Chapter Six
Official Feed Terms, Common or Usual Ingredient Names and Ingredient Definitions

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A Guide to Submitting New or Modified Ingredient Definitions to AAFCO

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The following guide is offered to assist in development of new or modified feed ingredient definitions. The roles of each party are described below. The definitions should be non-proprietary as not to favor one ingredient producer over another. Materials to be used as feed ingredients should have the following attributes: They should be consistent batch to batch. The material should not be a combination of other ingredients. The intended use should not be to mitigate, treat, or diagnose a disease **(other than a nutritional deficiency)**, but rather to provide nutrition, flavor, aroma for the animal or provide a technical effect in the feed. It is the manufacturer's responsibility to produce a safe ingredient for its intended purpose.

The Requester

Prior to submitting a request for a new or modified definition, the requester (industry, public, regulatory official, etc.) should consider the current ingredient definitions and develop a draft definition that includes the intended use. The requester should then contact the appropriate investigator (see the AAFCO *Official Publication* or website for current listing) by email to definitions@aafco.org to discuss the draft definition. Following the initial discussion, a requester should then make a request to the investigator in writing that contains the information described below, if pertinent, so there is sufficient information for the decision process:

(1) Firm and contact person.
(2) Summary of the request, including name of the ingredient, intended use, and rationale for the request.
    A. The proposed name shall:
        I. Not contain commas.
        II. Begin with the base material and then list any needed qualifiers (Beet Pulp plain dried).
        III. Be in alignment with common or usual name conventions in 21 CFR 502.5(a).
        IV. Alternate names to be used on labeling shall be clearly stated at the end of the definition. "'Plain Dried Beet Pulp' shall be used on all labeling."
        V. Not include a trade name or be proprietary in nature.
(3) Proposed definition.
(4) Description of the ingredient (e.g., source, physical characteristics, any marketed formulation(s)).
(5) Proposed labeling (can be generic).
(6) Historical regulation of the ingredient, if any.
(7) Description of the manufacturing processes to support identity, composition, and consistent manufacturing of the ingredient. Data to include:
    A. A description of the manufacturing process,

B. A list and regulatory citation for all substances used in its preparation,
C. Stability data (including packaging),
D. Homogeneity data when ingredient is used at low inclusion rate, and
E. Validation information of analytical methods to support testing and/or citation of official methods.

(8) Use limitations, if any.
(9) Intended use of the ingredient, including target animal species, use rate, purpose, etc.
A. Data and observations (e.g., published literature, animal feeding trials, in vitro studies, empirical data showing technical effect, etc.) to support intended use.
(10) Safety Assessment. The safety assessment should include a narrative specific to the target animal and, in the case of use in food producing animals, a human food safety assessment should also be provided. Intended uses specific to companion animals will only need to address target animal safety specific to the use description. The safety narrative(s) should assess all the available data. The supporting data, which serves as the basis of the safety narrative and conclusion, should include:
A. Assessment of the ingredient for known and/or potential contaminants and impurities.
B. Available safety information from published articles and/or unpublished studies.
I. Target animal safety information should demonstrate the margin of safety for the intended use.
II. For microbial products (source of DFM, enzymes, fermentation products), information to demonstrate that they are produced from nonpathogenic and nontoxigenic strains.
(11) List of cited literature.
(12) Copies of all cited analytical reports, studies, and referenced articles. These may be provided in hard copy on a CD in PDF Optical Character Recognition (OCR) format.

More specific description of information listed above may be found in FDA Guidance for Industry 221 Recommendations for Preparation and Submission of Animal Food Additive Petitions.

It is imperative that the requester provide all information that is available to support their request. Confidential business information should be clearly identified in the request. Only manufacturing information can be marked confidential business information. Safety and utility data are not considered confidential business information. It may be advisable to put confidential business information in a separate document that can be sent, if needed, only to the FDA during the scientific review. Confidential business information should not be disseminated by an investigator without requester's knowledge; also see Section 14(f) of the AAFCO Model Bill or applicable governing state laws.

If not enough information is available in the published literature, a feeding trial may be needed. Please contact FDA CVM Division of Animal Feeds (DAF) for consultation on study design and requirements. Protocols should be submitted to DAF for review prior to conducting the studies.

Once a request has been submitted, the firm should wait to market the ingredient until the definition has been voted on by the AAFCO Ingredient Definition Committee (IDC), AAFCO Board, and AAFCO members.

The requester may contact the investigator to determine whether the request has been submitted to FDA for their review at the 30-day mark and every 30 days after that time.

The requester may get questions from the investigator or DAF. Questions should be addressed in a timely manner. Pending questions not addressed within 24 months will result in the investigator removing the request from AAFCO consideration.

Some ingredients are fed to intentionally alter the composition of human food (as when making human health benefit claims); these ingredients are not appropriate for review by AAFCO and need to be submitted through the Food Additive Petition (FAP) process to FDA. Additional unanswered safety questions for the ingredient may necessitate an FAP as well. FAP issues will be addressed to the **Director, Division of Animal Feeds, Center for Veterinary Medicine, Food and Drug Administration**. Check the *Official Publication* for further contact information.

A requester wanting approval pursuant to the Canadian Feeds Act and Regulations is required to file a formal application with the Canadian Food Inspection Agency. Inquiries should be addressed to **Director, Animal Feed Division, Canadian Food Inspection Agency**. Check the *Official Publication* for further contact information.

The Investigator

The AAFCO Investigator is a one-person committee that will evaluate and manage the request for a new definition or modified definition. One of the goals of the investigator is to develop official feed definitions that are just and equitable in cooperation with the members of the industry producing the ingredient. A second goal is to ensure that the production, sale, and use of ingredients will result in safe and effective feeds. The ingredient definitions should be non-proprietary, meaning they do not include a trade name that would favor one producer over another.

Upon receipt of the request for a new AAFCO ingredient definition or request for modification of an existing ingredient definition, the investigator will:

(1) Determine whether the proposed ingredient definition fits in the requested section of the AAFCO OP. If not, the request will be referred to the appropriate investigator or to the chair of the Ingredient Definitions Committee with the requesting party notified of the referral.
(2) Confirm that the proposed ingredient does not fall within the scope of an existing ingredient definition.
(3) Confirm that a proposed revision to an existing ingredient definition will not cause it to be moved to a different section of the OP or fall within the scope of another existing ingredient definition.
(4) Conduct an initial evaluation to determine whether any unanswered safety questions exist. If so, the requester will be referred directly to **Director, Division of Animal Feeds, Center for Veterinary Medicine, Food and Drug Administration**, to pursue a food additive approval. If FDA issues a food additive regulation for the ingredient, the investigator will lead the process of bringing the recommendation before the IDC.
(5) Confirm that the ingredient definition request is complete and contains all the information needed from the requester listed in the requester section above.

Upon receiving a request for a new or modified AAFCO ingredient definition, the expected administrative review time for the AAFCO investigator is 30 calendar days. If the investigator expects their review to take longer than 30 days, he/she may request an extension from the chair of the Ingredient Definitions Committee or request the chair of the Ingredient Definitions Committee assign the definition to another investigator.

Once the administrative review is complete, the investigator will forward one copy (electronic copy is preferred, but if sent as PDF, use Optical Character Recognition (OCR) format) of the request to **Director, Division of Animal Feeds, Center for Veterinary Medicine, Food and Drug Administration**. If the requestor prefers to send

any manufacturing information that is confidential business information directly to FDA, that is acceptable. FDA acts in a consulting role to evaluate the safety and utility of the ingredient.

Confidential business information should not be disseminated by an investigator without knowledge of the requester (also see Section 14(f), AAFCO Model Bill or applicable governing state laws).

The expected time for FDA to complete their safety and utility review is 180 calendar days. The investigator will provide an update to the requester on the status of the submission when the requests for updates are reasonably timed. After a request has been at FDA for 180 days, the investigator may contact the FDA reviewer to determine the status.

It may be necessary for additional data and information to be submitted, which may lead to multiple iterations to completely review a request. If the FDA determines that additional data and information are necessary, they will notify the requestor and copy the investigator.

When FDA has completed their review and recommended publication of the ingredient definition, the investigator will prepare and forward an "Investigators Report" form to the chair of the Ingredient Definitions Committee. These reports will be added to the agenda of the next committee meeting and are open for viewing and comments.

The investigator may initiate a modification of an ingredient definition based upon their knowledge of the affected industry and not on a specific request from an external requester. It is the responsibility of the investigator to acquire sufficient documentation to support their actions, just as it is industry's responsibility to provide sufficient documentation to support their request.

Once a new ingredient definition is approved by the Ingredient Definitions Committee, they forward a recommendation to the AAFCO Board to place the definition in the *Official Publication* in Tentative status. The Board will vote for or against this recommendation before the next membership meeting so members can vote on the recommendation during the Annual or Midyear meetings. Once approved by the membership, the Tentative ingredient definition will be published in the *Official Publication*. Status of a definition only changes upon a vote of the association membership.

The AAFCO bylaws require that each OP-published Tentative definition be reviewed by the responsible investigator 30 business days prior to the IDC meeting at the Annual meeting. The investigator shall recommend to the IDC that the definition be deleted, modified, or moved to official or remain at Tentative.

After 90 business days in Tentative status, the responsible investigator may recommend the definition be moved to Official (or any other action deemed appropriate). Any recommended change in designation will be voted on by the IDC during the Annual, Midyear, or Webinar committee meetings and forwarded to the board for recommendations and then to membership for a vote.

The FDA

The Division of Animal Feeds in FDA's Center for Veterinary Medicine performs scientific reviews of AAFCO ingredient definition requests and provides recommendations to the IDC investigators for new and amended ingredient definitions.

It typically takes at least 180 calendar days to review a request for a new ingredient definition, depending on complexity of the request and FDA's current workload. The AAFCO investigator can contact the FDA reviewer after that time to inquire about the status. If FDA considers the request incomplete, FDA may contact the requester directly for that information but must copy the investigator on all communications. It may be

necessary for additional data and information to be submitted, which may lead to multiple iterations to completely review a request. If needed to support their scientific review, FDA may directly request confidential business information from the requester. FDA will provide a written response to the investigator with the conclusions of their review with the recommended ingredient definition. The requester should receive a copy of this response.

The Association

Once reviewed by the investigator and FDA, the proposed ingredient definition is submitted by the investigator to the chair of the Ingredient Definitions Committee. The IDC is the clearinghouse for all new or modified definitions by acting as a review panel for the investigator to ensure that definitions are acceptable and consistent with AAFCO policies and existing definitions. Membership of the committee is drawn from the ranks of AAFCO members. The deadline for submission to the chair is 30 business days before the next IDC meeting and is necessary to allow ample time for committee review and corresponding with the investigator. Once a new or modified ingredient definition is approved by the Ingredient Definitions Committee, the chair will forward a recommendation to the AAFCO Board to place the definition in the *Official Publication* in Tentative status. The Board will vote for or against this recommendation before the next membership meeting so members can vote on the recommendation during the Annual or Midyear meetings. Once approved by the membership, the Tentative ingredient definition will be published in the *Official Publication*. Status of a definition only changes upon a vote of the association membership. The AAFCO bylaws require that each OP-published Tentative definition be reviewed by the responsible investigator 30 business days prior to the IDC meeting at the Annual meeting. The investigator shall recommend to the IDC that the definition be deleted, modified, or moved to Official or remain at Tentative. After 90 business days in Tentative status, the responsible investigator may recommend the definition be moved to Official (or any other action deemed appropriate). Any recommended change in designation will be voted on by the IDC during the Annual, Midyear, or Webinar committee meetings and forwarded to the board for recommendations and then to membership for a vote. Firms may use the ingredient definition once the AAFCO membership vote has occurred affirming the recommended definition to appear in the *Official Publication*. Prior to publication in the *Official Publication*, firms wanting to manufacture feed with the ingredient may use committee minutes and general session minutes to document the completion of the process. These are typically posted on the AAFCO website. If deletion of an ingredient definition from the *Official Publication* is proposed, the investigator will follow the same dateline as if proposing any other ingredient definition change. This will allow the IDC the opportunity to review and discuss the proposed deletion.

Canadian Food Inspection Agency

The chair of the IDC will share all completed definition recommendations with Canadian officials for their information once the forms have been forwarded to the Ingredient Definitions Committee. A requester wanting approval pursuant to the Canadian Feeds Act and Regulations is required to file a formal application with the Canadian Food Inspection Agency. Inquiries should be addressed to **Director, Animal Feed Division, Canadian Food Inspection Agency**. Check the *Official Publication* for further contact information.

Additional Pathways to AAFCO Published Ingredient Definitions

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Animal Food Additives Approved by FDA

Animal food additives approved by FDA are listed in 21 CFR 573. The food additive regulation specifies the requirements for safe use of the food additive and establishes the common or usual name for the new ingredient. To ensure that the AAFCO *Official Publication* listing of defined feed ingredients is complete, the approved food additive, as specified in the published final rule, will be incorporated in the AAFCO *Official Publication's* Official Feed Terms, Common or Usual Ingredient Names and Ingredient Definitions chapter. The designated FDA representative to the IDC will provide the appropriate investigator with the food additive regulation and will prepare a recommendation form and forward it to the chair of the Ingredient Definitions Committee for consideration at the next committee meeting.

Since the ingredient has gone through the formal FDA approval process, once the AAFCO Ingredient Definitions Committee, the AAFCO Board, and AAFCO membership have approved the definition, the entry will be incorporated in the AAFCO *Official Publication* as Official.

GRAS Notified Substances with "No Questions" Letters from FDA

A list of GRAS Notices filed voluntarily by the notifiers pursuant to 21 CFR 570.205 that FDA has evaluated (21 CFR 570.265) and determined that it had no questions regarding the conclusion that the notified animal food substance is generally recognized as safe (GRAS) under the intended conditions of use is provided in Section 101 of Chapter 6 of the AAFCO OP. 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, and the most up to date version is posted at the following website: http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/GenerallyRecognizedasSafeGRASNotifications/ucm243845.htm. This section is provided as a convenience for the State Feed Control Officials. The Investigator of Section 101 will adapt the information as provided on the FDA website and consult with FDA on an appropriate common or usual name.

While the information on the substance and the intended use is specific to that provided by the notifier, other firms may use information within the notice along with other data specific to their substance to support the GRAS conclusion (see 21 CFR 570.3-570.280). Such other firms who conclude that an animal food substance is GRAS under the conditions of its intended use by relying on a posted GRAS notice submitted by another person shall carefully evaluate whether their production process, product specifications and intended conditions of use, fall within the parameters addressed by the referenced GRAS notice. GRAS conclusions are not legally required to be submitted to FDA, but may be voluntarily submitted in accordance with the GRAS Notice regulation (21 CFR Part 570.205). Nevertheless, firms that elect to make use of the independent GRAS provision must document their Independent Conclusions of GRAS prior to marketing a substance for a particular intended use. State Feed Control Officials may request the Independent Conclusion of GRAS documentation to support their registration or inspection duties.

The table in Section 101 is adapted from the FDA Animal GRAS Notification website and includes ingredient definition information (substance, common or usual name (from the FDA response letter), and intended use (including use limitations, if any)). For

other information, see the FDA response letter for the GRAS Notice (available at link provided above).

At each AAFCO IDC meeting, the section editor will provide an updated list of animal food GRAS Notices that have been evaluated by the FDA and have received a no questions letter from the Agency. Firms making GRAS conclusions should be prepared to answer questions from the Ingredient Definitions Committee or Association if needed. The notices are voted on by the Ingredient Definitions Committee, the AAFCO board, and accepted by the Association membership for publication in the AAFCO *Official Publication*.

Color Additives Approved by FDA

Color Additives intended for use in animal feed approved by FDA (specifically the Center for Food Safety and Applied Nutrition) are listed in 21 CFR 73 & 74. The color additive regulation specifies the requirements for safe use of the color additive and establishes the common or usual name for the new ingredient. To ensure that the AAFCO *Official Publication* listing of defined feed ingredients is complete, the approved color additive, as specified in the published final rule, will be incorporated in the AAFCO *Official Publication's* Official Common or Usual Names and Definition of Feed Ingredients chapter.

The designated FDA representative to the IDC will provide the appropriate investigator with the color additive regulation and will prepare a recommendation form and forward it to the Chair of the Ingredient Definitions Committee for consideration at the next committee meeting.

Since the ingredient has gone through the formal FDA approval process, once the AAFCO Ingredient Definitions Committee, the AAFCO Board, and AAFCO Membership have approved the definition, the entry will be incorporated in the AAFCO *Official Publication* as Official.

Feed Terms and Definitions

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Official Feed Terms

Note: Suggestions for changes should be addressed to the Feed Terms Investigator.

Official feed terms are listed in the following section to define nouns and/or processes to provide uniformity and clear understanding of words used when describing ingredients. It is acceptable to use a combination of a "process" feed term and a defined ingredient or common or usual name when describing an ingredient in the ingredient statement as long as the ingredient is not nutritionally altered from the original. If the ingredient has gone through a recognized review process the name may include a "part" feed term.

Additive. An ingredient or combination of ingredients added to the basic feed mix or parts thereof to fulfill a specific need. Usually used in micro quantities and requires careful handling and mixing.

(Note: A "Food Additive" is defined by federal laws as any substance which becomes a component of or affects the characteristics of a feed or food if such substance is not generally recognized among experts qualified by scientific training and experience to evaluate its safety as having been adequately shown through scientific procedures to be safe under the conditions of its intended use. Excepted are substances having "prior sanction" and pesticide chemicals under certain conditions. See Public Law 65-929 for details.)

Aerial parts. (Part) The above ground parts of plants.
Air ashed. (Process) Reduced by combustion in air to a mineral residue.
Ammoniated, ammoniating. (Process) Combined with or impregnated with ammonia or an ammonium compound.
Animal food. See *feed*.
Animal waste. Means a material composed of excreta, with or without bedding materials, and collected from poultry, ruminants or other animals except humans.
Antibiotics. A class of drug. They are usually synthesized by a living microorganism and in proper concentration inhibit the growth of other microorganisms.
Artificially dried. (Process) Moisture having been removed by other than natural means.
Aspic. A solid or semi-solid dressing produced by mixing a gelling agent(s) with broth or water, and/or common seasonings or flavor enhancer(s). If the aspic or gel is characterized as a meat, poultry, or fish aspic or gel, it must contain an extract or essence of meat, poultry, or fish in an amount sufficient to characterize it as such.
Aspirated, aspirating. Having removed chaff, dust, or other light materials by use of air.
Bagasse. (Part) Pulp from sugar cane. (*See pulp*.)
Balanced. A term that may be applied to a diet, ration, or feed having all known required nutrients in proper amount and proportion based upon recommendations of recognized authorities in the field of animal nutrition, such as the National Research Council, for a given set of physiological animal requirements. The species for which it is intended and the functions such as maintenance or maintenance plus production (growth, fetus, fat, milk, eggs, wool, feathers, or work) shall be specified.
Barn-cured. (Process) Forage material dried with forced ventilation in an enclosure.
Beans. Seed of leguminous plants especially of the genera *Phaseolus*, *Dolichos*, and *Vigna*.
Biscuits. (Physical form) Shaped and baked dough.

Bison. Common name for *Bison bison*. The meat or other ingredients derived from the animal (e.g. by-products, meal, fat) must be referred to as "bison," "North American buffalo," "bison _____," or "North American buffalo _____" with the specific non-meat ingredient filling in the blank.
Blending. (Process) To mingle or combine two or more ingredients of feed. It does not imply a uniformity of dispersion.
Blocked, blocking. (Process) Having agglomerated individual ingredients or mixtures in to a large mass.
Blocks. (Physical form) Agglomerated feed compressed into a solid mass cohesive enough to hold its form and weighing over two pounds, and generally weighing 30-50 pounds.
Blood. (Part) Vascular fluid of animals.
Blood albumin. (Part) One of the blood proteins.
Blowings. (Part) See *mill dust*.
Bolls. (Part) The pods or capsules of certain plants, especially flax or cotton.
Bolted, bolting. (Process) Separated by means of a bolting cloth as flour from bran.
Bone. (Part) Skeletal parts of vertebrates.
Boneless. (Process) The flesh resulting from removal of bone from accompanying flesh by means of knife separation.
Bran. (Part) Pericarp of grain.
Brand name. Any word, name, symbol or device or any combination thereof identifying the commercial feed of a distributor and distinguishing it from that of others.
Bricks. (Physical form) Agglomerated feed, other than pellets, compressed into a solid mass cohesive enough to hold its form and weighing less than two pounds. (See *blocks*.)
Browse. (Part) Small stems, leaves and/or flowers and fruits of shrubs, trees or woody vines.
Buttermilk. (Part) All residue from churning cream.
By-product. (Part) Secondary products produced in addition to the principal product.
Cake. (Physical form) The mass resulting from the pressing of seeds, meat, or fish in order to remove oils, fats, or other liquids.
Calcined, calcining. (Process) Treated at high temperature in the presence of air.
Canned. (Process) A term applied to animal feed that has been processed, commercially sterilized, and sealed according to 21 CFR part 113 in hermetically sealed containers such as but not limited to cans, pouches, tubs, and trays.
Cannery residue. (Part) Residue suitable for feeding obtained in preparing a product for canning.
Carcass meat trimmings. (Part) Clean flesh obtained from slaughtered animals. It is limited to striate, skeletal, and cardiac muscles, but may include the accompanying and overlaying fat and the portion of skin, sinew, nerve, and blood vessels which normally accompany the flesh.
Carcass residue, mammals. (Part) Residues from animal tissues including bones and exclusive of hair, hoofs, horns, and contents of the digestive tract.
Carrier. An edible material to which ingredients are added to facilitate uniform incorporation of the latter into feeds. The active substances are absorbed, impregnated or coated into or onto the edible materials in such a way as to physically carry the active ingredient.
Chaff. (Part) Glumes, husks, or other seed covering together with other plant parts separated from seed in threshing or processing.
Chipped, chipping. (Process) Cut or broken into fragments; also meaning prepared into small thin slices.
Chopped, chopping. (Process) Reduced in particle size by cutting with knives or other edged instruments.

Cleaned, cleaning. (Process) Removal of material by such methods as scalping, aspirating, magnetic separation, or by any other method.
Cleanings. (Part) Chaff, weed seeds, dust, and other foreign matter removed from cereal grains.
Cobs with grain. (Part) The ears of maize without the husks, but consisting of the entire cobs and adhering grain.
Cobs with husks. (Part) Kernel-free fibrous inner portion of the ear of maize with enveloping leaves.
Commercial feed. See *AAFCO Model Bill*.
Common foods. Common foods are commercially available and suitable for use in animal food but are not defined by AAFCO, 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.
Common or usual feed ingredient name. The common or usual name of a feed ingredient shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the ingredient or its characterizing properties. The name shall be uniform among all identical or similar ingredients and may not be confusingly similar to the name of any other ingredient that is not reasonably encompassed within the same name. Each ingredient shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from other ingredients. Some feed ingredients may be a common food; in this case the common or usual name should abide by the principles as provided in this feed term.
Complete feed. A nutritionally adequate feed for animals other than man; by specific formula 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.
Concentrate. A feed used with another to improve the nutritive balance of the total and intended to be further diluted and mixed to produce a supplement or a complete feed.
Condensed, condensing. (Process) Reduced to denser form by removal of moisture.
Conditioned, conditioning. (Process) Having achieved pre-determined moisture characteristics and/or temperature of ingredients or a mixture of ingredients prior to further processing.
Cooked, cooking. (Process) Heated in the presence of moisture to alter chemical and/or physical characteristics or to sterilize.
Cracked, cracking. (Process) Particle size reduced by a combined breaking and crushing action.
Cracklings. (Part) Residue after removal of fat from adipose tissue or skin of animals by dry heat.
Crimped, crimping. (Process) Rolled by use of corrugated rollers. It may curtail tempering or conditioning and cooling.
Crumbled, crumbling. (Process) Pellets reduced to granular form.
Crumbles. (Physical form) Pelleted feed reduced to granular form.
Crushed, crushing. (Process) See *rolled, rolling*.
Cubes. (Physical form) See *pellets*.
Cubes, range. (Physical form) See *pellets* and *range cubes*.
Cull. Material rejected as inferior to the process of grading or separating.
Culture. Nutrient medium inoculated with specific microorganisms which may be in a live or dormant condition.
Cultured, culturing. (Process) Biological material multiplied or produced in a nutrient media.

Cure, curing, cured. (Process) To prepare for keeping for use, or to use, or to preserve. The process may be by drying, use of chemical preservatives, smoking, salting, or by use of other processes and/or materials for preserving.
Customer-formula feed. Consists of a mixture of commercial feeds and/or feed ingredients each batch of which is manufactured according to the specific instructions of the final purchaser.
Cut, cutting. (Process) See *chopped, chopping*.
D-activated, D-activating. Plant or animal sterol fractions which have been vitamin D activated by ultra-violet light or by other means.
Deboned. (Process) The flesh resulting from removal of bones from accompanying flesh by mechanical deboning.
Decharacterize, decharacterized. (Process) Use of approved color additives to make a substance clearly distinguishable from the same substance for human consumption.
Defluorinated, defluorinating. (Process) Having had fluorine removed.
Degermed. (Process) Having had the embryo of seeds wholly or partially separated from the starch endosperm.
Dehulled, dehulling. (Process) Having removed the outer covering from grains or other seeds.
Dehydrating, dehydrated. (Process) Having been freed of moisture by thermal means.
Dextrose Equivalent (D.E.). is the reducing power calculated as dextrose, expressed as a percentage of the dry substance. It is used in conjunction with sugars and starch hydrolysates.
Diet. Feed ingredients or mixture of ingredients including water, which is consumed by animals.
Dietary starch. (Nutrient) An alpha-linked-glucose carbohydrate of or derived from plants, animals and/or microbes from which glucose is released through the hydrolytic actions of purified alpha-amylases and amyloglucosidases that are specifically active only on alpha-(1-4) and alpha-(1-6) linkages in samples that have been gelatinized in heated, mildly acidic buffer. Its concentration in feed is determined by enzymatically converting the alpha-linked-glucose carbohydrate to glucose and then measuring the liberated glucose. This definition encompasses plant starch, glycogen, maltooligosaccharides and maltose/isomaltose. (Proposed 2009)
Digested, digesting. (Process) Subjected to prolonged heat and moisture, or to chemicals or enzymes with a resultant change of decomposition of the physical or chemical nature.
Diluent. An edible substance used to mix with and reduce the concentrate of nutrients and/or additives to make them more acceptable to animals, safer to use, and more capable of being mixed uniformly in a feed. (It may also be a carrier.)
Distillation solubles. (Part) Stillage filtrate.
Dressed, dressing. (Process) Made uniform in texture by breaking or screening of lumps from feed and/or the application of liquid(s).
Dried, drying. (Process) Materials from which water or other liquid has been removed.
Drug. (as defined by FDA as applied to feed) A substance (a) intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals or (b) a substance other than food intended to affect the structure or any function of the body of man or other animals.
Dry-milled. (Process) Tempered with a small amount of water or steam to facilitate the separation of the various component parts of the kernel in the absence of any significant amount of free water.
Dry-rendered, dry-rendering. Dry rendered (Process) Residues of animal tissue cooked in open steam-jacketed vessels until the water has evaporated. Fat is removed by draining and pressing the solid residue.

Dust. (Part) Fine, dry pulverized particles of matter usually resulting from the cleaning or grinding of grain.
Ears. (Part) Fruiting heads of *Zea maize*, including only the cob and grain.
Egg albumin. (Part) Whites of eggs of poultry.
Emulsifier. A material capable of causing fat or oils to remain in liquid suspension.
Endosperm. (Part) Starchy portion of seed.
Ensiled. (Process) Aerial parts of plants which have been preserved by ensiling. Normally the original material is finely cut and blown into an airtight chamber as a silo, where it is pressed to exclude air and where it undergoes an acid fermentation that retards spoilage.
Environmental nutrition. The role of nutritional factors in altering animal impacts on the environment.
Enzymatic activity. The catalytic activity required to convert a given amount of assay substrate to a given amount of product per unit time under the standard conditions set forth in the assay procedure.
Enzyme. A protein made up of amino acids or their derivatives, which catalyzes a defined chemical reaction. Required cofactors should be considered an integral part of the enzyme.
Enzyme product. A processed, standardized enzyme-containing material which has been produced with the intention of being sold for use in animal feed and feed ingredients.
Etiolated. (Process) A material grown in the absence of sunlight, blanched, bleached, colorless or pale.
Evaporated, evaporating. (Process) Reduced to a denser form; concentrated as by evaporation or distillation.
Eviscerated. (Process) Having had all the organs in the great cavity of the body removed.
Expanded, expanding. (Process) Subjected to moisture, pressure, and temperature to gelatinize the starch portion. When extruded, its volume is increased, due to abrupt reduction in pressure.
Extracted, mechanical. (Process) Having removed fat or oil from materials by heat and mechanical pressure. Similar terms: expeller extracted, hydraulic extracted, "old process."
Extracted, solvent. (Process) Having removed fat or oil from materials by organic solvents. Similar term: "*new process.*"
Extruded. (Process) A process by which feed has been pressed, pushed, or protruded through orifices under pressure.
Fat. (Part) A substance composed chiefly of triglycerides of fatty acids, and solid or plastic at room temperature.
Fatty acids. (Part) Aliphatic monobasic acids containing only the elements carbon, hydrogen, and oxygen.
Feathers. (Part) The light, horny epidermal outgrowths that form the external coverings of birds.
Feed. Material consumed or intended to be consumed by animals other than humans that contributes nutrition, taste, or aroma or has a technical effect on the consumed material. This includes raw materials, ingredients, and finished product.
Feed grade. Material that has been determined to be safe, functional, and suitable for its intended use in animal food, is handled and labeled appropriately, and conforms to the Federal Food, Drug, and Cosmetic Act unless otherwise expressly permitted by the appropriate state or federal agency (suitable for use in animal feed).
Feed mixture. See *formula feed*.
Feedstuff. See *feed(s)*.
Fermentation aid. A substance added to assist in providing proper conditions which results in action by yeasts, molds or bacteria in a controlled aerobic or anaerobic process used for the manufacture of certain products.

Fermented, fermenting. (Process) Acted upon by yeasts, molds, or bacteria in a controlled aerobic or anaerobic process in the manufacture of such products as alcohols, acids, vitamins of the B-complex group, or antibiotics.
Fiber. (Nutrient) Any of a large class of plant carbohydrates that resist digestion hydrolysis.
Fines. (Physical form) Any materials which will pass through a screen whose openings are immediately smaller than the specified minimum crumble size or pellet diameter.
Flaked, flaking. (Process) See *rolled*.
Flakes. (Physical form) An ingredient rolled or cut into flat pieces with or without prior steam conditioning.
Flour. (Part) Soft, finely ground and bolted meal obtained from the milling of cereal grains, other seeds, or products. It consists essentially of the starch and gluten of the endosperm.
Fodder. (Part) The green or cured plant, containing all the ears or seed heads, if any, grown primarily for forage. (It has been applied more specifically to corn and sorghum.)
Food(s). When used in reference to animals, is synonymous with feed(s). See *feed(s)*.
Formula feed. Two or more ingredients proportioned, mixed, and processed according to specifications.
Free choice. A feeding system by which animals are given unlimited access to the separate components or groups of components constituting the diet.
Fresh. (Process) Ingredient(s) having not been subject to freezing, to treatment by cooking, drying, rendering, hydrolysis, or similar process, to the addition of salt, curing agents, natural or synthetic chemical preservatives or other processing aids, or to preservation by means other than refrigeration.
Fructans. (Nutrient) – Polysaccharides and oligosaccharides in which fructose is the major constituent and glucose is the minor constituent. Glucose content is 33% or less.
Fused, fusing. (Process) Melted by heat.
Gel. See *Aspic*.
Gelatinized, gelatinizing. (Process) Having had the starch granules completely ruptured by a combination of moisture, heat and pressure, and in some instances, by mechanical shear.
Germ. (Part) The embryo found in seeds and frequently separated from the bran and starch endosperm during the milling.
Gluten. (Part) The tough, viscid nitrogenous substance remaining when the flour of wheat or other grain is washed to remove the starch.
Gossypol. (Part) A phenolic pigment in cottonseed that is toxic to some animals.
Grain. (Part) Seed from cereal plants.
GRAS. Abbreviation for the phase "Generally Recognized as Safe." A substance which is generally recognized as safe by experts qualified to evaluate the safety of the substance for its intended use.
Gravy. A multiple component fluid dressing or topping consisting of a combination of one or more ingredients imparting special characteristics or flavors. It may be formulated separately and added to another ingredient or combination of ingredients. If the gravy is characterized as a meat, poultry or fish gravy it must contain an extract or essence of meat, poultry or fish in an amount sufficient to characterize it as such.
Grease. Animal fats with a titer below 40º C
Grit. Course ground, insoluble, non-nutritive material (e.g. granite rock) for the in vivo mechanical grinding of feed by avian species.)
Grits. (Part) Coarsely ground grain from which the bran and germ have been removed, usually screened to uniform particle size.
Groats. (Part) Grain from which the hulls have been removed.
Ground, grinding. (Process) Reduced in particle size by impact, shearing, or attrition.
Hay. (Part) The aerial portion of grass or herbage especially cut and cured for animal feeding.
Heads. (Part) The seed or grain-containing portions of a plant.

Heat-processed, heat-processing. (Process) Subjected to a method of preparation involving the use of elevated temperatures with or without pressure.
Heat-rendered, heat rendering. (Process) Melted, extracted, or clarified through use of heat. Usually, water and fat are removed.
Homogenized, homogenizing. (Process) Particles broken down into evenly distributed globules small enough to remain emulsified for long periods of time.
Hulls. (Part) Outer covering of grain or other seed.
Human grade. Every ingredient and the resulting product are stored, handled, processed, and transported in a manner that is consistent and compliant with regulations for current good manufacturing practices (cGMPs) for human edible foods as specified in 21 CFR Part 117.
Husks. (Part) Leaves enveloping an ear of maize; or the outer coverings of kernels or seeds, especially when dry and membranous.
Hydrolyzed, hydrolyzing. (Process) Complex molecules having been split to simpler units by chemical reaction with water, usually by catalysis.
Iodinated. (Process) Treated with iodine.
Iodize, iodized. (Process) To treat with iodine or an iodide.
Irradiated, irradiating. (Process) Treated, prepared, or altered by exposure to a specific radiation.
Juice. (Part) The aqueous substance obtainable from biological tissue by pressing or filtering with or without addition of water.
Kernel. (Part) A whole grain. For other species, dehulled seed.
Kibbled, kibbling. (Process) Cracked or crushed baked dough, or extruded feed that has been cooked prior to or during the extrusion process.
Laboratory method. A technique or procedure of conducting scientific experiment, test, investigation or observation according to a definite established logical or systematic plan.
Lard. (Part) Rendered fat of swine.
Leached. (Process) The condition of a product following subjection of the material to the action of percolating water or other liquid.
Leaves. (Part) Lateral outgrowths of stems that constitute part of the foliage of a plant, typically a flattened green blade, and primarily functions in photosynthesis.
Lecithin. (Part) A specific phospholipid. The principal constituent of crude phosphatides derived from oil-bearing seeds.
Liver. (Part) The hepatic gland.
Malt. (Part) Sprouted and steamed whole grain from which the radicle has been removed.
Malted, malting. (Process) Converted into malt or treated with malt or malt extract.
Mash. (Physical form) A mixture of ingredients in meal form. Similar term: *mash feed*.
Meal. (Physical form) An ingredient which has been ground or otherwise reduced in particle size.
Medicated feed. Any feed which contains drug ingredients intended or presented for the cure, mitigation, treatment, or prevention of diseases of animals other than man or which contains drug ingredients intended to affect the structure or any function of the body of animals other than man. Antibiotics included in a feed growth promotion and/or efficiency levels are drug additives and feeds containing such antibiotics are included in the foregoing definition of "Medicated Feed."
Micro-ingredients. Vitamins, minerals, antibiotics, drugs, and other materials normally required in small amounts and measured in milligrams, micrograms or parts per million (ppm).
Middlings. (Part) A by-product of flour milling comprising several grades of granular particles containing different proportions of endosperm, bran, germ, each of which contains different levels of crude fiber.
Milk. Total lacteal secretion from the mammary gland.

Mill by-product. (Part) A secondary product obtained in addition to the principal product in milling practice.
Mill dust. (Part) Fine feed particles of undetermined origin resulting from handling and processing feed and feed ingredients.
Mill run. (Part) The state in which a material comes from the mill, ungraded and usually uninspected.
Mineralize, mineralized. (Process) To supply, impregnate, or add inorganic mineral compounds to a feed ingredient or mixture.
Mixing. (Process) To combine by agitation two or more materials to a specific degree of dispersion.
Molasses. (Part) The thick, viscous by-product resulting from refined sugar production or the concentrated, partially dehydrated juices from fruits.
Natural. A feed or ingredient derived solely from plant, animal or mined sources, either in its unprocessed state or having been subject to physical processing, heat processing, rendering, purification, extraction, hydrolysis, enzymolysis or fermentation, but not having been produced by or subject to a chemically synthetic process and not containing any additives or processing aids that are chemically synthetic except in amounts as might occur unavoidably in good manufacturing practices.
Nutrient. A feed constituent in a form and at a level that will help support the life of an animal. The chief classes of feed nutrients are proteins, fats, carbohydrates, minerals and vitamins.
Offal. (Part) Material left as a by-product from the preparation of some specific product, less valuable portions and the by-products of milling.
Oil. (Part) A substance composed chiefly of triglycerides of fatty acids, and liquid at room temperature.
Organic. (Process) A formula feed or a specific ingredient within a formula feed that has been produced and handled in compliance with the requirements of the USDA National Organic Program (7 CFR Part 205).
Parboiling. A Hydrothermal process in which the crystalline form of starch is changed into the amorphous form, due to the irreversible swelling and fusion of starch. This is accomplished by soaking, steaming, drying and milling to produce physical and chemical modifications.
Part. A subcomponent of an original material. A "part" feed term can be used in an ingredient name if the ingredient part has gone through a recognized review process.
Pearled, pearling. (Process) Dehulled grains reduced by machine brushing into smaller smooth particles.
Peel. (Part) See *skin*.
Pelleted, pelleting. (Process) Having agglomerated feed by compaction and forced through die openings.
Pellets. (Physical form) Agglomerated feed formed by compacting and forcing through die openings by a mechanical process. Similar terms: *pelleted feed, hard pellet*.
Pellets, soft. (Physical form) Similar term: High Molasses Pellets. Pellets containing sufficient liquid to require immediate dusting and cooling.
Physical form. Shape, appearance or structure of a feed based on size, texture, particle size, density, hardness, moisture/dryness or other physical characteristics. Physical form may be used to further describe an ingredient name.
Polished, polishing. (Process) Having a smooth surface produced by mechanical process usually by friction.
Pomace. (Part) Pulp from fruit or vegetables. See *pulp*.
Popped, puffed. (Process) To expand whole or cracked processed grains or non-grains by heat with or without high pressure. Examples of grains are corn, rice, wheat, millet, barley, buckwheat. Example of non-grain is soybean.

Powder, powdered. (Process) Pulverizing a feed or feed ingredient into fine or very small particle size or atomization and drying of liquids.
Precipitated, precipitating. (Process) Separated from suspension or a solution as a result of some chemical or physical change brought about by a chemical reaction, by cold or by any other means.
Premix. A uniform mixture of one or more micro-ingredients with diluent and/or carrier. Premixes are used to facilitate uniform dispersion of the micro-ingredients in a large mix.
Premixing. (Process) The preliminary mixing of ingredients with diluents and/or carriers.
Preservative. A substance added to protect, prevent or retard decay, discoloration or spoilage under conditions of use or storage.
Pressed, pressing. (Process) Compacted or molded by pressure; also meaning having fat, oil, or juices extracted under pressure.
Presswater. The aqueous extract of fish or meat free from the fats and/or oils. Presswater is the result of hydraulic pressing of the fishing or meat followed by separation of the oil either by centrifuging or other means.
Process. A method used to prepare, treat, convert or transform materials into feeds or feed ingredients. A "process" feed term can be used to further describe an ingredient name as long as the ingredient is not nutritionally altered from the original.
Processed animal waste. Animal waste that has been artificially dried, dry stacked, ensiled, oxidized, chemically treated, micro-biologically digested, chemically or physically fractionated, or otherwise treated to render the material suitable for feeding.
Product. (Part) A substance produced from one or more other substances as a result of chemical or physical change.
Protein. (Nutrient) Any of a large class of naturally occurring complex combinations of amino acids.
Pulp. (Part) The solid residue remaining after extraction of juices from fruits, roots, or stems. Similar terms: *Bagasse* and *Pomace*.
Pulverized, pulverizing. (Process) See *ground, grinding*.
Range cake. (Physical form) See *cake*.
Range cubes. (Physical form) Large pellets designed to be fed on the ground. Similar term: *range wafer*.
Ration. The amount of the total feed which is provided to one animal over a 24-hour period.
Raw. Food in its natural or crude state not having been subjected to heat in the course of preparation as food.
Refuse. (Part) Damaged, defective, or superfluous edible material produced during or left over from a manufacturing or industrial process.
Rendered, rendering. (Process) A cooking and separating process in which conditions such as time and temperature, with or without pressure, are sufficient to remove water, kill pathogenic microorganisms, and separate fats and oils from other components.
Residue. Part remaining after the removal of a portion of its original constituents.
Rolled, rolling. (Process) Having changed the shape and/or size of particles by compressing between rollers. It may entail tempering or conditioning.
Roasted. (Process) Cooked, dried or browned by exposure to heat.
Roots. (Part) Subterranean parts of plants.
Rumen contents. Contents of the first two compartments of the stomach of a ruminant.
Rumen inert. Refers to a nutrient(s) that does not result in a change in rumen fermentation parameters yet is available to the animal in the intestine.
Rumen protected. Refers to a nutrient(s) fed in such a form that provides an increase in the flow of that nutrient(s), unchanged, to the abomasum, yet is available to the animal in the intestine.

