four (4) grams per ton.

(18) Menadione dimethylpyrimidinol bisulfite (21 CFR 573.620). Article or Substance Indicated: Crystalline menadione - dimethylpyrimidinol bisulfite-commercial feed grade. Status Under Food Additive Amendments: Chicken and turkey feeds at two (2) grams per ton Growing and finishing swine feeds at 10 grams per ton.

(19) Menadione nicotinamide bisulfite (21 CFR 573.625). Article or Substance Indicated: Source of vitamin K activity and supplemental niacin. Status Under Food Additive Amendments: Chicken and turkey feeds at two (2) grams per ton. Growing and finishing swine feeds at 10 grams per ton.

(20) Menadione sodium bisulfite complex. Article or Substance Indicated: The addition product of menadione and sodium bisulfite containing not less than 30 percent of menadione. Status Under Food Additive Amendments: Poultry two (2) to four (4) grams per ton.

(21) Menhaden oil. Article or Substance Indicated: The oil extracted from whole menhaden.

(22) Niacin; nicotinic acid (21 CFR 582.5530). Article or Substance Indicated: Crystalline nicotine acid - commercial feed grade. Status Under Food Additive Amendments: GRAS.

(23) Niacinamide; nicotinamide (21 CFR 582.5535). Article or Substance Indicated: Crystalline amide of nicotinic acid - commercial feed grade. Status Under Food Additive Amendments: GRAS.

(24) p-Aminobenzoic acid. Article or Substance Indicated: p-Aminobenzoic acid - commercial feed grade.

(25) Pyridoxine hydrochloride (21 CFR 582.5676). Article or Substance Indicated: Crystalline chloride of pyridoxine - commercial feed grade. Status Under Food Additive Amendments: GRAS.

(26) Riboflavin (21 CFR 582.5695). Article or Substance Indicated: Crystalline riboflavin-commercial feed grade. Status Under Food Additive Amendments: GRAS.

(27) Salmon oil. Article or Substance Indicated: The oil extracted from cannery refuse of salmon.

(28) Salmon liver oil. Article or Substance Indicated: The oil extracted from salmon livers.

(29) Sardine oil. Article or Substance Indicated: The oil extracted from cannery refuse of the packing of sardine.

(30) Shark liver oil. Article or Substance Indicated: The oil extracted from shark liver.

(31) Thiamine hydrochloride (21 CFR 582.5875). Article or Substance Indicated: Crystalline chloride of thiamine - commercial feed grade. Status Under Food Additive Amendments: GRAS.

(32) Thiamine mononitrate (21 CFR 582.5878). Article or Substance Indicated: Crystalline mononitrate of thiamine - commercial feed grade. Status Under Food Additive Amendments: GRAS.

(33) Tocopherol (21 CFR 582.5890). Article or Substance Indicated: a-Tocopherol - commercial feed grade. Status Under Food Additive Amendments: GRAS.

(34) a-Tocopherol acetate (21 CFR 582.5892). Article or Substance Indicated: Commercial feed grade dl-a- tocopheryl acetate d-a-tocopheryl acetate. Status Under Food Additive Amendments: GRAS.

(35) Tuna oil. Article or Substance Indicated: The oil extracted from cannery refuse of tuna.

(36) Vitamin A acetate (21 CFR 582.5933). Article or Substance Indicated: Vitamin A acetate - commercial feed grade. Status Under Food Additive Amendments: GRAS.

(37) Vitamin A palmitate (21 CFR 582.5936). Article or Substance Indicated: Vitamin A palmitate - commercial feed grade. Status Under Food Additive Amendments: GRAS.

(38) Vitamin A propionate. Article or Substance Indicated: Consists of retinol or esters of retinol formed from edible fatty acids.

(39) Wheat germ oil. Article or Substance Indicated: The oil extracted or expressed from wheat germ.

(r) Source of Vitamins and Their Levels.

(1) “Vitamin Compound” is the term to be used in ingredient statement when declaring fortification.

(2) “Vitamin” is the term to be used in guaranteed analysis statement when guaranteeing the level of the vitamin.

(3) “Vitamin/Vitamin Compound” is the ratio based on molecular weights and may not be proportional to biological activity.

(4) Vitamin Compound: L-Ascorbyl-2-polyphosphate. Vitamin: Ascorbic acid. Vitamin/Vitamin Compound: 0.800.

(5) Vitamin Compound: Menadione dimethylpyrimidinol bisulfite. Vitamin: Menadione. Vitamin/Vitamin Compound: 0.454.

(6) Vitamin Compound: Menadione sodium bisulfite complex. Vitamin: Menadione. Vitamin/Vitamin Compound: 0.330.

(7) Vitamin Compound: Riboflavin-5-phosphate. Vitamin: Riboflavin. Vitamin/Vitamin Compound: 0.730.

(8) Vitamin Compound: d-Calcium pantothenate. Vitamin: d-Pantothenic acid. Vitamin/Vitamin Compound: 0.920.

(9) Vitamin Compound: Thiamine hydrochloride. Vitamin: Thiamine. Vitamin/Vitamin Compound: 0.892.

(10) Vitamin Compound: Thiamine mononitrate. Vitamin: Thiamine. Vitamin/Vitamin Compound: 0.919.

(11) Vitamin Compound: Pyridoxine hydrochloride. Vitamin: Vitamin B6. Vitamin/Vitamin Compound: 0.823.

(12) Vitamin Compound: Choline chloride. Vitamin: Choline. Vitamin/Vitamin Compound: 0.746.

(13) Vitamin Compound: Choline bitartrate. Vitamin: Choline. Vitamin/Vitamin Compound: 0.469.

(14) Vitamin Compound: Sodium ascorbate. Vitamin: Ascorbic acid. Vitamin/Vitamin Compound: 0.889.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2807. Wheat Products.

(a) General Provisions.

(1) When “Ground Wheat Screenings” are added to any wheat product such screenings added must be limited to ground wheat screenings not exceeding the run of the mill; and screenings from outside sources must not be added. The declaration of “ground wheat screenings” must be made in the name and in the same size type as the product name itself; i.e., “Wheat Bran with Ground Wheat Screenings,” “Wheat Shorts with Ground Wheat Screenings.”

(b) Defatted Wheat Germ Meal is obtained after the removal of part of the oil or fat from wheat germ meal and must contain not less than 30 percent crude protein.

(c) Wheat Bran is the coarse outer covering of the wheat kernel as separated from cleaned and scoured wheat in the usual process of commercial milling.

(d) Wheat Flour consists principally of wheat flour together with fine particles of wheat bran, wheat germ, and the offal from the "tail of the mill." This product must be obtained in the usual process of commercial milling and must contain not more than 1.5 percent crude fiber.

(e) Wheat Germ Meal consists chiefly of wheat germ together with some bran and middlings or shorts. It must contain not less than 25 percent crude protein and seven (7) percent crude fat.

(f) [Specify] Wheat Gluten is the major water-insoluble proteinaceous fraction of wheat, consisting primarily of gliadin and glutenin proteins. Wheat gluten is prepared from wheat flour that is free from other seeds and foreign matter, by washing with water to remove most of the water-soluble non-protein components. Vital Wheat Gluten is dried gluten that has retained its viscoelasticity when hydrated, whereas Devitalized Wheat Gluten has reduced viscoelasticity as a result of denaturation by heat. Moisture content shall not exceed 10 percent. Wheat gluten, on a moisture-free basis, must contain not less than 80 percent crude protein (crude protein based on N x 6.25), and not more than 1.5 percent crude fiber and two (2.0) percent ash. (For identification of the viscoelastic properties on the ingredient label, "vital" or "devitalized" must be specified.) The words "vital" or "devitalized" are not required when listing as an ingredient in a manufactured feed.

(g) Wheat Middlings consists of fine particles of wheat bran, wheat shorts, wheat germ, wheat flour, and some of the offal from the "tail of the mill." This product must be obtained in the usual process of commercial milling and must contain not more than 11 percent crude fiber.

(h) Wheat Mill Run consists of coarse wheat bran, fine particles of wheat bran, wheat shorts, wheat germ, wheat flour, and the offal from the "tail of the mill." This product must be obtained in the usual process of commercial milling and must contain not more than 9.5 percent crude fiber.

(i) Wheat Red Dog consists of the offal from the "tail of the mill" together with some fine particles of wheat bran, wheat germ, and wheat flour. This product must be obtained in the usual process of commercial milling and must contain not more than four (4) percent crude fiber.

(j) Wheat Shorts consists of fine particles of wheat bran, wheat germ, wheat flour, and the offal from the "tail of the mill." This product must be obtained in the usual process of commercial milling and must contain not more than seven (7) percent crude fiber.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2808. Whole Grains.

(a) Whole grains are the feed grade seed of a plant which have not been processed (heated, steamed, rolled, crimped, ground, etc.) or mixed with another type of grain.

(b) Whole grains shall not contain more than five (5.0) percent foreign material. Foreign material includes all matter except the cultivated grain or seed.

(c) Whole grains shall be named using the common name of the species, including but not limited to corn, barley, grain sorghum, rye, wheat, oats, triticale, brown rice, rice, milo.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2809. Yeast.

(a) Active Dry Yeast is yeast which has been dried in such a manner as to preserve a large portion of its fermenting power. It must contain no added cereal or filler and must contain not less than 15 billion live yeast cells per gram.

(b) Brewers Dried Yeast is the dried, non-fermentative, non-extracted yeast of the botanical classification Saccharomyces resulting as a by-product from the brewing of beer and ale. It must contain not less than 35 percent crude protein. It must be labeled according to its crude protein content.

(c) Brewers Liquid Yeast is the non-fermentative, non-extracted yeast of the botanical classification Saccharomyces resulting as a by-product from the brewing of beer and ale. It must contain not less than 35 percent crude protein on a dry weight basis. The guaranteed analysis shall include the maximum moisture.

(d) Grain Distillers Dried Yeast is the dried, non-fermentative yeast of the botanical classification Saccharomyces resulting from the fermentation of grains and yeast, separated from the mash, either before or after distillation. It must contain not less than 40 percent crude protein.

(e) Hydrolyzed Yeast is a concentrated, non-extracted, partially soluble, yeast digest. Solubilization is accomplished by enzymatic hydrolysis of whole Saccharomyces cerevisiae cells. Salts may be added as processing aids in accordance with good manufacturing practices. It must not contain less than 35 percent crude protein.

(f) Irradiated Dried Yeast, Irradiated [Specify] Dried Yeast is the dried, non-fermentative yeast which has been subjected to ultraviolet rays in order to produce anti-rachitic potency. When Irradiated Dried Yeast or Irradiated [Specify] Dried Yeast is used as an ingredient of proprietary feeds for four-footed animals, the name may be followed by a parenthetical phrase (Source of Vitamin D_2).

(g) Molasses Hydrolyzed Yeast is a concentrated, non-extracted, partially soluble yeast digest. Yeast cells are sourced from the fermentation of molasses for ethanol production. Solubilization is accomplished by enzymatic hydrolysis of whole Saccharomyces cerevisiae cells. Salts may be added as processing aids in accordance with good manufacturing practices. It must not contain less than 30 percent crude protein.