Sauce. A multiple component fluid dressing or topping consisting of a combination of one or more ingredients imparting special characteristics or flavors. It may be formulated separately and added to another ingredient or combination of ingredients.
Scalped, scalping. (Process) Having removed larger material by screening.
Scratch. (Physical form) Whole, cracked, or coarsely cut grain. Similar terms: *scratch grain, scratch feed*.
Screened, screening. (Process) Having separated various sized particles by passing over and/or through screens.
Seed. (Part) The fertilized and ripened ovule of a plant.
Self fed. A feeding system where animals have continuous free access to some or all component(s) of a ration, either individually or as mixtures.
Separating. (Process) Classification of particles by size, shape, and/or density.
Separating, magnetic. (Process) Removing ferrous material by magnetic attraction.
Shells. (Part) The hard, fibrous, or calcareous covering of a plant or animal product, i.e., nut, egg, oyster.
Shoots. (Part) The immature aerial parts of plants, stems with leaves and other appendages in contrast to the roots.
Shorts. (Part) Fine particles of bran, germ, flour, or offal from the tail of the mill from commercial flour milling.
Sifted. (Process) Materials that have been passed through wire sieves to separate particles in different sizes. The separation of finer materials than would be done by screening.
Sizing. (Process) See *screened, screening*.
Skimmed. (Process) Material from which floating solid material has been removed. It is also applied to milk from which fat has been removed by centrifuging.
Skin. (Part) Outer coverings of fruits or seeds, as the rinds, husks, or peels. May also apply to dermal tissue of animals.
Sludge. The suspended or dissolved solid matter resulting from the processing of animal or plant tissue for human food.
Snack. See *treat*.
Solubles. Liquid containing dissolved substances obtained from processing animal or plant materials. It may contain some fine suspended solids.
Solvent extracted. (Process) A product from which oil has been removed by solvents.
Spent. Exhausted of active or effective properties, i.e., absorbing activity.
Spray dehydrated. (Process) Material which has been dried by spraying on the surface of a heated drum. It is recovered by scraping from the drum.
Spray dried. Material which has been dried by spraying or atomizing into a draft of heated dry air.
Stabilized. (Process) When an ingredient which may deteriorate has been processed to improve stability, the expression "stabilized," "stability improved" or "with improved stability" may appear following the ingredient in the statement of ingredients. The process used is to be specified, e.g., heat stabilized.
Stalk(s). (Part) The main stem of a herbaceous plant often with its dependent parts as leaves, twigs and fruit.
Starch. (Part) A white, granular polymer of plant origin. The principal part of seed endosperm.
Steamed, steaming. (Process) Having treated ingredients with steam to alter physical and/or chemical properties. Similar terms: steam cooked, steam rendered, tanked.
Steep-extracted, steep-extracting. (Process) Soaked in water or other liquid (as in the wet milling of corn) to remove soluble materials.
Steepwater. Water containing soluble materials extracted by steep-extraction, i.e., by soaking in water or other liquid (as in the wet milling of corn).

Stem. (Part) The coarse, aerial parts of plants which serve as supporting structures for leaves, buds, fruit, etc.

Sterols. (Part) Solid cyclic alcohols which are the major constituents of the unsaponfiable portion of animal and vegetable fats and oils.

Stick. See *stickwater* and *presswater*.

Stickwater, fish. (Part) The aqueous extract of cooked fish free from the oil. Stickwater contains the aqueous cell solutions of the fish and any water used in processing.

Stickwater, meat. (Part) The aqueous extract of meat free from the fat. Meat stickwater is the result of the wet rendering of meat products and contains the aqueous cell solution, the soluble glue proteins, and the water condensed from steam used in wet rendering.

Stillage. (Part) The mash from fermentation of grains after removal of alcohol by distillation.

Stover. (Part) The stalks and leaves of corn after the ears, or sorghum after the heads have been harvested.

Straw. (Part) The plant residue remaining after separation of the seeds in threshing. It includes chaff.

Sugars. (Nutrient) The sum of all free disaccharides and monosaccharides such as: sucrose, lactose, maltose, glucose, fructose and galactose or others digestible by enzymes found in an animal's digestive tract.

Suitable for use in animal feed. See *feed grade*.

Sun-cured. (Process) Material dried by exposure in open air to the direct rays of the sun.

Supplement. A feed used with another to improve the nutritive balance or performance of the total and intended to be:

(1) Fed undiluted as a supplement to other feeds: or,
(2) Offered free choice with other parts of the ration separately available; or
(3) Further diluted and mixed to produce a complete feed.

Syrup. (Part) Concentrated juice of a fruit or plant.

Tallow. (Part) Animal fats with titer above 40°C.

Tankage. (Part) See *carcass residue*.

Tempered, tempering. (Process) See *conditioned, conditioning*.

Titer. A property of fat determined by the solidification point of the fatty acids liberated by hydrolysis.

Toasted. (Process) Browned, dried, or parched by exposure to a fire, or to gas or electric heat.

Trace minerals. Mineral nutrients required by animals in micro amounts only (measured in milligrams per pound or smaller units.)

Tracer. (Part) A harmless substance present at insignificant levels in an animal food to assure the presence of and thorough mixing of a component (ingredient/premix) of that food.

Treat. A food provided occasionally for enjoyment, training, entertainment, or other purposes, and not generally intended or represented to be a complete feed or supplement.

Tubers. (Part) Short, thickened fleshy stems or terminal portions of stems or rhizomes that are usually formed underground, bear minute scaled leaves, each with a bud capable under suitable conditions of developing into a new plant, and constitutes the resting stage of various plants.

Twigs. (Part) Small shoots or branches, usually without leaves, portions of stems of variable length or size.

Type A medicated article is intended solely for use in the manufacture of another Type A medicated article or a Type B or Type C medicated feed. It consists of a new animal drug(s), with or without carrier (e.g., calcium carbonate, rice hull, corn gluten) with or without inactive ingredients. The manufacture of a Type A medicated article requires an application approved under 21 CFR 514.105.

Type B medicated feed is intended solely for the manufacture of other medicated feeds (Type B or Type C). It contains a substantial quantity of nutrients including vitamins and/or minerals and/or other nutritional ingredients in an amount not less than 25% of the weight. It is manufactured by diluting a Type A medicated article or another Type B medicated feed. The maximum concentration of animal drug(s) in a Type B medicated feed is 200 times the highest continuous use level for Category I drugs and 100 times the highest continuous use level for Category II drugs. The term "highest continuous use level" means the highest dosage at which the drug is approved for continuous use (14 days or more), or, if the drug is not approved for continuous use, it means the highest level used for disease prevention or control. If the drug is approved for multiple species at different use levels, the highest approved level of use would govern under this definition. The manufacture of a Type B medicated feed from a Category II, Type A medicated article requires a medicated feed mill license application approved under 21 CFR 515.20.

Type C medicated feed is intended as the complete feed for the animal or may be fed "top dressed" (added on top of usual ration) or offered "free choice" (e.g., supplement) in conjunction with other animal feed. It contains a substantial quantity of nutrients including vitamins, minerals, and/or other nutritional ingredients. It is manufactured by diluting a Type A medicated article or a Type B medicated feed. A Type C medicated feed may be further diluted to produce another Type C medicated feed. The manufacture of a Type C medicated feed from a Category II, Type A medicated article requires a medicated feed mill license application approved under 21 CFR 515.20.

Uncleaned. (Physical form) Containing foreign material.

Unsaponifiable matter. (Part) Ether soluble material extractable after complete reaction with strong alkali.

Vines. (Part) Any plant whose stems require support, or lie on the ground.

Viscera. (Part) All the organs in the great cavity of the body, excluding contents of the intestinal tract.

Viscera, fish. (Part) All organs in the great cavity of the body; it includes the gills, heart, liver, spleen, stomach, and intestines.

Viscera, mammals. (Part) All organs in the great cavity of the body; it includes the esophagus, heart, liver, spleen, stomach, and intestines, but excludes the contents of the intestinal tract.

Viscera, poultry. (Part) All organs in the great cavity of the body; it includes the esophagus, heart, liver, spleen, stomach, crop, gizzard, undeveloped eggs, and intestines.

Vitaminize, vitaminized. (Process) To provide or supplement with vitamins.

Vitamins. Organic compounds that function as parts of enzyme systems essential for the transmission of energy and the regulation of metabolisms of the body.

Wafered, wafering. (Process) Having agglomerated a feed of a fibrous nature by compressing into a form usually having a diameter or cross section measurement greater than its length.

Wafers. (Physical form) A form of agglomerated feed based on fibrous ingredients in which the finished form usually has a diameter or cross section measurement greater than its length.

Waste. (Part) See *refuse*.

Water Buffalo. Common name for *Bubalus bubalis*. The meat or other ingredients derived from the animal (e.g. by-products, meal, fat) must be referred to as "water buffalo" or "water buffalo _____" with the specific non-meat ingredient filling in the blank.

Water extract. The aqueous phase containing dissolved materials resulting from the treatment (e.g. by mixing or boiling) of a solid with water. All or part of the solid matrix may be dissolved in the extract.

Weathered. (Process) A material which has been subjected to the action of the elements.

Wet. (Physical form) Material containing liquid or which has been soaked or moistened with water or other liquid.
Wet-milled. (Process) Steeped in water with or without sulfur dioxide to soften the kernel in order to facilitate the separation of the various component parts.
Wet-rendered, wet-rendering. (Process) Cooked with steam under pressure in closed tanks.
Whey. (Part) The watery part of milk separated from the curd.
Whey solids. (Part) The solids of whey (proteins, fats, lactose, ash, and lactic acid)
Whole. (Physical form) Complete, entire.
Whole pressed, whole pressing. (Process) Having the entire seed to remove oil.
Wilted. (Physical form) A product without turgor as a result of water loss.
Wort. (Part) The liquid portion of malted grain. It is a solution of malt sugar and other water-soluble extracts from malted mash.

Deleted Feed Terms

The membership has voted to remove the following feed terms from use:

1. Ingredient, Feed Ingredient (2009)
2. Charcoal (2010)

Official Common or Usual Names and Definitions of Feed Ingredients

As Established By The Association Of American Feed Control Officials

The **bold print name** and international feed name (IFN) are both acceptable as ingredient names, unless designated otherwise in the definition.

Occasionally an item may be suggested as an ingredient in a mixed feed that is not listed in this publication. When this happens, the appropriate investigator should be contacted to develop an ingredient definition. Some ingredients, e.g. sugar, are so common there is no need to define them.

3. Alfalfa Products

Investigator and Section Editor—Erin Bubb, PA

Official

3.1 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." (Adopted prior to 1928, Amended 1937, 1965, 2004, 2021 rev. 1.)

IFN 1-00-104 Alfalfa hay sun-cured chopped
IFN 1-00-090 Alfalfa hay sun-cured 13% Protein
IFN 1-00-095 Alfalfa hay sun-cured 15% Protein
IFN 1-00-096 Alfalfa hay sun-cured 17% Protein
IFN 1-30-293 Alfalfa hay sun-cured 18% Protein
IFN 1-00-088 Alfalfa hay sun-cured 20% Protein
IFN 1-30-295 Alfalfa hay sun-cured 22% Protein
IFN 1-00-111 Alfalfa hay sun-cured ground
IFN 1-00-112 Alfalfa hay sun-cured ground 13% Protein
IFN 1-00-113 Alfalfa hay sun-cured ground 15% Protein
IFN 1-00-114 Alfalfa hay sun-cured ground 17% Protein
IFN 1-30-296 Alfalfa hay sun-cured ground 18% Protein
IFN 1-00-116 Alfalfa hay sun-cured ground 20% Protein
IFN 1-00-117 Alfalfa hay sun-cured ground 22% Protein

3.2 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. (Adopted 1928, Amended 1965, 1995, 2004.)

IFN 1-00-025 Alfalfa Meal dehydrated
IFN 1-00-021 Alfalfa Meal dehydrated 13% Protein
IFN 1-00-022 Alfalfa Meal dehydrated 15% Protein
IFN 1-00-023 Alfalfa Meal dehydrated 17% Protein
IFN 1-30-297 Alfalfa Meal dehydrated 18% Protein
IFN 1-00-024 Alfalfa Meal dehydrated 20% Protein
IFN 1-07-851 Alfalfa Meal dehydrated 22% Protein

NOTE 1: The following guarantees are recommended for the various grades of alfalfa meal and ground alfalfa hay:

For 15% Crude Protein, Crude Fiber not more than 30%
For 17% Crude Protein, Crude Fiber not more than 27%
For 18% Crude Protein, Crude Fiber not more than 25%

For 20% Crude Protein, Crude Fiber not more than 22%

For 22% Crude Protein, Crude Fiber not more than 20%

NOTE 2: 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) (Adopted 1941, Amended 1945 and 1966.)

NOTE 3: Brand names, such as "Doe's _____ % Alfalfa Meal with Animal Fat or Vegetable Oil," must be used 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. (Adopted 1963)

3.3 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. (Proposed 1982, Adopted 1983)

IFN 4-16-026 Alfalfa nutrient concentrate dehydrated

3.4 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%. (Proposed 1982. Adopted 1983)

IFN 4-16-027 Alfalfa solubles condensed

3.5 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. (Proposed 2016 rev. 1, Adopted 2018)

6. Amino Acids and Related Products

Investigator and Section Editor—Richard Ten Eyck, OR

Official

6.1 DL-Methionine Hydroxy Analogue Calcium is a product that contains a minimum of 97% racemic 2-hydroxy-4-(methylthio)butanoic acid calcium salt. The percentage of DL-Methionine Hydroxy Analogue Calcium must be guaranteed. (Adopted 1959, Amended 1974, 1978, 1989, 2005, 2009, Adopted 2011). 21 CFR 582.5477

IFN 5-03-087 DL-Methionine Hydroxy Analogue Calcium

6.2 DL-Methionine is a product containing a minimum of 99% racemic 2-amino-4-(methylthio)butanoic acid. The percentage of DL-Methionine must be guaranteed. (Adopted 1957, Amended 1975, 1978, 1989, 2005, 2009, Adopted 2011). 21 CFR 582.5475

IFN 5-03-086 DL-Methionine

6.3 Glycine is a product which contains a minimum of 97% amino acetic acid. The percentage of glycine must be guaranteed. (Adopted 1957.) 21 CFR 582.5049

IFN 5-02-127 Glycine

6.4 L-Lysine is a product which contains a minimum of 95% L-2,6-diaminohexanoic acid. The percentage of L-lysine must be guaranteed. (Proposed 1966, Adopted 1969, Amended 1975) 21 CFR 582.5411

IFN 5-08-022 L-Lysine

6.5 L-Threonine is a product which contains a minimum of 95% L-2-amino-3-hydroxybutanoic acid. The percentage of L-threonine must be guaranteed. (Proposed 1967, Adopted 1969, Amended 1975, Amended 2010, Adopted 2012) 21 CFR 582.5881

IFN 5-08-092 L-Threonine

6.6 DL-Tryptophan is a product which contains a minimum of 97% racemic 2-amino-3-(3-indolyl)-propionic acid. The percentage of DL-tryptophan must be guaranteed. Excessive tryptophan consumption in cattle (in excess of 0.17g tryptophan/100 pounds bodyweight/day) is associated with bovine pulmonary emphysema. (Proposed 1967, Adopted 1969, Amended 1975, Amended 2001, Adopted 2003.) 21 CFR 582.5915

IFN 5-08-093 DL-Tryptophan

6.7 DL-Methionine Hydroxyl Analogue Isopropyl Ester is a product containing a minimum of 90% 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. (Adopted 2008, Amended 2009, Adopted 2011)

6.8 DL-Methionine Hydroxy Analogue is a product containing a minimum of 88% racemic 2-hydroxy-4-(methylthio)butanoic acid. The percentage of DL-Methionine Hydroxy Analogue must be guaranteed. (Proposed 1980, Adopted 1985, Amended 1989, 2005, 2009, Adopted 2011). 21 CFR 582.5477

IFN 5-30-281 DL-Methionine Hydroxy Analogue

6.9 DL-Methionine Sodium is a product containing a minimum of 45.9% racemic 2-amino-(methylthio)butanoic acid sodium salt. The percentage of DL-methionine must be guaranteed. (Proposed 1983, Amended 1989, Adopted 1990, Amended 2005, Amended 2009, Adopted 2011)

IFN 5-16-730 DL-Methionine Sodium

6.10 L-Tryptophan is a product which contains a minimum of 97% L-2-amino-3-(3'indolyl)-propionic acid. The percentage of L-tryptophan must be guaranteed. Excessive tryptophan consumption in cattle (in excess of 0.17g tryptophan/100 pounds bodyweight/day) is associated with bovine pulmonary emphysema (Proposed 1985, Adopted 1987, Amended 2001, Adopted 2003) 21 CFR 582.5915

IFN 5-18-776 L-Tryptophan

6.11 L-Lysine Monohydrochloride is a product which contains a minimum of 95% L-2, 6-diaminohexanoic acid monohydrochloride. The percentage of L-lysine must be guaranteed. (Adopted 1989)

IFN 5-19-118 L-Lysine Monohydrochloride

6.12 Taurine is a product that contains a minimum of 97% 2-aminoethanesulfonic acid. The percentage of taurine must be guaranteed. It is used as a nutritional supplement in cat foods, dog foods, and 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% of the feed (21 CFR 573.980). (Proposed 2017 rev. 1, Adopted 2019 rev. 1)

IFN 5-09-821 Taurine

6.13 L-Arginine is a product which contains a minimum of 98% L-2-amino-5-guanidyl-valeric acid. The percentage of L-Arginine must be guaranteed. 21 CFR 582.5145 (Adopted 1990)

IFN 5-32-043 L-Arginine

6.14 DL-Arginine is a product which contains a minimum of 98% racemic 2-amino-5-guanidyl-valeric acid. The percentage of DL-Arginine must be guaranteed. 21 CFR 582.5145 (Adopted 1990)

IFN 5-32-044 DL-Arginine

6.15 L-Tyrosine is a product which contains a minimum of 98% L-2-amino-3-(4-hydroxyphenyl) propionic acid. The percentage of L-Tyrosine must be guaranteed. 21 CFR 582.5920 (Adopted 1990)

IFN 5-32-045 L-Tyrosine

6.16 L-Lysine Liquid is a product that contains a minimum of 50% L-2, 6-diaminohexanoic acid by weight in a water solution. The L-lysine content must not be less than 85% on a moisture-free basis. The percentage of L-lysine must be guaranteed. 21 CFR 582.5411 (Proposed 1999, Adopted 2001)

6.17 L-Methionine is a product containing a minimum of 98.5% 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. (Proposed 2015, Adopted 2017 rev. 1)

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

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

9. Animal Products

Investigator and Section Editor—Stan Cook, MO

Official

*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."**

***9.2 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. (Adopted 1938, Amended 1939, 1963)

IFN 5-00-394 Animal meat fresh

***9.3 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. (Proposed 1973, Adopted 1974, Amended 1978)

IFN 5-00-395 Animal meat by-products fresh

***9.7 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. (Adopted 1954, Amended 2006)

IFN 5-00-389 Animal livers meal

9.10 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 processing 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. (Proposed 1985, Adopted 1990, Amended 2000, Proposed 2016 rev. 1, Adopted 2018 rev. 1)

IFN 5-03-798 Poultry by-product meal rendered

9.11 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. (Adopted 1957)

IFN 5-03-796 Poultry hatchery by-product meal

***9.12 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%. (Proposed 1961, Adopted 1962, Amended 1964,1967)

IFN 5-00-393 Animal meat solubles dehydrated

9.14 Poultry By-Products consists of nonrendered 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 processing 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. (Proposed 1963, Adopted 1964, Amended 2000, Proposed 2016 rev. 1, Adopted 2018 rev. 1)

IFN 5-03-800 Poultry by-product fresh

9.15 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% of its crude protein content must be digestible by the pepsin digestibility method.** (Proposed 1961, Adopted 1965)

IFN 5-03-795 Poultry feathers meal hydrolyzed

***9.16 Fleshings Hydrolysate** is obtained by acid hydrolysis of the flesh from fresh or salted hides. It is defatted, strained, and neutralized. If evaporated to 50% solids, it shall be designated "Condensed Fleshings Hydrolysate." It must have a minimum crude protein and maximum salt guarantee. (Proposed 1967, Adopted 1968) Reg. 573.200

IFN 5-08-094 Animal skin fleshings hydrolyzed rendered

9.20 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% (as a percent of total protein) determined by colorimetric assay (Doumas, B. T., Watson, W. A., Biggs, H. G., Clin. Chim Acta. 1971) and the minimum globulin content is 20% (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). If the product bears a name descriptive of its kind, origin or composition, it must correspond thereto. (Proposed 1996, Adopted 2000)

9.21 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% 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. (Proposed 1996, Adopted 2000)

9.22 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% 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. (Proposed 1996, Adopted 2000)

9.24 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 processing 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 8%; a minimum crude protein of 90%; and a minimum solubility in water of 75%. If the product bears a name descriptive of its kind, origin, or composition, it must correspond thereto. (Proposed 1996, Adopted 1998)

***9.40 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 processing 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% Pepsin indigestible residue** and not more than 9% of the crude protein in the product shall be pepsin indigestible**. 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. (Proposed 1971, Adopted 1972, Amended 1985, Adopted 1993)

IFN 5-00-385 Animal meat meal rendered

***9.41 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 processing practices. It shall not contain added extraneous materials not provided for in this definition. It shall contain a minimum of 4.0% 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% pepsin indigestible residue** and not more than 9% of the crude protein in the product shall be pepsin indigestible**. 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. (Proposed 1985, Amended 1992, Adopted 1994)

IFN 5-00-388 Animal meat with bone rendered

***9.42 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 processing 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. (Proposed 1985, Amended 1992, Adopted 1993)

IFN 5-08-786

***9.50 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 processing factory 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% pepsin indigestible residue** and not more than 9% of the crude protein in the product shall be pepsin indigestible**. 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. (Proposed 1985, Amended 1992, Adopted 1994)

IFN 5-00-386 Animal tankage meal rendered

***9.51 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 processing 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 4.0% 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% pepsin indigestible residue** and not more than 9% of the crude protein in the product shall be pepsin indigestible**. 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. (Proposed 1985, Adopted 1994)

IFN 5-00-387 Animal tankage with bone rendered

***9.54 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% of its crude protein must be digestible by the pepsin digestibility method** (Proposed 1968, Adopted 1970)

IFN 5-08-997 Animal hair hydrolyzed

***9.55 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% moisture, not less than 60% crude protein, not more than 6% crude fiber, not more than 2.75% chromium, and with not less than 80% of its crude protein digestible by the pepsin digestibility method**. Hydrolyzed leather meal may be utilized in livestock feeds as provided in food additive regulation 573.540 (Proposed 1968, Adopted 1970)

IFN 5-08-998 Animal leather meal hydrolyzed

9.56 Spray Dried Animal Blood is produced from clean, fresh animal blood, exclusive of all extraneous material such as hair, stomach belching, urine, except in such traces as might occur unavoidably in good factory practice. Moisture is removed from the blood by a low temperature, evaporator under vacuum until it contains approximately 30% 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 8% and a minimum crude protein of 85%. It must be designated according to its minimum water solubility. (Proposed 1972, Amended 1976, Adopted 1978)

IFN 5-00-381 Animal blood spray dehydrated

9.57 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 processing 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. (Proposed 1978, Adopted 1979, Amended 1995, Amended 1997, Proposed 2016 rev. 1, Adopted 2018 rev. 1)

9.58 Hydrolyzed Whole Poultry is the product resulting from the hydrolyzation of whole carcasses of culled or dead, undecomposed, poultry including feathers, heads, feet, entrails, undeveloped eggs, blood and any other specific portions of the carcass. The product must be consistent with the actual proportions of whole poultry and must be free of added parts; including, but not limited to entrails, blood or feathers. The poultry 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°F, or 100°C at sea level, for 30 minutes; dry extrusion at a minimum temperature of 284°F or 140°C for 30 seconds with a pressure differential of approximately 40 atmospheres as the product exits the extruder; or their equivalents) and agitating (except in steam cooking

equipment). The product may, if acid or alkaline treated, be subsequently neutralized. If the product bears a name descriptive of its kind, the name must correspond thereto. (Proposed 1995, Adopted 1997, Amended 2000, Adopted 2003)

9.59 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°F, or 100°C 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. (Proposed 1978, Adopted 1980 Amended 1995, Adopted 1997)

9.60 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°F. It must be designated according to its protein and calcium content. (Proposed 1975, Adopted 1982)

IFN 6-26-004 Poultry egg shells meal

9.61 Blood Meal _____ 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 processing practices. The process used must be listed as a part of the product name such as conventional cooker dried, steamed or hydrolyzed. The product usually has a dark black like color and is rather insoluble in water. (Proposed 1975, Adopted 1979, Amended 1991, Adopted 1993)

IFN 5-26-005 Animal blood meal conventional cooker dehydrated

IFN Number _____ Animal blood meal steamed dehydrated

IFN Number _____ Animal blood meal hydrolyzed dehydrated

9.62 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 processes. 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%. (Proposed 1975, Adopted 1980)

IFN 5-26-006 Animal blood meal flash dehydrated

9.63 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 processes. If the product bears a name descriptive of its kind, composition or origin, it must correspond thereto. (Proposed 1975, Amended 1980, Adopted 1982, Amended 1993, Adopted 1994)

IFN 5-25-007 Animal blood fresh

***9.65 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. (Proposed 1979, Adopted 1980)

IFN 5-12-247 Animal glands meal

IFN 5-30-080 Animal glands meal water extracted

***9.67 Unborn Calf Carcasses** is the product obtained from whole unborn carcasses taken from slaughtered cows at government inspected slaughter plants. The product is produced by grinding the whole unborn carcass, exclusive of calf hides. The product is

denatured, fresh frozen and shall be suitable for use as an animal feed. (Proposed 1979, Adopted 1980)

IFN 5-30-081 Cattle fetus carcass without skin fresh[P SEP]

***9.68 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 factory practice and shall be suitable for animal feed. If it bears a name descriptive of its kind or flavor(s), it must correspond thereto. (Proposed 1981, Amended 1983, Adopted 1990)

IFN 5-06-935 Animal Digest Condensed

***9.69 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 processing practice. The labeling of this product shall include, but is not limited to, guarantees for minimum crude protein and minimum crude fat. (Proposed 1988, Adopted 1992)

***9.70 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 processing practice. The labeling of this product shall include, but is not limited to, guarantees for minimum crude protein and minimum crude fat. (Proposed 1988, Adopted 1992)

9.71 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 processing 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. (Proposed 1988, Adopted 1992, Proposed 2016 rev. 1, Adopted 2018 rev. 1)

9.72 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. (Proposed 1990, Adopted 1993)

9.73 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%. 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 4.0 or less. (Proposed 1990, Adopted 1992)

9.74 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 (9CFR, 590). This product shall be free of shells or other non-egg materials except in such amounts which might occur unavoidably in good processing practices, and contain a maximum ash content of 6% on a dry matter basis. (Proposed 1991, Adopted 1996, Amended 2008)

9.75 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 ppm 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% crude protein and not less than 85% of the protein shall be pepsin digestible**. (Adopted 1993, Amended 1999, Adopted 2001)

***9.77 _____ 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% 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 1 part crude protein). The product 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. (Proposed 1997, Amended 2001, Adopted 2002)

***9.78 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% minimum protein level, 1% maximum fat and 2% maximum ash. (Proposed 1993, Adopted 1994)

**Determined by AOAC method listed in the Check Sample Reference for Analytical Variations.

9.79 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 processing methods. The blood cells are dried by exposing the cells to a heated air stream and retaining them in the maximum moisture of 11%; and a minimum protein of 90%. If the product bears a name descriptive of its kind, origin, or composition it must correspond thereto. (Proposed 2008, Adopted 2010)

9.80 Hydrolyzed Whole Swine is the product resulting from the hydrolyzation of whole carcasses of culled or dead, undecomposed, swine, including heads, feet, viscera, blood and any other specific portions of the carcass. The product must be consistent with the actual proportions of whole swine and must be free of added parts; including, but not limited to viscera, blood or hair. The swine 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° F or 100° C at sea level for 30 minutes; dry extrusion at a minimum temperature of 284° F or 140°C for 30 seconds with a pressure differential of approximately 40 atmospheres as the product exits the extruder; or their equivalent) and agitating (except in steam cooking equipment). The product may, if acid or alkaline treated, be subsequently neutralized. If the product bears a name descriptive of its kind, the name must correspond thereto. (Proposed 2007, Adopted 2010)

12. Barley Products

Investigator and Section Editor—Dan King, MN

Official

12.1 Barley Hulls consist of the outer covering of the barley. (Adopted prior to 1928)

IFN 1-00-496 Barley hulls

12.3 Pearl Barley By-Product is the entire by-product resulting from the manufacture of pearl barley from clean barley. (Proposed 1961, Adopted 1962)

IFN 5-00-548 Barley pearl by-product

12.4 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. (Proposed 1961, Adopted 1962)

IFN 4-00-523 Barley mill run

Tentative

T12.8 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% crude protein on a dry matter basis. The finished ingredient should not contain more than 10% moisture. It is to be used in the feed of fish as a source of protein. (Proposed 2022 rev. 1)

15. Brewers Products

Investigator and Section Editor—Nathan Price, ID

Official

15.1 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 3%, evenly distributed. (Adopted 1965, Amended 1972)

IFN 5-00-516 Barley brewers grains dehydrated

15.2 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% 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. (Adopted 1942, Amended 1964, 1980)

IFN 5-00-545 Barley malt sprouts dehydrated

IFN 5-04-048 Rye malt sprouts dehydrated

IFN 5-29-796 Wheat malt sprouts dehydrated

15.3 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. (Adopted 1942)

IFN 5-00-544 Barley malt cleanings dehydrated

15.4 Malt Hulls consists almost entirely of hulls as obtained in the cleaning of malted barley. (Adopted 1942)

IFN 1-00-497 Barley malt hulls

15.5 Dried Spent Hops is obtained by drying the material filtered from hopped wort. (Adopted 1944)

IFN 5-02-396 Hop common fruit (hops) spent dehydrated

15.6 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. (Proposed 1971, Adopted 1974)

IFN 5-00-517 Barley brewers grains wet

15.7 Brewers Condensed Solubles is obtained by condensing liquids resulting as by-products from manufacturing beer or wort. It must contain not less than 20% total solids, 70% carbohydrates on a dry matter basis and the guaranteed analysis shall include maximum moisture. (Proposed 1975)

IFN 5-12-239 Barley brewers soluble condensed

18. Preservatives

Investigator and Section Editor—Richard Ten Eyck, OR

Official

18.1 Chemical Preservatives

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.

Name	FDA Regulations	Classification Under Food Additives Amendment	Limitations or Restrictions
Ascorbic acid IFN 7-00-433	Reg. 582.3013	Chemical preservative	None[a]
Ascorbyl palmitate IFN 8-26-245	Reg. 582.3149	Chemical preservative	None[a]
Benzoic acid IFN 8-26-244	Reg. 582.3021	Chemical preservative	Not to exceed 0.1%
Butylated hydroxy anisole (BHA)[b]	Reg. 582.3169	Chemical preservative	Total content of preservatives not more than 0.02% of fat or oil content including essential (volatile) oil content of food
Butylated hydroxytoluene (BHT)[b] IFN 8-01-045	Reg. 582.3173	Chemical preservative	Total content of preservatives not more than 0.02% of fat or oil content including essential (volatile) oil content of food
Calcium ascorbate IFN 8-26-246	Reg. 582.3189	Chemical preservative	None[a]
Calcium propionate IFN 8-01-085	Reg. 582.3221	Chemical preservative	None[a]
Calcium sorbate IFN 8-01-086	Reg. 582.3225	Chemical preservative	None[a]
Citric acid IFN 8-01-233	Reg. 582.6033, 21 CFR 582.1033	Chemical preservative	None[a]

(continued)

Name	FDA Regulations	Classification Under Food Additives Amendment	Limitations or Restrictions
Dilauryl thiodipropionate IFN 8-01-789	Reg. 582.3280	Chemical preservative	Total content of preservatives not more than 0.02% of fat or oil content including essential (volatile) oil content of food
Distearyl thiodipropionate IFN 8-01-792		Chemical preservative	Total content of preservatives not more than 0.02% of fat or oil content including essential (volatile) oil content of food
Erythorbic acid IFN 8-09-823	Reg. 582.3041	Chemical preservative	None[a]
Ethoxyquin IFN 8-01-841	Reg. 573.380	Chemical preservative	0.015% 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, and (2) as an aid in preventing the development of organic peroxides in canned pet food.
Gum guaiac IFN 8-03-909	Reg. 582.3336	Chemical preservative	0.1% (equivalent preservative activity 0.01%) only in edible fats or oils
Methylparaben IFN 8-03-088	Reg. 582.3490	Chemical preservative	0.1%
Potassium bisulfite IFN 8-26-302	Reg. 582.3616	Chemical preservative	Not for use in meats or vitamin B_1 sources
Potassium metabisulfite IFN 8-26-203	Reg. 582.3637	Chemical preservative	Not for use in meats or vitamin B_1 sources
Potassium sorbate IFN 8-03-761	Reg. 582.3640	Chemical preservative	None[a]
Propionic acid IFN 8-02-807	Reg. 582.3081	Chemical preservative	None[a]

(continued)

Name	FDA Regulations	Classification Under Food Additives Amendment	Limitations or Restrictions
Propyl gallate IFN 8-03-308	Reg. 582.3660	Chemical preservative	Total content of preservatives not more than 0.02% of fat or oil content including essential (volatile) oil content of food
Propylparaben IFN 8-03-810	Reg. 582.3670	Chemical preservative	0.1%
Sodium ascorbate IFN 8-26-304	Reg. 582.3731	Chemical preservative	None[a]
Sodium benzoate IFN 8-04-271	Reg. 582.3733	Chemical preservative	0.1%
Sodium bisulfite IFN 8-26-305	Reg. 582.3739	Chemical preservative	Not for use in meats or vitamin B_1 sources
Sodium metabisulfite IFN 8-26-306	Reg. 582.3766	Chemical preservative	Not for use in meats or vitamin B_1 sources
Sodium nitrite IFN 8-04-283	Reg. 573.700	Preservative and color fixative in canned pet food containing fish, meat, fish by-products, or meat by-products	20 ppm (0.002%)
Sodium propionate IFN 8-04-289	Reg. 582.3784	Chemical preservative	None[a]
Sodium sorbate IFN 8-04-290	Reg. 582.3795	Chemical preservative	None[a]
Sodium sulfite IFN 8-26-307	Reg. 582.3798	Chemical preservative	Not for use in meats or vitamin B_1 sources
Sorbic acid IFN 8-04-297	Reg. 582.3089	Chemical preservative	None[a]
Stannous chloride IFN 8-26-308	Reg. 582.3845	Chemical preservative	Not to exceed 0.0015% as tin
Sulfur dioxide IFN 8-26-309	Reg. 582.3862	Chemical preservative	Not for use in meats or vitamin B_1 sources

(continued)

Name	FDA Regulations	Classification Under Food Additives Amendment	Limitations or Restrictions
Tertiary butyl hydroquinone (TBHQ) IFN 8-04-829	I.R.P.[c]	Chemical Preservative	Total content of preservatives not more than 0.02% of fat or oil content including essential (volatile) oil content of food
Thiodipropionic acid IFN 8-04-830	Reg. 582.3109	Chemical preservative	Total content of preservatives not more than 0.02% of fat or oil content including essential (volatile) oil content of food
Tocopherols IFN 7-05-038	Reg. 582.3890	Chemical preservative	None[a]

[a]None = no quantitative restrictions, although use must conform to good manufacturing practices.
NOTE: When using any of the above materials, a statement of the fact that a chemical preservative has been added must be shown. Examples: BHA (a preservative), or preserved with BHT, or sorbic acid added to retard mold growth, etc.
NOTE: International feed name and AAFCO name are identical for the above chemical preservatives.
[b]For BHA and BHT either the name or the abbreviation may be used.
[c]I.R.P. = informal review process.

21. Citrus Products

Investigator and Section Editor—Michael Davidson, CA

Official

21.1 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. (Adopted 1958, Amended 1965)

IFN 4-01-237 Citrus pomace without fines dehydrated (pulp)

21.2 Dried Citrus Meal is the finer particles obtained by screening dried citrus pulp. (Adopted 1958, Amended 1965)

IFN 4-01-235 Citrus pomace fines dehydrated (pulp)

21.3 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. (Adopted 1958, Amended 1965)

IFN 5-01-239 Citrus seeds meal mechanical extracted.

22. Collective Terms

Investigator and Section Editor—Jacob Fleig, MO

Official

Collective terms recognize a general classification of ingredient origin, which perform a similar function, but do not imply equivalent nutritional values.

To be added to the particular collective term, the product shall correspond to the descriptor and category (e.g., be made from a forage to be in the forage products collective term or be a source of protein to be in the animal protein collective term).

When a collective term is used, individual ingredients within that group cannot be listed on the label.

The control official shall be provided, upon request, the ingredients that are being used within each collective term by the manufacturer using collective terms.

22.1 Animal Protein Products may include one or more of the following:

9.61	Blood Meal _____	9.51[a]	Meat and Bone Meal Tankage
9.42[a]	Animal By-Product Meal	9.40[a]	Meat Meal
54.2	Buttermilk, Condensed	9.50[a]	Meat Meal Tankage
54.1	Buttermilk, Dried	9.12[a]	Meat Solubles, Dried
54.16	Casein	54.18	Lactalbumin, Dried
54.21	Casein, Dried Hydrolyzed	54.19	Milk, Dried Feed Grade
54.17	Cheese Rind	54.20	Milk Protein, Dried
51.4	Crab Meal	9.14	Poultry By-Products
54.31	Dried Cheese	9.10	Poultry By-Product Meal
54.32	Dried Cheese Product	9.11	Poultry Hatchery By-Product
51.10	Fish By-Products	51.5	Shrimp Meal
51.34	Fish Liver and Glandular Meal	54.4	Skimmed Milk, Condensed
51.14	Fish Meal	54.6	Skimmed Milk, Condensed Cultured
51.9	Fish Protein Concentrate	54.3	Skimmed Milk, Dried
51.24	Fish Residue Meal	54.5	Skim Milk, Dried Cultured
51.6	Fish Solubles, Condensed	54.8	Whey, Condensed
51.7	Fish Solubles, Dried	54.15	Whey, Condensed Cultured
9.16[a]	Fleshings Hydrolysate	54.12	Whey, Condensed Hydrolyzed
9.54[a]	Hydrolyzed Hair	54.7	Whey, Dried
9.55[a]	Hydrolyzed Leather Meal	54.11	Whey, Dried Hydrolyzed
9.59	Hydrolyzed Poultry By-Product Aggregate	54.13	Whey Product, Condensed
9.15	Hydrolyzed Poultry Feathers	54.14	Whey Product, Dried
9.58	Hydrolyzed Whole Poultry	54.10	Whey Solubles, Condensed
9.75	Leather Hydrolysate	54.9	Whey Solubles, Dried
9.41[a]	Meat and Bone Meal		

[a]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."**

22.2 Forage Products may include one or more of the following:

3.2	Alfalfa Meal, Dehydrated or Pellets	71.3	Flax Plant Product
3.1	Alfalfa Hay, Ground	60.11	Ground Grass

3.1	Alfalfa Meal, Suncured or Pellets	45.1	Lespedeza Meal
60.27	Coastal Bermudagrass Hay	45.2	Lespedeza Stem Meal
48.20	Corn Plant, Dehydrated	84.2	Soybean Hay, Ground
60.	Dehydrated Silage (Ensilage Pellets)		

22.3 Grain Products—In any of the normal forms such as whole, ground, cracked, screen cracked, flaked, kibbled, toasted, or heat processed:

[a]	Barley	[a]	Wheat
48.3, 48.4, 48.5, 48.6	Corn	75.5	Brown Rice, Ground
48.11, 48.12, 48.19	(corn)	75.2	Rough Rice, Ground or Ground Paddy
42.1, 42.6	Grain Sorghum	75.4	Broken, or Chipped Rice
69.6	Mixed Feed Oats	75.4	Rice, Brewers
[a]	Oats	[a]	Rye
[a]	Triticale		

[a]No official definition for the grain product.

22.4 Plant Protein Products may include one or more of the following:

60.34	Beans, Dried	84.7, 84.60,	Soybean Meal
71.77	Canola Meal	84.61	
71.60, 71.61	Coconut Meal	84.71	Soybean Meal, Dehulled,
24.30, 24.31	Cottonseed Flakes		Mechanical Extracted
24.2	Cottonseed Cake	84.13	Soybean Meal, Kibbled
24.10, 24.12	Cottonseed Meal	84.11	Soybeans Heat Processed
24.50, 24.51	Cottonseed Meal, Low Gossypol	84.15	Whole Soybeans, Ground Extruded
24.4	Cottonseed, Whole Pressed	84.51	Soy Flour
		84.5	Soy Grits
60.18	Guar Meal	84.62	Soy Protein Isolate
84.63	Hydrolyzed Soy Protein	71.220,	Sunflower Meal
60.19	Kelp, Dried	71.221	
71.1, 71.11	Linseed Meal	71.210,	Sunflower Meal, Dehulled
71.9	Peanut Meal	71.211	
[a]	Peas	84.64	Textured Soy Protein Product
60.94	Potato Protein	96.2	Yeast, Active Dry
84.16	_____ Protein Modified	96.4	Yeast, Brewers Dried
60.76	Seaweed Meal, Dried	96.8	Yeast, Culture
71.130,	Safflower Meal	96.1	Yeast, Dried
71.131		96.1	Yeast, Primary Dried
84.12	Soy Protein Concentrate	96.7	Yeast, Torula Dried or Candida
84.4	Soybean Feed		Dried
84.1	Soybeans, Ground		

[a]No official definition for the plant protein product.

22.5 Processed Grain By-Products may include one or more of the following:

60.43	Aspirated Grain Fractions	48.16, 48.26	Hominy Feed
15.1	Brewers Dried Grains	15.2	Malt Sprouts

60.6	Buckwheat Middlings	69.1	Oat Groats
27.7	Condensed Distillers Solubles	69.3	Oat Meal, Feeding
48.24	Condensed Fermented Corn Extractives	42.10	Grain Sorghum Mill Feed
		12.3	Pearl Barley By-Product
48.2	Corn Bran	71.21	Peanut Skins
48.8	Corn Flour	75.3, 75.7	Rice Bran
48.22, 48.23	Corn Germ Meal	75.1	Rice Polishings
		78.2	Rye Middlings
48.13	Corn Gluten Feed	42.8	Sorghum Grain Flour, Gelatinized
48.14	Corn Gluten Meal	42.9	Sorghum Grain Flour, Partially Aspirated
48.7	Corn Grits	93.1	Wheat Bran
27.5	_____ Distillers Dried Grains	93.2	Wheat Flour
27.6	_____ Distillers Dried Grains With Solubles	93.6	Wheat Shorts
27.4	_____ Distillers Dried Solubles	93.3	Wheat Germ Meal
[a]	_____ Flour	93.8	Wheat Germ Meal, Defatted
42.4	Grain Sorghum Germ Cake	93.5	Wheat Middlings
42.4	Grain Sorghum Germ Meal	93.4	Wheat Mill Run
42.7	Grain Sorghum Grits	93.7	Wheat Red Dog

22.6 Roughage Products may include one or more of the following:

60.7	Almond Hulls	60.84	Psyllium Seed Husk
40.2	Apple Pectin Pulp, Dried	15.4	Malt Hulls
40.1	Apple Pomace, Dried	69.4	Clipped Oat By-Product
63.26	Bagasse	69.2	Oat Hulls
12.1	Barley Hulls	69.7	Oat Mill By-Product
12.4	Barley Mill By-Product	71.6	Peanut Hulls
63.36	Beet Pulp, Dried, Plain	75.6	Rice Hulls
60.17	Buckwheat Hulls	75.8	Rice Mill By-Product
21.2	Citrus Meal, Dried	78.1	Rye Mill Run
21.1	Citrus Pulp, Dried	84.3	Soybean Hulls
21.3	Citrus Seed Meal	84.8	Soybean Mill Feed
48.1	Corn Cob Fractions	84.9	Soybean Mill Run
24.6	Cottonseed Hulls	71.23	Sunflower Hulls
71.4	Flax Straw By-Product	60.10	Straw, Ground
48.21	Corn Cob, Ground	40.8	Tomato Pomace, Dried

22.7[a] Molasses Products may include one or more of the following:

63.1	Beet Molasses	36.10	Condensed Molasses Fermentation Solubles
63.39	Beet Molasses, Dried Product	63.6	Starch Molasses
63.37	Beet Pulp, Dried, Molasses	27.2	Molasses Distillers Cond. Solubles
63.7	Cane Molasses	27.1	Molasses Distillers Dried Solubles
63.3	Citrus Molasses		

63.81	Concentrated Separator By-Product	96.9	Molasses Yeast Condensed Solubles

[a]The molasses collective term is not recognized by the FDA (21 CFR 501.110).