(h) Molasses Yeast Condensed Solubles is obtained by condensing to a syrup consistency the broth remaining after the removal of baker's yeast cells propagated on molasses.

(i) Primary Dried Yeast or Dried Yeast is the dried, non-fermentative yeast of the botanical classification Saccharomyces which has been separated from the medium in which propagated. It must consist of yeast cells with no fillers and contain not less than 40 percent crude protein.

(j) Scheffersomyces stipitis Dried Yeast is the dried, non-viable yeast of the botanical classification Scheffersomyces stipitis that has been grown on thin stillage from the ethanol production process from the fermentation of a grain or grain mixture, and is separated by centrifugation from the media on which it was propagated. The product is produced in accordance with good manufacturing practices to control the potential for mycotoxin and other contaminants. The product is intended as a source of protein in cattle, sheep, goat, and swine feeds at levels up to 15 percent. It must contain not less than 40 percent crude protein. The label shall include guarantees for minimum crude protein and crude fat and maximum sulfur contents. Non-protein nitrogen content must be guaranteed when added.

(k) Torula Dried Yeast or Candida Dried Yeast is the dried, non-fermentative yeast of the botanical classification (torulopsis) Candida utilis (formerly Torulopsis utilis) which has been separated from the medium in which propagated. It must contain not less than 40 percent crude protein.

(l) Yeast Culture is the dried product composed of yeast (Saccharomyces cerevisiae and/or Kluyveromyces marxianus) and the media on which it was grown, dried in such a manner as to preserve the fermenting activity of the yeast. The media must be stated on the label. No reference to media in main ingredient listing is required when yeast culture forms a component of a proprietary mixed feed.

(m) Yeast Extract is the concentrated solubles of mechanically ruptured cells of a selected strain of the yeast, Saccharomyces cerevisiae. It may be dried or concentrated. It must contain not less than nine (9) percent crude protein.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2810. CFR Listed Feed Ingredients.

(a) The following list of Least Common Feed Ingredients are listed in 21 CFR 573 as food additives or 21 CFR 582 as GRAS ingredients. Ingredients marked with an asterisk (*) are also defined elsewhere in this Article.

(b) 21 CFR 573 Food Additives Permitted in Feed and Drinking Water of Animals.

(1) Subpart B Food Additive Listing.

(A) Acrylamide-acrylic acid resin (21 CFR 573.120); Ethylene dichloride (21 CFR 573.440); Hydrogenated corn syrup (21 CFR 573.530); Odorless light petroleum hydrocarbons (21 CFR 573.740); Poly(2-vinylpryidine-co-styrene) (21 CFR 573.870); Normal propyl alcohol (21 CFR 573.880); Xanthan gum* (21 CFR 573.1010).

(c) 21 CFR 582 Substances Generally Recognized as Safe in Animal Feeds.

(1) 21 CFR 582.80 Trace Minerals Added to Animal Feeds. These substances added to animal feeds as nutritional dietary supplements are generally recognized as safe when added at levels consistent with good feeding practices. All substances listed may be in anhydrous or hydrated form.

(A) Cobalt: Cobalt acetate*; Cobalt carbonate*; Cobalt chloride*; Cobalt oxide*; Cobalt sulfate*.

(B) Copper: Copper carbonate*; Copper chloride*; Copper gluconate*; Copper hydroxide*; Copper orthophosphate*; Copper oxide*; Copper pyrophosphate; Copper sulfate*.

(C) Iodine: Calcium iodate*; Calcium iodobehenate*; Cuprous iodide*; 3,5-Diiodosalicylic acid*; Ethylenediamine dihydroiodide*; Potassium iodate*; Potassium iodide*; Sodium iodate*; Sodium iodide*; Thymol iodide*.

(D) Iron: Iron ammonium citrate*; Iron carbonate*; Iron chloride*; Iron gluconate*; Iron oxide*; Iron phosphate*; Iron pyrophosphate*; Iron sulfate*; Reduced iron*.

(E) Manganese: Manganese acetate*; Manganese carbonate*; Manganese citrate (soluble)*; Manganese chloride*; Manganese gluconate*; Manganese orthophosphate*; Manganese phosphate (dibasic)*; Manganese sulfate*; Manganous oxide*.

(F) Zinc: Zinc acetate*; Zinc carbonate*; Zinc chloride*; Zinc oxide*; Zinc sulfate*.

(2) Subpart B General Purpose Food Additives.

(A) Acetic acid (21 CFR 582.1005); Adipic acid (21 CFR 582.1009); Citric acid* (21 CFR 582.1033); Hydrochloric acid (21 CFR 582.1057); Lactic acid (21 CFR 582.1061); Malic acid (21 CFR 582.1069); Phosphoric acid* (21 CFR 582.1073); Potassium acid tartrate (21 CFR 582.1077); Sodium acid pyrophosphate (21 CFR 582.1087); Succinic acid (21 CFR 582.1091); Sulfuric acid (21 CFR 582.1095); Tartaric acid (21 CFR 582.1099); Aluminum sulfate* (21 CFR 582.1125); Aluminum ammonium sulfate (21 CFR 582.1127); Aluminum potassium sulfate (21 CFR 582.1129); Aluminum sodium sulfate (21 CFR 582.1131); Ammonium bicarbonate (21 CFR 582.1135); Ammonium carbonate (21 CFR 582.1137); Ammonium hydroxide (21 CFR 582.1139); Ammonium phosphate* (21 CFR 582.1141); Ammonium sulfate* (21 CFR 582.1143); Bentonite* (21 CFR 582.1155); Butane (21 CFR 582.1165); Calcium carbonate* (21 CFR 582.1191); Calcium chloride* (21 CFR 582.1193); Calcium citrate (21 CFR 582.1195); Calcium gluconate* (21 CFR 582.1199); Calcium hydroxide* (21

CFR 582.1205); Calcium lactate (21 CFR 582.1207); Calcium oxide* (21 CFR 582.1210); Calcium phosphate* (21 CFR 582.1217); Caramel (21 CFR 582.1235); Carbon dioxide (21 CFR 582.1240); Dextrans (21 CFR 582.1275); Glycerin* (21 CFR 582.1320); Glyceryl monostearate (21 CFR 582.1324); Helium (21 CFR 582.1355); Hydrogen peroxide (21 CFR 582.1366); Lecithin* (21 CFR 582.1400); Magnesium carbonate* (21 CFR 582.1425); Magnesium hydroxide* (21 CFR 582.1428); Magnesium oxide* (21 CFR 582.1431); Methylcellulose (21 CFR 582.1480); Monoammonium glutamate (21 CFR 582.1500); Monopotassium glutamate (21 CFR 582.1516); Nitrogen (21 CFR 582.1540); Papain* (21 CFR 582.1585); Potassium bicarbonate* (21 CFR 582.1613); Potassium carbonate* (21 CFR 582.1619); Potassium citrate* (21 CFR 582.1625); Potassium hydroxide* (21 CFR 582.1631); Potassium sulfate* (21 CFR 582.1643); Propane (21 CFR 582.1655); Propylene glycol* (21 CFR 582.1666); Rennet (21 CFR 582.1685); Silica aerogel (21 CFR 582.1711); Sodium acetate (21 CFR 582.1721); Sodium bicarbonate* (21 CFR 582.1736); Sodium carbonate* (21 CFR 582.1742); Sodium carboxymethylcellulose* (21 CFR 582.1745); Sodium caseinate (21 CFR 582.1748); Sodium citrate (21 CFR 582.1751); Sodium hydroxide (21 CFR 582.1763); Sodium pectinate (21 CFR 582.1775); Sodium phosphate* (21 CFR 582.1778); Sodium aluminum phosphate (21 CFR 582.1781); Sodium sesquicarbonate* (21 CFR 582.1792); Sodium potassium tartrate (21 CFR 582.1804); Sodium tripolyphosphate* (21 CFR 582.1810); Triacetin (21 CFR 582.1901); Beeswax (21 CFR 582.1973); Bleached beeswax (21 CFR 582.1975); Carnauba wax (21 CFR 582.1978).

(3) Subpart C Anticaking Agents.

(A) Aluminum calcium silicate (21 CFR 582.2122); Calcium silicate* (21 CFR 582.2227); Magnesium silicate (21 CFR 582.2437); Sodium aluminosilicate*; (21 CFR 582.2727); Hydrated sodium calcium aluminosilicate (21 CFR 582.2729); Tricalcium silicate (21 CFR 582.2906).

(4) Subpart D Chemical Preservatives.

(A) Ascorbic acid* (21 CFR 582.3013); Benzoic acid* (21 CFR 582.3021); Erythorbic acid* (21 CFR 582.3041); Propionic acid* (21 CFR 582.3081); Sorbic acid* (21 CFR 582.3089); Thiodipropionic acid* (21 CFR 582.3109); Ascorbyl palmitate* (21 CFR 582.3149); Butylated hydroxyanisole* (21 CFR 582.3169); Butylated hydroxytoluene* (21 CFR 582.3173); Calcium ascorbate* (21 CFR 582.3189); Calcium propionate* (21 CFR 582.3221); Calcium sorbate* (21 CFR 582.3225); Dilauryl thiodipropionate* (21 CFR 582.3280); Gum guaiac* (21 CFR 582.3336); Methylparaben* (21 CFR 582.3490); Potassium bisulfite* (21 CFR 582.3616); Potassium metabisulfite* (21 CFR 582.3637); Potassium sorbate* (21 CFR 582.3640); Propyl gallate* (21 CFR 582.3660); Propylparaben* (21 CFR 582.3670); Sodium ascorbate* (21 CFR 582.3731); Sodium benzoate* (21 CFR 582.3733); Sodium bisulfite* (21 CFR 582.3739); Sodium metabisulfite* (21 CFR 582.3766); Sodium propionate* (21 CFR 582.3784); Sodium sorbate* (21 CFR 582.3795); Sodium sulfite* (21 CFR 582.3798); Stannous chloride* (21 CFR 582.3845); Sulfur dioxide* (21 CFR 582.3862); Tocopherols (21 CFR 582.3890).

(5) Subpart E Emulsifying Agents.

(A) Diacetyl tartaric acid esters of mono- and diglycerides of edible fats or oils, or edible fat- forming fatty acids* (21 CFR 582.4101); Mono- and diglycerides of edible fats or oils, or edible fat- forming acids* (21 CFR 582.4505); Monosodium phosphate derivatives of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids* (21 CFR 582.4521); Propylene glycol* (21 CFR 582.4666).

(6) Subpart F Nutrients and/or Nutritional Supplements. Amino acids listed in this subpart may be free hydrochloride salt, hydrated, or anhydrous form, where applicable.