24. Cottonseed Products

Investigator and Section Editor—Bernadette Mundo, SC

Official

24.14 Ammoniated Cottonseed Meal 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% 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% 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." (Reg. 573.140) (Proposed 1969, Adopted 1970.)

IFN 5-09-352 Cotton seeds meal solvent extracted ammoniated

24.10 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% 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%. 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. (Proposed 1984, Adopted 2002)

IFN 5-01-625 Cotton seeds meal mechanical extracted 36% protein

24.12 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% 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%. 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. (Proposed 1984, Adopted 2002)

IFN 5-01-632 Cotton seeds meal solvent extracted 36% protein

24.2 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% crude protein. The words "mechanical extracted" are not required when listing as an ingredient in a manufactured feed. (Proposed 1964, Adopted 1966, Amended 1968)

IFN 5-01-623 Cotton seeds mechanical extracted caked 36% protein

24.30 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% crude protein. The words "mechanical extracted" are not required when listing as an ingredient in a manufactured feed. (Proposed 1964, Adopted 1966, Amended 1968)

IFN 5-08-820 Cotton seeds mechanical extracted flaked 36% protein

24.31 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% crude protein. The words "solvent extracted" are not required when listing as an ingredient in a manufactured feed. (Proposed 1964, Adopted 1966, Amended 1968)

IFN 5-01-629 Cotton seeds solvent extracted flaked 36% protein

NOTE: The following levels of minimum crude fat and maximum crude fiber are adopted for cottonseed meals, cake, or flakes, of respective grade.

	Crude Fat		
Crude Protein	**Mechanical**	**Solvent**	**Crude Fiber**
36%	2.0%	0.5%	17%
41%	2.0%	0.5%	14%
43%	2.0%	0.5%	13%

IFN 5-01-617 Cotton seeds meal mechanical extracted 41% protein

IFN 5-01-627 Cotton seeds meal mechanical extracted 43% protein

IFN 5-01-621 Cotton seeds meal solvent extracted 41% protein

IFN 5-01-630 Cotton seeds meal solvent extracted 43% protein

This product (when sold or distributed singly) may be additionally labeled with the following bold face terms when the requirements thereinafter are met;

_____, **Prime Quality** must be free of mold, excess lint, and sour, musty, or burnt odors.

_____, **Off Quality** shall be that which does not meet the prime quality requirements.

24.4 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. (Proposed 1964, Adopted 1966, Amended 1968)

IFN 5-01-609 Cotton seeds meal mechanical extracted

24.50 Low Gossypol Cottonseed Meal, Mechanical Extracted, is a meal in which the gossypol is not more than 0.04% free gossypol. The words "mechanical extracted" are not required when listing as an ingredient in a manufactured feed. (Proposed 1964, Adopted 1966, Amended 1968)

IFN 5-09-002 Cotton seeds low gossypol meal mechanical extracted

24.51 Low Gossypol Cottonseed Meal, Solvent Extracted, is a meal in which the gossypol is not more than 0.04% free gossypol. The words "solvent extracted" are not required when listing as an ingredient in a manufactured feed. (Proposed 1964, Adopted 1966, Amended 1968)

IFN 5-01-633 Cotton seeds low gossypol meal solvent extracted

24.6 Cottonseed Hulls consist primarily of the outer covering of the cottonseed. (Proposed 1964, Adopted 1966)

IFN 1-01-599 Cotton hulls

24.7 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% crude protein and not more than 30% 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% ash, the words "sand" and/or "dirt" must appear in the product name. (Proposed 1980, Adopted 1983)

IFN 4-12-023 Cotton seed screenings

24.8 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% crude fiber, nor more than 15% 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% ash, the words "sand and/or dirt" must appear in the product name. (Proposed 1980, Adopted 1983, Amended 1984)

IFN 1-08-413 Cotton gin by-product

27. Distillers Products

Investigator and Section Editor—Dan King, MN

Official

27.1 Molasses Distillers Dried Solubles is obtained by drying the residue from the yeast fermentation of molasses after the removal of the alcohol by distillation. (Adopted 1943, Amended 1944)

IFN 4-04-698 Sugarcane molasses distillers solubles dehydrated

27.2 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. (Adopted 1946)

IFN 4-04-697 Sugarcane molasses distillers solubles condensed

27.3 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. (Adopted 1947)

IFN 5-03-773 Potato distillers residue dehydrated

27.4 _____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. (Proposed 1963, Adopted 1964)

IFN 5-00-520 Barley distillers solubles dehydrated
IFN 5-02-147 Cereals distillers solubles dehydrated
IFN 5-02-844 Maize distillers solubles dehydrated
IFN 5-04-026 Rye distillers solubles dehydrated
IFN 5-04-376 Sorghum distillers solubles dehydrated
IFN 5-05-195 Wheat distillers solubles dehydrated

27.5 _____ 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. (Proposed 1963, Adopted 1964)

IFN 5-00-518 Barley distillers grains dehydrated
IFN 5-02-144 Cereals distillers grains dehydrated
IFN 5-02-842 Maize distillers grains dehydrated
IFN 5-04-023 Rye distillers grains dehydrated
IFN 5-04-374 Sorghum distillers grains dehydrated
IFN 5-05-193 Wheat distillers grains dehydrated

27.6 _____ 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. (Proposed 1963, Adopted 1964)

IFN 5-12-185 Barley distillers grains with solubles dehydrated
IFN 5-07-987 Cereals distillers grains with solubles dehydrated
IFN 5-02-843 Maize distillers grains with solubles dehydrated
IFN 5-04-024 Rye distillers grains with solubles dehydrated
IFN 5-04-375 Sorghum distillers grains with solubles dehydrated
IFN 5-05-194 Wheat distillers grains with solubles dehydrated

27.7 _____ 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. (Proposed 1969, Adopted 1970)

IFN 5-12-210 Barley distillers solubles condensed
IFN 5-02-146 Cereals distillers solubles condensed
IFN 5-12-211 Maize distillers solubles condensed
IFN 5-12-212 Rye distillers solubles condensed
IFN 5-12-231 Sorghum distillers solubles condensed
IFN 5-12-213 Wheat distillers solubles condensed

27.8 _____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. (Proposed 1981, Adopted 1982, Amended 2007)

IFN 5-16-149 Cereals distillers grains wet

27.9 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 3% 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. (Proposed 2015, Adopted 2017 rev. 1)

Drugs and Medicated Feeds

Investigator and Section Editor—Dragan Momcilovic, FDA
(See Medicated Feed Section)

30. Enzymes

Investigator and Section Editor—Richard Ten Eyck, OR

*See the "Enzyme Marketing Coordination" document which appears on page 395.

The immediate following pages contain Table 30.1, Enzymes/Source Organisms Acceptable for Use in Animal Feeds. The purpose statement of a product label shall include a statement of enzyme functionality ("Function" and/or "Supported Use" as stated in Table 30.1) if enzymatic activity is represented in any manner.

For enzymes obtained from microorganisms, ingredient names shall use one of the applicable definitions, 36.6, 36.7, 36.11, or 36.12, from Section 36, Fermentation Products, 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 in Table 30.1, *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 Table 30.1 source organism, such as dried pineapple stem for bromelain, fig extract for ficin, or

dried pork stomach mucosa powder for pepsin. For more information about the labeling of enzyme products, see the labeling section in the Enzyme Marketing Coordination document.30.1 Enzymes/Source Organisms Acceptable for Use in Animal Feeds
In the case of microbial enzymes, it is understood that they are produced from nonpathogenic and nontoxigenic strains.

Classification/ Name	Source Organism	Typical Substrate[a]	Function	Supported Use[b]
Carbohydrases				
alpha-Amylase	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.	Corn silage, corn, corn feed meal, corn gluten feed, soybean meal, wheat, wheat middlings, barley, grain sorghum, pea, oat, tapioca, millet, rice	Hydrolyzes starch	
Maltogenic alpha-amylase	*Bacillus subtilis* containing a *Bacillus stearothermophilus* gene for maltogenic alpha-amylase	See alpha-amylase	Hydrolyzes starch with production of maltose	
beta-Amylase	Barley malt	See alpha-amylase	Hydrolyzes starch with production of maltose	

(continued)

Classification/ Name	Source Organism	Typical Substrate[a]	Function	Supported Use[b]
Cellulase	*Aspergillus niger*, var. *Humicola insolens* *Trichoderma longibrachiatum* (also known as *T. reesei* or *T. viride*)	Corn, barley, wheat, wheat, bran, rye, grain sorghum	Breaks down cellulose	
alpha-Galactosidase	*Aspergillus niger*, var. *Morteirella vinaceae* var. *raffinoseutilizer* *Saccharomyces* sp.	Sweet lupin, soybean meal	Hydrolyzes oligosaccharides	
beta-Glucanase	*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*)	Wheat, barley, canola meal, wheat by-product, oat groats, rye, triticale, grain sorghum	Hydrolyzes beta-glucans, a type of non-starch polysaccharide	Reduction of digesta viscosity with barley-based poultry diets, reduces soluble non-starch polysaccharides in digesta
beta-Glucosidase	*Aspergillus niger*, var.	Plant cell wall constituents	Hydrolyzes cellulose degradation products to glucose	
Glucoamylase (amyloglucosidase)	*Aspergillus niger*, var. *Aspergillus oryzae*, var. *Rhizopus niveus* *Rhizopus oryzae*, var.	See alpha-amylase	Hydrolyzes starch with production of glucose	
Hemicellulase	*Aspergillus aculeatus* *Aspergillus niger*, var. *Bacillus lentus* *Bacillus subtilis*, var. *Humicola insolens* *Paenibacillus lentus* *Trichoderma longibrachiatum* (also known as *T. reesei* or *T. viride*)	Corn, soybean meal, guar meal, barley, rye, grain sorghum, wheat, oats, peas, lentils	Breaks down hemicellulose	Reduction in stickiness of excreta in poultry fed guar meal

(continued)

Classification/ Name	Source Organism	Typical Substrate[a]	Function	Supported Use[b]
Invertase	*Aspergillus niger*, var. *Saccharomyces* sp.	Sucrose containing products and by-products	Hydrolyzes sucrose to glucose and fructose	
Lactase	*Aspergillus niger*, var. *Aspergillus oryzae*, var. *Candida pseudotropicalis* *Kluyveromyces marxianis* var. *lactis* (formerly *Saccharomyces* sp.)	Lactose containing products and by-products	Hydrolyzes lactose to glucose and galactose	
beta-Mannanase	*Aspergillus niger*, var. *Bacillus lentus* *Paenibacillus lentus* *Trichoderma longibrachiatum* (also known as *T. reesei* or *T. viride*)	Corn, soybean meal, guar meal, copra meal	Hydrolyzes beta-mannans, a component of hemicellulose	Reduction in stickiness of excreta in poultry fed guar meal
	Bacillus subtilis, var.	Distillers dried grains with solubles	Hydrolyzes beta-mannans, a component of hemicellulose	Reduction of digesta viscosity with swine diets
Pectinase	*Aspergillus aculeatus* *Aspergillus niger*, var. *Rhizopus oryzae*	Corn, wheat	Breaks down pectin	
Pullulanase	*Bacillus acidopullulyticus* *Bacillus licheniformis* containing a *Bacillus deramificans* gene for pullulanase	See alpha-amylase	Hydrolyzes starch	

(continued)

Classification/ Name	Source Organism	Typical Substrate[a]	Function	Supported Use[b]
Xylanase	*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*)	Corn, barley, rye, wheat, grain sorghum, triticale, oats	Hydrolyzes xylans, a component of hemicellulose	Reduction of digesta viscosity with poultry diets
Lipases				
Lipase	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*	Plant and animal sources of fats and oils	Hydrolyzes triglycerides	
Proteases				
Bromelain	Pineapples—stem, fruit	Plant and animal proteins	Hydrolyzes proteins	
Ficin	Figs	Plant and animal proteins	Hydrolyzes proteins	
Keratinase	*Bacillus licheniformis*	Plant and animal proteins	Hydrolyzes proteins	
Papain	Papaya	Plant and animal proteins	Hydrolyzes proteins	

(continued)

Classification/ Name	Source Organism	Typical Substrate[a]	Function	Supported Use[b]
Pepsin	Porcine or other animal stomachs	Plant and animal proteins	Hydrolyzes proteins	
Protease (general)	*Aspergillus niger*, var. *Aspergillus oryzae*, var. *Bacillus amyloliquefaciens* *Bacillus licheniformis* *Bacillus subtilis*, var.	Plant and animal proteins	Hydrolyzes proteins	
	Bacillus licheniformis expressing serine protease genes from *Nocardiopsis prasina*	Plant proteins	Hydrolyzes proteins	Increases the digestibility of protein in corn-soybean meal based diets
	Bacillus subtilis containing a *Bacillus amyloliquefaciens* gene for protease	Plant proteins	Hydrolyzes proteins	
Trypsin	Animal pancreas	Plant and animal proteins	Hydrolyzes proteins	
Oxidoreductases				
Catalase	*Aspergillus niger*, var. *Micrococcus lysodeikticus*	Hydrogen peroxide	Produces water and oxygen from hydrogen peroxide	
Glucose oxidase	*Aspergillus niger*, var.	Glucose	Degrades glucose to hydrogen peroxide and gluconic acid	

(continued)

Classification/ Name	Source Organism	Typical Substrate[a]	Function	Supported Use[b]
Phosphatases				
Phytase	*Aspergillus niger*, var. *Aspergillus oryzae*, var. *Aspergillus oryzae* expressing the *Peniophora lycii* phytase gene Phytase canola (*Brassica napus* expressing the *Aspergillus niger* phytase gene) *Pichia 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.	Corn, soybean meal, sunflower meal, hominy, tapioca, plant by-products	Hydrolyzes phytate	Increases the digestibility of phytin-bound phosphorus in poultry and swine diets
	Talaromyces funiculosus		Hydrolyzes phytate	Increases the digestibility of phytin-bound phosphorus in poultry diets

(Recombinant DNA risk groups are defined by the US National Institutes of Health.)
[a]This list is to provide guidance and is not all-inclusive.
[b]The Supported Use column references additional enzyme functionality beyond that in the Function column, and does not limit the enzyme functionality statement to specific animal species.

Enzyme Marketing Coordination

Section Editor—Mika Alewynse

NOTE: Sponsors of new enzyme/source organisms shall fully comply with this document by January 1, 1998.

Background

Enzymes are organic catalysts that affect the rate at which chemical reactions occur for specific substrates, including foods. AAFCO Policy Statement 7 describes the current sources of enzymes permitted in animal feeds. Rennet and papain are listed as GRAS under 21 CFR 582. All other enzyme materials to be used in animal feeds require a Food Additive regulation unless they are determined to be GRAS. The Center for Food Safety and Applied Nutrition (CFSAN) has published regulations for some enzyme preparations for use in human nutrition as secondary direct food additives under 21 CFR 173 and as GRAS food substances in 21 CFR 184. However, these applications are not directly transferable to animal use.

Definitions

The terms presented below are to clarify this document and do not represent nomenclature utilized by all enzyme manufacturers.

Enzyme. A protein made up of amino acids or their derivatives, which catalyzes a defined chemical reaction. Required cofactors should be considered an integral part of the enzyme.

Note: All other organic catalysts are excluded from consideration under this marketing coordination scheme.

Source organism. The organism that actually produces the enzyme(s).

Manufacturer. The firm or individual that actually produces the enzyme from the source organism.

Sponsor. The firm or individual that proposes adding an enzyme/source organism to the list published in the AAFCO Official Publication (Official Publication).

Enzyme preparation. A partially purified, unstandardized mixture of the enzyme(s) of interest and residues from the source organism. Enzyme preparations are not intended for sale or distribution for direct use on animal feed products without undergoing further processing.

Enzyme containing material. A material which is manufactured from the enzyme preparation, but is not necessarily, the final enzyme product. This material, if used in product development trials, must be substantially similar to the proposed product.

Enzyme product. A processed, standardized enzyme-containing material which has been produced with the intention of being sold for use on animal feed and feed ingredients. Examples of enzyme products would include feed grain treatments, commercial premixes and ready-to-use or apply materials.

Enzyme substrate. The material or substance which is acted upon catalytically by the enzyme.

Enzymatic activity (unit of). The catalytic activity required to convert a given amount of assay substrate to a given amount of product per unit time under the standard conditions set forth in the assay procedure.

Regulatory Approach

The US Food and Drug Administration (FDA) considers all feed enzymes to be either food additives or GRAS substances as defined by the Federal Food, Drug, and Cosmetic Act. However, the FDA plans at the present time to utilize regulatory discretion in the regulation of feed enzymes that present no safety concerns. A food additive petition will not be required for many products. However, if the Agency has concerns about an enzyme/source organism, a formal food additive petition may be required.

This document, written jointly by the AAFCO, FDA, Agriculture and Agri-Food Canada and industry, describes the information which may be necessary for confirmation of the suitability of an enzyme/source organism for inclusion in the Official Publication. Issuance of a favorable informal opinion by the FDA may provide the safety and functionality substantiation necessary for AAFCO to adopt an official definition for a feed enzyme/source organism. All marketed enzymes must meet at least one of the following criteria: 1) be published in the Official Publication; 2) be the subject of a Food Additive regulation under 21 CFR 573; 3) be affirmed as GRAS; 4) be GRAS; or 5) be the subject of an informal no objection letter from the FDA (will be published in the next Official Publication). If an enzyme is published in the Code of Federal Regulations as an approved food additive it will also be included in the Official Publication. It should be noted that publication of an enzyme/source organism in the Official Publication does not remove a firm's responsibility of complying with applicable Canadian regulations.

The sponsor of an unpublished enzyme/source organism is to provide information which addresses issues of safety, functionality, labeling, and manufacturing. The request for review should be sent to the designated AAFCO contact. The supporting information should be sent to the Division of Animal Feeds, Center for Veterinary Medicine, FDA. The FDA will be asked to evaluate the information and determine its adequacy. If the FDA determines that the enzyme/source organism does not require an approved food additive petition to ensure its safe use, AAFCO will be asked to propose a new or modify an existing definition under which the enzyme/source organism would be published in the Official Publication. Any restrictions on claims and use conditions will be addressed by the FDA in its statements to AAFCO and the sponsor. The official definition will include: trivial name and/or International Union of Biochemistry (IUB) name, if available; enzyme classification; source organism; and substrate(s).

In the information package the sponsor may include material from the literature or current research. International data are acceptable provided conditions of testing simulate practices in this country. Supporting empirical information should be summarized and appropriate statistical analysis applied. Information that must be submitted by the sponsor includes: the sponsor's name and address, the enzyme, its proposed use and source organism. If any material written in a foreign language is included, a complete translation must be provided.

An appropriate section of the Official Publication is to be reserved for listing an enzyme and its source organism(s). After FDA evaluation of the information submitted for a new enzyme/source organism, a letter will be sent to the designated AAFCO contact. A copy of the letter will also be sent to the sponsor. Both the States and FDA will monitor the industry for compliance.

The following specific areas must be addressed by the sponsor:

Enzyme Identity

The enzyme present in the enzyme preparation or product is to be identified and activity determined. The enzyme preparation or product is to be shown to contain no viable source organisms above an appropriate background. A suggested maximum is 1×10^4 colony forming units (CFU/gram) of the source organism. If the source organism is published in the Official Publication under definition 36.14, there shall be no restriction on source organism numbers.

Identity information should include the following:

a. Active enzyme substance-- should be identified, preferably using the nomenclature system developed by the IUB. Specific terminology, such as phytase, pectinase, amylase or glucanase, is preferred.
b. Enzyme substrate-- the specific substance on which the enzyme acts should be identified. General terminology such as carbohydrate, fiber, lipids, and protein are acceptable; however, specific terminology such as starch, cellulose, phytin, and lactose are preferred.
c. Reaction products-- the primary resultant product(s) from the enzyme-substrate reaction should be identified to the extent that it is practical.
d. Site of enzyme activity-- the site of activity is recognized to be on the feed/ingesta. Any other statement regarding site of activity is subject to FDA review.

Bioengineered Sources of Enzymes

A source organism may be bioengineered using recombinant deoxyribonucleic acid (rDNA) technology. This type of technology is defined as "any method by which DNA is manipulated in vitro and introduced into the source organism." Initially, use of bioengineered source organisms will be handled on a case-by-case basis. If the structure/amino acid sequence of an enzyme has not been significantly affected by changes in the genome of the source organism, it is not anticipated that additional requirements will be imposed for inclusion in the Official Publication. However, if a source organism has been modified by rDNA techniques to contain an antibiotic resistance gene, then the enzyme product should contain no detectable, viable source organisms and no transformable antibiotic resistance DNA.

Safety

Animal/Human/Environment

Safety is the overriding issue with food and food ingredients and thus, for enzyme/source materials for animal use. Initial questions will reside around whether the enzyme preparation has adverse effects on either the animal, the environment, or humans via edible products from animals fed the enzyme.

Animal Safety

Enzymes, as defined in this document, are amino acid-based catalysts used at low levels to alter animal feedstuffs. Because of this basic structure, it is reasonable to assume that these molecules will be digested in the gastro-intestinal tract, as would any other protein. Since an enzyme will be broken down into its constituent amino acids and cofactors and thus, be indistinguishable from other food molecules, the potential for residues in edible animal tissues appears minimal. Thus, the only other major factor

which may raise a safety concern is the possible presence of compounds produced by or derived from the source organism. Pariza and Foster (1983)[1] have developed a set of guidelines to assess the safety of enzymes used in food processing. These guidelines address the safety of the source organism and the enzyme itself. Enzyme preparations that meet or surpass the criteria proposed by Pariza and Foster for human food should be safe for use in animal feed when utilized at the low levels normally employed for these catalysts.

Alternatively, the sponsor can provide data demonstrating no adverse effects when the most sensitive target animal is fed at least 5 times the maximum supplementation level for a period of 90 days or 50% of the species normal growing period, whichever is less. The species will be determined by product labeling and/or manufacturer suggestions.

Enzyme sponsors should also address the presence of enzymatic cofactors in the enzyme preparation. The presence of cofactors, such as the vitamins or nicotinamide adenine dinucleotide (NAD) is not of concern, but should be reported. If the enzyme requires potentially toxic cofactors, such as selenium or molybdenum, the submission should indicate the identity and amount of the cofactor.

Enzymes produced using current good manufacturing practices from food animals, edible and nontoxic plants or nontoxigenic and nonpathogenic microorganisms which do not produce antibiotics, should be safe for consumption at the low levels one would normally expect to encounter in animal feeds. In addition, the enzyme preparation should comply with the chemical and microbiological purity standards established by the Joint FAO/WHO Expert Committee on Food Additives[2] and the Food Chemical Codex[3].

Carriers, diluents, and processing aids used in the production of enzyme preparations and products must be substances that are acceptable for feed usage. If an enzyme preparation or product is standardized or diluted with feed grade material, then applicable chemical and microbiological standards for the feed material will apply.

Human Safety

Enzymes, as defined in this document, are amino acid-based catalysts used at low levels to alter animal feedstuffs. Because of this basic structure, it is reasonable to assume that these molecules will be digested in the gastro-intestinal tract, as would any other protein. However, it is the responsibility of the sponsor to provide appropriate data to assure human safety. Enzymes used in animal feed that pass the safety assessment proposed by Pariza and Foster should raise no human safety concerns.

If the Pariza and Foster decision tree is not used to evaluate the enzyme preparation, the sponsor must provide information regarding the fate of the enzyme in the target animal. If it cannot be assured that the enzyme is broken down to non-toxic metabolites, it may be necessary to quantify the amount of residue and identify safety concerns for these molecules. If an enzyme preparation is currently approved for addition to or conditioning of human foods, human safety data may not be required. However, human food use must be substantiated and a statement of similar/identical usage will be required. If human food safety is an issue, a food additive petition under 21 CFR 570 will be required.

Environmental Safety

Information is required on each enzyme/source organism to assure that it does not adversely affect the environment. Information showing that the enzyme is composed of or broken down to normal non-toxic degradation products in the digestive tract of supplemented animals would be adequate to answer questions of environmental safety. If degradation metabolites have an unusual chemical composition not normally present in foods, it may be necessary to demonstrate metabolite safety for non-target species that may be exposed to target animal wastes. Environmental safety concerns could also be

allayed if it could be demonstrated that the same or similar enzymes in approximately the same concentrations are excreted by free living organisms in a similar environment.

Functionality

The functionality of the enzyme itself must be documented. Either *in vivo* or *in vitro* data are acceptable to demonstrate enzyme functionality. The functionality statement associated with an enzyme/source organism combination will be determined by the data submitted under this proposal. The chosen research approach, either *in vivo* or *in vitro*, should answer questions relating to the amount of enzyme material necessary to have the intended effect and the use conditions (restrictions) for the enzyme. All experimental protocols should be described as would be required for publication in a peer-review journal. The procedure used to determine enzyme functionality should be described in detail. If functionality is determined by end product measurements, assay sensitivity and cross-reactivity to other constituents/contaminants should be discussed. Functionality data must substantiate the proposed label. Animal experiments demonstrating enzyme functionality are highly recommended. Trial design should ensure that statistical analysis of experimental data is possible. The number of trials should be adequate to document enzyme functionality under field conditions. Indicators of enzyme functionality could include increased nutrient digestibility and/or increased free nutrient levels. Sponsors should note, however, that label/advertising claims for improved animal performance or health will cause an enzyme to be classified as a new animal drug.

Functionality can also be addressed using in vitro studies with either complete feeds, feed ingredients or feed substrates being utilized as the enzyme substrate. Experimental design and the accompanying statistical analysis must be adequate to support enzyme functionality under field conditions. Dependent on the reaction catalyzed, the sponsor may wish to measure the disappearance of undegraded feed substrate or the appearance of enzyme reaction products. This approach directly measures the enzymatic digestion of feedstuffs when compared to a similarly treated control sample. Either experimental approach is acceptable. However, the sponsor must explain how observed in vitro effects translate to practical functionality of the enzyme on feed or feed ingredients.

Factors which should be explained in detail in the submission include the apparatus/reagents/protocol used to conduct all functionality experiments. Buffer solutions should be selected so as to provide appropriate pH environments similar to those in which the enzyme product is expected to be used. All control (untreated) samples of feedstuffs shall be treated identically to the enzyme samples, except for the addition of the enzyme. Incubation temperatures for the digestion period should not exceed the range of temperatures normally encountered under practical conditions for enzyme use. The enzyme containing material may be either research or technical grade, but must be similar to that which will be used commercially.

Complete feeds, feed ingredients or feed substrates obtained from a feed ingredient, can be used to simulate the feed to which the enzyme will be applied. These experimental substrates should be similar in analysis and in physical/chemical treatment to the feed which the enzyme will be used for in commercial situations. No less than five samples of each grain/treatment should be used in the trial. Use of feed, feed ingredients or substrates containing grain from several different lots (origins) would be desirable. However, the experimental design should ensure that lots (origins) are not confounded with enzyme treatment, i.e. all of lot 1 treated with the enzyme, while all control samples came from a different lot.

Enzyme Functionality Tested by In Vitro Activity on Feed

- Collect samples of typical target feed or feed ingredient.
- Treat with candidate enzyme mixture for a given period of time at appropriate pH and temperature

- Analyze samples for increased levels of breakdown products or decreased concentrations of targeted substrate
- Compare results with untreated control samples.
- Enzyme treatments which result in significantly altered concentrations of targeted substrate or breakdown products are judged to be utilitarian for practical application

Quantification of Enzyme Product

Methodology is needed to measure the amount of activity of the enzyme product in its marketed concentrated (premix) form. Activity should be expressed as micromoles (moles) of released catalytic product per minute per gram of market product or in other standardized units. It is the responsibility of the sponsor to provide this methodology along with supporting information about its specificity, sensitivity, and accuracy.

a. Assay Methodology
    1. Enzyme product; and/or
    2. Finished feed
b. Specificity/Sensitivity
    1. Two-external laboratory validation; or
    2. AOAC International validation, which can include the short form; or
    3. Other recognized methods

Labeling

The label should: describe the enzyme source (specific microbial or other source) that is recognized by FDA/AAFCO as safe and useful for the intended purpose; have a full listing of ingredients in order of preponderance; have a guaranteed analysis that is stated in meaningful terms; show a net quantity of product; contain warning and caution statements as needed; not have therapeutic or production claims; allow product identification by means such as lot numbers, expiration dates or another appropriate method of identification; and provide information on product storage, if necessary.

The product should be labeled in accordance with AAFCO and federal regulations. The label will include a guarantee of enzyme activity(ies), expressed in appropriate units. Clear directions for use which are reasonably certain to be followed in practice must be included, as should any known product limitations, such as ineffectiveness on specific forages. Adequate directions for use to enable the user to achieve the functionality of the enzyme(s) should be included, such as the feed ingredient(s) that the enzyme(s) acts on, the amount of product necessary to produce the intended effect, and the length of time required to achieve this effect. If environmental factors, such as feed pH or moisture, or mechanical processing methods, like pelleting or extrusion affect enzyme activity, these restrictions should also be noted on the label. Draft labeling should be included in the initial request of the sponsor.

The label must contain the following sections:

Name of Product

Functionality Statement

"Contains a source of_____ (enzymatic activity) which can (function and/or current supported use as stated in Section 30.1)." (statement based on information present in submission)

Guaranteed Analyses

(see AAFCO regulations 3 and 4.)

Enzymatic guarantees shall be expressed in appropriate units using either metric or avoirdupois measurements. The chosen units shall correspond with those present in the Use section. The source organism for each type of enzymatic activity shall be specified, such as: Protease (*Bacillus subtilis*) 5.5 mg amino acids liberated/min./milligram.

If two sources have the same type of activity, they shall be listed in order of predominance based on the amount of enzymatic activity provided. However, the order of the ingredients in the Ingredients section is still determined by the amount (weight) of the different materials in the product.

Ingredients

(listed in order of predominance by weight)

Directions for Use

Use instructions shall clearly state amount of enzyme required to achieve intended effect and other necessary information required for enzyme functionality.

Caution/Warning Statements. (when required)

Quantity Statement

Manufacturing

The sponsor is to provide information on the manufacture of the enzyme or quality controls (specifications) on the enzyme. The quality controls on the raw materials, on the manufacturing process/conditions, and on the enzyme product are to be presented. Appropriate information on product stability, labeling restrictions and special marketing controls are to be provided.

[1] Pariza, M. W., and E. M. Foster. 1983. Determining the safety of enzyme used in food processing. Journal of Food Protection. 46(5): 453-468.

[2] JointFAO/WHO Expert Committee on Food Additives. 1990. General specifications for enzyme preparations used in food processing. Food and Nutrition Paper No. 49. Pages 80-03.

[3] Anonymous. 1980. Food Chemical Codex. Page 107. National Academy Press: Washington.

33. Fats and Oils

Investigator and Section Editor—Bernadette Mundo, SC

NOTE: 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.

NOTE: 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."

NOTE: 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.)

Official

33.1 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% total fatty acids, not more than 2.5% unsaponifiable matter, and not more than 1% 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% 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." (Proposed 1989, Amended 2017)

IFN 4-00-409 Animal poultry fat

33.2 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% total fatty acids, not more than 2% unsaponifiable matter and not more than 1% 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." (Proposed 1989)

IFN 4-05-077 Vegetable oil

33.3 Hydrolyzed _____ 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% total fatty acids, not more than 6% unsaponifiable matter, and not more than 1% insoluble impurities. Maximum moisture must also be guaranteed. Its source must be stated in the product name; 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." (Proposed 1989)

IFN 4-00-376 Animal fat hydrolyzed, IFN 4-05-076 Vegetable oil hydrolyzed

33.4 _____ Ester _____, Feed Grade, 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% total fatty acids, not more than 10% free fatty acids, not more than 6% unsaponifiable matter (2% for methyl esters) and not more than 1% insoluble matter. Its source must be stated in the product name; 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%) free methyl alcohol. If an antioxidant(s) is used, the common name or names must be indicated, followed by the word "preservative(s)." (Proposed 1958, Amended 1962, Adopted 1968.) Reg. 573.640

IFN 4-00-377 Animal fatty acids of ethyl ester

IFN 4-00-378 Animal fatty acids of methyl ester

IFN 4-00-379 Animal fatty acids of non-glyceride ester

IFN 4-12-240 Vegetable fatty acids of ethyl ester

IFN 4-05-075 Vegetable fatty acids of non-glyceride ester

IFN 4-05-074 Vegetable fatty acids of methyl ester

33.7 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% 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. (Proposed 1964, Adopted 1968, Amended 1980, Amended 1996, Adopted 1999)

IFN 4-05-078 Vegetable oil refinery lipid

33.8 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 7% ash nor less than 50% fat on a water-free basis. (Proposed 1964, Adopted 1968)

IFN 4-02-893 Maize syrup process residue

33.10 _____ 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% total fatty acids, not more than 2.5% unsaponifiable matter, and not more than 1% 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. (Proposed 2015, Adopted 2016 rev. 1)

33.14 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% 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 4% and moisture shall not exceed 5%. 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. (Adopted 1993)

33.15 Hydrolyzed _____ 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% total fatty acids, not more than 2% Sucrose Polyesters (hex ester and above), not more than 2% unsaponifiable matter, and not more than 2% insoluble

impurities. Maximum moisture must also be guaranteed. Its source must be stated in the product name; 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." (Proposed 1993, Adopted 1994)

33.16 Methyl Esters of Conjugated Linoleic Acid (cis-9, trans-11 and trans-10, cis-12-octadecadienoic acids) may be safely used in swine feed in accordance with the prescribed conditions:

(a) 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% methyl ester of cis-9, trans-11-octadecadienoic acid, and not less than 28% methyl ester of trans-10, cis-12-octadecadienoic acid with the sum of the other methyl esters of octadecadienoic acid not to exceed 4%. The additive shall contain not less than 35% of other fatty acid esters composed of oleic acid, palmitic acid, stearic acid, linoleic acid, and other associated acid esters.

(b) 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% in the finished feed.

(c) The additive meets the following specifications:
  (1) Free methyl alcohol not to exceed 0.015%.
  (2) Insoluble impurities not to exceed 0.1%.
  (3) Moisture not to exceed 0.5%
  (4) Unsaponifiable matter not to exceed 1.0%

(d) To assure safe use of the additive, in addition to the other information required by the act:
  (1) The label and labeling of the additive and any feed premix shall bear the following:
    (i) The name of the additive.
    (ii) 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.
  (2) The label and labeling of the additive, any feed premix, or complete feed prepared therefrom shall bear adequate directions for use.

21 CFR 573.637 (Proposed 2009, Adopted 2013)

33.17 Gamma-Linolenic Acid Safflower Oil—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:

(a) 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.
  (1) 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 paragraph (a)(2) of this section.
  (2) The additive or a safflower oil blend containing the additive for use in animal food meets the following specifications:

(i) Crude fat content of the additive or the safflower oil blend is not less than 99.5%.
(ii) Gamma-linolenic acid content is between 350 and 450 milligrams (mg) gamma-linolenic acid per gram of the additive or the safflower oil blend.
(iii) 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%.

(b) Addition of the additive, or the safflower oil blend, to complete dry adult maintenance dog food must meet the following:
(1) Addition of the additive or the safflower oil blend cannot provide more than 36 mg gamma-linolenic acid per kilogram body weight of the dog per day in more than 86 mg of the additive or the safflower oil blend. This maximum addition rate of the additive, or the safflower oil blend, is 0.3% of a complete dry adult maintenance dog food containing 3,600 kilocalories of metabolizable energy per kilogram of food as-fed.
(2) Adjustments must be made for differing concentrations of gamma-linolenic acid and for dog food formulas of different caloric density and/or that are fed to specific weights, breeds, or dogs of different activity levels to meet the requirements of this paragraph.

(c) Addition of the additive, or the safflower oil blend, to complete dry adult maintenance cat food must meet the following:
(1) Addition of the additive or the safflower oil blend cannot provide more than 33 mg gamma-linolenic acid per kilogram body weight of the cat per day in more than 79 mg of the additive or the safflower oil blend. This maximum addition rate of the additive, or the safflower oil blend, is 0.5% of a complete dry adult maintenance cat food containing 4,000 kilocalories of metabolizable energy per kilogram of food as-fed.
(2) Adjustments must be made for differing concentrations of gamma-linolenic acid and for cat food formulas of different caloric density and/or that are fed to specific weights, breeds, or cats of different activity levels to meet the requirements of this paragraph.

(d) To assure safe use of the additive, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling of the additive shall bear the following:
(1) The name of the additive, gamma-linolenic acid safflower oil, or GLA safflower oil;
(2) A guarantee for the minimum content of gamma-linolenic acid; and
(3) Adequate directions for use such that the finished animal food complies with the provisions of paragraphs (b) and (c) of this section.

21 CFR 573.492 (Adopted 2018 rev. 1, Amended 2020)

33.21 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% total fatty acids, not more than 2.5% unsaponifiable matter, not more than 0.5% insoluble impurities, and not more than 1% 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% insoluble impurities, then it must be labeled with the BSE caution statement "do not feed to cattle or other ruminants." (Proposed 2017, Adopted 2018)

33.24 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% total fatty acids, not more than 1% unsaponifiable matter, not more than 0.5% insoluble impurities, and not more than 1% 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." (Proposed 2017, Adopted 2018)

33.25 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 3% (w/w) 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% stearic acid, maximum 5% palmitic acid, minimum 99% total free fatty acids, maximum 1% sulfated ash, and maximum 5 ppm 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 AAFCO definitions, 33.1 (for Animal Fat) and 33.2 (for 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. (Proposed 2017 rev. 1, Adopted 2020 rev. 1)

33.26 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 2% (w/w) 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% palmitic acid, maximum 0.8% myristic acid, minimum 99% total free fatty acids, maximum 1% sulfated ash, and maximum 5 ppm 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 AAFCO definitions, 33.1 (for Animal Fat) and 33.2 (for 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. (Proposed 2017 rev. 1, Adopted 2020 rev. 1)

33.27 Marine Microalgae—The food additive marine microalgae may be safely used as a source of docosahexaenoic acid (DHA) and other omega-3 fatty acids in accordance with the following prescribed conditions:

(a) The additive is dried whole cells of nonviable, nontoxigenic, nonpathogenic *Schizochytrium* sp. algae grown as a pure culture.

(b) The additive is used in complete, dry adult maintenance food for dogs in accordance with good manufacturing and feeding practices not to exceed 16.5 pounds per ton (7.5 kilograms (kg) per 1000 kg) of complete, dry, adult maintenance dog food.

(c) The additive consists of not less than 17.0% (4Z,7Z,10Z,13Z,16Z,19Z)-docosa-4,7,10,13,16,19-hexaenoic acid (docosahexaenoic acid or DHA).

(d) The additive meets the following specifications:
   (1) Not less than 40% crude fat;
   (2) Not more than 12% ash;
   (3) Not more than 8% unsaponifiable matter;
   (4) Not more than 5% insoluble impurities;
   (5) Not more than 5% free fatty acids; and

(6) Not more than 6% water.

(e) To ensure the safe use of the additive, in addition to other information required by the Federal Food, Drug, and Cosmetic Act:

(1) The label and labeling of the additive, any feed premix, and complete feed, shall contain the name of the additive, marine microalgae.

(2) The label and labeling of the additive and any feed premix shall also contain:

(i) A statement to indicate that the maximum use level of the additive shall not exceed 16.5 pounds per ton (7.5 kg per 1000 kg) of complete, dry, adult maintenance dog food.

(ii) Adequate directions for use.

21 CFR 573.615 (Adopted 2019 rev. 1)

Tentative

T33.29 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 and 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% total fatty acids, not more than 2% unsaponifiable matter and not more than 1% 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." (Proposed 2022)

T33.29(A) 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, and adult dog food, 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% total fatty acids, not more than 2% unsaponifiable matter and not more than 1% 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." (Proposed 2022; Amended 2022 rev. 1)

36. Fermentation Products

Investigator and Section Editor—Maggie Faba, MN

Official

36.1 Condensed, Extracted Glutamic Acid Fermentation Product 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 5% of the total ration; and in cattle feed as a source of protein in an amount not to exceed 10% 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. (Proposed 1964, Adopted 1965, Amended 1995, Adopted 1997, Amended 2012, 2013, Adopted 2014 rev. 1) Reg. 573.500

36.2 Extracted _____ Presscake is the filtered and dried mycelium obtained from _____ fermentation. (For label identification the source must be indicated as *Penicillium*, *Streptomyces*, citric acid, etc.) (Adopted 1951)

IFN 5-07-154 *Penicillium* fermentation presscake dehydrated

IFN 5-07-155 *Streptomyces* fermentation presscake dehydrated

IFN 5-07-156 Citric acid fermentation presscake dehydrated

36.3 Extracted _____ Meal is the ground _____ presscake. (For label identification the source must be indicated as *Penicillium*, *Streptomyces*, citric acid, etc.) (Adopted 1951)

IFN 5-06-163 *Penicillium* fermentation presscake meal extracted

IFN 5-06-164 *Streptomyces* fermentation presscake meal extracted

IFN 5-06-162 Citric acid fermentation presscake meal extracted

36.4 Dried Extracted _____ Fermentation Solubles is the dried extracted broth obtained from _____fermentation. (For label identification the source must be indicated such as *Penicillium*, *Streptomyces*, or citric acid, or as permitted by FDA.) (Proposed 1988, Amended 1992, Amended 1997, Adopted 2000)

IFN 5-06-166 *Penicillium* fermentation solubles extracted dehydrated

IFN 5-06-176 *Streptomyces* fermentation solubles extracted dehydrated

IFN 5-06-165 Citric acid fermentation solubles extracted dehydrated

36.6 Dried _____ 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 _____ 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.) (Proposed 1988, Amended 1992, Amended 1997, Adopted 2000)

IFN 5-06-147 *Bacillus subtilis* fermentation extract dehydrated

IFN 5-06-148 *Aspergillus niger* fermentation extract dehydrated

IFN 5-06-149 *Aspergillus oryzae* fermentation extract dehydrated

36.7 Dried _____ 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 _____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.) (Proposed 1988, Amended 1992, Amended 1997, Adopted 2000)

IFN 5-29-779 *Bacillus subtilis* fermentation solubles dehydrated

IFN 5-29-781 *Aspergillus niger* fermentation solubles dehydrated

IFN 5-29-780 *Aspergillus oryzae* fermentation solubles dehydrated

36.9 Undried Extracted _____ Solids and Fermentation Solubles is undried mycelium and extracted broth or the extracted and undried mycelium and broth obtained from _____ fermentation. (For label identification the source must be indicated such as *Penicillium*, *Streptomyces*, citric acid, or as permitted by FDA.) (Proposed 1988, Amended 1997, Adopted 2000)

IFN 5-06-171 Citric acid fermentation solids with solubles liquid

IFN 5-06-172 *Penicillium* fermentation solids with solubles liquid

IFN 5-06-173 *Streptomyces* fermentation solids with solubles liquid

36.10 Condensed _____ 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." (Adopted 1958, Amended 1951, 1980, 2012, 2013, Adopted 2014 rev. 1)

IFN 5-06-300 Cattle whey fermentation solubles condensed

IFN 4-07-153 Cereals grain fermentation solubles condensed

IFN 5-25-399 Sugarcane molasses fermentation solubles condensed

36.11 Dried _____ 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* 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 bulgaricus* or *Enterococcus faecium*, or as permitted by FDA.] (Proposed 1976, Adopted 1983, Amended 1997, Amended 1999, Amended 2001, Adopted 2003, Amended 2010, Adopted 2014 rev. 1)

IFN 5-06-150 *Bacillus subtilis* fermentation product dehydrated

IFN 5-06-151 *Aspergillus niger* fermentation product dehydrated

IFN 5-06-152 *Aspergillus oryzae* fermentation product dehydrated

IFN 5-06-153 *Lactobacillus acidophilus* fermentation product dehydrated

IFN 5-06-154 *Lactobacillus bulgaricus* fermentation product dehydrated

IFN 5-06-155 *Enterococcus faecium* fermentation product dehydrated

36.12 Liquid _____ Fermentation Product is the liquid product derived by culturing or fermenting _____ 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 bulgaricus* or *Enterococcus faecium*, or as permitted by FDA.] (Proposed 1976, Amended 1979, Adopted 1983, Amended 1997)

IFN 5-06-156 *Bacillus subtilis* fermentation product liquid

IFN 5-06-157 *Aspergillus niger* fermentation product liquid

IFN 5-06-158 *Aspergillus oryzae* fermentation product liquid

IFN 5-06-159 *Lactobacillus acidophilus* fermentation product liquid

IFN 5-06-160 *Lactobacillus bulgaricus* fermentation product liquid

IFN 5-06-161 *Enterococcus faecium* fermentation product liquid

Note: Dried Cultured Skimmed Milk—refer to 54.5 Milk Products Section. Condensed Cultured Skimmed Milk—refer to 54.6 Milk Products Section.