(A) Ascorbic acid* (21 CFR 582.5013); Aspartic acid (21 CFR 582.5017); Aminoacetic acid (glycine)* (21 CFR 582.5049); Linoleic acid (21 CFR 582.5065); Alanine (21 CFR 582.5118); Arginine* (21 CFR 582.5145); Biotin* (21 CFR 582.5159); Calcium carbonate* (21 CFR 582.5191); Calcium citrate (21 CFR 582.5195); Calcium glycerophosphate (21 CFR 582.5201); Calcium oxide* (21 CFR 582.5210); Calcium pantothenate* (21 CFR 582.5212); Calcium phosphate* (21 CFR 582.5217); Calcium pyrophosphate (21 CFR 582.5223); Calcium sulfate* (21 CFR 582.5230); Carotene* (21 CFR 582.5245); Choline bitartrate* (21 CFR 582.5250); Choline chloride* (21 CFR 582.5252); Copper gluconate* (21 CFR 582.5260); Cysteine (21 CFR 582.5271); Cystine (21 CFR 582.5273); Ferric phosphate* (21 CFR 582.5301); Ferric pyrophosphate* (21 CFR 582.5304); Ferric sodium pyrophosphate (21 CFR 582.5306); Ferrous gluconate* (21 CFR 582.5308); Ferrous lactate (21 CFR 582.5311); Ferrous sulfate* (21 CFR 582.5315); Histidine (21 CFR 582.5361); Inositol* (21 CFR 582.5370); Iron reduced* (21 CFR 582.5375); Isoleucine (21 CFR 582.5381); Leucine (21 CFR 582.5406); Lysine* (21 CFR 582.5411); Magnesium oxide* (21 CFR 582.5431); Magnesium phosphate* (21 CFR 582.5434); Magnesium sulfate* (21 CFR 582.5443); Manganese chloride* (21 CFR 582.5446); Manganese citrate* (21 CFR 582.5449); Manganese gluconate* (21 CFR 582.5452); Manganese glycerophosphate (21 CFR 582.5455); Manganese hypophosphite (21 CFR 582.5458); Manganese sulfate* (21 CFR 582.5461); Manganous oxide* (21 CFR 582.5464); Mannitol (21 CFR 582.5470); Methionine* (21 CFR 582.5475); Methionine hydroxy analog and its calcium salts* (21 CFR 582.5477); Niacin* (21 CFR 582.5530); Niacinamide* (21 CFR 582.5535); D-Pantothenyl alcohol (21 CFR 582.5580); Phenylalanine (21 CFR 582.5590); Potassium chloride* (21 CFR 582.5622); Potassium glycerophosphate (21 CFR 582.5628); Potassium iodide* (21 CFR 582.5634); Proline (21 CFR 582.5650); Pyridoxine hydrochloride* (21 CFR 582.5676); Riboflavin* (21 CFR 582.5695); Riboflavin-5-phosphate* (21 CFR 582.5697); Serine (21 CFR 582.5701); Sodium pantothenate (21 CFR 582.5772); Sodium phosphate* (21 CFR 582.5778); Sorbitol (21 CFR 582.5835); Thiamine hydrochloride* (21 CFR 582.5875); Thiamine mononitrate* (21 CFR 582.5878); Threonine* (21 CFR 582.5881); Tocopherols* (21 CFR 582.5890); Alpha-tocopherol acetate* (21 CFR 582.5892); Tryptophane* (21 CFR 582.5915); Tyrosine* (21 CFR 582.5920); Valine (21 CFR 582.5925); Vitamin A* (21 CFR 582.5930); Vitamin A acetate* (21 CFR 582.5933); Vitamin A palmitate* (21 CFR 582.5936); Vitamin B12* (21 CFR 582.5945); Vitamin D2* (21 CFR 582.5950);

Vitamin D3* (21 CFR 582.5953); Zinc chloride* (21 CFR 582.5985); Zinc gluconate (21 CFR 582.5988); Zinc oxide* (21 CFR 582.5991); Zinc stearate (21 CFR 582.5994); Zinc sulfate* (21 CFR 582.5997).

(7) Subpart G Sequestrants.

(A) Citric acid* (21 CFR 582.6033); Sodium acid phosphate (21 CFR 582.6085); Tartaric acid (21 CFR 582.6099); Calcium acetate (21 CFR 582.6185); Calcium chloride* (21 CFR 582.6193); Calcium citrate (21 CFR 582.6195); Calcium diacetate (21 CFR 582.6197); Calcium gluconate* (21 CFR 582.6199); Calcium hexametaphosphate (21 CFR 582.6203); Monobasic calcium phosphate* (21 CFR 582.6215); Calcium phytate (21 CFR 582.6219); Dipotassium phosphate (21 CFR 582.6285); Disodium phosphate* (21 CFR 582.6290); Isopropyl citrate (21 CFR 582.6386); Monoisopropyl citrate (21 CFR 582.6511); Potassium citrate* (21 CFR 582.6625); Sodium citrate (21 CFR 582.6751); Sodium diacetate (21 CFR 582.6754); Sodium gluconate (21 CFR 582.6757); Sodium hexametaphosphate* (21 CFR 582.6760); Sodium metaphosphate (21 CFR 582.6769); Sodium phosphate* (21 CFR 582.6778); Sodium pyrophosphate (21 CFR 582.6787); Tetra sodium pyrophosphate* (21 CFR 582.6789); Sodium tartrate (21 CFR 582.6801); Sodium potassium tartrate (21 CFR 582.6804); Sodium thiosulfate (21 CFR 582.6807); Sodium tripolyphosphate* (21 CFR 582.6810); Stearyl citrate (21 CFR 582.6851).

(8) Subpart H Stabilizers.

(A) Agar-agar (21 CFR 582.7115); Guar gum* (21 CFR 582.7339); Ammonium alginate (21 CFR 582.7133); Locust bean gum* (21 CFR 582.7343); Calcium alginate (21 CFR 582.7187); Sterculia gum (21 CFR 582.7349); Chondrus extract* (21 CFR 582.7255); Gum tragacanth (21 CFR 582.7351); Gum Arabic (21 CFR 582.7330); Potassium alginate (21 CFR 582.7610); Gum ghatti (21 CFR 582.7333); Sodium alginate (21 CFR 582.7724).

(9) Spices and Other Natural Seasonings and Flavorings (21 CFR 582.10). Botanical name of plant source is in the CFR.

(A) Alfalfa herb and seed*; Allspice; Ambrette seed; Angelica; Angelica root; Angelica seed; Angostura (cusparia bark); Anise*; Anise, star; Balm (lemon balm) Basil, bush; Basil, sweet Bay Calendula; Camomile (chamomile), English or Roman; Camomile (chamomile), German or Hungarian; Capers; Capsicum*; Caraway; Caraway, black (black cumin); Cardamom (cardamon); Cassia, Chinese; Cassia, Padang or Batavia; Cassia, Saigon; Cayenne pepper; Celery seed; Chervil; Chives; Cinnamon, Ceylon; Cinnamon, Chinese; Cinnamon, Saigon; Clary (clary sage); Clover; Cloves; Coriander; Cumin (cummin); Cumin, black (black caraway); Dill; Elder flowers; Fennel, common*; Fennel, sweet (finocchio, Florence fennel)*; Fenugreek*; Galanga (galangal); Garlic; Geranium; Ginger*; Glycyrrhiza; Grains of paradise; Horehound (hoarhound); Horseradish; Hyssop; Lavender; Licorice; Linden flowers; Mace; Marigold, pot; Marjoram, pot; Marjoram, sweet; Mustard, black or brown; Mustard, brown; Mustard, white or yellow; Nutmeg; Oregano (oreganum, Mexican oregano, Mexican sage, origan); Paprika; Parsley; Pepper, black; Pepper, cayenne; Pepper, red; Pepper, white;

Peppermint; Poppy seed; Pot marigold; Pot marjoram; Rosemary; Rue; Saffron; Sage; Sage, Greek; Savory, summer; Savory, winter; Sesame; Spearmint; Star anise; Tarragon; Thyme; Thyme, wild or creeping; Turmeric; Vanilla; Zedoary.

(10) Essential Oils, Oleoresins (Solvent-Free), and Natural Extractives (Including Distillates) As a Source of Flavor (21 CFR 582.20). Botanical name of plant source is in the CFR.

(A) Alfalfa; Allspice; Almond, bitter (free from prussic acid); Ambrette (seed); Angelica root; Angelica seed; Angelica stem; Angostura (cusparia bark); Anise; Asafetida; Balm (lemon balm); Balsam of Peru; Basil; Bay leaves; Bay (myrcia oil); Bergamot (bergamot orange); Bitter almond (free from prussic acid); Bois de rose; Cacao; Camomile (chamomile) flowers, Hungarian; Camomile (chamomile) flowers, Roman or English; Cananga; Capsicum; Caraway; Cardamom seed (cardamon); Carob bean; Carrot; Cascarilla bark; Cassia bark, Chinese; Cassia bark, Padang or Batavia; Cassia bark, Saigon; Celery seed; Cherry, wild, bark; Chervil; Chicory; Cinnamon bark, Ceylon; Cinnamon bark, Chinese; Cinnamon bark, Saigon; Cinnamon leaf, Ceylon; Cinnamon leaf, Chinese; Cinnamon leaf, Saigon; Citronella; Citrus peels; Clary (clary sage); Clove bud; Clove leaf; Clove stem; Clover; Coca (decocainized); Coffee; Cola nut; Coriander; Corn silk; Cumin (cummin); Curacao orange peel (orange, bitter peel); Cusparia bark; Dandelion; Dandelion root; Dill; Dog grass (quackgrass, triticum); Elder flowers; Estragole (esdragol, esdragon, tarragon); Estragon (tarragon); Fennel, sweet Fenugreek; Galanga (galangal); Garlic; Geranium; Geranium, East Indian; Geranium, rose; Ginger; Glycyrrhiza; Glycyrrhizin, ammoniated*; Grapefruit; Guava; Hickory bark; Horehound (hoarhound); Hops; Horsemint; Hyssop; Immortelle; Jasmine; Juniper (berries); Kola nut; Laurel berries; Laurel leaves; Lavender; Lavender, spike; Lavandin; Lemon; Lemon balm (see balm); Lemon grass; Lemon peel; Licorice; Lime; Linden flowers; Locust bean; Lupulin; Mace; Malt (extract); Mandarin; Marjoram, sweet; Mate 1; Melissa (see balm); Menthol; Menthyl acetate; Molasses (extract); Mustard; Naringin; Neroli, bigarade; Nutmeg; Onion; Orange, bitter, flowers; Orange, bitter, peel; Orange leaf; Orange, sweet; Orange, sweet, flowers; Orange, sweet, peel; Origanum; Palmarosa; Paprika; Parsley; Pepper, black; Pepper, white; Peppermint; Peruvian balsam; Petitgrain; Petitgrain lemon; Petitgrain mandarin or tangerine; Pimenta; Pimenta leaf; Pipsissewa leaves; Pomegranate; Prickly ash bark; Rose absolute; Rose (otto of roses, attar of roses); Rose buds; Rose flowers; Rose fruit (hips); Rose geranium; Rose leaves; Rosemary; Rue; Saffron; Sage; Sage, Greek; Sage, Spanish; St. John’s bread; Savory, summer; Savory, winter; Schinus molle; Sloe berries (blackthorn berries); Spearmint; Spike lavender; Tamarind; Tangerine; Tannic acid; Tarragon; Tea; Thyme; Thyme, white; Thyme, wild or creeping; Triticum (see dog grass); Tuberose; Turmeric; Vanilla; Violet flowers; Violet leaves; Violet leaves absolute; Wild cherry bark; Ylang-ylang; Zedoary bark.