36.13 Extracted _____ _____ is the filtered and dried mycelium obtained from _____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.) (Proposed 1988, Adopted 1997)

IFN 5-07-154 *Penicillium* fermentation presscake dehydrated
IFN 5-07-155 *Streptomyces* fermentation presscake dehydrated
IFN 5-07-156 Citric acid fermentation presscake dehydrated
IFN 5-06-163 *Penicillium* fermentation presscake meal extracted
IFN 5-06-164 *Streptomyces* fermentation presscake meal extracted
IFN 5-06-162 Citric acid fermentation presscake meal extracted

36.14 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.

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
**Enterococcus cremoris*
**Enterococcus diacetylactis*
Enterococcus faecium
Enterococcus intermedius*, correct to *Streptococcus intermedius*
**Enterococcus lactis*
Enterococcus thermophilus*, correct to *Streptococcus thermophilus*
Lactobacillus acidophilus
Lactobacillus animalis
Lactobacillus brevis
Lactobacillus buchneri (cattle only)
Lactobacillus bulgaricus, renamed to *Lactobacillus delbrueckii***
Lactobacillus casei
Lactobacillus cellobiosus, renamed to *Lactobacillus fermentum***
Lactobacillus curvatus
Lactobacillus delbrueckii
Lactobacillus farciminis (swine only)
Lactobacillus fermentum
Lactobacillus helveticus
Lactobacillus lactis, renamed to *Lactobacillus delbrueckii***
Lactobacillus plantarum
Lactobacillus reuteri
Leuconostoc mesenteroides
Megasphaera elsdenii (cattle only)
Pediococcus acidilactici
Pediococcus cerevisiae (damnosus), renamed to *Pediococcus damnosus****

Pediococcus pentosaceus
Propionibacterium acidipropionici (cattle only)
Propionibacterium freudenreichii
Propionibacterium shermanii, renamed to *Propionibacterium freudenreichii***
Rhodopseudomonas palustris (broiler chickens only)
Saccharomyces cerevisiae
Yeast (as defined elsewhere)
*Formerly cataloged as *Streptococcus.*
**Date of compliance January 2022.
***Date of compliance January 2023.
(Proposed 1991, Adopted 1993, Amended 2001, 2004, 2006, 2011, 2017, 2018 rev. 1)

36.15 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% 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. (Proposed 2007, Adopted 2010)

36.16 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% on a dry matter basis. The label shall include guarantees for minimum L-lysine and maximum sulfur. (Proposed 2014 rev. 1, Adopted 2015 rev. 1)

36.17 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% on a dry matter basis. The label shall include guarantees for minimum L-lysine and maximum sulfur. (Proposed 2010, Adopted 2014 rev. 1)

39. Flax Products

(See **Other Oilseed Products** Section 71)

40. Human Food By-Products

Investigator and Section Editor—David Dressler, PA

NOTE: 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.

*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.**"

Official

40.1 (old 60.1) Dried Apple Pomace is the sound, dried residue obtained by the removal of cider from apples. (Adopted 1929)

IFN 4-00-423 Apple pomace dehydrated

40.2 (old 60.2) Dried Apple Pectin Pulp is the sound, dried residue obtained by the removal of pectin from apple products. (Adopted 1929)

IFN 4-00-425 Apple pomace without pectin dehydrated

40.8 (old 60.8) 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." (Adopted 1953, Amended 1964)

IFN 5-05-041 Tomato pomace dehydrated

40.14 (old 60.14) Cereal Food Fines consists of particles of breakfast cereals obtained as a by-product of their processing. (Adopted 1957)

IFN 5-01-199 Cereals food fines

40.15 (old 60.15) 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% salt, the maximum percentage of salt must be a part of the name; i.e. Dried Bakery Product with _____ % Salt. (Proposed 1962, Adopted 1967)

IFN 4-00-466 Bakery waste dehydrated

40.28 (old 60.28) 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 3% hydrate of lime which may be added to aid in processing. (Proposed 1972, Adopted 1973)

IFN 4-03-775 Potato process residue dehydrated

40.29 (old 60.29) 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% digestible protein as determined by the AOAC pepsin method 22.025-22.031. A 25% maximum of diatomaceous earth will not be exceeded. This product is for use in poultry feeds not to exceed 5% of the total rations. (Proposed 1972, Adopted 1973)

IFN 5-14-503 Gelatin process residue

40.34 (old 60.34) Dried Beans are the residue of the normal packaging and processing of _____ dried beans for human consumption. This residue shall consist of the broken, small, shriveled, and cull _____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, i.e., ground roasted _____ dried beans. (Proposed 1976, Adopted 1977)

IFN 5-00-594 Bean seeds

IFN 5-00-600 Bean kidney seeds

IFN 5-00-623 Bean navy seeds

IFN 5-00-624 Bean pinto seeds

40.35 (old 60.35) 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% total sugar expressed as invert. It shall be free from foreign materials harmful to animals. (Proposed 1976, Adopted 1977)

IFN 4-20-865 Sugar foods process residue

40.93 (old 60.93) 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. (Proposed 1995, Adopted 1996)

***40.96 (old 60.96) 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% moisture and designated as

"Dehydrated Food Processing Waste." If part of the grease and fat is removed, it must be designated as "Degreased." (Proposed 1998, Adopted 2000)

***40.97 (old 60.97) 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% moisture and designated as "Dehydrated Restaurant Food Waste." If part of the grease and fat is removed it must be designated as "Degreased." (Proposed 1998, Adopted 2000)

40.100 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. (Proposed 2017, Adopted 2019)

40.107 (old 60.107) 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. (Proposed 2004, Adopted 2006)

40.112 (old 60.112) (*blank - fruit) 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, etc. Moisture may be removed by an acceptable method and the term "dried" included in the name, i.e., dried apple pomace, etc. (Proposed 2015, Adopted 2015 rev. 1)

*Acceptable products: apple

42. Grain Sorghums (Milo, Hegari, Kaffir, or Feterita)

Investigator and Section Editor—Dan King, MN

Official

42.1 Ground Grain Sorghum is the entire product made by grinding the grains of grain sorghum. (Adopted 1947, Amended 1962, 1964)

IFN 4-04-379 Sorghum grain ground

IFN 4-04-378 Sorghum grain cracked

NOTE: The word "cracked" must be substituted for the word "ground" in the above definition when the product is cracked instead of ground.

42.2 Grain Sorghum Gluten 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. (Adopted 1948, Amended 1950)

IFN 5-04-389 Sorghum gluten with bran meal

42.3 Grain Sorghum Gluten Meal is that 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. (Adopted 1948, Amended 1950)

IFN 5-04-388 Sorghum gluten meal

42.4 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. (Adopted 1948, Amended 1950, 1960, 1963)

IFN 5-04-377 Sorghum germs meal mechanical extracted

IFN 5-12-178 Sorghum germs mechanical extracted caked

42.6 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. (Adopted 1953)

IFN 4-04-380 Sorghum grain rolled

42.7 Grain Sorghum Grits consists of the hard flinty portions of sorghums containing little or no bran or germ. (Adopted 1959)

IFN 4-04-384 Sorghum grits

42.8 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 1% crude fiber. (Proposed 1965, Adopted 1966)

IFN 4-08-035 Sorghum flour gelatinized

42.9 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% crude fiber. (Proposed 1965, Adopted 1966)

IFN 4-08-036 Sorghum flour partially aspirated gelatinized

42.10 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 5% crude fat and not more than 6% crude fiber. (Proposed 1964, Adopted 1968)

IFN 4-04-385 Sorghum grits by-product

NOTE: Any of the types shown parenthetically in the heading for this section may be substituted for the words "grain sorghums" in the above definitions. If the name of the type is given it must correspond thereto.

45. Lespedeza Products

Investigator and Section Editor—Erin Bubb, PA

Official

45.1 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% crude fiber. (Adopted 1938, Amended 1963)

IFN 1-02-523 Lespedeza hay sun-cured ground

45.2 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. (Adopted 1938, Amended 1963)

IFN 1-02-529 Lespedeza stems sun-cured ground

48. Maize Products

Investigator and Section Editor—Dan King, MN

Official

48.1 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). (Proposed 1958, Adopted 1964)

IFN 1-02-779 Maize cob fractions screened

48.2 Corn Bran is the outer coating of the corn kernel, with little or none of the starchy part of germ. (Adopted 1931)

IFN 4-02-841 Maize bran

48.3 Corn Feed Meal is the fine siftings obtained from screened cracked corn, with or without its aspiration products added. (Adopted 1941)

IFN 4-02-880 Maize grain fines

48.4 Ground Corn is the entire corn kernel ground or chopped. It must contain not more than 4% foreign material. May also appear in the ingredient list of a mixed feed as Corn Meal or Corn Chop. (Adopted 1931)

IFN 4-02-861 Maize grain ground

48.5 Cracked Corn is the entire corn kernel ground or chopped. It must contain not more than 4% foreign material. (Adopted 1931)

IFN 4-02-854 Maize grain cracked

48.6 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 4% foreign material. (Adopted 1941)

IFN 4-02-862 Maize grain cracked screened

48.7 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. (Adopted 1941)

IFN 4-02-886 Maize grits

48.8 Corn Flour is the fine sized hard flinty portions of ground corn containing little or none of the bran or germ. (Adopted 1941, Amended 1960)

IFN 4-08-024 Maize flour

48.9 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. (Adopted prior to 1928, Amended 1956)

IFN 4-02-849 Maize ears ground

48.10 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. (Adopted prior to 1928, Amended 1956)

IFN 4-02-850 Maize ears with husks ground

48.11 Flaked Corn is obtained by running cracked corn which has been aspirated and properly tempered, over smooth flaking rolls and subsequently dried and cooled. (Adopted 1946)

IFN 4-02-859 Maize grain flaked

48.12 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. (Adopted 1953)

IFN 4-02-860 Maize grain flaked toasted

48.13 Corn Gluten Feed is that part of the commercial shelled corn that remains after the extraction of the larger portion of the starch, gluten, 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. (Adopted 1936, Amended 1960)

IFN 5-02-903 Maize gluten with bran

48.14 Corn Gluten 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. (Adopted 1936, Amended 1960)

IFN 5-02-900 Maize gluten meal

48.16 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 4% crude fat. If prefixed with the words "white" or "yellow," the product must correspond thereto. (Adopted 1935)

IFN 4-02-887 Maize grits by-product (Hominy Feed)

IFN 4-02-011 Maize dent yellow grits by-product (Hominy Feed)

IFN 4-02-990 Maize dent white grits by-product (Hominy Feed)

48.17 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. (Proposed 1971, Adopted 1973)

IFN 4-02-892 Maize syrup dehydrated

48.18 Hydrolyzed Corn Protein is the product resulting from complete hydrolysis of isolated corn gluten, and after partial removal of the glutamic acid. (Adopted 1956)

IFN 5-02-901 Maize gluten hydrolyzed

48.19 Kibbled Corn is obtained by cooking cracked corn under steam pressure and extruding from an expeller or other mechanical pressure device. (Adopted 1958)

IFN 4-02-866 Maize grain kibbled

48.20 Dehydrated Corn Plant is the entire corn plant consisting of the ear, leaves, and stalk, which has been artificially dried and ground. (Adopted 1958)

IFN 1-02-768 Maize aerial part dehydrated

48.21 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% 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% must pass through a number 10 sieve. If it is designated as "Dehydrated," it must contain not more than 10% moisture. (Adopted 1958)

IFN 1-02-780 Maize cobs dehydrated coarse ground

IFN 1-02-781 Maize cobs dehydrated fine ground

IFN 1-02-782 Maize cobs ground

48.22 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. (Definitions combined 1960)

IFN 5-02-894 Maize germs meal dry milled mechanical extracted

48.23 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. (Proposed 1960, Adopted 1961)

IFN 5-02-897 Maize germs without extractives meal wet milled mechanical extracted

IFN 5-02-898 Maize germs without extractives meal wet milled solvent extracted

48.24 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. (Proposed 1959, Amended 1960, Adopted 1961)

IFN 4-02-890 Maize extractives fermented condensed

48.25 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. (Proposed 1971, Adopted 1973)

IFN 4-08-023 Maize starch heat hydrolyzed

48.26 Solvent Extracted Hominy Feed is hominy feed from which the fat has been extracted by the solvent process. (Proposed 1965, Adopted 1966)

IFN 4-08-025 Maize grits by-product solvent extracted (Hominy feed)

IFN 4-29-354 Maize grain heat processed

IFN 4-02-863 Maize grain heat processed flaked

IFN 4-02-864 Maize grain heat processed ground

IFN 4-02-865 Maize grain heat processed pelleted

48.30 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% solid. (Proposed 1978, Amended 2002, Adopted 2004)

IFN 4-28-211 Maize grain hydrolyzed liquid

48.31 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 1% crude fiber. (Proposed 1978, Adopted 2002)

IFN 4-07-022 Maize flour gelatinized

48.32 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. (Proposed 2002, Adopted 2004)

48.88 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. (Proposed 1993, Adopted 2005)

48.89 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% protein on a moisture free basis and not more than 1% 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 processes. Vegetable oils or other appropriate ingredients as defined in Section 87 in the Association of American Feed Control Officials Official Publication (AAFCO OP) may be added in concentrations not to exceed 3% to reduce dust during handling. The name of the conditioning dust control agent, if used, must be shown as an added ingredient. (Adopted 2008, Amended 2010)

51. Marine Products

Investigator and Section Editor—Michael Blume, SD

Official

51.14 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 3% 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 7%. 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. (Adopted 1933, Amended 1984, Amended 2003, 2004)

IFN 5-01-977 Fish meal mechanical extracted

51.24 Fish Residue Meal is the clean, dried, undecomposed residue from the manufacture of glue from non-oily fish. If it contains more than 3% 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 7%. (Adopted 1933, Amended 2003)

IFN 5-01-966 Fish glue residue meal

51.34 Fish Liver and Glandular Meal is obtained by drying the complete viscera of the fish. At least 50% of the dry weight of the product must be derived from fish liver and must contain at least 18 milligrams of riboflavin per pound. (Adopted 1944, Amended 1945)

IFN 5-01-973 Fish viscera meal

51.4 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% crude protein. If it contains more than 3% 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 7%. (Adopted 1933, Amended 2003)

IFN 5-01-663 Crab process residue meal

51.5 Shrimp Meal is the undecomposed ground dried waste of shrimp and contains parts and/or whole shrimp. If it contains more than 3% 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 7%. (Adopted 1933, Amended 1963, Amended 2003)

IFN 5-04-226 Shrimp process residue meal

51.6 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. (Proposed 1993, Adopted 1996)

51.7 Dried Fish Solubles is obtained by dehydrating the stickwater. It must contain not less than 60% crude protein. (Proposed 1963, Adopted 1964)

IFN 5-01-971 Fish solubles dehydrated

51.8 Fish Oil is the oil from rendering whole fish or cannery waste. (Proposed 1963, Adopted 1964)

IFN 7-01-965 Fish oil

51.9 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% protein and not more than 10% moisture. If the degree of fineness is stated, it must conform thereto. Solvent residues are not to exceed those established in Food Additive Regulations. (Proposed 1969, Adopted 1970, Amended 1971) Reg. 573.440

IFN 5-09-334 Fish protein concentrate solvent extracted

51.10 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). (Proposed 1974, Adopted 1975)

IFN 5-14-509 Fish process residue fresh

51.11 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% protein and not more than 10% 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. (Proposed 1978, Adopted 1979, Amended 2009)

IFN 5-18-778 Fish Protein hydrolyzed dehydrated

51.12 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% protein. (Proposed 1978, Adopted 1979)

IFN 5-17-779 Fish Protein hydrolyzed condensed

51.13 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. (Proposed 1978, Adopted 1979)

IFN 5-27-467 Fish Protein Residue hydrolyzed dehydrated

51.15 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% 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 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. (Proposed 1999, Amended 2001, Adopted 2002, Amended 2015)

51.16 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% crude protein with not more than 10% 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. (Proposed 2001, Adopted 2002)

54. Milk Products

Section Editor—Kent Kitade, Life Member

Official

54.1 Dried Buttermilk, Feed Grade, is the residue obtained by drying buttermilk. It contains 8% maximum moisture, 13% maximum ash, and 5% minimum milk fat (Roese-Gottlieb method).* (Adopted 1932, Amended 1964)

IFN 5-01-160 Cattle buttermilk dehydrated

54.2 Condensed Buttermilk is the residue obtained by evaporating buttermilk. It contains 27% minimum total solids, 0.055% minimum milk fat for each % of total solids, and 0.14% maximum ash for each % of total solids. (Adopted prior to 1928, Amended 1944, 1964)

IFN 5-01-159 Cattle buttermilk condensed

54.3 Dried Skimmed Milk, Feed Grade, is the residue obtained by drying defatted milk. It contains 8% maximum moisture.* (Adopted 1930, Amended 1964)

IFN 5-01-175 Cattle skim milk dehydrated

54.4 Condensed Skimmed Milk is the residue obtained by evaporating defatted milk. It contains 27% minimum total solids. (Adopted 1930, Amended 1964)

IFN 5-01-172 Cattle skim milk condensed

54.5 Dried Cultured Skim Milk is the residue obtained by drying lactic acid bacteria cultured in defatted milk. It contains 8% maximum moisture. (Adopted 1932, Amended 1964)

IFN 5-01-174 Cattle skim milk cultured dehydrated

54.6 Condensed Cultured Skim Milk is the residue obtained by evaporating lactic acid bacteria cultured defatted milk. It contains 27% minimum total solids. (Adopted 1932, Amended 1964)

IFN 5-01-173 Cattle skim milk cultured condensed

54.7 Dried (Dry) Whey is the product obtained by removing water from whey. It contains not less than 11% protein nor less than 61% lactose. (Adopted 1934, Amended 1948, 1950, 1951, 1964, 1981)

IFN 4-01-182 Cattle whey dehydrated

54.8 Condensed Whey is the product obtained by partially removing water from whey. Minimum percentage of solids must be prominently declared on the label. (Adopted 1944, Amended 1951, 1963, 1964, 1982)

IFN 4-01-180 Cattle whey condensed

54.9 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. (Adopted 1944, Amended 1964, 1982)

IFN 4-01-189 Cattle whey solubles dehydrated

54.10 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. (Adopted 1944, Amended 1964, 1982)

IFN 4-01-188 Cattle whey solubles condensed

54.11 Dried Hydrolyzed Whey is the residue obtained by drying lactase enzyme hydrolyzed whey. It contains 30% minimum total glucose and galactose. (Adopted 1955, Amended 1964)

IFN 4-01-184 Cattle whey hydrolyzed dehydrated

54.12 Condensed Hydrolyzed Whey is the residue obtained by evaporating lactase enzyme hydrolyzed whey. It contains 50% minimum total solids and 0.3% minimum total glucose and galactose for each percent total solids. (Adopted 1955, Amended 1964)

IFN 4-01-183 Cattle whey hydrolyzed condensed

54.13 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. (Adopted 1948, Amended 1964, 1982)

IFN 4-01-185 Cattle whey low lactose condensed

54.14 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. (Adopted 1951, Amended 1952, 1964, 1982)

IFN 4-01-186 Cattle whey low lactose dehydrated

54.15 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. (Adopted 1949, Amended 1964)

IFN 4-01-181 Cattle whey cultured condensed

54.16 Casein is the solid residue obtained by acid or rennet coagulation of defatted milk. It contains 80% minimum crude protein. (Adopted 1946, Amended 1964)

IFN 5-01-162 Casein acid precipitated dehydrated

54.17 Cheese Rind is obtained by cooking cheese trimming devoid of fat other than milk fat. (Adopted 1935, Amended 1964)

IFN 5-01-163 Cattle cheese rind

54.18 Dried Lactalbumin is the dried coagulated protein residue from whey. It contains 80% minimum crude protein on a moisture free basis. (Adopted 1952, Amended 1964, 1989)

IFN 5-01-177 Cattle whey albumin

54.19 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% 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)* (Adopted 1952, Amended 1964, 1995)

54.20 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. (Proposed 1965, Adopted 1966)

IFN 5-08-044 Cattle milk protein dehydrated

54.21 Dried Hydrolyzed Casein is the residue obtained by drying the water-soluble product resulting from the enzymatic digestion of casein. It contains 74% minimum crude protein. (Proposed 1966, Adopted 1967)

IFN 5-08-055 Casein hydrolyzed dehydrated

54.22 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% 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. (Adopted 1982)

IFN 5-30-260 Cattle milk process residue

54.23 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% nonlactose carbohydrate for each percent solids. The minimum percent of solids and the maximum percent ash must be prominently declared on the label. (Adopted 1982)

IFN 4-01-188 Cattle whey solubles condensed

54.24 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. (Adopted 1982)

IFN 4-08-134 Cattle whey fresh

54.25 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% minimum crude protein. The minimum percent of crude protein and lactose and the maximum percent ash must be prominently declared on the label. (Adopted 1982)

IFN 5-06-836 Cattle whey protein dehydrated

54.26 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. (Proposed 1988, Adopted 1989)

IFN 5-30-43 Cattle whey low lactose cultured dehydrated

54.27 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.

NOTE: This is the dried version of 54.15 condensed, cultured whey. AOAC HPLC methods are recommended to be used to quantitate the amino acids. (Proposed 1992, Adopted 1993)

54.28 Dried Chocolate Milk is the residue obtained by drying chocolate milk originally intended for human consumption. (Proposed 1992, Adopted 1993)

54.31 Dried Cheese is the product obtained by dehydrating cheeses as defined in 21 CFR, Part 133. No more than 10% of the fat may be other than milk fat. (Proposed 1992, Adopted 1999)

54.32 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. (Proposed 2001, Adopted 2003)

54.33 Bovine Colostrum is lacteal secretions obtained within 48 hours after parturition. It contains 3% maximum lactose, 15% minimum total solids, and 60% minimum of the solids must be protein. The minimum specific gravity is 1.04 g/mL. (Proposed 2014 rev. 1, Adopted 2017 rev. 1)

54.34 Dried Bovine Colostrum is the product obtained by removing water from bovine colostrum. It contains 8% maximum moisture, 20% maximum lactose, and 50% minimum of the solids must be protein. (Proposed 2014 rev. 1, Adopted 2017 rev. 1)

**The words "feed grade" are not required when listed as an ingredient in a manufactured feed.*

57. Mineral Products

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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 of the Official Publication.

(See Official Guidelines for Contaminant Levels Permitted in Mineral Feed Ingredients located on page 306)

*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."**

Official

57.265 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% nitrogen (equivalent to 160% crude protein). It must contain not more than 0.1% moisture, 0.4% salt (NaCl), 15 ppm iron (Fe), 3 ppm arsenic (As), and 10 ppm heavy metals reported as lead. It may be treated with not more than 1.0% 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 1.0% ammonium chloride in the total daily ration to provide not more than 1.6% 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." (Adopted 1984, Amended 2001, Adopted 2003, Amended 2011, Adopted 2014 rev. 1)

IFN 8-08-814 Ammonium Chloride

57.27 Ammonium Sulfate is the product resulting from the neutralization of sulfuric acid with ammonia. It shall contain not less than 21% nitrogen (N) and not less than 24% sulfur (S). It shall contain not more than 75 ppm arsenic (As) and 30 ppm 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 2% of equivalent crude protein in the total daily ration. If a premix, concentrate, or supplement contains more than 2% 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." (Proposed 1969, Adopted 1972) Reg. 582.1143

IFN 6-09-339 Ammonium sulfate

57.154 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. (Proposed 1995, Adopted 1997)

57.1 Bone Ash is the ash obtained by burning bones with free access to air, and containing a minimum of 15.3% phosphorus (P). The label must show a guarantee for calcium (Ca) and phosphorus (P). (Adopted 1935, Amended 1952)

IFN 6-00-401 Animal bone ash

57.2 Bone Charcoal is obtained by charring bones in closed retorts. It must contain a minimum of 14% 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.) (Adopted 1938, Amended 1952, 1963)

IFN 6-00-402 Animal bone charcoal

57.17 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% 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.) (Adopted 1938, Amended 1952, 1963)

IFN 6-00-404 Animal bone charcoal spent

***57.141 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. (Proposed 1984)

IFN 6-17-171 Animal bone meal boiled

***57.18 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. (Proposed 1957, Adopted 1962, Amended 1964)

IFN 6-00-400 Animal bone meal steamed

57.14 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% phosphorus (P). It must be labeled with guarantees for calcium (Ca) and phosphorus (P). (Proposed 1952, Amended 1963, Amended 1997)

IFN 6-00-406 Animal bone phosphate

57.3 Calcite is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33% calcium (Ca). (Adopted 1952)

IFN 6-01-067 Calcite ground

57.10 Calcium Carbonate is a product true to name which contains a minimum of 38% calcium (Ca). (Adopted 1946, Amended 1963) Reg. 582.5191.

IFN 6-01-069 Calcium carbonate

57.7 Calcium Carbonate, Precipitated, is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33% calcium (Ca). Precipitated calcium carbonate must be used in all labeling. (Adopted 1952)

IFN 6-01-071 Calcium carbonate, precipitated $CaCO_3$

57.51 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. (Adopted 1975)

IFN 6-20-774 Calcium chloride $CaCl_2$

57.52 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. (Adopted 1975)

IFN 6-01-073 Calcium gluconate monohydrate $Ca(C_6H_{11}O_7)_2 \cdot H_2O$

57.53 Calcium Hydroxide is the hydrated form of calcium oxide generally expressed as $Ca(OH)_2$. Minimum calcium (Ca) must be specified. (Adopted 1975)

IFN 6-14-014 Calcium hydroxide $Ca(OH)_2$

57.54 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. (Adopted 1975)

IFN 6-01-075 Calcium iodate $Ca(IO_3)_2 \cdot 6H_2O$

IFN 6-16-610 Calcium iodate monohydrate $Ca(IO_3)_2 \cdot H_2O$

57.55 Calcium Iodobehenate is the calcium salt of iodobehenic acid generally expressed as $Ca(C_{21}H_{42}ICO_2)_2$ and its hydrated forms. Minimum calcium (Ca) and minimum iodine (I) must be specified. (Adopted 1975)

IFN 6-01-077, Calcium iodobehenate $Ca(C_{21}H_{42}ICO_2)_2$

57.56 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. (Adopted 1975)

IFN 6-14-003 Calcium oxide CaO

57.25 Calcium Periodate 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% by weight of penta calcium orthoperiodate containing 28 to 31% by weight of iodine. It is used or intended for use in salt for livestock as a source of iodine. Reg. 573.240 (Proposed 1969, Adopted 1971)

IFN 6-09-355 Calcium periodate $Ca_5(IO_6)_2$

57.57 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. (Adopted 1975)

IFN 6-01-087 Calcium sulfate anhydrous $CaSO_4$

IFN 6-01-090 Calcium sulfate dihydrate $CaSO_4 \cdot 2H_2O$

57.73 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% calcium as calcium carbonate and 2.3% magnesium as magnesium carbonate. It shall not contain more than 40 ppm fluorine, 40 ppm iodine, 5 ppm lead, and 5 ppm arsenic. (Proposed 2011, Adopted 2014 rev. 1)

57.8 Chalk, Precipitated, is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33% calcium (Ca). Precipitated chalk must be used in all labeling. (Adopted 1952)

IFN 6-01-201, Chalk precipitated

57.155 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 ppb 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. (Proposed 1996, Adopted 2000, Amended 2010, Adopted 2012)

57.6 Chalk Rock is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33% of calcium (Ca). (Adopted 1952)

IFN 6-01-202 Chalk rock ground

57.131 Clam Shells, Ground, is an acceptable source of calcium carbonate. It must be true to name and contain not less than 35% calcium (Ca). (Proposed 1979, Adopted 1981)

IFN 6-01-259 Clam shells ground

57.58 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. (Adopted 1975)

IFN 6-01-554 Cobalt acetate $Co(C_2H_3O_2)_2$

57.59 Cobalt Carbonate is the cobalt salt of carbonic acid generally expressed as $CoCO_3$ and its hydrated forms. Minimum cobalt (Co) must be specified. (Adopted 1975)

IFN 6-01-566 Cobalt carbonate $CoCO_3$

57.60 Cobalt Chloride is the cobalt salt of hydrochloric acid generally expressed as $CoCl_2$, and its hydrated forms. Minimum cobalt (Co) must be specified. (Adopted 1975)

IFN 6-01-556 Cobaltous chloride anhydrous $CoCl_2$

57. 123 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." (Proposed 1976)

IFN 6-20-869 Cobalt choline citrate complex

57.148 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. (Proposed 1988, Adopted 1989)

IFN 6-19-211 Cobalt glucoheptonate

57.147 Cobalt Gluconate is the cobalt salt of gluconic acid, generally expressed as $Co(C_6H_{11}0_7)_2$, and its hydrated forms. Minimum cobalt (Co) must be specified. (Proposed 1988, Adopted 1989)

IFN 6-19-210 Cobalt gluconate

57.61 Cobalt Oxide is the oxide form of cobalt generally expressed as CoO. Minimum cobalt (Co) must be specified. (Adopted 1975)

IFN 6-01-560 Cobalt Oxide

57.62 Cobalt Sulfate is the cobalt salt of sulfuric acid generally expressed as $CoSO_4$ and its hydrated forms. Minimum cobalt (Co) must be specified. (Adopted 1975)

IFN 6-01-562 Cobalt sulfate monohydrate $CoSO_4 \cdot H_2O$

IFN 6-01-564 Cobalt sulfate heptahydrate $CoSO_4 \cdot 7H_2O$

57.153 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. (Proposed 1993, Adopted 2000)

57.63 Copper Carbonate is the copper salt of carbonic acid generally expressed as $CuCO_3$. Minimum copper (Cu) must be specified. (Adopted 1975)

IFN 6-01-703 Cupric carbonate $CuCO_3$

57.64 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. (Adopted 1975)

IFN 6-07-135 Cuprous chloride $CuCl_2$

IFN 6-01-705 Cupric chloride dihydrate. $CuCl_2 \cdot 2H_2O$

57.122 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." (Proposed 1976, Adopted 1977)

IFN 6-20-868 Copper choline citrate complex

57.158 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 ppm of total dietary copper. Minimum copper (Cu) must be specified. (Proposed 1997, Adopted 2000)

57.65 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. (Adopted 1975)

IFN 6-01-707 Cupric gluconate $Cu(C_6H_{11}C_7)_2$

57.66 Copper Hydroxide is the hydrated form of copper oxide generally expressed as $Cu(OH)_2$. Minimum copper (Cu) must be specified. (Adopted 1975)

IFN 6-01-709 Cupric hydroxide $Cu(OH)_2$

57.67 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. (Adopted 1975)

IFN 6-01-713 Cupric orthophosphate $Cu_3(PO_4)_2$

57.68 Copper Oxide is the oxide form of copper generally expressed as CuO or Cu_2O. Minimum copper (Cu) must be specified. (Adopted 1975)

IFN 6-28-224 Cuprous oxide Cu_2O

IFN 6-01-711 Cupric oxide CuO

57.69 Copper Sulfate is the copper salt of sulfuric acid generally expressed as $CuSO_4$ and its hydrated forms. Minimum copper (Cu) must be specified. (Adopted 1975)

IFN 6-01-717 Cupric sulfate anhydrous $CuSO_4$

IFN 6-01-719 Cupric sulfate pentahydrate $CuSO_4 \cdot 5H_2O$

57.70 Cuprous Iodide is the copper salt of hydriodic acid generally expressed as CuI. Minimum copper (Cu) must be specified. (Adopted 1975)

IFN 6-01-721 Cuprous iodide CuI

57.72 Diiodosalicylic Acid is an iodine compound of salicylic acid generally expressed as $C_7H_4I_2O_3$. Minimum iodine (I) must be specified. (Adopted 1975)

IFN 6-01-787 Diiodosalicylic acid $C_7H_4I_2O_3$

57.75 Ethylenediamine Dihydroiodide is an organic compound of iodine generally expressed as $C_2H_8N_2 \cdot 2HI$. Minimum iodine (I) must be specified. (Adopted 1975)

IFN 6-01-842 Ethylenediamine dihydriodide $C_2H_4NH_2 \cdot 2HI$

57.76 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. (Adopted 1975)

IFN 6-01-857 Ferric ammonium citrate

57.78 Ferric Chloride is the iron salt of hydrochloric acid generally expressed as $FeCl_3$ and its hydrated forms. Minimum iron (Fe) must be specified. (Adopted 1975)

IFN 6-01-865 Ferric chloride $FeCl_3$

57.121 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." (Adopted 1977)

IFN 6-20-867 Ferric choline citrate complex

57.127 Ferric Formate is an iron salt of formic acid generally expressed as $Fe(HCO_2)_3$. (Adopted 1980)

IFN 6-630-089 Ferric formate monohydrate $Fe(HCO_2)_3 \cdot H_2O$

57.81 Ferric Phosphate is the iron salt of phosphoric acid generally expressed as $FePO_4$ and its hydrated forms. Minimum iron (Fe) must be specified. (Adopted 1975)

IFN 6-01-859 Ferric phosphate $FePO_4$

57.82 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. (Adopted 1975)

IFN 6-01-861 Ferric pyrophosphate $Fe_4(P_2O_7)_3$

57.129 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. (Adopted 1980)

IFN 6-30-086 Ferric sulfate $Fe_2(SO_4)_3$

57.77 Ferrous Carbonate is the iron salt of carbonic acid generally expressed as $FeCO_3$. Minimum iron (Fe) must be specified. (Adopted 1975)

IFN 6-01-863 Ferrous carbonate $FeCO_3$

57.128 Ferrous Chloride is the iron salt of hydrochloric acid generally expressed as $FeCl_2$ and its hydrated forms. Minimum iron (Fe) must be specified. (Proposed 1979, Adopted 1981)

IFN 6-30-090 Ferrous chloride $FeCl_2$

57.164 Ferrous Fumarate is an iron salt of fumaric acid generally expressed as $FeC_4H_2O_4$. Minimum iron (Fe) must be specified. (Adopted 1975)

IFN 6-08-097 Ferrous fumarate $FeC_4H_2O_4$

57.79 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. (Adopted 1975)

IFN 6-01-867 Ferrous gluconate dihydrate $Fe(C_6H_{11}O_7)_2 \cdot 2H_2O$

57.139 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. (Proposed 1984)

IFN 6-17-227 Ferrous glycine complex $FeC_4N_2H_8O_4$

57.83 Ferrous Sulfate is the iron salt of sulfuric acid generally expressed as $FeSO_4$ and its hydrated forms. Minimum iron (Fe) must be specified. (Adopted 1975)

IFN 6-01-869 Ferrous sulfate monohydrate $FeSO_4 \cdot H_2O$

IFN 6-20-734 Ferrous sulfate heptahydrate $FeSO_4 \cdot 7H_2O$

57.30 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). (Proposed 1977, Adopted 1981)

IFN 6-14-505 Shale gypsiferrous

57.80 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. (Adopted 1975)

IFN 6-02-431 Ferric oxide Fe_2O_3

57.84 Iron, Reduced, is a metallic form of iron obtained by reducing ferric oxide with hydrogen. Minimum iron (Fe) must be specified. (Adopted 1975)

IFN 6-02-429 Iron Reduced

57.9 Limestone, Ground, is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33% calcium (Ca). Ground limestone must be used in all labeling. (Adopted 1952)

IFN 6-02-632 Limestone ground

57.11 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% magnesium (Mg) and must be declared as an ingredient as magnesium limestone or dolomitic limestone. (Adopted 1946, Amended 1952, 1965)

IFN 6-02-633 Limestone dolomitic ground

IFN 6-06-934 Limestone magnesium ground

57.85 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. (Adopted 1975)

IFN 6-02-754 Magnesium carbonate $MgCO_3 \cdot Mg(OH)_2$

IFN 6-08-797 Magnesium carbonate trihydrate $MgCO_3 \cdot Mg(OH)_2 \cdot 3H_2O$

IFN 6-29-798 Magnesium carbonate pentahydrate $MgCO_3 \cdot Mg(OH)_2 \cdot 5H_2O$

57.126 Magnesium Chloride is the magnesium salt of hydrochloric acid generally expressed as $MgCl_2$ and its hydrated forms. Minimum magnesium (Mg) must be specified. (Proposed 1976, Adopted 1977)

IFN 6-20-872 Magnesium chloride $MgCl_2$

57.161 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. (Proposed 2000, Adopted 2002)

57.86 Magnesium Hydroxide is the hydrated form of magnesium generally expressed as $Mg(OH)_2$. Minimum magnesium (Mg) must be specified. (Adopted 1975)

IFN 6-26-012 Magnesium hydroxide $Mg(OH)_2$

57.140 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. (Proposed 1984)

IFN 6-23-294 Magnesium phosphate $MgHPO_4$

57.87 Magnesium Oxide is the oxide of magnesium generally expressed as MgO. Minimum magnesium (Mg) must be specified. (Adopted 1975)

IFN 6-02-756 Magnesium oxide MgO

57.24 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). (Proposed 1968, Adopted 1971, Amended 1987)

IFN 6-08-999 Magnesium-Mica

57.88 Magnesium Sulfate is the magnesium salt of sulfuric acid generally expressed as $MgSO_4$ and its hydrated forms. Minimum magnesium (Mg) must be specified. (Adopted 1975)

IFN 6-26-134 Magnesium sulfate MgSO4.

IFN 6-12-209 Magnesium sulfate monohydrate $MgSO_4 \cdot H_2O$.

IFN 6-02-758 Magnesium sulfate heptahydrate $MgSO_4 \cdot 7H_2O$

57.89 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. (Adopted 1975)

IFN 6-03-034 Manganese acetate tetrahydrate $Mn(C_2H_3O_2)_2 \cdot 4H_2O$

57.90 Manganese Carbonate is the manganese salt of carbonic acid generally expressed as $MnCO_3$ and its hydrated forms. Minimum Manganese (Mn) must be specified. (Adopted 1975)

IFN 6-03-036 Manganous carbonate $MnCO_3$

57.91 Manganese Chloride is the manganese salt of hydrochloric acid generally expressed as $MnCl_2$ and its hydrated forms. Minimum manganese (Mn) must be specified. (Adopted 1975)

IFN 6-03-038 Manganous chloride tetrahydrate $MnCl_2 \cdot 4H_2O$

57.92 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. (Adopted 1975)

IFN 6-03-040 Manganous citrate soluble $Mn_3(C_6H_5O_7)_2$

57.93 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. (Adopted 1975)

IFN 6-03-044 Manganous gluconate $Mn(C_6H_{11}O_7)_2$

57.94 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. (Adopted 1975)

IFN 6-03-047 Manganese orthophosphate trihydrate $Mn_3(PO_4)_2 \cdot 3H_2O$

57.95 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. (Adopted 1975)

IFN 6-03-048 Manganese phosphate dibasic $MnHPO_4$

57.96 Manganese Sulfate is the manganese salt of sulfuric acid generally expressed as $MnSO_4$ and its hydrated forms. Minimum manganese (Mn) must be specified. (Adopted 1975)

IFN 6-03-050, Manganous sulfate tetrahydrate $MnSO_4 \cdot 4H_2O$

57.97 Manganous Oxide is an oxide form of manganese generally expressed as MnO. Minimum manganese (Mn) must be specified. (Adopted 1975)

IFN 6-03-054 Manganous oxide MnO

57.150 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.(Adopted 1990)

IFN 6-32-053 Copper amino acid complex
IFN 6-32-054 Zinc amino acid complex
IFN 6-32-055 Magnesium amino acid complex
IFN 6-32-056 Iron amino acid complex
IFN 6-32-057 Cobalt amino acid complex
IFN 6-32-058 Calcium amino acid complex
IFN 6-32-059 Potassium amino acid complex
IFN 6-32-060 Manganese amino acid complex

57.151 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 (Proposed 1991, Adopted 1992)

IFN Copper lysine complex
IFN Zinc lysine complex
IFN 6-16-294 Ferric methionine complex
IFN 6-19-212 Manganese methionine complex
IFN 6-16-293 Zinc methionine complex

57.142 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. (Proposed 1986, Adopted 1988, Amended 2009)

IFN 6-20-981 Calcium amino acid chelate
IFN 6-20-982 Cobalt amino acid chelate
IFN 6-20-983 Copper amino acid chelate
IFN 6-20-984 Iron amino acid chelate
IFN 6-20-985 Magnesium amino acid chelate
IFN 6-20-986 Manganese amino acid chelate
IFN 6-20-987 Zinc amino acid chelate

57.28 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% for copper, 13% for manganese and 16% for zinc. (Proposed 2012, Adopted 2014 rev. 1)

57.29 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 (Proposed 1971, Adopted 1973, Amended 2007)

IFN 8-09-822 Copper polysaccharide complex

IFN 8-09-898 Iron polysaccharide complex

IFN 8-09-899 Zinc polysaccharide complex

IFN 8-19-206 Magnesium polysaccharide complex

57.160 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. (Proposed 2017 rev. 1, Adopted 2017 rev. 1)

57.166 Chromium Propionate—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:

(a) 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, $[Cr_3(O)(CH_3CH_2CO_2)_6(H_2O)_3]CH_3CH_2CO_2$.

(b) It is added to feed as follows:
  (1) In the complete feed for broiler chickens and swine at a level not to exceed 0.2 mg of chromium from chromium propionate per kilogram of feed.
  (2) In cattle diets at a level not to exceed 0.5 mg 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.
  (3) In feed for horses at a level not to exceed an intake of 4 mg of chromium from chromium propionate per horse per day.