(11) Natural Substances Used in Conjunction with Spices and Other Natural Seasonings and Flavorings (21 CFR 582.30). Botanical name of plant source is in the CFR.

(A) Algae, brown (kelp); Algae, red; Dulse.

(12) Natural Extractives (Solvent-Free) Used in Conjunction with Spices, Seasonings, and Flavorings (21 CFR 582.40). Botanical name of plant source is in the CFR.

(A) Algae, brown; Algae, red; Apricot kernel (persic oil); Dulse; Kelp (sea algae, brown); Peach kernal (persic oil); Peanut stearine; Persic oil (see apricot kernel and peach kernel); Quince seed.

(13) Certain Other Spices, Seasonings, Essential Oils, Oleoresins, and Natural Extracts (21 CFR 582.50). Scientific name of source is in the CFR.

(A) Ambergris; Castioreum; Civet (zibeth, zibet, zibetum); Cognac oil, white and green; Musk (Tonquin musk).

(14) Synthetic Flavoring Substances and Adjuvants (21 CFR 582.60).

(A) Acetaldehyde (ethanal); Acetoin (acetyl methylcarbinol); Aconitic acid (equisetic acid, citridic acid, achilleic acid); Anethole (parapropenyl anisole); Benzaldehyde (benzoic aldehyde); N-Butyric acid (butanoic acid); d-or l-Carvone (carvol); Cinnamaldehyde (cinnamic aldehyde); Citral (2,6-dimethyloctadien-2,6,al-8, geranial, neral); Decanal (N-decylaldehyde, capraldehyde, capric aldehyde, caprinaldehyde, aldehydeC-10); Diacetyl (2,3-butandeione); Ethyl acetate; Ethyl butyrate; 3-Methyl-3-phenyl glycidic acid ethyl ester (ethyl-methyl-phenyl-glycidate, so-called strawberry aldehyde, C-16 aldehyde); Ethyl vanillin; Eugenol; Geraniol (3,7-dimethyl-2,6 and 3,6-octadien-l-ol); Geranyl acetate (geraniol acetate); Glycerol (glyceryl) tributyrate (tributyrin, butyrin); Limonene (d-, l-, and dl-); Linalool (linalol, 3,7-dimethyl-1,6- octadien-(3-ol); Linalyl acetate (bergamol); l-Malic acid; Methyl anthranilate (methyl-2- aminobenzoate); Piperonal (3,4-methylenedioxy- benzaldehyde-heliotropin); Vanillin.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.

§2811. GRAS Notified Substances Intended for Animal Food.

(a) General Provisions.

(1) The following is a list of GRAS Notices filed voluntarily by the notifiers pursuant to 21 CFR 570.205 that the FDA has evaluated (21 CFR 570.265) and determined that it had no questions regarding the conclusion that the notified animal food substance is GRAS under the intended conditions of use.

(2) The filed notice and the FDA response letter provide information (identity, manufacture, specifications, intended effect, and safety) on the substance under the intended use conditions; the most up-to-date version is posted at the following website: https://www.fda.gov/animal-veterinary/generally-recognized-safe-gras-notification-program/current-animal-food-gras-notices-inventory.

(b) Hydrophobic silica. Common or Usual Name: Hydrophobic silica. Intended Use: As a defoaming component of a defoamer used in the removal of oil from condensed distillers solubles, at levels up to 20 parts per million. Intended Species: Beef cattle,

dairy cattle, poultry (turkey, broiler chickens, and egg laying hens), sheep, goats, and swine.

(c) Polyethylene glycol (400) dioleate. Common or Usual Name: Polyethylene glycol (400) dioleate. Intended Use: As an emulsifier component of a defoamer used in the removal of oil from condensed distillers, at levels up to 64 parts per million. Intended Species: Beef cattle, dairy cattle, poultry (turkey, broiler chickens, and egg laying hens), sheep, goats, and swine.

(d) Polyoxyethylene (20) sorbitan monostearate (polysorbate 60). Common or Usual Name: Polysorbate 60. Intended Use: As an emulsifier component of a defoamer used in the removal of oil from condensed distillers solubles, at levels up to 20 parts per million. Intended Species: Beef cattle, dairy cattle, poultry (turkey, broiler chickens, and egg laying hens), sheep, goats, and swine.

(e) Phytase enzyme produced by an Aspergillus oryzae strain expressing a synthetic gene coding for a 6-phytase from Citrobacter braakii. Common or Usual Name: Phytase. Intended Use: To increase the digestibility of phytin-bound phosphorous or to increase phosphorous availability from phytate in poultry diets when fed at the rate of 250–4000 FYT/kg feed. Intended Species: Poultry (turkey, broiler chickens, and egg laying hens).

(f) Phytase enzyme produced by an Aspergillus oryzae strain expressing a synthetic gene coding for a 6-phytase from Citrobacter braakii. Common or Usual Name: Phytase. Intended Use: To increase the digestibility of phytin-bound phosphorous or to increase phosphorous availability from phytate in swine diets when fed at the rate of 500–4000 FYT/kg feed. Intended Species: Swine.