(c) The additive meets the following specifications:
  (1) Total chromium content, 8 to 10%.
  (2) Hexavalent chromium content, less than 2 parts per million (ppm).
  (3) Arsenic, less than 1 ppm.
  (4) Cadmium, less than 1 ppm.
  (5) Lead, less than 0.5 ppm.
  (6) Mercury, less than 0.5 ppm.
  (7) Viscosity, not more than 2,000 centipoise.

(d) The additive shall be incorporated into feed as follows:
  (1) 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 mg of added chromium from chromium propionate per pound.
  (2) 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.
  (3) Chromium from all sources of supplemental chromium cannot exceed:
    (i) A level of 0.2 ppm of the complete feeds for broiler chickens and swine;
    (ii) A level of 0.5 ppm of the complete feed for cattle; and
    (iii) An intake of 4 mg per horse per day.

(e) To assure safe use of the additive in addition to the other information required by the Federal Food, Drug, and Cosmetic Act:
  (1) The label and labeling of the additive, any feed premix, and complete feed shall contain the name of the additive.

(2) The label and labeling of the additive and any feed premix shall also contain:
(i) A guarantee for added chromium content.
(ii) Adequate directions for use and cautions for use including these statements: "Caution: Follow label directions" and consistent with the directions for use, the following:
(A) “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.”
(B) “Chromium from all sources of supplemental chromium cannot exceed 4 milligrams per horse per day.”

(21 CFR 573.304) (Adopted 2017 rev. 1, Amended 2021)

57.23 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. (Proposed 1967, Adopted 1970, Amended 1977, Amended 1987)

IFN 6-09-896 Copper proteinate
IFN 6-09-897 Zinc proteinate
IFN 6-26-149 Magnesium proteinate
IFN 6-26-150 Iron proteinate
IFN 6-26-151 Cobalt proteinate
IFN 6-16-834 Manganese proteinate
IFN 6-16-833 Calcium proteinate

57.4 Oyster Shell Flour is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33% calcium (Ca). (Adopted 1952)

IFN 6-03-481 Oyster shells fine ground (Oyster shell flour)

57.22 Ammonium Polyphosphate Solution is the product resulting from the neutralization of superphosphoric acid. It must contain not less than 9% nitrogen (N) and 13% phosphorus (P). It must contain not more than one (1) part fluorine (F) to 100 parts phosphorus (P), 75 ppm of arsenic (As), and 30 ppm 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 2% 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% 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 nutrionally 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 _____%
equivalent crude protein which is not
nutritionally available to swine.)

If a premix, concentrate or supplement for ruminants contains more than 2% equivalent crude protein from ammonium polyphosphate or if a premix concentrate or supplement for non-ruminants contains more than 1.25% 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**.” (Proposed 1966, Adopted 1967, Amended 1981)

IFN 6-08-42 Ammonium polyphosphate solution

57.134 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. (Proposed 1980, Adopted 1981)

IFN 6-12-311 Calcium phosphate

57.16 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% nitrogen (N) and 20% phosphorus (P). It must contain not more than 1 part fluorine (F) to 100 parts phosphorus (P), 75 ppm of arsenic (As), and 30 ppm 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 2% 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% 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 _____%
equivalent crude protein which is not
nutritionally available to swine.)

If a premix, concentrate or supplement for ruminants contains more than 2% equivalent crude protein from diammonium phosphate or if a premix concentrate or supplement for non-ruminants contains more than 1.25% 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.**" (Proposed 1961, Amended 1967, 1981)

IFN 6-00-370 Ammonium phosphate dibasic $(NH_4)_2HPO_4$

57.71 Dicalcium Phosphate is a calcium salt of phosphoric acid generally expressed as $CaHPO_4$ and its hydrated forms. Minimum phosphorus (P), minimum calcium (Ca) and maximum fluorine (F) must be specified. It must not contain more than 1 part of fluorine (F) to 100 parts phosphorus (P). (Adopted 1975)

IFN 6-01-080 Calcium phosphate dibasic from defluorinated phosphoric acid.

IFN 6-26-335 Calcium phosphate dibasic from furnaced phosphoric acid (Dicalcium phosphate)

57.32 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 1 part fluorine (F) to 100 parts phosphorus (P). (Adopted 1975)

IFN 6-04-286 Sodium phosphate dibasic Na_2HPO_4

57.33 Monoammonium Phosphate is the product resulting from the neutralization of phosphoric acid, feed grade, or defluorinated wet-process phosphoric acid which contains not less than 9% nitrogen (N) and 23% phosphorus (P). It must contain not more than 1 part fluorine (F) to 100 parts phosphorus (P), 75 ppm of arsenic (As) and 30 ppm 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 2% 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% 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 _____%
equivalent crude protein which is not
nutritionally available to swine.)

If a premix, concentrate or supplement for ruminants contains more than 3% equivalent crude protein from mono-ammonium phosphate or if a premix concentrate or supplement for non-ruminants contains more than 1.25% 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**." (Proposed 1973, Adopted 1976) Reg. 582.1141

IFN 6-09-338 Ammonium phosphate monobasic $(NH_4)H_2PO_4$

57.98 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 1 part fluorine (F) to 100 parts phosphorus (P). (Adopted 1975)

IFN 6-01-082 Calcium phosphate, monobasic, from defluorinated phosphoric acid

IFN 6-26-334 Calcium phosphate, monobasic, from furnaced phosphoric acid (monocalcium phosphate)

57.99 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 1 part fluorine (F) to 100 parts phosphorus (P). (Adopted 1975)

IFN 6-04-288 Sodium phosphate monobasic monohydrate $NaH_2PO_4 \cdot H_2O$

57.19 Phosphoric Acid, _____%, 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." (Proposed 1957, Adopted 1962, Amended 1967, 1968, 1975, 1976)

IFN 6-03-707 Phosphoric acid H_3PO_4

57.12 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. (Adopted 1952, Amended 1965)

IFN 6-01-780 Phosphate defluorinated

IFN 6-12-330 Phosphate defluorinated 18.5% phosphorus

IFN 6-12-324 Phosphate defluorinated 18% phosphorus

IFN 6-12-331 Phosphate defluorinated 21% phosphorus

57.15 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 9% phosphorus (P) and 15% calcium (Ca), and not more than 30% clay and

1.5% fluorine (F). The term soft rock phosphate must be used in all labeling. (Proposed 1961, Adopted 1963, Amended 1965)

IFN 6-03-947 Rock phosphate soft

57.20 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. (Proposed 1963, Adopted 1964)

IFN 6-03-945 Rock phosphate ground

57.21 Rock Phosphate, Ground, Low Fluorine is ground phosphate rock that contains not more than 0.5% 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). (Proposed 1963, Adopted 1964)

IFN 6-03-946 Rock phosphate ground low fluorine

57.132 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. (Proposed 1980, Adopted 1981)

IFN 6-12-315 Sodium hexametaphosphate $(NaPO_3)x \cdot H_2O$ (x=6-20)

57.110 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 1 part fluorine (F) to 100 parts phosphorus (P). (Adopted 1975)

IFN 6-08-076, Sodium tripolyphosphate $Na_5P_3O_{10}$

57.125 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 1 part fluorine (F) to 100 parts of phosphorus (P). (Proposed 1976, Adopted 1977)

IFN 6-20-871 Sodium phosphate tribasic Na_3PO_4

57.113 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 1 part fluorine (F) to 100 parts phosphorus (P). (Adopted 1975)

IFN 6-01-084 Calcium phosphate tribasic

57.100 Potassium Bicarbonate is a potassium salt of carbonic acid generally expressed as $KHCO_3$. Minimum potassium (K) must be specified. (Adopted 1975)

IFN 6-09-337 Potassium bicarbonate $KHCO_3$

57.101 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. (Adopted 1975, Revised 2020 rev. 1)

IFN 6-09-336 Potassium carbonate K_2CO_3

57.130 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. (Adopted 1980)

IFN 6-30-087 Potassium citrate $K_3C_6H_5O_7 \cdot H_2O$

57.102 Potassium Chloride, is the potassium salt of hydrochloric acid generally expressed as KCl. Minimum potassium (K) must be specified. (Adopted 1975)

IFN 6-03-755 Potassium chloride KCl

57.162 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. (Proposed 2000, Adopted 2002)

57.124 Potassium Hydroxide is the hydroxyl form of potassium generally expressed as KOH. Minimum potassium (K) must be specified. (Proposed 1976, Adopted; 1977) Reg. 582-1631.

IFN 6-20-870 Potassium hydroxide KOH

57.103 Potassium Iodate is the potassium salt of iodic acid generally expressed as KIO_3. Minimum potassium (K) and minimum iodine (I) must be specified. (Adopted 1975)

IFN 6-08-072 Potassium iodate KIO_3

57.104 Potassium Iodide is the potassium salt of hydriodic acid generally expressed as KI. Minimum potassium (K) and iodine (I) must be specified. (Adopted 1975)

IFN 6-03-759 Potassium iodide KI

57.105 Potassium Sulfate is the potassium salt of sulfuric acid generally expressed as K_2SO_4. Minimum potassium (K) and sulfur (S) must be specified. (Adopted 1975)

IFN 6-08-098 Potassium sulfate K_2SO_4

57.31 Salt is an acceptable source of sodium chloride. It must be true to name and contain not less than 95% sodium chloride. (Proposed 1973, Adopted 1975)

IFN 6-04-152 Salt NaCl

57.13 Iodized Salt, is a common salt (NaCl) containing not less than 0.007% iodine, uniformly distributed. (Adopted 1942)

IFN 6-04-151 Salt iodine added 0.007% iodine

57.5 Shell Flour is an acceptable source of calcium carbonate. It must be true to name and contain not less than 33% calcium (Ca). (Adopted 1952)

IFN 6-05-688 Mollusks shells fine ground

57.137 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 1 part fluorine (F) to 100 parts phosphorus (P). (Adopted 1984)

IFN 6-16-830 Sodium, Pyrophosphate, Hexahydrate

57.106 Sodium Bicarbonate is the sodium salt of carbonic acid generally expressed as $NaHCO_3$. Minimum sodium (Na) must be specified. (Proposed 1988, Adopted 1989)

IFN 6-04-272 Sodium bicarbonate $NaHCO_3$

57.133 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. (Proposed 1980, Adopted 1981)

IFN 6-12-316 Sodium carbonate Na_2CO_3

57.107 Sodium Iodate is the sodium salt of iodic acid generally expressed as $NaIO_3$. Minimum iodine (I) must be specified. (Adopted 1975)

IFN 6-04-277 Sodium iodate $NaIO_3$

57.108 Sodium Iodide is the sodium salt of hydriodic acid generally expressed as NaI. Minimum sodium (Na) and minimum iodine (I) must be specified. (Adopted 1975)

IFN 6-04-279 Sodium iodide NaI

57.145 Sodium Molybdate is the sodium salt of molybdenum, generally expressed as Na_2MoO_4, and its hydrated forms. Minimum molybdenum must be specified (Proposed 1987, Adopted 1988)

IFN 6-19-30 Sodium molybdate

57.120 Sodium Selenate 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." (Adopted 1975) Reg. 573.920

IFN 6-26-014 Sodium selenate Na_2SeO_4

57.119 Sodium Selenite 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." (Adopted 1975) Reg. 573.920

IFN 6-26-013 Sodium selenite Na_2SeO_3

57.138 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% of the hydrated double salt with 42% minimum sodium carbonate, 33% minimum sodium bicarbonate, and providing not less than 27.5% sodium. (Proposed 1988, Adopted 1989.

IFN 6-17-895 Sodium sesquicarbonate

57.109 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. (Adopted 1975)

IFN 6-04-291, Sodium sulfate decahydrate $Na_2SO_4 \cdot 10H_2O$

57.111 Sulfur is elemental sulfur generally expressed as sulfur (S). Minimum sulfur (S) must be specified. (Adopted 1975)

IFN 6-04-705 Sulfur

57.112 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. (Adopted 1975)

IFN 6-04-857 Thymol iodide $C_{20}H_{24}I_2O_2$

57.114 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. (Adopted 1975)

IFN 6-05-547, Zinc acetate dihydrate $Zn(C_2H_3O_2)_2 \cdot 2H_2O$

57.115 Zinc Carbonate is the zinc salt of carbonic acid generally expressed as $ZnCO_3$ and its hydrated forms. Minimum zinc (Zn) must be specified. (Adopted 1975)

IFN 6-05-549 Zinc carbonate $ZnCO_3$

57.116 Zinc Chloride is the zinc salt of hydrochloric acid generally expressed as $ZnCl_2$ and its hydrated forms. Minimum zinc (Zn) must be specified. (Adopted 1975)

IFN 6-05-551 Zinc chloride $ZnCl_2$

57.143 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. (Proposed 1986, Adopted 1987)

IFN 6-20-988 Zinc chloride diammine complex

57.117 Zinc Oxide is the oxide form of zinc generally expressed as ZnO. Minimum zinc (Zn) must be specified. (Adopted 1975)

IFN 6-05-553 Zinc oxide ZnO

57.118 Zinc Sulfate is the zinc salt of sulfuric acid generally expressed as $ZnSO_4$ and its hydrated forms. Minimum zinc (Zn) must be specified. (Adopted 1975)

IFN 6-05-555 Zinc sulfate monohydrate $ZnSO_4 \cdot H_2O$

IFN 6-20-729 Zinc sulfate heptahydrate $ZnSO_4 \cdot 7H_2O$

57.163 Selenium Yeast 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 2% 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, and to complete dog foods at a level not to exceed 0.333 part per million of selenium on a dry matter basis;

2) feed supplements for limit feeding for beef cattle, bison, and horses at a level not to exceed an intake of 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 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.

Selenium yeast shall be incorporated into each ton of complete feed by adding no less than 1 pound of a premix containing no more than 272.4 milligrams of added selenium per pound. 21 CFR 573.920. **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."** (Proposed 2002, Amended 2003, 2004, 2007*, 2008, 2009, Adopted 2011, Amended 2017)

57.165 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% 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% chloride, 90 ppm lead, 15 ppm chromium, 10 ppm arsenic, 10 ppm cadmium, and 0.2 ppm mercury. (Proposed 2015 rev. 1, Adopted 2017 rev. 1)

57.167 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% 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% chloride, 50 ppm lead, 50 ppm arsenic, 10 ppm cadmium, and 0.5 ppm mercury. (Proposed 2019 rev. 1, Adopted 2021)

57.168 Selenomethionine Hydroxy Analogue [R,S-2-hydroxy-4-methylselenobutanoic acid (CAS 873660-49-2)] 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% total selenium by weight with a selenomethionine hydroxy analogue content of not less than 98% of total selenium. The total organic selenium content of the additive is not less than 99% of total selenium.

(a) The selenomethionine hydroxy analogue meets the following specifications:
    (1) Arsenic, not more than 2 parts per million (ppm);
    (2) Cadmium, not more than 1 ppm;
    (3) Lead, not more than 1 ppm; and
    (4) Mercury, not more than 1 ppm.
(b) Selenium, as selenomethionine hydroxy analogue, is added to feed as follows:
    (1) In complete feed for chickens, turkeys, swine, beef cattle, and dairy cattle at a level not to exceed 0.3 ppm.
    (2) In feed supplements for limit feeding for beef cattle at a level not to exceed an intake of 3 milligrams per head per day.

(3) In salt-mineral mixtures for free-choice feeding for beef cattle up to 120 ppm in a mixture for free-choice feeding at a rate not to exceed an intake of 3 milligrams per head per day.

(c) To ensure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling of selenomethionine hydroxy analogue in its packaged form shall contain:
(1) The name, selenomethionine hydroxy analogue;
(2) Minimum and maximum guarantees for a total selenium content of not less than 2.08% (weight/weight) and not more than 2.24%;
(3) Minimum guarantee for selenomethionine hydroxy analogue content of not less than 5.2%;
(4) The following statement, "Storage Conditions: Selenomethionine hydroxy analogue must be stored in a closed package at temperatures not higher than 20°C (68°F)."; and
(5) An expiration date not to exceed 1 year from the date of manufacture.

(d) Selenomethionine hydroxy analogue, shall be incorporated into each ton of complete feed by adding no less than 1 pound of a premix containing no more than 272.4 milligrams of added selenium per pound.

(e) 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.

(f) 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."

21 CFR 573.920 (Adopted 2020, Amended 2022)

57.169 Iron-Choline Citrate Complex 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. 21 CFR 573.580 (Proposed 2020, Adopted 2021 rev. 1)

Descriptions of Salts, Complexes and Chelates

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.

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.

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.

60. Miscellaneous Products

Investigator and Section Editor—Erin Bubb, PA

*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.**"

Official

60.7 Almond Hulls are obtained by drying the pericarp which surrounds the nut. Almond hulls shall contain not more than 13% moisture, 15% crude fiber and 9% ash. Total soluble sugars expressed as invert shall not be less than 18%. Almond hulls shall be processed in accordance with good manufacturing practices and be reasonably free of foreign material. (Proposed 1984, Adopted 1985)

IFN 4-00-358 Almond hulls ground

60.72 Almond Hulls with Almond Shells—Almond hulls with almond shells must not contain more than 29% crude fiber, 9% ash and 13% moisture. They shall be processed in accordance with good manufacturing practices and be reasonably free of foreign material. (Proposed 1984, Adopted 1985)

IFN 1-27-475 Almond hulls with shells

60.42 Ground Almond Shells is obtained by drying and grinding that portion of the almond fruit which surrounds the nut. It must be reasonably free of the nut shell and other foreign material. (Adopted 1953)

IFN 4-00-358 Almond hulls ground

60.44 Ground Whole Aspen and/or Parts is generally recognized as a feed ingredient in cattle diets when used in accordance with good nutritional 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. (Proposed 1979, Adopted 1980)

IFN 1-30-183 Aspen quaking/Aspen large toothed aerial part ground

IFN 1-12-241 Aspen aerial part ground

60.43 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% ash. It shall not contain aspirations from medicated feeds. (Proposed 1979, Amended 1980, Adopted 1980)

IFN 4-12-208 Cereals-oil seeds grain and seed fractions aspirated

60.27 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." (Proposed 1971, Adopted 1972)

IFN 1-10-609 Bermudagrass coastal dehydrated

IFN 1-00-716 Bermudagrass coastal hay

60.17 Buckwheat Hulls is the product consisting primarily of the outer covering of the buckwheat obtained in the milling of buckwheat flour. (Proposed 1963, Adopted 1968)

IFN 1-12-238 Buckwheat hulls

60.6 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% crude fiber. (Adopted 1944)

IFN 5-12-237 Buckwheat flour by-product without hulls

60.98 L-Carnitine is a nutritional supplement with a minimum content of 97.0% L-Carnitine and a maximum of 0.5% D-isomer. L-Carnitine is for use in swine feeds at levels not to exceed 0.1% (1000 ppm) of complete feed, for use in chicken and turkey feeds at levels not to exceed 0.02% (200 ppm) of complete feed, for use in fish feed at levels not to exceed 0.25% (2500 ppm) of complete feed, for use in milk replacers for ruminant animals at levels not to exceed 0.075% (750 ppm) of milk replacer powder. L-Carnitine is also for use for dog foods at levels not to exceed 0.075% (750 mg/kg) on a dry matter basis, and for use in cat foods (intended for adult maintenance only) at levels not to exceed 0.10% (1000 mg/kg) on a dry matter basis. L-Carnitine is a fatty acid carrier that plays a role in fat oxidation in the body. (Proposed 1997, Amended 1999, Amended 2002, Adopted 2004, Amended 2009, Amended 2011, Adopted 2012, 2013)

60.11 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. (Adopted 1949, Amended 1964)

IFN 1-02-215 Grass hay sun-cured ground

60.18 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." (Proposed 1966, Adopted 1968)

IFN 5-05-687 Guar seeds without endosperm ground

60.19 Dried Kelp is dried seaweed of the families Laminariacae 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." (Proposed 1966, Adopted 1968)

IFN 1-08-073 Seaweed kelp whole dehydrated

60.24 Paunch Product, Dehydrated is a product composed of the contents of the rumen of slaughtered cattle, dehydrated at temperatures over 100°C to a moisture content of 12% or less, such dehydration designed to destroy any pathogenic bacteria. It shall be dehydrated promptly after removal from the rumen to prevent decomposition. (Proposed 1969, Adopted 1970)

IFN 1-09-327 Animal rumen contents dehydrated

60.12 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. (Proposed 2002, Ingredient Definition Number Amended 2010, Adopted 2012)

60.20 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. (Proposed 1967, Adopted 1968)

IFN 3-08-812 Alfalfa silage dehydrated pelleted

60.10 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." (Adopted 1948, Amended 1964)

IFN 1-04-682 Cereals straw ground

IFN 1-12-232 Alfalfa straw ground

IFN 1-12-233 Bluegrass straw ground

60.9 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." (Adopted prior to 1928)

IFN 5-02-158 Cereals vinegar fermentation grains dehydrated

IFN 5-02-159 Cereals yeast fermentation grains dehydrated

60.73 Salts of Volatile Fatty Acids 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. (Proposed 1985, Adopted 1986, Amended 2017) Reg 21 CFR 573.914

60.74 Tapioca/Manioca and Cassava Root is the whole root chipped mechanically into small pieces and sun dried on concrete surfaces for 2 to 3 days and then the chips are pelleted. (Adopted 1993)

IFN 4-18-896 Cassava Tubers, Sun-cured Pelleted

60.75 Ethyl Alcohol Containing Ethyl Acetate is a product containing not less than 92.5% ethyl alcohol, each 100 gallons having had added the equivalent of 4.25 gallons of 100% ethyl acetate. It is used in ruminant feed supplements as a source of added energy. (Proposed 1986, Adopted 1990) Reg. 21CFR 584.200

IFN 4-18-895 Ethyl Alcohol-Ethyl Acetate

60.76 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.

Note: 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. (Proposed 1986, Adopted 1991, Amended 1994)

IFN 5-18-897 Algae Whole Meal

60.78 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% alkaloids. (Proposed 1993, Adopted 1996)

60.79 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% alkaloids. (Proposed 1993, Adopted 1996)

60.80 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% alkaloids. It must contain not more than 7% crude fiber. (Proposed 1993, Adopted 1996)

Note: 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.

60.84 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. (Proposed 1991, Adopted 1993)

IFN 1-32-187 Plantago seed husk

60.86 1, 3-Butylene Glycol (1, 3-Butanediol) is a viscous, colorless liquid of 99% 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 9% of the dry matter of the total ration. It should be thoroughly mixed in feed, not less than 5 minutes after its addition, with equipment adapted for the addition of liquids. (Reference 21 CFR 573.225 and 21 CFR 173.220. (Proposed 1992, Adopted 1996)

60.94 Potato Protein is derived from de-starched potato juice from which the proteinaceous fraction has been precipitated by thermal coagulation followed by dehydration. (Proposed 1996, Adopted 2000)

60.95 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. (Proposed 1997, Adopted 2007)

60.99 Chia Seed consists of cleaned, sound, dry, whole seed of the chia plant (*Salvia hispanica*). Typically it contains 18% crude protein, 32% crude fat and 32% crude fiber. (Proposed 1998, Adopted 2006)

60.101 Hydrolyzed Roughage is the residue from the acid hydrolysis and steam stripping of roughage products. The product will contain a minimum of 50% acid detergent fiber and a maximum of 5% ash. The product is used as a carrier for oils, fats, and molasses and as a source of acid detergent fiber for ruminants. (Proposed 2000, Adopted 2010)

60.104 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% inulin and no more than 13% moisture. (Proposed 2002, Adopted 2006)

60.105 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% fructooligosaccharide on a dry weight basis. (Proposed 2003, Adopted 2005)

60.106 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% inulin on a dry matter basis. It may contain products of partially hydrolyzed inulin. (Proposed 2004, Adopted 2010)

***60.108 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. (*The asterisk indicates that this ingredient may be subject to 21 CFR 589.2000). (Proposed 2004, Amended 2006, Adopted 2011)

***60.109 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. (*The asterisk indicates that this ingredient may be subject to 21 CFR 589.2000.) (Proposed 2004, Amended 2006, Adopted 2011)

60.110 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. (Proposed 2009, Adopted 2011)

60.111 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% insoluble impurities. It is intended as a source of energy in livestock diets. It must contain not less than 80% glycerin, not more than 15% water, not more than 0.5% methanol, and not more than 5 ppm heavy metals. It may contain up to 8% 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% of the complete feed for ruminants and 10% of the complete feed for all other livestock species, including poultry. (Proposed 2015, Adopted 2016 rev. 1)

60.113 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% 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). (Proposed 2015, Adopted 2016 rev. 1)

Accepted pulse crops:

Lentil (*Lens culinaris*)

IFN 05-17-726 Pea (*Pisum sativum* L.)

60.114 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% crude protein and not more than 3% 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). (Proposed 2015, Adopted 2016 rev. 1)

Accepted pulse crops:
Lentil (*Lens culinaris*)
IFN 05-17-726 Pea (*Pisum sativum* L.)

60.115 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% 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. (Proposed 2016 rev. 1, Adopted 2018)

Accepted pulse crops:
Lentil (*Lens culinaris*)
IFN 05-17-726 Pea (*Pisum sativum* L.)

60.116 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% 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. (Proposed 2016 rev. 1, Adopted 2018)

Accepted pulse crops:
Lentil (*Lens culinaris*)
IFN 05-17-726 Pea (*Pisum sativum* L.)

60.117 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% moisture. It is for use in salmonid, poultry, and swine feed as a source of protein and fat consistent with good feeding practices. (Proposed 2021, Adopted 2022)

60.118 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. (Proposed 2020, Adopted 2021 rev. 1)

Tentative

T60.117(C) 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% moisture. It is for use in salmonid, poultry, and swine feed and in adult dog food, as a source of protein and fat consistent with good feeding practices." (Proposed 2022)

63. Molasses and Molasses Products

Investigator and Section Editor—Mark LeBlanc, LA

Official

63.1 Beet Molasses is a by-product of the manufacture of sucrose from sugar beets. It must contain not less than 48% total sugars expressed as invert. (Adopted 1941, Amended 1960, 2008)

IFN 4-30-289 Beet sugar molasses

63.3 Citrus Molasses is the partially dehydrated juices obtained from the manufacture of dried citrus pulp. It must contain not less than 45% total sugars expressed as invert. (Adopted 1952, Amended 1960, 2008)

IFN 5-01-241 Citrus syrup

63.5 Hemicellulose Extract 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%. (Proposed 1965, Adopted 1966) Reg. 573.520

IFN 4-08-030 Hemicellulose extract

63.6 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% reducing sugars expressed as dextrose and not less than 50% total sugars expressed as dextrose. It shall contain not less than 73% total solids. (Proposed 1967, Adopted 1968)

IFN 4-08-037 Maize-sorghum grain starch molasses

63.7 Cane Molasses is a by-product of the manufacture of sucrose from sugar cane. It must contain not less than 43% total sugars expressed as invert and not less than 73% total solids. (Proposed 1973, Adopted 1987, 2008)

IFN 4-13-251 Sugarcane molasses

63.26 Bagasse is that portion of the stalk of sugar cane, after removal of leaves and tops, remaining after extraction of the juice. (Proposed 1971, Adopted 1972)

IFN 1-04-686 Sugarcane bagasse dehydrated

63.36 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. (Proposed 1976, Adopted 1977)

IFN 4-00-669 Beet sugar pulp dehydrated

63.37 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. (Proposed 1976, Adopted 1977)

IFN 4-00-672 Beet sugar pulp with molasses dehydrated

63.38 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. (Proposed 1976, Adopted 1977)

IFN 4-00-675 Beet sugar pulp with steffens filtrate dehydrated

63.39 Beet molasses, dried product, is the properly dried mixture of molasses and molasses dried beet pulp containing not less than 45% total sugar expressed as invert. (Proposed 1976, Adopted 1977)

IFN 4-20-866 Beet sugar pulp with molasses dehydrated more than 45% invert sugar

63.41 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). (Proposed 1978, Adopted 1979)

IFN 5-00-679 Beet sugar steffens filtrate condensed

63.81 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. (Proposed 1991, Adopted 1993)

IFN 5-32-051 Beet, Sugar, separator by-product, condensed

63.83 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% and an ash content of not more than 3%. (Proposed 1991, Adopted 1993)

IFN 1-32-188 Beet, Sugar-Fiber, Dehydrated

66. Non-Protein Nitrogen

Investigator and Section Editor—George Ferguson, NC

Official

66.1 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% nitrogen (equivalent to 281.25% crude protein). If it contains less than 45% N but 41% 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% conditioner(s) to the mixed feed, the conditioner(s) must be named in the mixed ingredient list. (Proposed 1958, Amended 1962, 1963, 1964, Adopted 1968)

IFN 5-05-070 Urea 45% nitrogen 281% protein equivalent

66.2 Feed Grade Biuret is predominantly composed of biuret (55% 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% nitrogen (equivalent to 218.7% crude protein) with not more than 15% nitrogen (equivalent to 93.75% crude protein) being from urea. It shall not contain more than 0.5% 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:
    (a) 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.

(b) 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. (Proposed 1972, Adopted 1974, Amended 1975, 2004) Reg. 573.220

IFN 5-09-824 Biuret

66.3 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°F), moisture (15 to 30%) 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% 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% 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.**" (Proposed 1972, Adopted 1975)

IFN 5-14-506 Starch-urea product gelatinized

66.4 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°F), moisture (50 to 70%) 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% 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% 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.**" (Proposed 1978, Adopted 1980)

IFN 5-30-264 Starch-urea product liquid

66.5 Fermented Ammoniated Condensed Whey is the product produced by the *Lactobacillus bulgaricus* fermentation of whey with the addition of ammonia. It must contain 35% to 55% crude protein and not more than 42% 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:

(a) Store in closed vented tank equipped for agitation. Agitate five (5) minutes before using. Do not store at temperatures above 110°F (43°C).

(b) 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% of free choice liquid feed.

(c) 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% 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.**" (Proposed 1979, Amended 1980, Adopted 1981, Amended 1983) Reg. 573.450

IFN 5-28-223 Cattle whey fermented ammoniated condensed

Notes

Ammoniated Cottonseed Meal. See Definition 87.9 in Special Purpose Products Section; Ammoniated Cottonseed Meal as source of Non-Protein Nitrogen.

Ammoniated Rice Hulls. See Definition 87.7 in Special Purpose Products Section; Ammoniated Rice Hulls as a source of Non-Protein Nitrogen.

Ammonium Chloride. See Definition 57.265 in Mineral Products Section; Ammonium Chloride as a source of Non-Protein Nitrogen.

Ammonium Polyphosphate Solution. See Definition 57.22 in Mineral Products Section; Ammonium Polyphosphate Solution as source of Non-Protein Nitrogen.

Ammonium Sulfate. See Definition 57.27 in Mineral Products Section; Ammonium Sulfate as source of Non-Protein Nitrogen.

Anhydrous Ammonia. See Definition 87.11 in Special Purpose Products Section; Anhydrous ammonia as source of Non-Protein Nitrogen.

Condensed, Extracted Glutamic Acid Fermentation Product. See Definition 36.1 in Fermentation Products Section; Condensed, Extracted Glutamic Acid Fermentation Product as a source of Non-Protein Nitrogen.

Condensed____ Fermentation Solubles. See Definition 36.10 in Fermentation Products Section; Condensed ____ Fermentation Solubles as a source of Non-Protein Nitrogen.

Diammonium Phosphate. See Definition 57.16 in Mineral Products Section; Diammonium Phosphate as source of Non-Protein Nitrogen.

Dried Fermentation Biomass. See Definition 36.15 in Fermentation Products Section; Dried Fermentation Biomass as source of Non-Protein Nitrogen.

Monoammonium Phosphate. See Definition 57.33, in Mineral Products Section Mono-Ammonium Phosphate as source of Non-Protein Nitrogen.

69. Oat Products

Investigator and Section Editor—Dan King, MN

Official

69.1 Oat Groats are cleaned oats with the hulls removed. (Adopted 1931, Amended 1963)

IFN 4-03-331 Oats groats

69.2 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. (Adopted prior to 1928, Amended 1963)

IFN 1-03-281 Oats hulls

69.3 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 4% crude fiber. (Adopted 1938)

IFN 4-03-303 Oats cereal by-product less than 4% fiber

69.4 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. (Adopted prior to 1928)

IFN 1-03-269 Oats grain clipped by-product

69.6 Mixed Feed Oats consists of a mixture of grain containing at least 30% of cultivated oats provided that the mixture consists of either (a) not less than 65% of cultivated and wild oats combined or (b) not less than 65% of wild oats. It must contain more than 25% of other grains, not more than 6% heat damaged kernels of oats, wild oats, and other grains, and not more than 10% foreign material which may include 4% fine seeds. (Adopted 1958, Amended 1964)

IFN 4-08-026 Oats wild--oats grain

NOTE: Foreign material must be all matter except wild oats and grains for which standards have been established under the United States Grain Standards Act.

69.7 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% crude fiber. (Proposed 1963, Adopted 1964)

IFN 1-03-332 Oats groats by-product less than 22% fiber

69.8 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 and pet food. (Proposed 2019, Adopted 2020 rev. 1)

71. Other Oilseed Products

Investigator and Section Editor—Falina Hutchinson, MT

Official

71.35 *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 2.0% 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% of the total diet. The maximum sulfur content must be guaranteed. (Proposed 2017 rev. 1, Adopted 2019 rev. 1)

71.300 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% crude protein, and a maximum of 12% crude fiber. It may contain up to 15% 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% of the diet. (Proposed 2010, Amended 2011, Adopted 2013)

71.77 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 2% 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 5 micromoles of allyl glucosinolates per gram of air dry, oil free solid. It must contain a maximum of 12% 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 practice. (Proposed 1987, Adopted 1991, Amended 1995, Adopted 1998, Amended 2011, Adopted 2013, Amended 2021)

IFN 5-05-145 Canola Meal Prepress Solvent Extracted, Low Erucic Acid, Low Glucosinolate

IFN 5-05-146 Canola Meal Solvent Extracted, Low Erucic Acid, Low Glucosinolate

71.60 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." (Adopted 1955, Amended 1963, 1968)

IFN 5-01-572 Coconut kernels with coats meal mechanical extracted

71.61 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." (Adopted 1955, Amended 1963, 1968)

IFN 5-01-573 Coconut kernels with coats meal solvent extracted

71.62 Crambe Meal, Heat Toasted, 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, Section 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% of the total ration. (Proposed 1982, Adopted 1983) Reg. 21CFR 573.310

IFN 5-16-280 Crambe abyssinian seeds meal solvent extracted toasted

71.1 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% fiber. (Adopted 1943, Amended 1947, 1949, 1960, 1961, 1964, 1968)

IFN 5-30-287 Flax seeds meal mechanical extracted

71.11 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% fiber. (Adopted 1943, Amended 1947, 1949, 1960, 1961, 1964, 1968)

IFN 5-30-288 Flax seeds meal solvent extracted

71.40 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 2% 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 5 micromoles of allyl glucosinolates per gram of air dry, oil free solid. It must contain a maximum of 2% erucic acid, a maximum of 12% 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 practice. (Proposed 2019, Adopted 2020, Amended 2021)

71.30 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% 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. (Proposed 2015 rev. 1, Adopted 2017 rev. 1)

IFN 5-12-149 Mustard seeds meal solvent extracted

71.2 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. (Adopted 1943, Amended 1962, 1964, 1968)

IFN 5-12-228 Flax seed screenings meal solvent extracted

71.3 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 9% crude protein and a maximum of 35% crude fiber. (Adopted 1957)

IFN 1-12-230 Flax fiber process residue dehydrated

71.4 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 2% crude protein and not more than 70% crude fiber. (Proposed 1964, Adopted 1968)

IFN 1-12-229 Flax straw fiber process residue ground

71.21 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. (Adopted 1946, Amended 1964)

IFN 1-03-631 Peanut seed coats

71.6 Peanut Hulls consists of the outer hull of the peanut shell. (Proposed 1965, Adopted 1966)

IFN 1-08-028 Peanut pods (hulls)

71.7 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. (Adopted 1978)

IFN 5-03-655 Peanut pods with seeds meal mechanical extracted

IFN 5-03-656 Peanut pods with seeds meal solvent extracted

71.8 Ground Peanut Hay is composed of ground peanut leaves and stems from which the peanuts have been removed. (Proposed 1976)

IFN 1-03-627 Peanut hay sun-cured ground

71.9 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 7% crude fiber. (Adopted 1978)

IFN 5-03-649 Peanut seeds without coats meal mechanical extracted

IFN 5-03-650 Peanut seeds without coats meal solvent extracted

71.130 Safflower Meal, Mechanical Extracted,** is the ground residue obtained after extracting the oil from whole safflower seed by a mechanical extraction process. (Adopted 1954, Amended 1964, 1968)

IFN 5-04-109 Safflower seeds meal mechanical extracted

71.131 Safflower Meal, Solvent Extracted,** is the ground residue obtained after extracting the oil from whole safflower seed by a solvent extraction process. (Adopted 1954, Amended 1964, 1968)

IFN 5-04-110 Safflower seeds meal solvent extracted

71.23 Sunflower Hulls consists of the outer covering of sunflower seed. (Proposed 1967, Adopted 1968)

IFN 1-04-720 Sunflower hulls

71.210 Sunflower Meal, Dehulled, Mechanical Extracted,** is obtained by grinding the residue remaining after the extraction process. (Proposed 1967, Adopted 1969)

IFN 5-30-033 Sunflower seeds without hulls meal mechanical extracted

71.211 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. (Proposed 1967, Adopted 1969)

IFN 5-30-034 Sunflower seeds without hulls meal solvent extracted

71.220 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. (Proposed 1967, Adopted 1969)

IFN 5-27-477 Sunflower seeds meal mechanical extracted

71.221 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. (Proposed 1967, Adopted 1969)

IFN 5-30-032 Sunflower seeds meal solvent extracted

Section Note: ** after an ingredient name means the words "Mechanical Extracted" or "Solvent Extracted" are not required when listed as an ingredient in a manufactured feed.

73. Technical Additives

Section Editor—Richard Ten Eyck, OR

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.

Official

73.001 Technical Additives Table

Name	FDA Regulation[a]	Classification Under Food Additives Amendment	Limitations or Restrictions
Aluminum sulfate IFN 8-20-861	21 CFR 582.1125	Anti-gelling agent for molasses, dewater of beetpulp	In accordance with good manufacturing practices

(continued)

Name	FDA Regulation[a]	Classification Under Food Additives Amendment	Limitations or Restrictions
Attapulgite clay IFN 8-14-008		Anti-caking agent and pelleting aid Suspension aid in liquid feed supplement	Not to exceed 2.0%[c] Not to exceed 2.5% in supplement[c]
Calcium silicate IFN 8-08-043	21 CFR 573.260	Anti-caking agent	Not to exceed 2%
Calcium aluminates		Pellet binder	Maximum of 2% in poultry, swine, and rodent feeds, and a maximum of 1% in feed for all other species
Calcium stearate IFN 8-09-345	21 CFR 573.280 (feed grade)	Anti-caking agent	In accordance with good manufacturing practices
Carrageenan	21 CFR 172.620	Emulsifier, stabilizer, or thickener for pet foods	To be refined only from those red seaweed sources listed in 21 CFR 172.620
Chondrus extract IFN 8-07-247	21 CFR 582.7255	Stabilizer	In accordance with good manufacturing practices
Diacetyl tartaric acid esters of mono and diglycerides of edible fats or oils, or edible fat-forming fatty acids IFN 8-07-248	21 CFR 582.4101	Emulsifying agent	In accordance with good manufacturing practices
Diatomaceous earth IFN 8-09-363	21 CFR 573.340	Inert carrier and anti-caking agent	Not to exceed 2% of total ration
Disodium EDTA IFN 8-05-689	21 CFR 573.360	To solubilize trace minerals in aqueous solutions	Not to exceed 0.024% (240 ppm) in finished feed
Ethyl cellulose IFN 4/-08-045	21 CFR 573.420	Binder or filler in dry vitamin preparations	
Ethoxylated mono and diglycerides	21 CFR 172.834	Emulsifier	Not to exceed 0.5% in dry milk replacers
Fumaric acid		pH adjuster, preservative, or flavoring agent	Not to exceed 0.5% of the diet

(continued)

Name	FDA Regulation[a]	Classification Under Food Additives Amendment	Limitations or Restrictions
Gellan gum	21 CFR 172.665	Stabilizer and/or thickener in canned dog or cat food	Not to exceed 0.4% in canned dog or cat food
Glucono-delta-lactone	21 CFR 184.1318	pH control agent in pet or specialty pet food only	In accordance with good manufacturing practices
Guar gum (mucilage) IFN 8-08-099	21 CFR 582.7339	Stabilizer	In accordance with good manufacturing practices
Hydrophobic silica	21CFR 584.700	Anti-caking free flow agent	Not to exceed 5% in vitamin preparations
Iron ammonium citrate IFN 6-01-857	21 CFR 573.560	Anti-caking agent in salt	Not to exceed 0.0025% (25 ppm) in the finished salt
Kaolin IFN 8-08-040		Anti-caking agent (in non-medicated feeds)	Not to exceed 2.5% in finished feed[c]
Lecithin IFN 8-08-041	21 CFR 582.1400	Stabilizer	In accordance with good manufacturing practices
Locust bean gum (Carob bean gum) IFN 8-07-250	21 CFR 582.7343	Stabilizer	In accordance with good manufacturing practices
Magnesium stearate		Die lubricating and release agent in the tableting process	In accordance with good manufacturing practices
Methyl glucoside Coconut oil ester IFN 8-09-346	21 CFR 573.660	Surfactant in molasses	Not to exceed 0.032% (320 ppm) in the molasses
Mineral oil IFN 8-03-123	21 CFR 573.680	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	Not to exceed 3% in mineral supplements. Not to exceed 0.06% of the total ration. To serve as a diluent carrier in the manufacture of feed grade biuret.

(continued)

Name	FDA Regulation[a]	Classification Under Food Additives Amendment	Limitations or Restrictions
Mono and diglycerides of edible fats or oils, or edible fat-forming acids IFN 8-07-251	21 CFR 582.4505	Emulsifying agent	In accordance with good manufacturing practices
Monosodium phosphate derivatives of mono and diglycerides of edible fats or oils, or edible fat-forming fatty acids IFN 8-07-252	21 CFR 582.4521	Emulsifying agent	In accordance with good manufacturing practices
Montmorillonite clays IFN 8-09-364		Anti-caking aid, pelleting aid, and non-nutritive carrier	Not to exceed 2% of the finished material[c]
Paraffin IFN 8-02-027		Dust control agent	Not to exceed 3% in mineral supplements. Not to exceed 0.06% of the total ration.
Petrolatum or a combination of mineral oil and petrolatum IFN 8-05-691	21 CFR 573.720	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	Not to exceed 3% in mineral supplements. Not to exceed 0.06% of the total ration.
Petroleum jelly IFN 8-08-029	21 CFR 573.720	Dust control agent in mineral mixes	Not to exceed 3% in mineral supplements. Not to exceed 0.06% of the total ration.
Polyethylene glycol (400) mono and dioleate IFN 8-09-348	21 CFR 573.800	Processing aid when present as a result of its additions to molasses	Not to exceed 0.025% (250 ppm) in the molasses
Polyoxyethylene glycol (400) mono and dioleates IFN 8-08-053	21 CFR 573.820	Emulsifier	Calf milk replacers

(continued)

Name	FDA Regulation[a]	Classification Under Food Additives Amendment	Limitations or Restrictions
Polysorbate 80 IFN 8-08-053 Polysorbate 80	21 CFR 573.860 FDA/CVM/ DAF letter of 5/21/08	Emulsifier Emulsifier	Calf milk replacers Vitamin and mineral premixes
Polysorbate 60 (Polyoxy ethylene (20) sorbitan monostearate) IFN 8-08-032	21 CFR 573.840	Emulsifier	Calf milk replacers and mineral premixes
Polyvinyl alcohol		Processing aid for dry granular feed enzymes	Not to exceed 200 mg/kg in finished feed
Propylene glycol IFN 8-03-809	21 CFR 582.1666	Emulsifying agent	GRAS[b] except in cat food
Stearic acid	21 CFR 172.860	Lubricant/binder in tablets and pellets	Not to exceed 3% (wt/wt) in finished feed
Sodium carboxymethyl-cellulose IFN 8-08-100	21 CFR 582.1745	Stabilizer	Not to exceed 2% in finished feed
Sodium hexametaphosphate	21 CFR 582.6760	Sequestrant	In accordance with good manufacturing or feeding practices as a tartar control agent coated on dry food products for reducing the accumulation of dental tartar in dogs and cats
Sodium silico aluminate IFN 8-08-101	21 CFR 582.2727	Anti-caking agent	Not to exceed 2% in finished feed **Remove this item in the 2023 OP, replaced with 73.052 Sodium Aluminosilicate.**
Sodium stearoyl lactylate	21 CFR 172.846	Emulsifier for dry, semi-moist, and canned dog food	Not to exceed 0.35% in finished dog food

(continued)

Name	FDA Regulation[a]	Classification Under Food Additives Amendment	Limitations or Restrictions
Sorbitan monostearate with or without polysorbate 60 IFN 8-05-695	21 CFR 573.960	Emulsifier in mineral premixes and dietary supplement for animal feed	In accordance with good manufacturing practices
Talc IFN 8-16-378	FDA/CVM/DAF letters of 8/5/83 and 4/6/86	Die lubricant, finishing agent, and anti-caking agent	Not to exceed 2% in the finished feed. Not to exceed 10% as a carrier in animal feed premixes.
Tara gum		Thickener, stabilizer in dry powdered and reconstituted liquid calf milk replacers	Up to 0.25% in dry powdered calf milk replacer, or 0.04% in reconstituted liquid calf milk replacer
Tetra sodium pyrophosphate IFN 8-20-862	21 CFR 582.6789	Dispersant	In accordance with good manufacturing practices
Urea formaldehyde IFN 8-08-995		Coating for feed grade urea for ruminant animal feed	Not to exceed 1% of the finished product
Yellow prussiate of soda IFN 8-05-697	21 CFR 573.1020	Anti-caking agent in salt	Not to exceed 0.0013% (13 ppm)

[a]Ingredients listed in 21 CFR part 582 are subject to the GMPs located at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=582.1.
[b]GRAS = abbreviation for the phrase "generally recognized as safe." A substance that is generally recognized as safe by experts qualified to evaluate the safety of the substance (for its intended use.)
[c]NOTE: Attapulgite Clay, Bentonite, Kaolin, and Montmorillonite Clays are "GRAS" in non-medicated feeds as binders or pelleting aids when used in accordance with good manufacturing practices and do not exceed the limitations listed above. These special purpose products are not prohibited in medicated feeds for the same purpose and at the same level when it can be demonstrated that they do not interfere with the analysis of the drug 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 these products in a feed containing a drug. Based on current information, these products are acceptable for use in medicated feeds containing the following drugs:

Chlortetracycline	4 Nitrophenyl-Arsonic Acid
IFN 8-01-224	IFN 8-05-561
Lasalocid Sodium	Ractopamine
IFN 6-26-333	
Lincomycin Hydrochloride	Sulfathiazole
IFN 8-12-192	IFN 8-04-704
Melengestrol Acetate	Sulfaquinoxaline

IFN 8-08-197	IFN 8-04-703
Monensin	Tylosin
IFN 8-09-373	IFN 8-05-069

Based on current information found in the new animal drug regulations (part 558) the following drugs are not permitted in animal feeds containing bentonite because bentonite has been shown to interfere with the analysis of the drugs by the acceptable methods:

Amprolium	558.55	
IFN 8-00-373		
Carbadox	558.115	NOTE:
IFN 8-20-775		International feed
Decoquinate	558.195	name and AAFCO
IFN 8-09-371		names are identical
Morantel tartrate	558.360	for these 25 drugs.
IFN 8-16-451		
Pyrantel Tartrate	558.485	
IFN 8-14-011		
Robenidine hydrochloride	558.515	
IFN 8-14-012		
Thiabendazole	558.615	
IFN 8-04-827		
Tilmicosin	558.618	

Acidifiers (73.020–029)

73.020 Ammonium Formate—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% ammonia gas and 99% formic acid in a continuous loop reactor to produce a solution made up of 37% ammonium salt of formic acid and 62% 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% 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% 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 Federal Food, Drug, and Cosmetic Act (the act), the label and labeling shall contain:
  (1) The name of the additive.
  (2) 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.
  (3) Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2% 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 Federal Food, Drug, and Cosmetic Act and paragraph (d) of this section, the label and labeling shall contain:
  (1) Appropriate warnings and safety precautions concerning ammonium formate (37% ammonium salt of formic acid and 62% formic acid).

(2) Statements identifying ammonium formate in formic acid (37% ammonium salt of formic acid and 62% formic acid) as a corrosive and possible severe irritant.
(3) Information about emergency aid in case of accidental exposure as follows:
(i) 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.
(ii) Contact address and telephone number for reporting adverse reactions or to request a copy of the Safety Data Sheet (SDS).

(Proposed 2011, Adopted 2013, Amended 2017, Amended 2019) 21 CFR 573.170

73.021 Benzoic Acid—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% of the complete feed.
(b) The additive consists of not less than 99.5% 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% by weight.
(c) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act and paragraph (b) of this section, the label and labeling shall contain:
(1) The name of the additive;
(2) 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;
(3) Appropriate warnings and safety precautions concerning benzoic acid;
(4) A warning statement identifying benzoic acid as a possible irritant;
(5) Information about emergency aid in case of accidental exposure; and
(6) Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS).

(Proposed 2015, Adopted 2016 rev. 1)
21 CFR 573.210

73.025 Formic Acid 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% of the silage on a dry weight basis or 0.45% when direct cut, as follows:
(1) The top foot of silage stored should not contain formic acid and
(2) Silage should not be fed to livestock within 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% of the complete feed.
(1) The additive consists of not less than 85% formic acid (CAS 64-18-6).
(2) The additive meets the following specifications:
(i) Free methyl alcohol not to exceed 1,000 parts per million (ppm);
(ii) Methyl formate not to exceed 1,000 ppm; and
(iii) Moisture not to exceed 15%.

(3) To assure safe use of the additive, formic acid and formate salts from all added sources cannot exceed 1.2% of complete feed when multiple sources of formic acid and its salts are used in combination.

(4) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug and Cosmetic Act, the label and labeling shall contain:
   (i) The name of the additive.
   (ii) 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.
   (iii) Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2% of complete feed when multiple sources of formic acid and its salts are used in combination.

(5) To ensure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act and paragraph (b) (4) of this section, the label and labeling shall contain:
   (i) Appropriate warnings and safety precautions concerning formic acid (85% formic acid).
   (ii) Statements identifying formic acid (85% formic acid) as a corrosive and possible severe irritant.
   (iii) Information about emergency aid in case of accidental exposure.
      (A) 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.
      (B) Contact address and telephone number for reporting adverse reactions or to request a copy of the Safety Data Sheet (SDS). 21 CFR 573.480 (Proposed 2011, Adopted 2012, 2013, Amended 2015 rev. 1, 2017, Amended 2019)

73.026 Feed Grade Sodium Formate—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% formic acid and 50% sodium hydroxide in water to produce a solution made up of at least 20.5% sodium salt of formic acid and not more than 61% 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% 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% 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 Federal Food, Drug, and Cosmetic Act, the label and labeling shall contain:
   (1) The name of the additive.
   (2) 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.

(3) Cautions for use including this statement: Caution: Follow label directions. Formic acid and formate salts from all added sources cannot exceed 1.2% 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 act and paragraph (d) of this section, the label and labeling shall contain:

(1) Appropriate warnings and safety precautions concerning feed grade sodium formate.

(2) Statements identifying feed grade sodium formate as a corrosive and possible severe irritant.

(3) Information about emergency aid in case of accidental exposure as follows:

(i) 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. 8

(ii) Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS).

21 CFR § 573.696 (Adopted 2017 rev. 1)

Antimicrobial Agents (73.030–039)

73.030 Formaldehyde—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:

(1) For animal fat in combination with certain oilseed meals, as a component of dry, nonpelleted feeds for beef and non-lactating dairy cattle.

(i) 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. The feed ingredients are those defined by the "Official Publication" of the Association of American Feed Control Officials, Inc., 2003 small ed., small pp. 303, 308, and 309, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the Assistant Secretary-Treasurer, Association of American Feed Control Officials Inc., PO Box 478, Oxford, IN 47971, or you may examine a copy at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(ii) Formaldehyde (37% solution) is added to the mixture at a level of 4% of the dry matter weight of the oilseed meals and animal fat. This mixture, upon drying, contains not more than 1% formaldehyde and not more than 12% moisture.

(iii) To assure the safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act (the Act), the label and labeling of the dried mixture shall bear:

(A) The name of the additive.
(B) Adequate directions for use providing that the feed as consumed does not contain more than 25% of the mixture.

(2) 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.

(i) 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% and the fat content will be 20 to 45%. The feed ingredients are those defined by the "Official Publication" of the Association of American Feed Control Officials, Inc., 2003 ed., pp. 301, 307, 308, and 309, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the Assistant Secretary-Treasurer, Association of American Feed Control Officials Inc., PO Box 478, Oxford, IN 47971, or you may examine a copy at the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

(ii) Formaldehyde (37% solution) is added to the mixture at a level of 2.7% 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% formaldehyde and not more than 12% moisture.

(iii) To assure the safe use of the additive, in addition to the other information required by the Act, the label and labeling of the dried mixture shall bear:

(A) The name of the additive.
(B) The statement, "This supplement is not to exceed 12.5% of the total ration. Dietary calcium and magnesium levels should be considered when supplementing the diet with fat."
(C) The minimum and maximum levels of crude fat must be guaranteed and must be between −5% and +5% of the analyzed fat content for each batch.

(b)

(1) The food additive is formaldehyde (CAS No. 50-00-0; 37% 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.

(2) To assure safe use of the additive, in addition to the other information required by the Act, the label and labeling shall contain:

(i) The name of the additive.
(ii) A statement that formaldehyde solution which has been stored below 40 deg. F or allowed to freeze should not be applied to complete animal feeds or feed ingredients.
(iii) 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."

(iv) The labeling for feed or feed ingredients to which formaldehyde has been added under the provisions of paragraph (b)(1) of this section is required to carry the following statement: "Treated with formaldehyde to maintain feed *Salmonella* negative. Use within 21 days."

(3) To assure safe use of the additive, in addition to the other information required by the Act, the label and labeling shall contain:

(i) Appropriate warnings and safety precautions concerning formaldehyde.

(ii) Statements identifying formaldehyde as a poison with potentials for adverse respiratory effects.

(iii) Information about emergency aid in case of accidental inhalation.

(iv) 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.

(v) Contact address and phone number for reporting adverse reactions or to request a copy of the Materials Safety Data Sheet (MSDS). [68 FR 65633, Nov. 21, 2003]

(Proposed 1977, Adopted 1978, Amended 1996, 2005, Adopted 2008, Amended 2011)

IFN 8-26-243 Formaldehyde solution

Anticaking Agents (73.040–060)

73.040 Bentonite 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 2% 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 73.001. (Proposed 1974, Adopted 1975) Reg. 582.1155

IFN 8-00-695 Bentonite

73.042 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% 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 ppm in complete feed. (Proposed 2011, Adopted 2012)

73.044 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 4% by weight of the product in which it is present as a processing aid. (Proposed 1977, Amended 1978, Adopted 1979)

IFN 8-26-242 Perlite

73.045 Pyrophyllite (aluminum silicate monohydrate) 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 2% in complete animal feed. (Adopted 2018 rev. 1)

21 CFR 573.900

73.046 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 2% 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 Federal Food, Drug, and Cosmetic Act, including 21 CFR 501.

To ensure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, 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 2% by weight of the complete feed.

(Adopted 2021 rev. 1)

73.048 Sodium Bentonite 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 1% and not more than 2% 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 2% in total ration. To reduce seepage in silage, the amount added would not exceed 1% 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 73.1. (Proposed 1974, Adopted 1975, Amended 1983) Reg. 582.1155

IFN 8-14-512 Sodium bentonite

73.050 Verxite (exfoliated hydrobiotite), an additive, is a magnesium-aluminum-iron silicate conforming to one of the following:

Verxite Granules contain a minimum of 98% Hydrobiotite, is thermally expanded and has a bulk density of 5 to 9 pounds per cubic foot.

IFN 8-08-993 Verxite granules

It is used or intended for use in poultry feed at a level not to exceed 5% 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, dog, or ruminant feeds, in an amount not to exceed that necessary to accomplish its intended effect and in no case to exceed 1.5% of the dog feed or 5% of the final feed for other animals.

Verxite Flakes contain a minimum of 98% Hydrobiotite and has a bulk density of 20 to 30 pounds per cubic foot.

IFN 8-08-994 Verxite flakes

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 1% by weight of the final feed for ruminants.

Verxite Grits contains a minimum of 80% Hydrobiotite. It has a bulk density of from 40 to 50 pounds per cubic foot.

IFN 8-09-350 Verxite grits

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 1% 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 act, the name of the additive (verxite granules or verxite flakes or verxite grits) and when the additive is present in excess of 1%, a statement of the quantity of the additive contained therein and the term "non-nutritive" in juxtaposition therewith. (Reg. 573.1000) (Proposed 1961, Adopted 1964, Amended 1968 and 1969)

73.051 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 8% iron(III) on a dry weight basis. It must contain no more than 1.5% oxalic acid, 3 ppm arsenic, 2 ppm lead, and 1 ppm mercury on a dry weight basis. The maximum iron tartrates inclusion rate (calculated as iron) is not more than 12 ppm. (Proposed 2018 rev. 1, Adopted 2019 rev. 1)

73.052 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% silicon dioxide; 9.0 to 13.0% aluminum oxide; and 4.0 to 7.0% sodium oxide, on a dry basis. It is used as an anticaking agent not to exceed 2% in finished feed. (Proposed 2020, Adopted 2021 rev. 1)

Binders (73.106–130)

73.107 Lignin Sulfonate 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% by weight) or dry form (moisture not to exceed 6% by weight). It may be used in animal feed in amounts calculated on a dry weight basis, as: (1) A pelleting aid, in the liquid or dry form, in an amount not to exceed 4% of the finished pellets. (2) A binding aid, in the liquid form, in the flaking of feed grains in an amount not to exceed 4% of the flaked grain. (3) A surfactant in molasses used in feeds, as liquid lignin sulfonate, in an amount not to exceed 11% of the molasses. (4) A source of metabolizable energy, in the liquid or dry form, in an amount not to exceed 4% of the finished feed. Reg. 573.600. (Proposed 1963, Adopted 1964, Amended 1970, 1971, and 1973)

IFN 8-02-627 Lignin sulfonate dehydrated

IFN 8-29-786 Lignin sulfonate condensed

73.109 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 AAFCO definition 33.3 (Hydrolyzed Vegetable Fats, or Oils, Feed Grade) and

the AAFCO definition 33.2 (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 8% by weight. It may be used in animal feed in amounts calculated on an "as-is" basis not to exceed 5.5 lb./ton. Sodium Salts of Fatty Acids shall be labeled with guarantees on an "as-is" basis for no more than 0.5% free fatty acids, no more than 12% glycerin, not less than 67% total sodium salts of fatty acids, and no more than 1% unsaponifiable matter. (Proposed 2015 rev. 1, Adopted 2017 rev. 1)

73.111 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 AAFCO definition 33.3 (Hydrolyzed Vegetable Fats, or Oils, Feed Grade) and the AAFCO definition 33.2 (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% by weight. It may be used in animal feed in amounts calculated on an "as-is" basis not to exceed 15.5 lb./ton. Potassium Salts of Fatty Acids shall be labeled with guarantees on an "as-is" basis for no more than 0.5% free fatty acids, no more than 10% glycerin, not less than 24% total potassium salts of fatty acids, and no more than 1% unsaponifiable matter. (Proposed 2015 rev. 1, Adopted 2017 rev. 1)

Biofuel Production (73.090–104)

73.100 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.

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.

and/or

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. (Proposed 2013, 2014, rev. 1, Adopted 2015 rev. 1)

Emulsifiers (73.200–220)

73.200 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 in canned dog and cat foods.

Maximum inclusion levels are 0.1% in calf milk replacers (as fed) and 0.25% in liquid feed supplements and canned dog and cat foods. (Proposed 2013, Adopted 2015 rev. 1)

Floculants (73.221–240)

73.221 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% of the feed. Proteinaceous material coagulated with chitosan must have safety and efficacy data approved before it can be registered or offered for sale. (Proposed 1984, Adopted 1985)

IFN 8-17-730 Chitosan

73.223 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 8% moisture by weight. It is used; (1) as an aid in recovering proteinaceous material during the rendering process, limited to 0.1% of the crax, (2) in the clarification of spent grease, and (3) as a coating agent for fat soluble vitamins limited to 50% of the vitamin premix matrix and 3% of the finished feed. (Proposed 1993, Amended 1994, Adopted 2003)

Nutritional Diluents (73.241–249)

73.241 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% 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 5% of the total daily ration. (Proposed 1986, Adopted 2012)

IFN 1-18-898 Peat Whole Dehydrated

Pelleting Aids (73.300–340)

73.305 Hide Glue (Technical Gelatin) is a collagen-based product manufactured only from cattle hide pieces. Maximum moisture is 13.5%, maximum ash is 4% and minimum protein is 90%. The product is used as a processing aid, pelleting aid, or feed binder, not to exceed 2% of the feed by weight. (Either term, "hide glue" or "technical gelatin," may be used in the ingredient statement.) (Proposed 2003, Adopted 2010)

73.307 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 5% crude protein, 1.5% crude fat, and not more than 25% crude fiber. (Proposed 1965, Adopted 1966, Amended 1967)

IFN 1-08-033 Rice hull fines

73.309 Urea Formaldehyde Condensation Polymer is a pelleting aid for use in animal feeds, excluding aquatic species. Restrictions: Not to exceed 0.1 ppm free formaldehyde in the finished pelleted product. (Proposed 1989, Adopted 1990)

IFN 8-30-422 Urea Formaldehyde Condensation Polymer

73.310 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 4% moisture by weight. It must contain, and be guaranteed for, not less than 83% total lignin (including acid insoluble and acid soluble lignins) and not more than 3.5% 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 4% of the finished pellets. (Proposed 2013, Adopted 2015 rev. 1)

73.311 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 4 lb. per ton of complete feed. Specifications of animal fats or vegetable oils used to produce the hydrogenated glycerides must meet the requirements stated in AAFCO definition 33.1 (for Animal Fat) and AAFCO definition

33.2 (for Vegetable Fat, or Oil), respectively. The specification for tallow must specify insoluble impurities not more than 0.15% to be consistent with BSE feed regulation 21 CFR 589.2000 and 589.2001, and a guaranteed titer above 40°C. 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% total ester content, not more than 0.8 % unsaponifiable matter, not more than 0.001% heavy metals, and not more than 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." (Proposed 2019 rev. 1, Adopted 2020 rev. 1)

Surfactants (73.341–360)

73.341 Poloxalene 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 1% of the conditioner, and the conditioner is added to the feed grain at a rate of 1 quart per ton of feed grain. (Reg. 573.760) (Proposed 1970, Adopted 1971)

IFN 8-08-063 Poloxalene

Thickening Agents (73.370–390)

73.370 Cassia Gum is the purified flour from the endosperm of the seeds of *Cassia tora* or *Cassia obtusifolia*, which belong to the family Leguminosae. It is a galactomannan comprised of at least 75% polysaccharide consisting primarily of a linear chain of 1,4-B-D-mannopyranose units. The ratio of galactose to mannose is 1:5. Cassia gum is the product obtained by mechanical separation of the endosperm from the germ and husk in a heated process, with subsequent purification by sieving, pulverization, extraction, and drying. It contains not more than 10 ppm chrysophanic acid. Cassia gum is suitable for use as a stabilizer (thickening and gelling agent) in canned dog and cat food and shall be permitted at concentrations up to 4000 ppm. (Proposed 1999, Adopted 2002)

Tracers (73.400–425)

73.400 Iron Nickel Tracer the particles resulting from water atomization of high purity iron and nickel. The nickel content of the particles is between 35% and 51% 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 ppm in the finished food. The label shall include a maximum nickel guarantee and a caution statement indicating the maximum permitted inclusion level. (Proposed 2017 rev. 1, Adopted 2019 rev. 1)

73.401 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 ppm in the finished food. The label shall include a caution statement indicating the maximum permitted inclusion level. (Proposed 2019 rev. 1, Adopted 2020 rev. 1)

Sequestrants (73.426–449)

73.430 L-Lactic Acid is a sequestrant with a minimum content of 97% L-lactic acid on a dry matter basis for use in dry cat food products (less than 20% moisture). It is intended for use as a dental plaque and tartar control agent for adult maintenance cat food at levels not to exceed 1.2% on a dry matter basis. (Proposed 2021 rev. 1, Adopted 2022 rev. 1)

Antioxidants (73.450–500)

73.450 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 mg/kg in fats and oils. The level of cashew nut shell liquid in complete feed must not exceed 600 mg/kg. The liquid ingredient must contain, and be guaranteed for, not less than 10% cardol, not less than 55% cardanol, and not more than 1% moisture. (Proposed 2019, Adopted 2020 rev. 1)

Tentative

T73.309 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 ppm 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 1% of the treated soybean meal. (Proposed 2022)

74. Processed Animal Waste Products

Investigator and Section Editor—Dan King, MN

Any person seeking or receiving registration of any processed animal waste product shall test, by representative sampling and assaying of such samples, and keep accurate records thereof, the processed animal waste product for which the registration is sought or received. The sample shall be of sufficient size so as to provide meaningful data, statistically reliable in carrying out the purpose of such sampling and analysis.

The registrant, manufacturer, or producer of any such processed animal waste product ingredient shall conform to the following sample and assay requirements, in addition to quality standards, testing on the same production run of lots:

(a) Drugs suspected or known to be used in the feed or as a therapeutic treatment of source animals.
(b) Pesticides used on the source animal, facility, and wastes for pest control.
(c) Pathogenic organisms, at least to include *Salmonella* and *E. coli*.
(d) Heavy metals: arsenic, cadmium, copper, lead, mercury and selenium, at least.
(e) Parasitic larva or ova.
(f) Mycotoxins, such as aflatoxins.

Periodic analyses shall be conducted on production runs no less than one per calendar quarter, except that less frequent testing may be allowed where analytical results show continued uniformity and a consistent margin of compliance. Any processed animal waste product that does not meet the quality standards for the product shall be further processed until standards are met, or shall be diverted to non-feed uses or destroyed.

If a product contains drug residues, then the label shall contain the following statement in bold face type: "**WARNING: THIS PRODUCT CONTAINS DRUG RESIDUES. DO NOT USE WITHIN 15 DAYS OF SLAUGHTER AND DO NOT USE 15 DAYS PRIOR TO OR DURING THE FOOD PRODUCTION PERIOD OF DAIRY ANIMALS AND LAYING HENS.**"

If the product contains 25 ppm or greater of copper, a maximum guarantee of copper and the following statement in bold face type is required: "**WARNING: CONTAINS HIGH LEVELS OF COPPER: DO NOT FEED TO SHEEP.**"

Any person seeking or receiving registration of any processed animal waste product shall keep for a period of two years, accurate records of:

(a) All sources of raw materials and date acquired, including information on drug and pesticide usage.
(b) All production output, including a code or other method to identify the date of production.

(c) All sales and distribution, including the name and address of the purchaser or to whom distributed, date, quantity and product code.

(d) Sample and assay records of testing specified above.

Product definitions—Processed animal waste products as a class, offered for sale or distributed for sale, shall not contain extraneous materials such as, but not limited to, metal, glass, nails or other harmful matter. They shall be free of harmful pathogenic organisms, pesticide residues, parasites, or drug residues, above levels permitted by State or Federal statute or regulation, which could be harmful to animals or could result in residues in human food products or by-products of animals at levels in excess or those allowed by State or Federal statute or regulation.

74.1 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%. It shall contain not less than 18.0% crude protein, and not more than 15.0% crude fiber, 30.0% ash, and 1.0% feathers. (Adopted 1982)

IFN 4-07-255 Poultry manure non-protein nitrogen extracted dehydrated

74.2 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%. It shall contain not less than 11.0% crude protein, and not more than 15.0% crude fiber, 30.0% ash, and 1.0% feathers. (Adopted 1982)

IFN 4-07-255 Poultry manure non-protein nitrogen extracted dehydrated

74.3 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%. It shall contain not less than 18.0% crude protein, and not more than 25.0% crude fiber, 20.0% ash, and 4.0% feathers. (Adopted 1982)

IFN 5-05-587 Poultry manure and litter dehydrated

74.4 Dried Ruminant Waste (DRW) means a processed animal waste product composed primarily of processed ruminant excreta which has been artificially dehydrated to a moisture content not in excess of 15.0%. It shall contain not less than 12.0% crude protein, and not more than 40.0% crude fiber, including straw, woodshavings, etc., and not more than 30.0% ash. (Adopted 1982)

IFN 1-07-526 Animal manure dehydrated

74.5 Dried Swine Waste (DSW) means a processed animal waste product composed primarily of swine excreta which has been artificially dehydrated to a moisture content not in excess of 15.0%. It shall contain not less than 20.0% crude protein, not more than 35.0% crude fiber, including other material such as straw, woodshavings, or acceptable other bedding materials, and not more than 20.0% ash. (Adopted 1982)

IFN 5-02-790 Swine manure dehydrated

74.6 Undried Processed Animal Waste Products means a processed animal waste product composed of excreta, with or without litter, from poultry, ruminants or any other animal except humans, which may or may not include other feed ingredients, and which contains in excess of 15.0% feed ingredients, and which contains in excess of 15.0% moisture. It shall contain no more than 30% combined wood, woodshavings, litter, dirt, sand, rocks, and similar extraneous materials. The specific name of each component material in the product must be declared on the label. (Adopted 1982)

IFN 2-07-258 Animal-poultry manure and litter processed wet

74.7 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. (Adopted 1982)

IFN 1-07-307 Animal waste processed derivative

75. Rice Products

Investigator and Section Editor—Dan King, MN

Official

75.1 Rice Polishings is a by-product of rice obtained in the milling operation of brushing the grain to polish the kernel. (Adopted 1938)

IFN 4-03-943 Rice polishings

75.2 Ground Rough Rice or Ground Paddy is the entire product obtained in grinding the whole rice grain including the hulls. (Adopted prior to 1928, Amended 1959)

IFN 4-03-938 Rice grain ground

75.3 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% crude protein and not more than 14% crude fiber. (Adopted 1951, Amended 1959)

IFN 4-03-930 Rice bran with germ meal solvent extracted

75.4 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. (Proposed 1959, Adopted 1960)

IFN 4-03-932 Rice groats polished broken

75.5 Ground Brown Rice is the entire product obtained in grinding the rice kernels after the hulls have been removed. (Proposed 1959, Adopted 1960)

IFN 4-03-935 Rice groats ground

75.6 Rice Hulls consists primarily of the outer covering of the rice. (Proposed 1959, Adopted 1960)

IFN 1-08-075 Rice hulls

75.7 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% crude fiber. When the calcium carbonate exceeds 3% (Ca.-1.2%), the percentage must be declared in the brand name; i.e., Rice Bran with Calcium Carbonate not exceeding _____%. (Proposed 1963, Adopted 1964)

IFN 4-03-928 Rice bran with germs

75.8 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%. (Proposed 1961, Adopted 1965)

IFN 1-03-941 Rice mill run NOTE: See also 87.6 and 87.7

75.9 Parboiled Rice Bran is about 5 to 7% 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. (Proposed 1992, Adopted 1996)

75.10 _____ 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 4%. (AOAC 940.28)

Stabilization process must be specified (i.e., Heat Stabilized Rice Bran). (Proposed 2013, Adopted 2015 rev. 1)

78. Rye Products

Investigator and Section Editor—Dan King, MN

Official

78.1 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% crude fiber. (Adopted 1946)

IFN 4-04-034 Rye mill run less than 9.5% fiber

78.2 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% crude fiber. (Adopted 1946)

IFN 4-04-031 Rye flour by-product less than 8.5% fiber

81. Screenings

Investigator and Section Editor—Dan King, MN

Official

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.

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 must be those named as such by the seed control law of the state in which the screenings is sold or used.

EPA allows a "Non-Food/Non-Feed" status for some crops on a state-by-state basis. This allows the producer a wider range of pesticides to use in the production of a seed crop. This is especially important for minor seed crops. In some states alfalfa, clover, carrot and cabbage seed may be designated non-food/non-feed in their state pesticide laws. When so designated there are special labeling, record keeping, and by-product disposal requirements. Most cereal grains and large seeds like bean, pea, and corn have never been allowed a non-food/non-feed status due to their propensity to enter food channels. If you are using seed screenings in the manufacture of a feed, you should check with your state pesticide regulatory authority as to the non-food/non-feed status of that commodity.

All grades of screenings must bear minimum guarantees of crude protein and crude fat and maximum guarantees of crude fiber and ash. (Adopted 1953, Amended 1959, 1960)

81.1 Grain Screenings are those screenings containing 70% 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%) may be declared as the first word or words in the name. It may contain no more than 6.5% ash. (Proposed 1989, Adopted 1992)

IFN 4-00-542 Barley screenings

IFN 4-20-687 Maize screenings

IFN 4-03-329 Oats screenings

IFN 4-08-085 Rice screenings

IFN 4-27-721 Sorghum screenings

IFN 4-05-216 Wheat screenings

81.2 Mixed Screenings are screenings excluded from the preceding definition. It must contain not more than 27% crude fiber and not more than 15% ash. (Adopted 1953, Amended 1954, 1960)

IFN 4-02-157 Cereals mixed grain screenings

81.3 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% ash the words "sand" and "dirt" must appear on the label. (Adopted 1953)

IFN 4-02-149 Cereals--legumes chaff and/or dust

84. Soybean Products

Investigator and Section Editor—Falina Hutchinson, MT

Official

84.1 Ground Soybeans is obtained by grinding whole soybeans without cooking or removing any of the oil. (Adopted 1933)

IFN 5-04-596 Soybean seeds ground

84.2 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% crude fiber. (Adopted 1944, Amended 1964)

IFN 1-04-559 Soybean hay sun-cured ground

84.3 Soybean Hulls consist primarily of the outer covering of the soybean. (Adopted 1948)

IFN 1-04-560 Soybean seed coats (hulls)

***84.4 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.(Adopted 1948, Amended 1960, 1964)

IFN 5-04-613 Soybean seeds low protein low carbohydrates meal solvent extracted

84.5 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 4.0% crude fiber. (Proposed 1978, Adopted 1980)

IFN 5-12-176 Soybean grits mechanical extracted

IFN 5-04-592 Soybean grits solvent extracted

84.7 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% crude fiber. It may contain calcium carbonate or an anti-caking agent not to exceed 0.5% as defined in section 87 (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.(Proposed 1989, Adopted 1992)

IFN 5-04-612 Soybean seeds without hulls meal solvent extracted

84.8 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% crude protein and not more than 32% crude fiber. (Proposed 1960, Adopted 1961, Amended 1964)

IFN 4-04-594 Soybean flour by-product

84.9 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% crude protein and not more than 35% crude fiber. (Proposed 1960, Adopted 1961, Amended 1964)

IFN 4-04-595 Soybean mill run

84.10 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. (Proposed 1958, Adopted 1961)

IFN 4-04-562 Soybean lecithin

84.11 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. (Proposed 1960, Adopted 1964, Amended 1991, Adopted 1992)

IFN 5-04-597 Soybean seeds heat processed

84.12 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% protein on a moisture-free basis. (Proposed 1988, Adopted 1990)

IFN 5-32-183 Soybean protein concentrate

84.13 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 7% crude fiber. (Proposed 1969, Adopted 1971)

IFN 5-09-343 Soybean seeds kibbled solvent extracted

84.14 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%. (Proposed 1983, Adopted 1990)

IFN 5-09-344 Soybean solubles condensed

84.15 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. (Proposed 1974, Adopted 1975)

IFN 5-14-005 Soybean seeds extruded ground

IFN 5-26-010 Soybean protein product chemically modified

84.16 _____ 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 under Section 84 of the applicable soybean product so modified shall be declared in the product name. (Proposed 1982, Adopted 1983, Amended 2000, Adopted 2009)

84.17 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. (Proposed 1983, Adopted 1990)

IFN 5-16-733 Soybean Solubles dehydrated

84.51 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 4.0% crude fiber. (Proposed 1978, Adopted 1980)

IFN 5-12-177 Soybean flour mechanical extracted

IFN 5-04-593 Soybean flour solvent extracted

84.60 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 7.0% crude fiber. It may contain calcium carbonate or an anti-caking agent not to exceed 0.5% as defined in section 87 (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. (Proposed 1989, Adopted 1992)

IFN 5-04-600 Soybean seeds meal mechanical extracted

84.61 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 7.0% crude fiber. It may contain calcium carbonate or an anti-caking agent not to exceed 0.5% as defined in section 87 (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. (Proposed 1989, Adopted 1992)

IFN 5-04-604 Soybean seeds meal solvent extracted

84.62 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% protein on a moisture-free basis. (Proposed 1988, Adopted 1990)

IFN 5-24-811 Soy Protein Isolate

84.63 Hydrolyzed Soy Protein is made from soybean flours, concentrates or isolates, treated with an acid or a base or an enzyme and then dried. (Proposed 1993, Adopted 1994)

84.64 Textured Soy Protein Product is made from defatted soy flour mixed with water and/or steam, extruded and then dried. (Proposed 1993, Adopted 1994)

84.71 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% crude fiber and not less than 46.5% crude protein. It may contain calcium carbonate or an anti-caking agent not to exceed 0.5% as defined in section 87 (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. (Proposed 2004, Adopted 2009)

87. Special Purpose Products

Section Editor—Richard Ten Eyck, OR

Color, flavor, sweetener, tissue pigmentor (color additive), miscellaneous and/or general purpose, manure odor control, crude fiber source, non-protein nitrogen source, roughage replacement.

It is impracticable to list all common special purpose feed ingredients, together with the status, classification, tolerance, and limitations or restrictions, in the Official Publication.

The Association of American Feed Control Officials regard such common special purpose feed ingredients as salt, sugar, and pepper as safe for their intended use, when used in accordance with good manufacturing practice.

The less common special purpose feed ingredients, together with the status, classification, tolerance, and limitations or restrictions, are listed in the Official Publication.

The least common special purpose feed ingredients, together with the status, classification, tolerance, and limitations or restrictions, are also listed in the Code of Federal Regulations; Title 21, Food and Drugs; Chapter 1—Food and Drug Administration, Department of Health and Human Services; Sub-Chapter A—General; Part 73—Color Additives, or Part 74—Color Certification, or Sub-Chapter E—Animal Drugs, Feeds, and Related Products; Part 573—Food Additives Permitted in Feed and Drinking Water of Animals or Part 582—Substances Generally Recognized as Safe or Part 584—Food Substances Affirmed as Generally Recognized as Safe in Feed and Drinking Water of Animals.

A number of ingredients have been approved by the FDA Informal Review Process (I.R.P.) (see AAFCO Official Publication: A guide to submitting New Ingredient Definitions to AAFCO).

Official

87.1 Dried Algae Meal—The color additive, dried algae meal, may be safely used in the manufacture of chicken feed in accordance with the following prescribed conditions:

(a) 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% ethoxyquin. The algae cells are produced by suitable fermentation, under controlled conditions, from a pure culture of the genus *Spongiococcum*.

(b) Uses and restrictions.
The color additive dried algae meal may be safely used in chicken feed in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the yellow color of chicken skin and eggs.

(2) The quantity of the color additive incorporated in the feed is such that the finished feed:

(i) is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (b)(1) of this definition; and

(ii) meets the tolerance limitation for ethoxyquin in animal feed prescribed in part 573.380 of Title 21 of the Code of Federal Regulations (21 CFR 573.380).

(c) 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
(1) a statement of the concentrations of xanthophyll and ethoxyquin contained therein; and
(2) adequate directions to provide a final product complying with the limitations prescribed in paragraph (b) of this definition.

(d) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.275
(Adopted 2017)

87.5 Additional Special Purpose Products:

Name	FDA Regulation[a]	Classification Under Food Additives Amendment	Limitations or Restrictions
Aloe vera gel concentrate		Flavoring agent	Not to exceed 125 ppm (0.0125%) in finished feed
Anise seed IFN 8-00-416	21 CFR 582.10	Spices, seasonings, essential oils, oleo resins, and natural extractives	In accordance with good manufacturing practices
Capsicum; red pepper IFN 8-03-685	21 CFR 582.10	Spices, seasonings, etc.	In accordance with good manufacturing practices
Fennel IFN 8-01-855	21 CFR 582.10	Spices, seasonings, essential oils, etc.	In accordance with good manufacturing practices
Fenugreek seed IFN 8-01-856	21 CFR 582.10	Spices, seasonings, essential oils, etc.	In accordance with good manufacturing practices
Fumaric acid		pH adjuster, preservative, or flavoring agent	Not to exceed 0.5% of the diet
Ginger IFN 8-02-122	21 CFR 582.10	Spices, seasonings, essential oils, etc.	In accordance with good manufacturing practices
Glutamic acid	n/a	Flavoring agent	Up to 400 ppm in finished feed
Glycyrrhizin ammoniated IFN 8-08-099	21 CFR 582.20	Spices, seasonings, essential oils, etc.	In accordance with good manufacturing practices
Monosodium glutamate IFN 8-09-347	21 CFR 582.1	Spices, seasonings, etc.	In accordance with good manufacturing practices

(continued)

Name	FDA Regulation[a]	Classification Under Food Additives Amendment	Limitations or Restrictions
Phosphoric acid IFN 6-03-707	21 CFR 582.1073	Misc. and/or general purpose	In accordance with good manufacturing practices
Saccharin sodium IFN 8-04-103	GRAS[b]	Non-nutritive sweeteners	In accordance with good manufacturing practices
Sodium bisulfate		General purpose feed additive	

[a]Ingredients listed in 21 CFR part 582 are subject to the GMPs located at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=582.1.
[b]GRAS = abbreviation for the phrase "generally recognized as safe." A substance that is generally recognized as safe by experts qualified to evaluate the safety of the substance (for its intended use.)

87.6 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 5% crude protein, 1.5% crude fat, and not more than 25% crude fiber. (Proposed 1965, Adopted 1966, Amended 1967)

IFN 1-08-033 Rice hull fines

87.7 Ammoniated Rice Hulls is obtained by the treatment of ground rice hulls with monocalcium phosphate and anhydrous ammonia at a temperature of 350 F and a pressure of 175 lb. per square inch. It is to be used in beef cattle feeds at a level not to exceed 20% 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% 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.**" (Reg. 573.160) (Proposed 1966, Adopted 1968)

IFN 1-05-698 Rice hulls ammoniated

87.8 Polyethylene Roughage Replacement 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 × 0.8 + 0.1 × 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 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. (Proposed 1969, Adopted 1970) Reg. 573.780

IFN 8-09-351 Polyethylene

87.9 Ammoniated Cottonseed Meal 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% 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% 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.**"

(Reg. 573.140) (Proposed 1969, Adopted 1970)

IFN 5-09-352 Cotton seeds meal solvent extracted ammoniated

87.11 Anhydrous Ammonia 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% ammonia, with molasses, minerals, and not less than 83% crude protein. The labeling must bear the following statements:
    (a) An expiration date of not less than 10 weeks after date of manufacture,
    (b) 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 1% of their body weight daily in shelled corn, and
    (c) do not use additional trace mineral supplementation with treated silage;
(2) After being diluted to a 15 to 30% aqueous ammonia solution (by weight) and:
    (a) does not exceed anhydrous ammonia equivalent to 0.3% of the corn plant material,
    (b) the corn plant material contains 28 to 38% dry matter, and
    (c) the treated silage is fed to dairy cattle only; and
(3) Directly, and
    (a) does not exceed anhydrous ammonia equivalent to 0.35% of the corn plant material,
    (b) the corn plant material contains 30 to 35% dry matter,
    (c) 75 to 85% of the anhydrous ammonia is liquid at ambient pressure during the direct application, and
    (d) the treated material is used in dairy or beef cattle rations.

The labeling of the article must contain the following information in addition to any other required information:

(1) The name of the article.
(2) The concentration of ammonia.
(3) The maximum percentage of equivalent crude protein from non-protein nitrogen
(4) Directions for use consistent with 1) (b) and (c), 2) (c), and 3) (d) above, and
(5) A prominent: **"Warning--This feed should be used only in accordance with the directions furnished on the label."** (Proposed 1974, Adopted 1975, Revised 1982, Adopted 1983) Reg. 573.180.

IFN 5-14-511 Ammonia anhydrous

87.14 Powdered Cellulose is purified, mechanically disintegrated cellulose prepared by processing alpha cellulose obtained as a pulp from fibrous plant materials. (Proposed 1975, Adopted 1976)

IFN 1-15-514 Cellulose powdered

87.20 Guanidinoacetic acid: The food additive guanidinoacetic acid may be safely used in poultry feeds in accordance with the following prescribed conditions:

(a) The additive is manufactured by reacting glycine with cyanamide in an aqueous solution.
(b) The additive is used or intended for use at levels not to exceed 0.12% of the complete feed:
    (1) to spare arginine in broiler chicken and turkey feeds, or
    (2) as a precursor of creatine in poultry feeds.
(c) The additive consists of not less than 97% guanidinoacetic acid [N-(aminoiminomethyl)-glycine] (CAS 352-97-6) by weight.
(d) The additive meets the following specifications:
    (1) Dicyandiamide not to exceed 0.5%;
    (2) Cyanamide not to exceed 0.01%;
    (3) Melamine not to exceed 15 parts per million (ppm);
    (4) Sum of ammeline, ammelide, and cyanuric acid not to exceed 35 ppm; and
    (5) Water not to exceed 1%.
(e) To ensure safe use of the additive in addition to the other information required by the Federal Food, Drug, and Cosmetic Act:
    (1) The label and labeling of the additive, any feed premix, and complete feed shall contain the name of the additive.
    (2) The label and labeling of the additive and any feed premix shall also contain:
        (i) A statement to indicate that the maximum use level of guanidinoacetic acid must not exceed 0.12% of the complete feed for poultry; and
        (ii) Adequate directions for use.