(g) L-methionine 85 percent produced by a bioengineered Escherichia coli K-12. Common or Usual Name: L-methionine 85 percent. Intended Use: Nutrient at levels up to 0.3 percent in animal feed. Intended Species: All animals.

(h) Canthaxanthin. Common or Usual Name: Canthaxanthin. Intended Use: To be used in breeder hen diets at the rate of six (6) milligrams per kilogram of feed as a nutritive antioxidant to support the development of chicks. Intended Species: Breeder hens used for hatching egg production.

(i) L-Glutamine. Common or Usual Name: L-Glutamine. Intended Use: Utility information not evaluated for GRAS, see FDA’s letter for more information. Intended Species: Post-weaning horses.

(j) Inactivated modified Saccharomyces cerevisiae. Common or Usual Name: Saccharomyces cerevisiae expressing xylose isomerase from Piromyces sp. E2. Intended Use: As a component of animal feed when used in the fermentation of corn to produce ethanol. Intended Species: Poultry (broilers, layers, and breeding chickens; turkeys), swine (piglets, growers, finishers, gestating and lactating sows), bovine (beef and dairy), fish (salmonoids, catfish, tilapia), and minor species such as ducks, quail, sheep, and goats.

(k) Ground grain obtained from a corn (Zea mays) variety that expresses an altered appA 6-phytase gene obtained from Escherichia coli strain K12. Common or Usual

Name: Phytase. Intended Use: To increase the digestibility of phytin-bound phosphorous or to increase phosphorous availability from phytate in poultry feeds when used at a rate of 75 g to 1.7 kg per ton of complete feed and providing 250-6000 phytase units (FTU)/kg complete feed. Intended Species: Poultry.

(l) L-methionine 90 percent produced by a bioengineered Escherichia coli K-12. Common or Usual Name: L-methionine 90 percent. Intended Use: To be used as a nutrient in animal food. Intended Species: All animals.

(m) Dried Methylobacterium extorquens biomass. Common or Usual Name: Dried Methylobacterium extorquens biomass. Intended Use: To be used as a source of protein in food for finfish species at a level up to 10 percent of the diet. Intended Species: Finfish species.

(n) Ground grain obtained from a corn (Zea mays) variety that expresses an altered appA 6-phytase gene obtained from Escherichia coli strain K12 (transformation event PY203). Common or Usual Name: Phytase. Intended Use: To increase the digestibility of phytin-bound phosphorous or to increase phosphorous availability from phytate in swine feeds when used to provide 500-4500 phytase activity units (FTU)/kg complete feed. Intended Species: Swine.

(o) Clinoptilolite of sedimentary origin. Common or Usual Name: Clinoptilolite of sedimentary origin. Intended Use: To be used as an anti- caking agent at levels up to one (1) percent by weight in the complete diet. Intended Species: Cattle, swine, goats, sheep, broiler chickens, turkeys for meat.

(p) Ground grain obtained from a corn (Zea mays) variety that expresses an altered AC1 beta-glucanase gene obtained from an environmental DNA library (transformation event FG259). Common or Usual Name: Beta-glucanase. Intended Use: To decrease viscosity of digesta in poultry consuming feeds containing high amounts of soluble non-starch polysaccharides when used to provide 200–400 beta-glucanase activity units per kg of complete feed. Intended Species: Poultry.

(q) Ground grain obtained from a corn (Zea mays) variety that expresses an altered appA 6-phytase gene obtained from Escherichia coli strain K12 (transformation event PY1203). Common or Usual Name: Phytase. Intended Use: To increase the digestibility of phytin- bound phosphorus or to increase phosphorous availability from phytate in swine feeds when used to provide 500–4500 phytase activity units (FTU)/kg complete feed, or poultry feeds when used to provide 250–6000 FTU/ kg complete feed. Intended Species: Swine and poultry.

(r) Dried Methylobacterium extorquens biomass. Common or Usual Name: Dried Methylobacterium extorquens biomass. Intended Use: To be used as a source of protein in food for aquaculture crustacean species at a level up to six (6) percent of the diet. Intended Species: Crustacean species.

(s) Dried L-threonine fermentation product (2:75 percent L-threonine) produced by bioengineered Cornybacterium glutamicum. Common or Usual Name: Dried L-threonine fermentation product. Intended Use: To be used as a source of the nutrient L-threonine in food for livestock and poultry. Intended Species: Livestock and poultry.

(t) Butyrivibrio fibrisolvens ASCUSDY19. Common or Usual Name: Dried Butyrivibrio fibrisolvens fermentation product. Intended Use: Utility information not evaluated for GRAS, see FDA's letter for more information. Intended Species: Dairy cattle.

(u) Xylanase enzyme prepared from Komagataella phaffii expressing the gene encoding xylanase from Orpinomyces sp. Common or Usual Name: Endo-1,4-B-xylanase enzyme. Intended Use: Utility information not evaluated for GRAS, see FDA's letter for more information. Intended Species: Swine and poultry.

(v) Dried L-valine fermentation product. Common or Usual Name: Dried L-valine fermentation product. Intended Use: To be used as a source of L-valine in livestock and poultry feed. Intended Species: Livestock and poultry.

(w) Ground grain obtained from a corn (Zea mays) variety that expresses an altered AC1 betaglucanase gene obtained from an environmental DNA library (transformation event FG259). Common or Usual Name: Beta-glucanase. Intended Use: Utility information not evaluated for GRAS, see FDA's letter for more information. Intended Species: Swine.

Note: Authority cited: Sections 407 and 14902, Food and Agricultural Code. Reference: Sections 14992 and 15011, Food and Agricultural Code.