21 CFR 573.496 (Adopted 2018, Amended 2022)

87.22 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. (Proposed 1995, Adopted 2003)

87.25 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 ppm of complete feed. (Proposed 2005, Adopted 2007)

87.29 *Yucca schidigera* Extract 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, livestock, rats, mice, hamsters, gerbils, and hedgehogs. The inclusion rate shall be the minimum quantity necessary to produce the intended effect, but not exceeding 125 ppm in the finished feed. 21 CFR 172.510. (Proposed 2015 rev. 1, Adopted 2017 rev. 1)

IFN 8-19-700 Yucca, Mohave extract

87.30 Flavoring Agents. Flavoring substances and adjuvants may be safely used in animal food in accordance with the following conditions.

(a) They are used in the minimum quantity required to produce their intended technical effect and in accordance with all the principles of good manufacturing practice.
(b) 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:

Common Name	Botanical Name of Plant Source	Limitations
Aloe	*Aloe perryi* Baker, *Aloe barbadensis* Mill., *Aloe ferox* Mill., and hybrids of this sp. with *Aloe Africana* Mill. and *Aloe spicata* Baker	
Althea root and flowers	*Althea officinalis* L.	
Amyris (West Indian sandalwood)	*Amyris balsamifera* L.	
Artemisia (wormwood)	*Artemisia* spp.	Finished food thujone free[a]
Benzoin resin	*Styrax benzoin* Dryander, *Styrax paralleloneurus* Perkins, *Styrax tonkinensis* (Pierre) Craib ex Hartwich, or other spp. of the Section *Anthostyrax* of the genus *Styrax*	
Blackberry bark	*Rubus*, Section *Eubatus*	
Boronia flowers	*Boronia megastigma* Nees	
Buchu leaves	*Barosma betulina* Bartl. et Wendl., *Barosma crenulata* (L.) Hook. or *Barosma serratifolia* Willd	
Cajeput	*Melaleuca leucadendron* L. and other *Melaleuca* spp.	
Camphor tree	*Cinnamomum camphora* (L.) Nees et *Eberm*	Safrole free
Cascara sagrada	*Rhamnus purshiana* DC	
Cassie flowers	*Acacia farnesiana* (L.) Willd	
Castor oil	*Ricinus communis* L.	
Catechu, black	*Acacia catechu* Willd	
Cedar, white (aborvitae), leaves and twigs	*Thuja occidentalis* L.	Finished food thujone free[a]
Cherry pits	*Prunus avium* L. or *Prunus cerasus* L.	Not to exceed 25 ppm prussic acid
Cherry-laurel leaves	*Prunus laurocerasus* L.	Not to exceed 25 ppm prussic acid
Chestnut leaves	*Castanea dentate* (Marsh.) Borkh	
Copaiba	South American spp. of *Copaifera* L.	
Costus root	*Saussurea lappa* Clarke	
Cubeb	*Piper cubeba* L.	
Currant, black, buds and leaves	*Ribes nigrum* L.	

(continued)

Common Name	Botanical Name of Plant Source	Limitations
Damiana leaves	*Turnera diffusa* Willd	
Davana	*Artemisia pallens* Wall	
Dill, Indian	*Anethum sowa* Roxb. (*Peucedanum graveolens* Benth et Hook., *Anethum graveolens* L.)	
Dittany of Crete	*Origanum dictamnus* L.	
Dragon's blood (dracorubin)	*Daemonorops* spp.	
Elemi	*Canarium commune* L. or *Canarium Luzonicum Miq*	
Erigeron	*Erigeron canadensis* L.	
Eucalyptus globulus leaves	*Eucalyptus globulus* Labill	
Fir ("pine") needles and twigs	*Abies sibirica* Ledeb., *Abies alba* Mill., *Abies sachalinesis* Masters, or *Abies mayriana* Miyabe et Kudo	
Fir, balsam, needles and twigs	*Abies balsamea* (L.) Mill	
Galbanum	*Ferula galbaniflua* Boiss. et Buhse and other *Ferula* spp.	
Gambir (catechu, pale)	*Uncaria gambir* Roxb	
Genet flowers	*Spartium junceum* L.	
Gentian rhizome and roots	*Gentiana lutea* L.	
Guaiac	*Guaiacum officinale* L., *Guaiacum santum* L., *Bulnesia sarmienti* Lor	
Guarana	*Paullinia cupana* HBK	
Haw, black, bark	*Viburnum prunifolium* L.	
Hemlock needles and twigs	*Tsuga canadensis* (L.) Carr. or *Tsuga heterophylla* (Raf.) Sarg	
Hyacinth flowers	*Hyacinthus orientalis* L.	
Imperatoria	*Peucedanum ostruthium* (L.) Koch (*Imperatoria ostruthium* L.)	
Labdanum	*Cistus* spp.	
Linaloe wood	*Bursera delpechiana* Poiss. and other *Bursera* spp.	
Lovage	*Levisticum officinale* Koch	
Lungmoss (lungwort)	*Sticta pulmonacea* Ach	
Maple, mountain	*Acer spicatum* Lam	
Mimosa (black wattle) flowers	*Acacia decurrens* Willd. var. *dealbata*	

(continued)

Common Name	Botanical Name of Plant Source	Limitations
Myrrh	*Commiphora molmol* Engl., *Commiphora abyssinica* (Berg) Engl., or other *Commiphora* spp.	
Oak, white, chips	*Quercus alba* L.	
Oak moss	*Evernia prunastri* (L.) Ach., *Evernia furfuracea* (L.) Mann, and other lichens	Finished food thujone free[a]
Olibanum	*Boswellia carteri* Birdw. and other *Boswellia* spp.	
Opopanax (bisabolmyrrh)	*Opopanax chironium* Koch (true opopanax) of *Commiphora erythraea* Engl. var. *Llabrescens*	
Orris root	*Iris germanica* L. (including its variety *florentina* Dykes) and *Iris pallida* Lam	
Passion flower	*Passiflora incarnate* L.	
Patchouli	*Pogostemon cablin* Benth. and *Pogostemon heyneanus* Benth	
Pennyroyal, American	*Hedeoma pulegioides* (L.) Pers	
Pennyroyal, European	*Mentha pulegium* L.	
Pine, dwarf, needles and twigs	*Pinus mugo* Turra var. *pumilio* (Haenke) Zenari	
Pine, Scotch, needles and twigs	*Pinus sylvestris* L.	
Pine, white oil	*Pinus palustris* Mill. and other *Pinus* spp.	
Quassia	*Picrasma excelsa* (Sw.) Planch, or *Quassia amara* L.	
Quebracho bark	*Aspidosperma quebracho-blanco* Schlecht, *Schinopsis lorentzii* (Griseb.) Engl., or *Quebrachia lorentzii* (Griseb.)	
Quillaia (soapbark)	*Quillaja saponaria* Mol	
Rhatany root	*Krameria triandra* Ruiz et Pav. or *Krameria argentea* Mart	
Rhubarb root	*Rheum officinale* Baill., *Rheum palmatum* L., or other spp. (excepting *Rheum rhaponticum* L. or hybrids of *Rheum* grown in China)	
Sandalwood, white (yellow, or East Indian)	*Santalum album* L.	

(continued)

Common Name	Botanical Name of Plant Source	Limitations
Sarsaparilla	*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)	
Sassafras leaves	*Sassafras albidum* (Nutt.) Nees	Safrole free
Senna, Alexandria	*Cassia acutifolia* Delile	
Snakeroot, Canadian (wild ginger)	*Asarum canadense* L.	
Spruce needles and twigs	*Picea glauca* (Moench) Voss or *Picea mariana* (Mill.) BSP	
Storax (styrax)	*Liquidambar orientalis* Mill. or. *Liquidambar styraciflua* L.	
Tagetes (marigold)	*Tagetes patula* L., *Tagetes erecta* L., or *Tagetes minuta* L. (*Tagetes glandulifera* Schrank)	As oil only
Thymus capitatus (Spanish "origanum")	*Thymus capitatus* Hoffmg. et Link	
Tolu	*Myroxylon balsamum* (L.) Harms	
Turpentine	*Pinus palustris* Mill. and other *Pinus* spp. that yield terpene oils exclusively	
Valerian rhizome and roots	*Valeriana officinalis* L.	
Violet, Swiss	*Viola calcarata* L.	
Walnut husks (hulls), leaves, and green nuts	*Juglans nigra* L. or *Juglans regia* L.	
Yerba santa	*Eriodictyon californicum* (Hook et Arn.) Torr.	
Yucca, Joshua-tree	*Yucca brevifolia* Engelm.	
Yucca, Mohave	*Yucca schidigera* Roezl ex Ortgies (*Yucca mohavensis* Sarg.)	

[a]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. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(Table Adopted 2015 rev. 1)

87.35 Glucose Syrup 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% mass/mass (m/m) and reducing sugar content (dextrose equivalent), expressed as D-glucose, not less than 20.0% m/m calculated on a dry basis. The sulfated ash content is not more than 1.0% m/m (calculated on a dry basis), and the sulfur dioxide content is not more than 40 mg/kg. If the product bears a name descriptive of its kind or origin, e.g., "corn syrup," "grain sorghum syrup," it must correspond thereto. (21 CFR 168.120) (Proposed 2017, Adopted 2019 rev. 1)

87.36 Phaffia Yeast—The color additive, phaffia yeast, may be safely used in the manufacture of salmonid fish feed in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive phaffia yeast consists of the killed, dried cells of a nonpathogenic and nontoxicogenic strain of the yeast *Phaffia rhodozyma*.

(2) 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 part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring foods.

(b) 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 practice:

Physical state, solid.
Lead (as Pb), not more than 5 parts per million.
Arsenic (as As), not more than 2 parts per million.
Mercury (as Hg), not more than 1 part per million.
Heavy metals, not more than 10 parts per million.
Astaxanthin, not less than 0.4%.

(c) Uses and restrictions.

Phaffia yeast may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) 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.

(d) Labeling requirements.

(1) 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 paragraph (c) of this definition.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this definition shall be declared in accordance with 21 CFR 501.4.

(3) 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).

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.355 (Proposed 2015, Adopted 2016 rev. 1, Amended 2017)

87.50 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 ppm in complete feed. The liquid ingredient must contain not less than 59% anacardic acid, not less than 18% cardol, and not more than 3% moisture. Minimum percent anacardic acid must be guaranteed. (Proposed 2019, Adopted 2020 rev. 1)

87.100 FD&C Blue No. 1—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:

(a) Identity.

(1) The color additive FD&C Blue No. 1 is principally the disodium salt of ethyl [4-[p-[ethyl (m-sulfobenzyl) amino]-α-(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]-α-(o-sulfophenyl) benzylidene]-2,5-cyclohexadien-1-ylidene] (p-sulfobenzyl) ammonium hydroxide inner salt and ethyl [4-[p-[ethyl (o-sulfobenzyl) amino]-α-(o-sulfophenyl) benzylidene]-2,5-cyclohexadien-1-ylidene] (o-sulfobenzyl) ammonium hydroxide inner salt.

(2) 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 part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring foods.

(b) 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 practice:

Sum of volatile matter (at 135°C) and chlorides and sulfates (calculated as sodium salts), not more than 15.0%.
Water-insoluble matter, not more than 0.2%.
Leuco base, not more than 5%.
Sum of o-, m-, and p-sulfobenzaldehydes, not more than 1.5%.
N-Ethyl,N-(m-sulfobenzyl)sulfanilic acid, not more than 0.3%.
Subsidiary colors, not more than 6.0%.
Chromium (as Cr), not more than 50 parts per million.
Manganese (as Mn), not more than 100 parts per million.
Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 10 parts per million.
Total color, not less than 85.0%.

(c) Uses and restrictions.

FD&C Blue No. 1 may be safely used for coloring foods generally in amounts consistent with good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) 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.

(e) Certification.
All batches of FD&C Blue No. 1 shall be certified in accordance with regulations in 21 CFR 80.

(Adopted 2017) 21 CFR 74.101

87.102 FD&C Blue No. 2—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:

(a) Identity.
(1) 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.
(2) 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 part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring foods.

(b) 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 practice:
Sum of volatile matter at 135°C (275°F) and chlorides and sulfates (calculated as sodium salts), not more than 15%.
Water-insoluble matter, not more than 0.4%.
Isatin-5-sulfonic acid, not more than 0.4%.
5-Sulfoanthranilic acid, not more than 0.2%.
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%.
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 2%.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85%.

(c) 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 practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) 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.

(e) Certification.

All batches of FD&C Blue No. 2 shall be certified in accordance with regulations in 21 CFR 80.

(Adopted 2017) 21 CFR 74.102

87.103 FD&C Green No. 3—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:

(a) Identity.

(1) 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]-4-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 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 5-amino-2-formylbenzenesulfonate. This amine is diazotized, and the resulting diazonium salt is hydrolyzed to the desired 2-formyl-5-hydroxybenzenesulfonic acid.

(2) 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 part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring food.

(b) 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 practice:

Sum of volatile matter at 135°C (275°F) and chlorides and sulfates (calculated as sodium salts), not more than 15%.

Water-insoluble matter, not more than 0.2%.

Leuco base, not more than 5%.

Sum of 2-, 3-, 4-formylbenzenesulfonic acids, sodium salts, not more than 0.5%.

Sum of 3- and 4-[[ethyl(4-sulfophenyl)amino]methyl] benzenesulfonic acid, disodium salts, not more than 0.3%.
2-Formyl-5-hydroxybenzenesulfonic acid, sodium salt, not more than 0.5%.
Subsidiary colors, not more than 6%.
Chromium (as Cr), not more than 50 parts per million.
Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 10 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 85%.

(c) 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 practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) 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.

(e) Certification.
All batches of FD&C Green No. 3 shall be certified in accordance with regulations in 21CFR 80.

(Adopted 2017) 21 CFR 74.203

87.104 FD&C Red No. 3—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:

(a) Identity.
(1) 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.
(2) 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 part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring foods.

(b) 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 practice:
Volatile matter (at 135°C) and chlorides and sulfates (calculated as the sodium salts), total not more than 13%.
Water-insoluble matter, not more than 0.2%.
Unhalogenated intermediates, total not more than 0.1%.
Sodium iodide, not more than 0.4%.
Triiodoresorcinol, not more than 0.2%.
2(2′,4′-Dihydroxy-3′, 5′-diiodobenzoyl) benzoic acid, not more than 0.2%.
Monoiodofluoresceins not more than 1.0%.
Other lower iodinated fluoresceins, not more than 9.0%.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total color, not less than 87.0%.

(c) Uses and restrictions.
FD&C Red No. 3 may be safely used for coloring foods generally in amounts consistent with good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) 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.

(e) Certification.
All batches of FD&C Red No. 3 shall be certified in accordance with regulations in 21 CFR 80.

(Adopted 2017) 21 CFR 74.303

87.105 FD&C Red No. 40—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:

(a) Identity.
(1) 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.
(2) 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 part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring foods.
(3) 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.

(b) 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 practice:
Sum of volatile matter (at 135°C) and chlorides and sulfates (calculated as sodium salts), not more than 14.0%.
Water-insoluble matter, not more than 0.2%.
Higher sulfonated subsidiary colors (as sodium salts), not more than 1.0%.
Lower sulfonated subsidiary colors (as sodium salts), not more than 1.0%.
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 1.0%.
Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid (Schaeffer's salt), not more than 0.3%.
4-Amino-5-methoxy-o-toluenesulfonic acid, not more than 0.2%.
Disodium salt of 6,6′-oxybis (2-naphthalene-sulfonic acid), not more than 1.0%.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Total color, not less than 85.0%.

(c) Uses and restrictions.
FD&C Red No. 40 may be safely used for coloring foods generally in amounts

consistent with good manufacturing practice except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) 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.

(e) Certification.
All batches of FD&C Red No. 40 and lakes thereof shall be certified in accordance with regulations in 21 CFR 80.

(Adopted 2017) 21 CFR 74.340

87.106 FD&C Yellow No. 6—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:

(a) Identity.

(1) 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.

(2) 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 part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring foods.

(b) 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 practice:

Sum of volatile matter (at 135°C) and chlorides and sulfates (calculated as sodium salts), not more than 13%.

Water-insoluble matter, not more than 0.2%.

Sodium salt of 4-aminobenzenesulfonic acid, not more than 0.2%.

Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid, not more than 0.3%.

Disodium salt of 6,6′-oxybis[2-naphthalenesulfonic acid], not more than 1%.

Disodium salt of 4,4′-(1-triazene-1,3-diyl)bis[benzenesulfonic acid], not more than 0.1%.

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 1%.

Sum of the trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid and other higher sulfonated subsidiaries, not more than 5%.

4-Aminoazobenzene, not more than 50 parts per billion.
4-Aminobiphenyl, not more than 15 parts per billion.
Aniline, not more than 250 parts per billion.
Azobenzene, not more than 200 parts per billion.
Benzidine, not more than 1 part per billion.
1,3-Diphenyltriazene, not more than 40 parts per billion.
1-(Phenylazo)-2-naphthalenol, not more than 10 parts per million.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 87%.

(c) 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 practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) Labeling requirements.
(1) 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 of this chapter.

(e) Certification.
All batches of FD&C Yellow No. 6 shall be certified in accordance with regulations in 21 CFR 80.

(Adopted 2017) 21 CFR 74.706

87.107 FD&C Yellow No. 5—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:

(a) Identity.
(1) 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.
(2) 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 part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring foods.

(b) 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 practice:
Sum of volatile matter at 135°C (275°F) and chlorides and sulfates (calculated as sodium salts), not more than 13%.
Water-insoluble matter, not more than 0.2%.
4,4′-[4,5-Dihydro-5-oxo-4-[(4-sulfophenyl)hydrazono]-1H-pyrazol-1,3-diyl]bis[benzenesulfonic acid], trisodium salt, not more than 1%.

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 1%.
Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl) hydrazono]-1H-pyrazole-3-carboxylate, disodium salt, not more than 1%.
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%.
4-Aminobenzenesulfonic acid, sodium salt, not more than 0.2%.
4,5-Dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylic acid, disodium salt, not more than 0.2%.
Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylate, sodium salt, not more than 0.1%.
4,4′-(1-Triazene-1,3-diyl)bis[benzenesulfonic acid], disodium salt, not more than 0.05%.
4-Aminoazobenzene, not more than 75 parts per billion.
4-Aminobiphenyl, not more than 5 parts per billion.
Aniline, not more than 100 parts per billion.
Azobenzene, not more than 40 parts per billion.
Benzidine, not more than 1 part per billion.
1,3-Diphenyltriazene, not more than 40 parts per billion.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 1 part per million.
Total color, not less than 87%.

(c) Uses and restrictions.
FD&C Yellow No. 5 may be safely used for coloring foods generally in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) 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.

(e) Certification.
All batches of FD&C Yellow No. 5 shall be certified in accordance with regulations in 21 CFR 80.

(Adopted 2017) 21 CFR 74.705

87.110 Annatto Extract—The color additive, annatto extract, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) 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 paragraph (a)(1)(i) and (ii) of this definition:

(i) 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 paragraph (a)(1)(ii) of this definition. Food-grade alkalis or carbonates may be added to adjust alkalinity.

(ii) Acetone, ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, trichloroethylene.

(2) Color additive mixtures for food use made with annatto extract may contain only diluents that are suitable and that are listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe in color additive mixtures for coloring foods.

(b) Specifications.

Annatto extract, including pigments precipitated therefrom, shall conform to the following specifications:

(1) Arsenic (as As), not more than 3 parts per million; lead (as Pb), not more than 10 parts per million.

(2) When solvents listed under paragraph (a)(1)(ii) of 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.

(c) Uses and restrictions.

Annatto extract may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) 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 paragraph (a)(1)(ii) of this definition.

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.30

87.112 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:

(a) Identity.

(1) The color additive astaxanthin dimethyldisuccinate is 3,3′-bis(4-methoxy-1,4-dioxobutoxy)-β,β-carotene-4,4′-dione.

(2) 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 part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring foods.

(b) 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 practice:

(1) Physical state, solid.
(2) 0.05% Solution in chloroform, complete and clear.
(3) Absorption maximum wavelength 484 to 493 nanometers (in chloroform).
(4) Residue on ignition, not more than 0.1%.
(5) Total carotenoids other than astaxanthin dimethyldisuccinate, not more than 4%.
(6) Lead, not more than 5 milligrams per kilogram (mg/kg) (5 parts per million).
(7) Arsenic, not more than 2 mg/kg (2 parts per million).
(8) Mercury, not more than 1 mg/kg (1 part per million).
(9) Heavy metals, not more than 10 mg/kg (10 parts per million).
(10) Assay including astaxanthin dimethyldisuccinate, astaxanthin monomethylsuccinate, and astaxanthin, minimum 96%.

(c) Uses and restrictions.
Astaxanthin dimethyldisuccinate may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:
(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.
(2) 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 mg/kg, which is equivalent to 80 mg/kg astaxanthin (72 grams per ton).

(d) Labeling requirements.
(1) 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 paragraph (c) of this definition.
(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this definition shall be declared in accordance with 21 CFR 501.4.

87.114 Astaxanthin—The color additive, astaxanthin, may be safely used in the manufacture of salmonid fish feed in accordance with the following prescribed conditions:

(a) Identity.
(1) The color additive astaxanthin is 3, 3′-dihydroxy-β, β-carotene-4, 4′-dione.
(2) 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 part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring foods.

(b) 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 practice:
Physical state, solid.
0.05% Solution in chloroform, complete and clear.
Absorption maximum wavelength 484 to 493 nanometers (in chloroform).
Residue on ignition, not more than 0.1%.
Total carotenoids other than astaxanthin, not more than 4%.
Lead, not more than 5 parts per million.

Arsenic, not more than 2 parts per million.
Mercury, not more than 1 part per million.
Heavy metals, not more than 10 parts per million.
Assay, minimum 96%.

(c) Uses and restrictions.
Astaxanthin may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:
(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.
(2) 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.

(d) Labeling requirements.
(1) 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 paragraph (c) of this definition.
(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this definition shall be declared in accordance with 21 CFR 501.4.
(3) 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).

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.35

87.115 Canthaxanthin—The color additive canthaxanthin may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.
(1) The color additive canthaxanthin is β-carotene-4,4′-dione.
(2) Color additive mixtures for food use made with canthaxanthin may contain only those diluents that are suitable and that are listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring foods.

(b) 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 practice:
Physical state, solid.
1% solution in chloroform, complete and clear.
Melting range (decomposition), 207 to 212°C (corrected).
Loss on drying, not more than 0.2%.
Residue on ignition, not more than 0.2%.
Total carotenoids other than trans-canthaxanthin, not more than 5%.
Lead, not more than 10 parts per million.
Arsenic, not more than 3 parts per million.
Mercury, not more than 1 part per million.
Assay, 96 to 101%.

(c) Use and restrictions.

(1) The color additive canthaxanthin may be safely used for coloring foods generally subject to the following restrictions:
(i) The quantity of canthaxanthin does not exceed 30 milligrams per pound of solid or semisolid food or per pint of liquid food; and
(ii) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.
(2) 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.
(3) Canthaxanthin may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:
(i) Canthaxanthin may be added to the fish feed only in the form of a stabilized color additive mixture;
(ii) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish; and
(iii) The quantity of color additive in feed shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) Labeling requirements.
(1) 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.
(2) 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 paragraph (c)(3) of this definition.
(3) The presence of the color additive in feed prepared according to paragraph (c) of this definition shall be declared in accordance with 21 CFR 501.4.
(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).

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.75 (Adopted 2018)

87.116 Caramel—The color additive, caramel, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.
(1) 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.
Sucrose.

(2) The food-grade acids, alkalis, and salts listed in this subparagraph may be employed to assist caramelization, in amounts consistent with good manufacturing practice.
   (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.

(3) Polyglycerol esters of fatty acids, identified in part 172.854 of Title 21 of the Code of Federal Regulations (21 CFR 172.854), may be used as antifoaming agents in amounts not greater than that required to produce the intended effect.

(4) 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.

(b) Specifications.
Caramel shall conform to the following specifications:
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Mercury (as Hg), not more than 0.1 part per million.

(c) Uses and restrictions.
Caramel may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) 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.

(e) 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 section 721(c) of Federal Food, Drug, and Cosmetic Act.

21 CFR 73.85

87.118 Carmine—The color additive, carmine, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) 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.)].

(2) Color additive mixtures for food use made with carmine may contain only diluents that are suitable and that are listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe in color additive mixtures for coloring foods.

(b) Specifications.
Carmine shall conform to the following specifications:

Volatile matter (at 135°C for 3 hours), not more than 20.0%.
Ash, not more than 12.0%.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Carminic acid, not less than 50.0%.

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 section 201(s) of the Federal Food, Drug, and Cosmetic Act or, if they are food additives as so defined, are used in conformity with regulations established pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act.

(c) Uses and restrictions.
Carmine may be safely used for coloring foods generally in amounts consistent with good manufacturing practice, except that they may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) 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.

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.100

87.120 Carrot Oil—The color additive, carrot oil, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.
(1) 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 section 401 of the Federal Food, Drug, and Cosmetic Act.
(2) Color additive mixtures for food use made with carrot oil may contain only those diluents listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable in color additive mixtures for coloring foods.

(b) Specifications.
Carrot oil shall contain no more than 25 parts per million of hexane.

(c) Uses and restrictions.
Carrot oil may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used

to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless the use of added color is authorized by such standards.

(d) 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.

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.300

87.122 Cochineal Extract—The color additive, cochineal extract, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.
(1) 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.
(2) Color additive mixtures for food use made with cochineal extract may contain only diluents that are suitable and that are listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe in color additive mixtures for coloring foods.

(b) Specifications.
Cochineal extract shall conform to the following specifications:
pH, not less than 5.0 and not more than 5.5 at 25°C.
Protein (N × 6.25), not more than 2.2%.
Total solids, not less than 5.7% and not more than 6.3%.
Methyl alcohol, not more than 150 parts per million.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Carminic acid, not less than 1.8%.
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 section 201(s) of the Federal Food, Drug, and Cosmetic Act or, if they are food additives as so defined, are used in conformity with regulations established pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act.

(c) Uses and restrictions.
Cochineal extract may be safely used for coloring foods generally in amounts consistent with good manufacturing practice, except that they may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) 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.

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.100

87.124 Corn Endosperm Oil—The color additive, corn endosperm oil, may be safely used in the manufacture of chicken feed in accordance with the following prescribed conditions:

(a) Identity.
(1) 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 section 401 of the Federal Food, Drug, and Cosmetic Act.
(2) Color additive mixtures for food use made with corn endosperm oil may contain only those diluents listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable in color additive mixtures for coloring foods.

(b) Specifications.
Corn endosperm oil shall conform to the following specifications:
Total fatty acids, not less than 85%.
Iodine value, 118 to 134.
Saponification value, 165 to 185.
Unsaponifiable matter, not more than 14%.
Hexane, not more than 25 parts per million.
Isopropyl alcohol, not more than 100 parts per million.

(c) Uses and restrictions.
The color additive corn endosperm oil may be safely used in chicken feed in accordance with the following prescribed conditions:
(1) The color additive is used to enhance the yellow color of chicken skin and eggs.
(2) 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 paragraph (c)(1) of this definition.

(d) 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.

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.315

87.126 Dehydrated Beets—The color additive, dehydrated beets, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive dehydrated beets is a dark red powder prepared by dehydrating sound, mature, good quality, edible beets.
(2) Color additive mixtures made with dehydrated beets may contain as diluents only those substances listed in this part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable for use in color additive mixtures for coloring foods.

(b) Specifications.
The color additive shall conform to the following specifications:
Volatile matter, not more than 4%.
Acid insoluble ash, not more than 0.5%.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Mercury (as Hg), not more than 1 part per million.

(c) Uses and restrictions.
Dehydrated beets may be safely used for the coloring of foods generally in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of added color is authorized by such standards.

(d) 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 21 CFR 70.25.

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.40

87.128 Fruit Juice—The color additive, fruit juice, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.
(1) 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 section 401 of the Federal Food, Drug, and Cosmetic Act. However, where a standard of identity for a particular fruit juice has been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act, it shall conform to such standard.
(2) Color additive mixtures made with fruit juice may contain as diluents only those substances listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable in color additive mixtures for coloring foods.

(b) Uses and restrictions.
Fruit juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of added color is authorized by such standards.

(c) 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 Federal Food, Drug, and Cosmetic Act, labeling in accordance with the provisions of 21 CFR 70.25.

(d) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.250

87.130 Haematococcus Algae Meal—The color additive, Haematococcus algae meal, may be safely used in the manufacture of salmonid fish feed in accordance with the following prescribed conditions:

(a) Identity.
(1) The color additive haematococcus algae meal consists of the comminuted and dried cells of the alga *Haematococcus pluvialis*.
(2) 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 part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring foods.

(b) 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 practice:
Physical state, solid.
Lead (as Pb), not more than 5 parts per million.
Arsenic (as As), not more than 2 parts per million.
Mercury (as Hg), not more than 1 part per million.
Heavy metals, not more than 10 parts per million.
Astaxanthin, not less than 1.5%.

(c) Uses and restrictions.
Haematococcus algae meal may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:
(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.
(2) 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.

(d) Labeling requirements.
(1) 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 paragraph (c) of this definition.
(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this definition shall be declared in accordance with 21 CFR 501.4.
(3) 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).

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.185

87.132 Paprika Oleoresin—The color additive, paprika oleoresin, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.
(1) 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 section 401 of the Federal Food, Drug, and Cosmetic Act.
(2) Color additive mixtures made with paprika oleoresin may contain as diluents only those substances listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable in color additive mixtures for coloring foods.

(b) Specifications.
Paprika oleoresin shall contain no more residue of the solvents listed in paragraph (a)(1) of this definition than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in 21 CFR 170 through 189.

(c) Uses and restrictions.
Paprika oleoresin may be safely used for the coloring of foods generally in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of added color is authorized by such standards.

(d) 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 Federal Food, Drug, and Cosmetic Act, labeling in accordance with the provisions of 21 CFR 70.25 of this chapter.

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 345

87.134 Paprika—The color additive, paprika, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.
(1) 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 section 401 of the Federal Food, Drug, and Cosmetic Act.

(2) Color additive mixtures made with paprika may contain as diluents only those substances listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable in color additive mixtures for coloring foods.

(b) Uses and restrictions.
Paprika may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of added color is authorized by such standards.

(c) 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 Federal Food, Drug, and Cosmetic Act, labeling in accordance with the provisions of 21 CFR 70.25 of this chapter.

(d) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 340

87.136 Paracoccus Pigment—The color additive, paracoccus pigment, may be safely used in the manufacture of salmonid fish feed in accordance with the following prescribed conditions:

(a) Identity.
(1) 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.
(2) Color additive mixtures for fish feed use made with paracoccus pigment may contain only those diluents that are suitable and are listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring foods.

(b) 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 practice:
(1) Physical state, solid.
(2) Lead (as Pb), not more than 5 milligrams per kilogram (mg/kg) [5 parts per million (ppm)].
(3) Arsenic (as As), not more than 2 mg/kg (2 ppm).
(4) Mercury (as Hg), not more than 1 mg/kg (1 ppm).
(5) Heavy metals, not more than 10 mg/kg (10 ppm).
(6) Astaxanthin, not less than 1.75%.

(c) Uses and restrictions.
Paracoccus pigment may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:
(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.
(2) 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 mg/kg (72 grams per ton) of finished feed.

(d) Labeling requirements.
(1) 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 paragraph (c) of this definition.
(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this definition shall be declared in accordance with 21 CFR 501.4.
(3) 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).

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 352

87.138 Riboflavin—The color additive, riboflavin, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.
(1) 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. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW, Washington, DC 20418, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.
(2) Color additive mixtures made with riboflavin may contain as diluents only those substances listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable for use in color additive mixtures for coloring foods.

(b) Specifications.
Riboflavin shall meet the specifications given in the Food Chemicals Codex, third edition (1981), which is incorporated by reference. The availability of this incorporation by reference is given in paragraph (a)(1) of this definition.

(c) Uses and restrictions.
Riboflavin may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of added color is authorized by such standards.

(d) Labeling.
The label of the color additive shall conform to the requirements of 21 CFR 70.25.

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.450

87.140 Saffron—The color additive, saffron, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) 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 section 401 of the Federal Food, Drug, and Cosmetic Act.

(2) Color additive mixtures made with saffron may contain as diluents only those substances listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable in color additive mixtures for coloring foods.

(b) Uses and restrictions.

Saffron may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of added color is authorized by such standards.

(c) 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 act, labeling in accordance with the provisions of 21 CFR 70.25.

(d) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.500

87.142 Synthetic Iron Oxide—The color additive, synthetic iron oxide, may be safely used in the manufacture of dog and cat foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive synthetic iron oxide consists of any one or any combination of synthetically prepared iron oxides, including the hydrated forms. It is free from admixture with other substances.

(2) Color additive mixtures for food use made with synthetic iron oxide may contain only those diluents that are suitable and that are listed in this part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe for use in color additive mixtures for coloring foods.

(b) Specifications.

Synthetic iron oxide for dog and cat food use shall conform to the following specifications:

Arsenic (as As), not more than 5 parts per million.
Lead (as Pb), not more than 20 parts per million.
Mercury (as Hg), not more than 3 parts per million.

(c) Uses and restrictions.

Synthetic iron oxide may be safely used for the coloring of dog and cat foods in an amount not exceeding 0.25% by weight of the finished food.

(d) Labeling requirements.

The label 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.

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.200

87.144 Tagetes (Aztec Marigold) Extract—The color additive, tagetes (Aztec marigold) extract, may be safely used in the manufacture of chicken feed in accordance with the following prescribed conditions:

(a) 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% ethoxyquin. It may also be mixed with soy flour or corn meal as a carrier.

(b) 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:
Melting point, 53.5–55.0°C.
Iodine value, 132–145.
Saponification value, 175–200.
Acid value, 0.60–1.20.
Titer, 35.5–37.0°C.
Unsaponifiable matter, 23–27%.
Hexane residue, not more than 25 parts per million.
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°C 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.

(c) Uses and restrictions.
The color additive tagetes (Aztec marigold) extract may be safely used in chicken feed in accordance with the following prescribed conditions:
(1) The color additive is used to enhance the yellow color of chicken skin and eggs.
(2) The quantity of the color additive incorporated in the feed is such that the finished feed
(i) is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (c)(1) of this definition; and
(ii) meets the tolerance limitation for ethoxyquin in animal feed prescribed in part 573.380 of Title 21 of the Code of Federal Regulations (21 CFR 573.380).

(d) Labeling requirements.
The label of the color additive and any premixes prepared therefrom shall bear, in addition to the information required 21 CFR 70.25:
(1) A statement of the concentrations of xanthophyll and ethoxyquin contained therein.
(2) Adequate directions to provide a final product complying with the limitations prescribed in paragraph (c) of this definition.

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.295

87.145 Tagetes (Aztec Marigold) Meal—The color additive, tagetes (Aztec marigold) meal, may be safely used in the manufacture of chicken feed in accordance with the following prescribed conditions:

(a) 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% ethoxyquin.

(b) 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.

(c) Uses and restrictions.
The color additive tagetes (Aztec marigold) meal may be safely used in chicken feed in accordance with the following prescribed conditions:
(1) The color additive is used to enhance the yellow color of chicken skin and eggs.
(2) The quantity of the color additive incorporated in the feed is such that the finished feed
(i) is supplemented sufficiently with xanthophyll and associated carotenoids so as to accomplish the intended effect described in paragraph (c)(1) of this definition; and
(ii) meets the tolerance limitation for ethoxyquin in animal feed prescribed in part 573.380 of Title 21 of the Code of Federal Regulations (21 CFR 573.380).

(d) Labeling requirements.
The label of the color additive and any premixes prepared therefrom shall bear, in addition to the information required 21 CFR 70.25:
(1) A statement of the concentrations of xanthophyll and ethoxyquin contained therein.
(2) Adequate directions to provide a final product complying with the limitations prescribed in paragraph (c) of this definition.

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.295

87.146 Titanium Dioxide—The color additive, titanium dioxide, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.
(1) The color additive titanium dioxide is synthetically prepared TiO_2, free from admixture with other substances.
(2) Color additive mixtures for food use made with titanium dioxide may contain only those diluents that are suitable and that are listed in part 73.1 of Title 21 of the Code of Federal Regulations (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 2% total.

(b) Specifications.

Titanium dioxide shall conform to the following specifications:

Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Antimony (as Sb), not more than 2 parts per million.
Mercury (as Hg), not more than 1 part per million.
Loss on ignition at 800°C (after drying for 3 hours at 105°C), not more than 0.5%.
Water-soluble substances, not more than 0.3%.
Acid-soluble substances, not more than 0.5%.
TiO_2, not less than 99.0% after drying for 3 hours at 105°C.
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.

(c) Uses and restrictions.

The color additive titanium dioxide may be safely used for coloring foods generally, subject to the following restrictions:

(1) The quantity of titanium dioxide does not exceed 1% by weight of the food.
(2) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) 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.

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.575

87.148 Toasted Partially Defatted Cooked Cottonseed Flour—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:

(a) Identity.

(1) 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.
(2) 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 this part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe in color additive mixtures for coloring foods.

(b) Specifications.

Toasted partially defatted cooked cottonseed flour shall conform to the following specifications:

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.
Lead (as Pb), not more than 10 parts per million.
Free gossypol content, not more than 450 parts per million.

(c) 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 practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act, unless added color is authorized by such standards.

(d) 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.

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.140

87.150 Tomato Lycopene Concentrate—The color additive, tomato lycopene concentrate, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.
(1) 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.
(2) Color additive mixtures made with tomato lycopene concentrate may contain only those diluents listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable for use in color additive mixtures for coloring food.

(b) Specifications.
Tomato lycopene concentrate shall conform to the following specifications: Lycopene, not less than 60% of oleoresin as determined by the method entitled "Qualitative Analysis of Lycopene, Its Isomers and Other Carotenoids in Different Concentrations of Lyc-O-Mato® (Tomato Oleoresin) and in Tomato Pulp by High Performance Liquid Chromatography (HPLC)," S.O.P. number: Lab/119/01, Revision 01, dated May 30, 2001, published by LycoRed Natural Products Industries, which is incorporated by reference, or an equivalent method. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the method from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. You may inspect a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(c) Uses and restrictions.
Tomato lycopene concentrate may be safely used for coloring foods generally

in amounts consistent with good manufacturing practice, except that they may not be used to color foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of added color is authorized by such standards.

(d) Labeling.
The label of the color additive shall conform to the requirements of 21 CFR 70.25.

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.585

87.152 Tomato Lycopene Extract—The color additive, tomato lycopene extract, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.
(1) 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.
(2) Color additive mixtures made with tomato lycopene extract may contain only those diluents listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable for use in color additive mixtures for coloring food.

(b) Specifications.
Tomato lycopene extract shall conform to the following specification: Lycopene, not less than 5.5% of oleoresin as determined by the method entitled "Qualitative Analysis of Lycopene, Its Isomers and Other Carotenoids in Different Concentrations of Lyc-O-Mato® (Tomato Oleoresin) and in Tomato Pulp by High Performance Liquid Chromatography (HPLC)," S.O.P. number: Lab/119/01, Revision 01, dated May 30, 2001, published by LycoRed Natural Products Industries, which is incorporated by reference, or an equivalent method. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of the method from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. You may inspect a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202)741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(c) Uses and restrictions.
Tomato lycopene extract may be safely used for coloring foods generally in amounts consistent with good manufacturing practice, except that they may not be used to color foods for which standards of identity have been issued under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of added color is authorized by such standards.

(d) Labeling.
The label of the color additive shall conform to the requirements of 21 CFR 70.25.

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.585

87.154 Turmeric Oleoresin—The color additive, turmeric oleoresin, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.
(1) 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 section 401 of the Federal Food, Drug, and Cosmetic Act.
(2) Color additive mixtures made with turmeric oleoresin may contain as diluents only those substances listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable in color additive mixtures for coloring foods.

(b) Specifications.
Turmeric oleoresin shall contain no more residue of the solvents listed under paragraph (a)(1) of this definition than is permitted for the corresponding solvents in spice oleoresins under applicable food additive regulation in 21 CFR parts 170 through 189.

(c) Uses and restrictions.
Turmeric oleoresin may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of added color is authorized by such standards.

(d) 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 act, labeling in accordance with the provisions of 21 CFR 70.25.

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.615

87.155 Turmeric—The color additive, turmeric, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.
(1) 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 section 401 of the Federal Food, Drug, and Cosmetic Act.

(2) Color additive mixtures made with turmeric may contain as diluents only those substances listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable in color additive mixtures for coloring foods.

(b) Uses and restrictions.
Turmeric may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of added color is authorized by such standards.

(c) 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 act, labeling in accordance with the provisions of 21 CFR 70.25.

(d) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.600

87.156 Ultramarine Blue—The color additive, ultramarine blue, may be safely used to color salt intended for animal foods in accordance with the following prescribed conditions:

(a) 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°C. Sodium sulfate and silica may also be incorporated in the mixture in order to vary the shade. The pigment is a complex sodium aluminum sulfosilicate having the approximate formula $Na_7Ai_6Si_6O_{24}S_3$.

(b) Specifications.
Ultramarine blue shall conform to the following specifications:
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Mercury (as Hg), not more than 1 part per million.

(c) 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% by weight of the salt.

(d) Labeling requirements.
The color additive shall be labeled in accordance with the requirements of part 70.25 of Title 21 of the Code of Federal Regulations (21 CFR 70.25).

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.50

87.158 Vegetable Juice—The color additive, vegetable juice, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.
(1) 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 section 401 of the Federal Food, Drug, and Cosmetic Act. However, where a standard of identity for a particular vegetable juice has been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act, it shall conform to such standard.

(2) Color additive mixtures made with vegetable juice may contain as diluents only those substances listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe and suitable in color additive mixtures for coloring foods.

(b) Uses and restrictions.
Vegetable juice may be safely used for the coloring of foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act, unless the use of added color is authorized by such standards.

(c) 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 Federal Food, Drug, and Cosmetic Act, labeling in accordance with the provisions of 21 CFR 70.25.

(d) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.260

87.160 β-Apo-8′-Carotenal—The color additive, β-apo-8′-carotenal, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.

(1) The color additive is β-apo-8′-carotenal.

(2) Color additive mixtures for food use made with β-apo-8′-carotenal may contain only diluents that are suitable and that are listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe in color additive mixtures for coloring foods.

(b) Specifications.
β-Apo-8′-carotenal shall conform to the following specifications:
Physical state, solid.
1% solution in chloroform, clear.
Melting point (decomposition), 136–140°C (corrected).
Loss of weight on drying, not more than 0.2%.
Residue on ignition, not more than 0.2%.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Assay (spectrophotometric), 96–101%.

(c) Uses and restrictions.
The color additive β-apo-8′-carotenal may be safely used for coloring foods generally, subject to the following restrictions:

(1) The quantity of β-apo-8′-carotenal does not exceed 15 milligrams per pound of solid or semisolid food or 15 milligrams per pint of liquid food.

(2) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) 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.

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.90

87.164 β-Carotene—The color additive, β-carotene, may be safely used in the manufacture of animal foods in accordance with the following prescribed conditions:

(a) Identity.
(1) The color additive is β-carotene prepared synthetically or obtained from natural sources.
(2) Color additive mixtures for food use made with β-carotene may contain only diluents that are suitable and that are listed in part 73.1 of Title 21 of the Code of Federal Regulations (21 CFR 73.1) as safe in color additive mixtures for coloring foods.

(b) Specifications.
β-Carotene shall conform to the following specifications:
Physical state, solid.
1% solution in chloroform, clear.
Loss of weight on drying, not more than 0.2%.
Residue on ignition, not more than 0.2%.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 3 parts per million.
Assay (spectrophotometric), 96–101%.

(c) Uses and restrictions.
The color additive β-carotene may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color those foods for which standards of identity have been promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act unless added color is authorized by such standards.

(d) 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.

(e) 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 section 721(c) of the Federal Food, Drug, and Cosmetic Act.

21 CFR 73.95

90. Vitamins

Investigator and Section Editor—Tom Phillips, MD

Official

90.1 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). (Adopted 1937, Amended 1945, 1950, 1973, 1995, 1996)

IFN 7-01-993 Fish cod liver oil

90.2 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). (Adopted 1948, Amended 1950, 1964, 1967)

IFN 7-08-047 Fish cod liver oil vitamins A and D added

90.3 Vitamin A Oil is an oil of animal or vegetable origin with or without vitamin A supplementation for which vitamin A potency is claimed. (Adopted 1944, Amended 1945, 1959, 1964, 1967)

IFN 7-05-141 Vitamin A oil

90.4 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. (Adopted 1956, Amended 1973, 1995, 1996)

IFN 7-05-149 Vitamin D2 supplement

90.5 Vitamin D Oil is an oil of animal or vegetable origin with or without vitamin D supplementation for which vitamin D potency is claimed. (Adopted 1944, Amended 1945, 1959, 1964, 1967)

IFN 7-05-147 Vitamin D oil

90.6 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. (Adopted 1944, Amended 1945, 1950, 1959, 1964, 1967)

IFN 7-05-145 Vitamin A and D oil

90.7 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 D3). (Adopted 1942, Amended 1993.)

IFN 7-00-408 Animal sterol irradiated

90.8 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 D2). (Adopted 1944, Amended 1993)

IFN 7-03-728 Plant sterol irradiated

90.9 25-hydroxyvitamin D_3—The food additive 25-hydroxyvitamin D_3 may be safely used in accordance with the following prescribed conditions:

(a) 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:
  (1) In feed or drinking water of chickens not to exceed 69 parts per billion (ppb) in feed or 34.5 ppb in drinking water.
  (2) In feed or drinking water of turkeys not to exceed:
    (i) 92 ppb in feed; or
    (ii) in drinking water, 25 ppb for turkeys up to 3 weeks of age, 36 ppb for turkeys from 4 to 11 weeks of age, or 45 ppb for turkeys over 11 weeks of age.

(b) The additive consists of not less than 94% 25-hydroxyvitamin D_3 (9,10-secocholesta-5,7,10(19)-triene-3β, 25-diol).

(c) The additive meets the following specifications:
  (1) Not more than 1% of any individual sterol.
  (2) Not more than 5% water.

(3) Not more than 20 parts per million (ppm) lead.
(4) Not more than 20 ppm aluminum.
(5) Not more than 1.0% solvents and non-detectable levels of 2', 4', 5', 7' tetraiodofluorescin.
(6) Not more than 1 ppb 1,25-dihydroxycholecalciferol.

(d) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act, the label and labeling shall contain:
(1) The name of the additive.
(2) A statement to indicate the maximum use level of 25-hydroxyvitamin D_3 must not exceed 69 ppb in feed or 34.5 ppb in drinking water for chickens.
(3) A statement to indicate for turkeys the maximum use level of 25-hydroxyvitamin D_3 must not exceed 92 ppb in feed; or in drinking water, 25 ppb for turkeys up to 3 weeks of age, 36 ppb for turkeys from 4 to 11 weeks of age, or 45 ppb for turkeys over 11 weeks of age.
(4) Adequate use directions to ensure that 25-hydroxyvitamin D_3 (and all premixes) is uniformly blended throughout the feed or drinking water.
(5) An expiration date on all premix labeling.
(6) A statement on all premix labeling (feed and drinking water forms) that 25-hydroxyvitamin D_3 cannot be used simultaneously in both feed and water.

21 CFR 573.550, 584.725 (Adopted 2019 rev. 1)

90.11 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. (Adopted 1952)

IFN 7-05-146 Vitamin B12 supplement

90.12 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. (Adopted 1953, Amended 1967)

IFN 7-05-150 Vitamin E supplement

90.13 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. (Adopted 1957)

IFN 7-03-921 Riboflavin supplement

90.14 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. (Proposed 1959, Adopted 1960, Amended 1973, 1995, 1996)

IFN 7-05-144 Vitamin A supplement

90.15 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. (Proposed 1966)

IFN 7-05-699 Vitamin D3 supplement

90.16 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. (Adopted 1980, Amended 1981)

IFN 7-26-003 Niacin supplement

90.17 Betaine (hydrochloride or anhydrous) is the crystalline chloride of betaine or anhydrous betaine; a partial replacement for choline. (Proposed 1990, Adopted 1991)

IFN 7-00-722 Betaine hydrochloride

90.25 Additional Officially Recognized Vitamin Ingredients for Animal Feed Use at Nutritional Levels and in Conformity with Current Good Manufacturing Practices

Recognized English Name	Article or Substance Indicated	Status Under Food Additive Amendments 21 CFR
Ascorbic acid IFN 7-00-433	Crystalline ascorbic acid commercial feed grade	Reg. 582.5013 (GRAS[a])
L-Ascorbyl-2-polyphosphate	Stabilized ascorbic acid feed grade	
L-Ascorbyl-2-sulfate	Stabilized ascorbic acid feed grade	Aquatic species (salmon, trout, catfish, shrimp, and tilapia)
Biotin IFN 7-00-723	Biotin—commercial feed grade	Reg. 582.5159 (GRAS)
Calcium ascorbate	Commercial grade	Vitamin C activity in dry feeds (<13% moisture) only
Calcium L-ascorbyl-2-monophosphate	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	
Calcium pantothenate IFN 7-07-079	Crystalline calcium pantothenate—commercial feed grade	Reg. 582.5212 (GRAS)
Carotene IFN 7-01-134	The refined crystalline carotene fraction of plants	Reg. 582.5245 (GRAS)
Choline chloride IFN 7-01-228	Choline chloride—commercial feed grade	Reg. 582.5252 (GRAS)
Choline pantothenate IFN 7-01-229	Crystalline choline pantothenate—commercial feed grade	
Choline xanthate IFN 7-01-230	Choline xanthate—commercial feed grade	Reg. 573.300
Erythorbic acid (Iso ascorbic acid) IFN 7-09-823	Either the acid or the sodium salt	Reg. 582.3041
Folic acid IFN 7-02-066	Crystalline folic acid—commercial feed grade	

(continued)

Recognized English Name	Article or Substance Indicated	Status Under Food Additive Amendments 21 CFR
Herring oil IFN 7-08-048	The oil extracted from whole parts of herring	
Inositol IFN 7-09-354	Vitamin B complex vitamin; lipotropic, chemical name—cyclohexandehexol. Also referred to as i-inostol or meso-inositol.	Reg. 582.5370 (GRAS)
Magnesium L-ascorbyl-2-phosphate	Stablized ascorbic acid	Fish feeds only
Menadione	Crystalline menadione—commercial feed grade	Poultry 2 to 4 g/ton
Menadione dimethylpyrimidinol bisulfite IFN 7-08-102	Crystalline menadione—dimethylpyrimidinol bisulfite—commercial feed grade	Reg. 573.620 Chicken and turkey feeds at 2 g/ton Growing and finishing swine feeds at 10 g/ton 21 CFR 573.620
Menadione nicotinamide bisulfite	Source of vitamin K activity and supplemental niacin	Chicken and turkey feeds at 2 g/ton Growing and finishing swine feeds at 10 g/ton 21 CFR 573.625
Menadione sodium bisulfite complex IFN 7-03-078	The addition product of menadione and sodium bisulfite containing not less than 30% of menadione	Poultry 2 to 4 g/ton
Menhaden oil IFN 7-08-049	The oil extracted from whole menhaden	
Niacin; nicotinic acid IFN 7-03-219	Crystalline nicotine acid—commercial feed grade	Reg. 582.5530 (GRAS)
Niacinamide; nicotinamide IFN 7-03-215	Crystalline amide of nicotinic acid—commercial feed grade	Reg. 582.5535 (GRAS)
p-Aminobenzoic acid IFN 7-03-513	p-Aminobenzoic acid—commercial feed grade	
Pyridoxine hydrochloride IFN 7-03-822	Crystalline chloride of pyridoxine—commercial feed grade	Reg. 582.5676 (GRAS)
Riboflavin IFN 7-03-920	Crystalline riboflavin—commercial feed grade	Reg. 582.5695 (GRAS)
Salmon oil IFN 7-08-050	The oil extracted from cannery refuse of salmon	

(continued)

Recognized English Name	Article or Substance Indicated	Status Under Food Additive Amendments 21 CFR
Salmon liver oil IFN 7-02-013	The oil extracted from salmon livers	
Sardine oil IFN 7-02-016	The oil extracted from cannery refuse of the packing of sardine	
Shark liver oil IFN 7-02-019	The oil extracted from shark liver	
Thiamine hydrochloride IFN 7-04-828	Crystalline chloride of thiamine—commercial feed grade	Reg. 582.5875 (GRAS)
Thiamine mononitrate IFN 7-04-829	Crystalline mononitrate of thiamine—commercial feed grade	Reg. 582.5878 (GRAS)
Tocopherol IFN 7-00-001	a-Tocopherol—commercial feed grade	Reg. 582.5890 (GRAS)
a-Tocopherol acetate IFN 7-18-777	Commercial feed grade dl-a-tocopheryl acetate d-a-tocopheryl acetate	Reg. 582.5892 (GRAS)
Tuna oil IFN 7-02-024	The oil extracted from cannery refuse of tuna	
Vitamin A acetate IFN 7-05-142	Vitamin A acetate—commercial feed grade	Reg. 582.5933 (GRAS)
Vitamin A palmitate IFN 7-05-143	Vitamin A palmitate—commercial feed grade	Reg. 582.5936 (GRAS)
Vitamin A propionate IFN 7-26-311	Consists of retinol or esters of retinol formed from edible fatty acids	
Wheat germ oil IFN 7-05-207	The oil extracted or expressed from wheat germ	

[a]GRAS = abbreviation for the phrase "generally recognized as safe" by experts qualified to evaluate the safety of the substance for its intended use.

90.26 Source of Vitamins and Their Levels

Vitamin Compound[a]	Vitamin[b]	Vitamin/Vitamin[c] Compound
L-Ascorbyl-2-polyphosphate	Ascorbic acid	0.800
Menadione dimethylpyrimidinol bisulfite	Menadione	0.454
Menadione sodium bisulfite complex	Menadione	0.330
Riboflavin-5-phosphate	Riboflavin	0.730
d-Calcium pantothenate	d-Pantothenic acid	0.920
Thiamine hydrochloride	Thiamine	0.892

(continued)

Vitamin Compound[a]	Vitamin[b]	Vitamin/Vitamin[c] Compound
Thiamine mononitrate	Thiamine	0.919
Pyridoxine hydrochloride	Vitamin B_6	0.823
Choline chloride	Choline	0.746
Choline bitartrate	Choline	0.469
Sodium ascorbate	Ascorbic acid	0.889

[a]Term to be used in ingredient statement when declaring fortification, Model Bill, Section 5.
[b]Term to be used in guaranteed analysis statement when guaranteeing the level of the vitamin, Model Regulation 4(c).
[c]The ratio is based on molecular weights and may not be proportional to biological activity. (Adopted 1991, Amended 2007)

90.27 Vitamin Ingredient Nomenclature for Labeling of Finished Pet Foods
The names in the Label Listing column may be used to represent the vitamins in the right- hand column in finished foods and treats for dogs and cats. This table is intended to aid in the labelling of pet foods and provide more familiar names for vitamins for consumers.
This table is not intended to list all available vitamins for use in pet food. In all cases the ingredient definition should be reviewed to ensure that it is appropriate for the intended use.

Label Listing	AAFCO Ingredient Definition or 21 CFR listing
Vitamin A (Vitamin A Acetate)	90.25 Vitamin A acetate
Vitamin A (Vitamin A Palmitate)	90.25 Vitamin A palmitate
Vitamin A (Vitamin A Propionate)	90.25 Vitamin A propionate
Vitamin B_1 (Thiamine Hydrochloride)	90.25 Thiamine hydrochloride
Vitamin B_1 (Thiamine Mononitrate)	90.25 Thiamine mononitrate
Vitamin B_2 (Riboflavin)	90.25 Riboflavin
Vitamin B_2 (Riboflavin-5-Phosphate)	21 CFR 582.5697 Riboflavin-5-phosphate
Vitamin B_3 (Niacin)	90.25 Niacin; nicotinic acid
Vitamin B_3 (Niacinamide)	90.25 Niacinamide; nicotinamide
Choline (Choline Pantothenate)	90.25 Choline pantothenate
Choline (Choline Chloride)	90.25 Choline chloride
Choline (Choline Bitartrate)	90.26 Choline bitartrate
Vitamin B_5 (Calcium Pantothenate)	90.25 Calcium pantothenate
Vitamin B_5 (Choline Pantothenate)	90.25 Choline pantothenate
Vitamin B_5 (D-Pantothenyl Alcohol)	21 CFR 582.5580 D-Pantothenyl alcohol
Vitamin B_5 (Sodium Pantothenate)	21 CFR 582.5772 Sodium pantothenate
Vitamin B_6 (Pyridoxine Hydrochloride)	90.25 Pyridoxine hydrochloride
Vitamin B_7 (Biotin)	90.25 Biotin

(continued)

Label Listing	AAFCO Ingredient Definition or 21 CFR listing
Vitamin B_9 (Folic Acid)	90.25 Folic acid
Vitamin C (Ascorbic Acid)	90.25 Ascorbic acid
Vitamin C (L-Ascorbyl-2-Polyphosphate)	90.25 L-Ascorbyl-2-polyphosphate
Vitamin C (Calcium Ascorbate)[a]	90.25 Calcium ascorbate
Vitamin C (Calcium L-Ascorbyl-2-Monophosphate)	90.25 Calcium L-ascorbyl-2-monophosphate
Vitamin C (Erythorbic Acid)	90.25 Erythorbic acid (Iso ascorbic acid)
Vitamin D_2 (Ergocalciferol)	21 CFR 582.5950 Vitamin D_2
Vitamin D_3 (Cholecalciferol)	21 CFR 582.5953 Vitamin D_3
Vitamin E (α-Tocopherol Acetate)	90.25 a-Tocopherol acetate
Vitamin E (Tocopherols)	90.25 Tocopherol (a-tocopherol)

[a]Vitamin C activity in dry feeds of <13% moisture only.

93. Wheat Products

Investigator and Section Editor—Dan King, MN

Official

93.1 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. (Adopted prior to 1928)

IFN 4-05-190 Wheat bran

93.2 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% crude fiber. (Adopted 1949)

IFN 4-05-199 Wheat flour less than 1.5% fiber

93.3 Wheat Germ Meal consists chiefly of wheat germ together with some bran and middlings or shorts. It must contain not less than 25% crude protein and 7% crude fat. (Adopted 1949, Amended 1953)

IFN 5-05-218 Wheat germs ground

93.4 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% crude fiber. (Proposed 1959, Adopted 1960)

IFN 4-05-206 Wheat mill run less than 9.5% fiber

93.5 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% crude fiber. (Proposed 1959, Adopted 1960, Amended 2017 rev. 1)

IFN 4-05-205 Wheat flour by-product less than 9.5% fiber

93.6 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 7% crude fiber. (Proposed 1959, Adopted 1960)

IFN 4-05-201 Wheat flour by-product less than 7% fiber

93.7 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 4% crude fiber. (Proposed 1959, Adopted 1960)

IFN 4-05-203 Wheat flour by-product less than 4% fiber

93.8 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% crude protein. (Proposed 1960, Adopted 1962, Amended 1964)

IFN 5-05-217 Wheat germs meal mechanical extracted

NOTE: 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."

93.9 _____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%. Wheat gluten, on a moisture-free basis, must contain not less than 80% crude protein (crude protein based on N × 6.25), and not more than 1.5% crude fiber and 2.0% 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. (Proposed 2013, Adopted 2017 rev. 1)

96. Yeast

Investigator and Section Editor—Darrell Johnson, KY

Official

96.1 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% crude protein. (Adopted 1955, Amended 1993, Adopted 1997)

IFN 7-05-533 Yeast primary dehydrated

96.2 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. (Adopted 1951)

IFN 7-05-524 Yeast active dehydrated

96.3 Irradiated Dried Yeast, Irradiated _____ Dried Yeast is the dried, non-fermentative yeast which has been subjected to ultraviolet rays in order to produce anti-rachitic potency. (Proposed 1958, Adopted 1959)

IFN 7-05-529 Yeast irradiated dehydrated

NOTE: When Irradiated Dried Yeast or Irradiated _____ 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). (Adopted 1945, Amended 1959)

96.4 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% crude protein. It must be labeled according to its crude protein content. (Adopted 1955, Amended 1975, Adopted 1978)

IFN 7-05-527 Yeast brewers dehydrated

96.5 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% crude protein. (Adopted 1955, Withdrawn 1993, Proposed 2006, Adopted 2009)

96.7 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% crude protein. (Adopted 1955, Amended 1993)

IFN 7-05-534 Yeast torula dehydrated

96.8 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. (Adopted 1957, Amended 2008)

IFN 7-05-520 Yeast culture dehydrated

*NOTE: No reference to media in main ingredient listing is required when yeast culture forms a component of a proprietary mixed feed.

96.9 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. (Proposed 1973, Amended 1974)

IFN 5-14-009 Sugarcane molasses yeast solubles condensed

96.10 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% crude protein on a dry weight basis. The guaranteed analysis shall include the maximum moisture. (Proposed 1976, Adopted 1978)

IFN 7-20-878 Yeast brewers liquid

96.11 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 9% crude protein. (Proposed 1998, Amended 2006, Adopted 2010)

96.12 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 practice. It must not contain less than 35% crude protein. (Proposed 2007, Adopted 2010)

96.13 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% crude protein. (Proposed 2015, Adopted 2017 rev. 1)

96.14 *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%. It must contain not less than 40% 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. (Proposed 2018, Adopted 2019 rev. 1)

99. Withdrawn Ingredients

Section Editor—Richard Ten Eyck, OR

33.5 Fat Product, Feed Grade, is any fat product that does not meet the definitions for animal fat, vegetable fat or oil, hydrolyzed fat or fat ester. It must be sold on its individual specifications, which will include the minimum percentage of total fatty acids, the maximum percentage of unsaponifiable matter, the maximum percentage of insoluble impurities, the maximum percentage of free fatty acids and moisture. The above listed specifications must be guaranteed on the label. If an antioxidant(s) is used, the common name or names must be indicated, followed by the words "used as a preservative." (Proposed 1989, Withdrawn 2016 rev. 1 and replaced with 33.20)

IFN 4-00-414 Animal vegetable fat product

33.19 Hydrogenated Glycerides are obtained by hydrogenation of animal fats or vegetable oils. Specifications of animal fats or vegetable oils used to produce the hydrogenated glycerides must meet the requirements stated in AAFCO definition 33.1 (for Animal Fat) and AAFCO definition 33.2 (for Vegetable Fat, or oil), respectively. The specification for tallow must specify insoluble impurities not more than 0.15% to be consistent with BSE feed regulation 21 CFR 589.2000 and 589.2001 and a guaranteed titer above 40°C. 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% total ester content, not more than 0.8% unsaponifiable matter, not more than 0.001% heavy metals, and not more than 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." (Proposed 2012, Adopted 2015)

Table 87.5 Ball Clay (withdrawn) is not accepted for use as a feed ingredient. (Removed 1999)

T57.152 Calcium Formate (withdrawn) is the calcium salt of formic acid generally expressed as $Ca(HOCO_2)_2$ and its hydrated forms. It is to be used as a source of supplemental calcium in swine diets, not to supply more than 0.6% calcium to the diet. Calcium Formate is currently considered an unapproved food additive, and a food additive petition must be approved prior to its use in feeds. (Adopted 1993, Amended 1999, Removed 1999)

T57.164 Chromium L-Methionine Complex (withdrawn) is the stable, water-soluble monohydrochloride complex containing one molar equivalent of chromium (III) and three molar equivalents of L-methionine generally expressed as $(C_5H_{10}NO_2S)_3Cr(III)HCl$. It is not accepted for use as a feed ingredient. (Proposed 2004, Removed 2007, Amended 2010)

T71.25 Rapeseed Meal, Mechanical Extracted. (withdrawn)** Rapeseed meal, mechanical extracted, obtained by grinding the cake which remains after removal of most of the oil by mechanical extraction of the seed from the rapeseed plant (Brassica). It must contain a minimum of 32% protein and a maximum of 12% crude fiber. (Proposed 1970, Adopted 197, Removed 2011)

IFN 5-03-870 Rape seeds meal mechanical extracted

Charcoal (feed term) (withdrawn). Dark-colored porous forms of carbon made from the organic parts of vegetable or animal substances, by their incomplete combustion. (Removed 2010)

100. CFR Listed Feed Ingredients

Section Editor—David Edwards, FDA

The following list of Least Common Feed Ingredients are listed in the US Code of Federal Regulations as food additives (21 CFR 573) or generally recognized as safe (GRAS) ingredients (21 CFR 582).

Please note the ingredients marked with • are also defined elsewhere in the OP.

PART 573—Food Additives Permitted in Feed and Drinking Water of Animals

Subpart B—Food Additive Listing

573.120	Acrylamide-acrylic acid resin.	573.870	Poly(2-vinylpryidine-co-styrene).
573.440	Ethylene dichloride.	573.880	Normal propyl alcohol.
573.530	Hydrogenated corn syrup.	573.1010	Xanthan gum. •
573.740	Odorless light petroleum hydrocarbons.		

PART 582——Substances Generally Recognized as Safe in Animal Feeds

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 practice. All substances listed may be in anhydrous or hydrated form.

Element	Source compounds	Element	Source compounds
Cobalt	Cobalt acetate •	Iron	Iron ammonium citrate •
	Cobalt carbonate •		Iron carbonate •
	Cobalt chloride •		Iron chloride •
	Cobalt oxide •		Iron gluconate •
	Cobalt sulfate •		Iron oxide •
Copper	Copper carbonate •		Iron phosphate •
	Copper chloride •		Iron pyrophosphate •
	Copper gluconate •		Iron sulfate •
	Copper hydroxide •		Reduced iron •
	Copper orthophosphate •	Manganese	Manganese acetate •
	Copper oxide •		Manganese carbonate •
	Copper pyrophosphate		Manganese citrate (soluble) •
	Copper sulfate •		Manganese chloride •
Iodine	Calcium iodate •		Manganese gluconate •
	Calcium iodobehenate •		Manganese orthophosphate •
	Cuprous iodide •		Manganese phosphate (dibasic) •
	3,5-Diiodosalicylic acid •		Manganese sulfate •
	Ethylenediamine dihydroiodide •		Manganous oxide •
	Potassium iodate •	Zinc	Zinc acetate •
	Potassium iodide •		Zinc carbonate •
	Sodium iodate •		Zinc chloride •
	Sodium iodide •		Zinc oxide •
	Thymol iodide •		Zinc sulfate •

Subpart B——General Purpose Food Additives

Section	Source compounds
582.1005	Acetic acid
582.1009	Adipic acid
582.1033	Citric acid •
582.1057	Hydrochloric acid
582.1061	Lactic acid
582.1069	Malic acid
582.1073	Phosphoric acid •
582.1077	Potassium acid tartrate
582.1087	Sodium acid pyrophosphate
582.1091	Succinic acid
582.1095	Sulfuric acid
582.1099	Tartaric acid
582.1125	Aluminum sulfate •
582.1127	Aluminum ammonium sulfate
582.1129	Aluminum potassium sulfate
582.1131	Aluminum sodium sulfate
582.1135	Ammonium bicarbonate
582.1137	Ammonium carbonate
582.1139	Ammonium hydroxide
582.1141	Ammonium phosphate •
582.1143	Ammonium sulfate •
582.1155	Bentonite •
582.1165	Butane
582.1191	Calcium carbonate •
582.1193	Calcium chloride •
582.1195	Calcium citrate
582.1199	Calcium gluconate •
582.1205	Calcium hydroxide •
582.1207	Calcium lactate
582.1210	Calcium oxide •
582.1217	Calcium phosphate •
582.1235	Caramel
582.1240	Carbon dioxide
582.1275	Dextrans
582.1320	Glycerin •
582.1324	Glyceryl monostearate
582.1355	Helium
582.1366	Hydrogen peroxide
582.1400	Lecithin •
582.1425	Magnesium carbonate •
582.1428	Magnesium hydroxide •
582.1431	Magnesium oxide •
582.1480	Methylcellulose
582.1500	Monoammonium glutamate
582.1516	Monopotassium glutamate
582.1540	Nitrogen
582.1585	Papain •
582.1613	Potassium bicarbonate •
582.1619	Potassium carbonate •
582.1625	Potassium citrate •
582.1631	Potassium hydroxide •
582.1643	Potassium sulfate •
582.1655	Propane
582.1666	Propylene glycol (not in or on cat food, 21 CFR 589.1001) •
582.1685	Rennet
582.1711	Silica aerogel
582.1721	Sodium acetate
582.1736	Sodium bicarbonate •
582.1742	Sodium carbonate •
582.1745	Sodium carboxymethylcellulose •
582.1748	Sodium caseinate
582.1751	Sodium citrate
582.1763	Sodium hydroxide
582.1775	Sodium pectinate
582.1778	Sodium phosphate •
582.1781	Sodium aluminum phosphate
582.1792	Sodium sesquicarbonate •
582.1804	Sodium potassium tartrate
582.1810	Sodium tripolyphosphate •
582.1901	Triacetin
582.1973	Beeswax
582.1975	Bleached beeswax
582.1978	Carnauba wax

Subpart C——Anticaking Agents

Section	Source compounds
582.2122	Aluminum calcium silicate
582.2227	Calcium silicate •
582.2437	Magnesium silicate
582.2727	Sodium aluminosilicate •
582.2729	Hydrated sodium calcium aluminosilicate
582.2906	Tricalcium silicate

Subpart D——Chemical Preservatives

582.3013 Ascorbic acid •
582.3021 Benzoic acid •
582.3041 Erythorbic acid •
582.3081 Propionic acid •
582.3089 Sorbic acid •
582.3109 Thiodipropionic acid •
582.3149 Ascorbyl palmitate •
582.3169 Butylated hydroxyanisole •
582.3173 Butylated hydroxytoluene •
582.3189 Calcium ascorbate •
582.3221 Calcium propionate •
582.3225 Calcium sorbate •
582.3280 Dilauryl thiodipropionate •
582.3336 Gum guaiac •
582.3490 Methylparaben •
582.3616 Potassium bisulfite •
582.3637 Potassium metabisulfite •
582.3640 Potassium sorbate •
582.3660 Propyl gallate •
582.3670 Propylparaben •
582.3731 Sodium ascorbate •
582.3733 Sodium benzoate •
582.3739 Sodium bisulfite •
582.3766 Sodium metabisulfite •
582.3784 Sodium propionate •
582.3795 Sodium sorbate •
582.3798 Sodium sulfite •
582.3845 Stannous chloride •
582.3862 Sulfur dioxide •
582.3890 Tocopherols •

Subpart E—Emulsifying Agents

Section	Source compounds	Section	Source compounds
582.4101	Diacetyl tartaric acid esters of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids •	582.4521	Monosodium phosphate derivatives of mono- and diglycerides of edible fats or oils, or edible fat-forming fatty acids •
582.4505	Mono- and diglycerides of edible fats or oils, or edible fat-forming acids •	582.4666	Propylene glycol (not in or on cat food, 21 CFR 589.1001) •

Subpart F—Nutrients and/or Nutritional Supplements[1]

[1]Amino acids listed in this subpart may be free hydrochloride salt, hydrated, or anhydrous form, where applicable.

Section	Source compounds	Section	Source compounds
582.5013	Ascorbic acid •	582.5273	Cystine
582.5017	Aspartic acid	582.5301	Ferric phosphate •
582.5049	Aminoacetic acid (glycine) •	582.5304	Ferric pyrophosphate •
582.5065	Linoleic acid	582.5306	Ferric sodium pyrophosphate
582.5118	Alanine	582.5308	Ferrous gluconate •
582.5145	Arginine •	582.5311	Ferrous lactate
582.5159	Biotin •	582.5315	Ferrous sulfate •
582.5191	Calcium carbonate •	582.5361	Histidine
582.5195	Calcium citrate	582.5370	Inositol •
582.5201	Calcium glycerophosphate	582.5375	Iron reduced •
582.5210	Calcium oxide •	582.5381	Isoleucine
582.5212	Calcium pantothenate •	582.5406	Leucine
582.5217	Calcium phosphate •	582.5411	Lysine •
582.5223	Calcium pyrophosphate	582.5431	Magnesium oxide •
582.5230	Calcium sulfate •	582.5434	Magnesium phosphate •
582.5245	Carotene •	582.5443	Magnesium sulfate •
582.5250	Choline bitartrate •	582.5446	Manganese chloride •
582.5252	Choline chloride •	582.5449	Manganese citrate •
582.5260	Copper gluconate •	582.5452	Manganese gluconate •
582.5271	Cysteine	582.5455	Manganese glycerophosphate

582.5458 Manganese hypophosphite
582.5461 Manganese sulfate •
582.5464 Manganous oxide •
582.5470 Mannitol
582.5475 Methionine •
582.5477 Methionine hydroxy analog and its calcium salts •
582.5530 Niacin •
582.5535 Niacinamide •
582.5580 D-Pantothenyl alcohol
582.5590 Phenylalanine
582.5622 Potassium chloride •
582.5628 Potassium glycerophosphate
582.5634 Potassium iodide •
582.5650 Proline
582.5676 Pyridoxine hydrochloride •
582.5695 Riboflavin •
582.5697 Riboflavin-5-phosphate •
582.5701 Serine
582.5772 Sodium pantothenate
582.5778 Sodium phosphate •
582.5835 Sorbitol
582.5875 Thiamine hydrochloride •
582.5878 Thiamine mononitrate •
582.5881 Threonine •
582.5890 Tocopherols •
582.5892 Alpha-tocopherol acetate •
582.5915 Tryptophane •
582.5920 Tyrosine •
582.5925 Valine
582.5930 Vitamin A •
582.5933 Vitamin A acetate •
582.5936 Vitamin A palmitate •
582.5945 Vitamin B12 •
582.5950 Vitamin D2 •
582.5953 Vitamin D3 •
582.5985 Zinc chloride •
582.5988 Zinc gluconate
582.5991 Zinc oxide •
582.5994 Zinc stearate
582.5997 Zinc sulfate •

Subpart G—Sequestrants

Section	Source compounds	Section	Source compounds
582.6033	Citric acid •	582.6625	Potassium citrate •
582.6085	Sodium acid phosphate	582.6751	Sodium citrate
582.6099	Tartaric acid	582.6754	Sodium diacetate
582.6185	Calcium acetate	582.6757	Sodium gluconate
582.6193	Calcium chloride •	582.6760	Sodium hexametaphosphate •
582.6195	Calcium citrate	582.6769	Sodium metaphosphate
582.6197	Calcium diacetate	582.6778	Sodium phosphate •
582.6199	Calcium gluconate •	582.6787	Sodium pyrophosphate
582.6203	Calcium hexametaphosphate	582.6789	Tetra sodium pyrophosphate •
582.6215	Monobasic calcium phosphate •	582.6801	Sodium tartrate
582.6219	Calcium phytate	582.6804	Sodium potassium tartrate
582.6285	Dipotassium phosphate	582.6807	Sodium thiosulfate
582.6290	Disodium phosphate •	582.6810	Sodium tripolyphosphate •
582.6386	Isopropyl citrate	582.6851	Stearyl citrate
582.6511	Monoisopropyl citrate		

Subpart H—Stabilizers

582.7115 Agar-agar
582.7133 Ammonium alginate
582.7187 Calcium alginate
582.7255 Chondrus extract •
582.7330 Gum arabic
582.7333 Gum ghatti
582.7339 Guar gum •
582.7343 Locust bean gum •
582.7349 Sterculia gum
582.7351 Gum tragacanth
582.7610 Potassium alginate
582.7724 Sodium alginate

582.10 Spices and Other Natural Seasonings and Flavorings

Botanical name of plant source is in the CFR.

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

582.20 Essential Oils, Oleoresins (Solvent-Free), and Natural Extractives (Including Distillates) As a Source of Flavor

Botanical name of plant source is in the CFR.

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

582.30 Natural Substances Used in Conjunction with Spices and Other Natural Seasonings and Flavorings

Botanical name of plant source is in the CFR.

Algae, brown (kelp)
Algae, red
Dulse

582.40 Natural Extractives (Solvent-Free) Used in Conjunction with Spices, Seasonings, and Flavorings

Botanical name of plant source is in the CFR.

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

582.50 Certain Other Spices, Seasonings, Essential Oils, Oleoresins, and Natural Extracts

Scientific name of source is in the CFR.

Ambergris
Castioreum
Civet (zibeth, zibet, zibetum)
Cognac oil, white and green
Musk (Tonquin musk)

582.60 Synthetic Flavoring Substances and Adjuvants

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, aldehyde*C*-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)
I-Malic acid
Methyl anthranilate (methyl-2-aminobenzoate)
Piperonal (3,4-methylenedioxy-benzaldehyde-heliotropin)
Vanillin

101. GRAS Notified Substances Intended for Animal Food

Section Editor—Nathan Price, ID

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 generally recognized as safe (GRAS) under the intended conditions of use. 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, and 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. This section is provided as a convenience for the State Feed Control Officials.

While the information on the substance and the intended use is specific to that provided by the notifier, other firms may use information within the notice along with other data specific to their substance to support the GRAS conclusion (see 21 CFR 570.3-570.280). Such other firms who conclude that an animal food substance is GRAS under the conditions of its intended use by relying on a posted GRAS notice submitted by another person shall carefully evaluate whether their production process, product specifications, and intended conditions of use fall within the parameters addressed by the referenced GRAS notice. GRAS conclusions are not legally required to be submitted to the FDA but may be voluntarily submitted in accordance with the GRAS Notice regulation (21 CFR Part 570.205). Nevertheless, firms that elect to make use of the GRAS provision must document their GRAS conclusions prior to marketing a substance for a particular intended use. State Feed Control Officials may request the GRAS Conclusion to support their registration or inspection duties.

Table 101.1 is adapted from the FDA Animal GRAS Notification website and includes ingredient definition information [substance, common or usual name (from the FDA response letter), and intended use (including use limitations, if any)]. For other information, see the FDA response letter for the GRAS Notice (available at link provided above).

At each AAFCO Ingredient Definitions Committee (IDC) meeting, the section editor will provide an updated list of animal food GRAS Notices that have been evaluated by the FDA and have received a no questions letter from the Agency. Firms making GRAS conclusions should be prepared to answer questions from the IDC or Association if needed. The listed notices below have been voted on by the IDC and accepted by the Association for publication in the *AAFCO Official Publication*.

Table 101.1. GRAS Notified Substances with No Questions Letters from the FDA

AGRN (select for detailed record)	Notifier	Substance	Common or Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
5 (PDF, 67 pages)	Emerald Carolina Chemicals LLC	Hydrophobic silica	Hydrophobic silica	As a defoaming component of a defoamer used in the removal of oil from condensed distillers solubles, at levels up to 20 ppm	Beef cattle, dairy cattle, poultry (turkey, broiler chickens, and egg laying hens), sheep, goats, and swine	May 12, 2011	FDA has no questions. (PDF, 3 pages)
6 (PDF, 57 pages)	Emerald Carolina Chemicals LLC	Polyethylene glycol (400) dioleate	Polyethylene glycol (400) dioleate	As an emulsifier component of a defoamer used in the removal of oil from condensed distillers, at levels up to 64 ppm	Beef cattle, dairy cattle, poultry (turkey, broiler chickens, and egg laying hens), sheep, goats, and swine	May 12, 2011	FDA has no questions. (PDF, 3 pages)
7 (PDF, 101 pages)	Emerald Carolina Chemicals LLC	Polyoxyethylene (20) sorbitan monostearate (polysorbate 60)	Polysorbate 60	As an emulsifier component of a defoamer used in the removal of oil from condensed distillers solubles, at levels up to 20 ppm	Beef cattle, dairy cattle, poultry (turkey, broiler chickens, and egg laying hens), sheep, goats, and swine	May 12, 2011	FDA has no questions. (PDF, 3 pages)

(continued)

AGRN (select for detailed record)	Notifier	Substance	Common or Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
14 (PDF, 576 pages)	DSM Nutritional Products	Phytase enzyme produced by an *Aspergillus oryzae* strain expressing a synthetic gene coding for a 6-phytase from *Citrobacter braakii*	Phytase	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	Poultry (turkey, broiler chickens, and egg laying hens)	Nov 14, 2012	FDA has no questions. (PDF, 3 pages)
15 (PDF, 505 pages)	DSM Nutritional Products	Phytase enzyme produced by an *Aspergillus oryzae* strain expressing a synthetic gene coding for a 6-phytase from *Citrobacter braakii*	Phytase	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	Swine	Aug 8, 2013	FDA has no questions. (PDF, 3 pages)
16 (PDF, 87 pages)	Metabolic Explorer	L-methionine 85% produced by a bioengineered *Escherichia coli* K-12	L-methionine 85%	Nutrient at levels up to 0.3% in animal feed	All animals	Jan 3, 2014	FDA has no questions. (PDF, 4 pages)

(continued)

AGRN (select for detailed record)	Notifier	Substance	Common or Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
17 (PDF, 170 pages)	DSM Nutritional Products	Canthaxanthin	Canthaxanthin	To be used in breeder hen diets at the rate of 6 mg/kg of feed as a nutritive antioxidant to support the development of chicks	Breeder hens used for hatching egg production	Jul 22, 2014	FDA has no questions. (PDF, 4 pages)
19 (PDF, 123 pages)	Freedom Health L.L.C.	L-Glutamine	L-Glutamine	Utility information not evaluated for GRAS, see FDA's letter for more information.	Post-weaning horses.	Mar 22, 2016	FDA has no questions. (PDF, 3 pages)
20 (PDF, 899 pages)	DSM Innovation Inc., BioProducts & Services Division	Inactivated modified *Saccharomyces cerevisiae*	*Saccharomyces cerevisiae* expressing xylose isomerase from *Piromyces* sp. E2	As a component of animal feed when used in the fermentation of corn to produce ethanol	Pets, 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	Apr 29, 2016	FDA has no questions. (PDF, 4 pages)

(continued)

AGRN (select for detailed record)	Notifier	Substance	Common or Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
21 (PDF, 598 pages)	Agrivida, Inc.	Ground grain obtained from a corn (*Zea mays*) variety that expresses an altered appA 6-phytase gene obtained from *Escherichia coli* strain K12	Phytase	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.	Poultry	Jul 28, 2016	FDA has no questions. (PDF, 4 pages)
24 (PDF, 194 pages)	CJ CheilJedang Corporation	L-methionine 90% produced by a bioengineered *Escherichia coli* K-12	L-methionine 90%	To be used as a nutrient in animal food.	All animals	Aug 17, 2017	FDA has no questions. (PDF, 4 pages)

(continued)

AGRN (select for detailed record)	Notifier	Substance	Common or Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
26 Part 1 (PDF, 385 pages) Part 2 (PDF, 190 pages) Part 3 (PDF, 191 pages)	KnipBio, Inc.	Dried *Methylobacterium extorquens* biomass	Dried *Methylobacterium extorquens* biomass	To be used as a source of protein in food for finfish species at a level up to 10% of the diet	Finfish species	Feb 7, 2018	FDA has no questions. (PDF, 5 pages)
27 (PDF, 177 pages)	Agrivida, Inc.	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)	Phytase	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.	Swine	Sep 6, 2018	FDA has no questions. (PDF, 4 pages)

(continued)

AGRN (select for detailed record)	Notifier	Substance	Common or Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
29 (PDF, 138 pages)	G-Science, Inc.	Clinoptilolite of sedimentary origin	Clinoptilolite of sedimentary origin	To be used as an anti-caking agent at levels up to 1% by weight in the complete diet.	Cattle, swine, goats, sheep, broiler chickens, turkeys for meat, cats and dogs	Dec 11, 2018	FDA has no questions. (PDF, 5 pages)
30 (PDF, 307 pages)	Aker BioMarine Antarctic	*Euphausia superba* (krill) meal	Krill meal	To be used as a source of protein and lipid in food for adult dogs at a maximum inclusion level of 3% by weight of dry food.	Adult dogs	Feb 19, 2019	FDA has no questions. (PDF, 4 pages)
31 (PDF, 208 pages)	Agrivida Inc.	Ground grain obtained from a corn (*Zea mays*) variety that expresses an altered AC1 beta-gluconase gene obtained from an environmental DNA library (transformation event FG259)	Beta-gluconase	To decrease viscosity of digesta in poultry consuming feeds containing high amounts of soluble non-starch polysaccharides when used to provide 200–400 beta-gluconase activity units per kg of complete feed.	Poultry	Jul 15, 2019	FDA has no questions. (PDF, 4 pages)

(continued)

AGRN (select for detailed record)	Notifier	Substance	Common or Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
32 (PDF, 105 pages)	Agrivida Inc.	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)	Phytase	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.	Swine and poultry	Jul 24, 2019	FDA has no questions. (PDF, 4 pages)
33 (PDF, 64 pages)	KnipBio Inc.	Dried *Methylobacterium extorquens* biomass	Dried *Methylobacterium extorquens* biomass	To be used as a source of protein in food for aquaculture crustacean species at a level up to 6% of the diet.	Crustacean species	Sep 20, 2019	FDA has no questions. (PDF, 4 pages)

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AGRN (select for detailed record)	Notifier	Substance	Common or Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
34 (PDF, 494 pages)	CJ CheilJedang Corporation	Dried L-threonine fermentation product (≥75% L-threonine) produced by bioengineered *Cornybacterium glutamicum*	Dried L-threonine fermentation product	To be used as a source of the nutrient L-threonine in food for livestock and poultry.	Livestock and poultry	Nov 26, 2019	FDA has no questions. (PDF, 4 pages)
36 Part 1 (PDF, 1,023 pages) Part 2 (PDF, 1,023 pages)	Veramaris USA LLC	Marine microalgae oil from *Schizochytrium* sp.	Marine microalgae oil	To be used as a source of long chain polyunsaturated fatty acids (PUFAs), docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) in canned and dry/extruded dog foods	Dogs	Jan 2, 2020	FDA has no questions. (PDF, 4 pages)

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AGRN (select for detailed record)	Notifier	Substance	Common or Usual Name	Intended Use	Intended Species	Date of Filing	FDA's Letter (select to view letter)
37 Part 1 (PDF, 400 pages) Part 2 (PDF, 585 pages)	Veramaris USA LLC	Marine microalgae oil from *Schizochytrium* sp.	Marine microalgae oil	To be used as a source of long chain polyunsaturated fatty acids (PUFAs), docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) in canned and dry/ extruded cat foods	Cats	Jun 29, 2020	FDA has no questions. (PDF, 4 pages)