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Ingredient Definitions Committee 2/12/16 Report

IDC recommendations to the Board and Association Members. *Text for the OP is in attachment A at the end of this document. This document is 44 pages long, please consider not printing it to review.*

1. Publish the tentative definition in the OP for T33.21 Yellow Grease, Feed Grade.
2. Replace the current definition of 87.1 Algae Meal with the official definition (from the color additive definition 21 CFR 73.275) in the OP of 87.1 Dried Algae Meal.
3. Add the new official definition (from the color additive definition 21 CFR 73.355) in the OP of 87.36 Phaffia Yeast.
4. Publish official definitions for the following color additives in the OP:
 - 87.100 FD&C Blue No 1.
 - 87.102 FD&C Blue No 2.
 - 87.103 FD&C Green No 3.
 - 87.104 FD&C Red No 3.
 - 87.105 FD&C Red No 40.
 - 87.106 FD&C Yellow No 6.
 - 87.107 FD&C Yellow No 5.
 - 87.110 Annatto Extract
 - 87.112 Astaxanthin dimethyldisuccinate
 - 87.114 Astaxanthin
 - 87.116 Caramel
 - 87.118 Carmine
 - 87.120 Carrot Oil
 - 87.122 Cochineal Extract
 - 87.124 Corn Endosperm Oil
 - 87.126 Dehydrated Beets
 - 87.128 Fruit Juice
 - 87.130 Haematococcus algae meal
 - 87.132 Paprika Oleoresin
 - 87.134 Paprika
 - 87.136 Paracoccus pigment
 - 87.138 Riboflavin
 - 87.140 Saffron
 - 87.142 Synthetic Iron Oxide
 - 87.144 Tagetes (Aztec Marigold) Extract
 - 87.145 Tagetes (Aztec Marigold) Meal
 - 87.146 Titanium Dioxide
 - 87.148 Toasted Partially Defatted Cooked Cottonseed Flour



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- 87.150 Tomato Lycopene Concentrate
- 87.152 Tomato Lycopene Extract
- 87.154 Turmeric Oleoresin
- 87.155 Turmeric
- 87.156 Ultramarine Blue
- 87.158 Vegetable Juice
- 87.160 β -Apo-8'-carotenal
- 87.164 β -Carotene

5) Renumber Section 73 ingredients of the OP according to the list in attachment A, and leave the cross-reference to the old number there for 2 years and then remove cross-reference:

6) Publish the modified definition in the OP for 60.73 Salts of Volatile Fatty Acids.



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Minutes of 2/12/2016 IDC Webinar Meeting: (Meeting was web recorded and is posted in the Feed BIN.)

Role:

Committee Members: Bob Church, Jan Jarman (thinking of becoming a member), Richard Ten Eyck, Alan Harrison, April Hunt, Steve Gramlich, Charlotte Conway, David Dressler, Mark LeBlanc, Jacob Fleig, Mika Alewynse

Advisors: Leah Wilkinson, Kristi Smedley, Jean Hofve, Susan Thixton, David Meeker, Vince Sewalt, Mollie Morrissette

The meeting was convened at 8:30 am PST by Chairperson Ten Eyck.

1. Approve Minutes of last meeting

Steve Gramlich moves to ACCEPT the minutes from the January meeting. Jacob Fleig seconds. Motion PASSES.

2. Work Group Reports

- a) AAFCO Affirmed GRAS workgroup report. Richard Ten Eyck informed the IDC that the GRAS Workgroup met this week to start drafting the survey requested at the January meeting; the Workgroup plans to complete the survey draft in the next two weeks or so. If any questions, please post these to IDC Team.

3. New Definitions, deletes & edits:

New Term: Animal Food – Ali Kashani and Charlotte Conway are working on this. Animal food is the more modern term and feed is a more historic term in FDA's vernacular. Having both terms defined is still desired. *Under consideration nothing was proposed or voted on in terms:*

- a) **Animal food** – Food for animals other than humans and includes pet food, specialty pet food, nutritional supplements, raw materials and ingredients. No Motion
- b) **Feed(s)** – Edible materials(s) which are consumed by animals, **other than humans**, and contribute energy and/or nutrients to the animal's diet. (2016 OP pg 225) No Motion
- c) T33.21 Yellow Grease, Feed Grade. Steve Gramlich moves to ACCEPT this definition. Jacob Fleig seconds. Dave Meeker said it is fine with NRA. Motion PASSES.
- d) ~~List of standard food names from USDA – Richard – need form~~
- e) 87.1 Dried Algae Meal. Steve Gramlich moves to ACCEPT definition. Jacob



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Fleig seconds. Mika Alewynse explains that this is a more careful definition of this color ingredient and is the same language as is in the Color Additive definition. Motion PASSES.

- f) 87.36 Phaffia yeast. Jacob Fleig moves to ACCEPT this color additive definition. Steve Gramlich seconds. Motion PASSES.
- g) =====+++++ Accept as a group? ++++
Angel Thompson mentioned that some are misspelled, especially turmeric, and this was corrected. The purpose is to include most of the CFR-listed color additives (evaluated through the Color Additive Petition process) into the AAFCO OP; however, this is not the complete list because some of these additives are not accepted for use in animal food. Each regulation includes the CFR text so that firms will see the appropriate information. Mika Alewynse pointed out that there was a discrepancy in the regulation for canthaxanthin in that it is already defined in the OP as a special purpose ingredient. It is not included in this current list of color additives since Mika Alewynse is seeking clarification of this discrepancy.

Steve Gramlich moves to ACCEPT this group h) through qq) of official definitions. Jacob Fleig seconds. Motion PASSES.

- h) 87.100 FD&C Blue No 1.
- i) 87.102 FD&C Blue No 2.
- j) 87.103 FD&C Green No 3.
- k) 87.104 FD&C Red No 3.
- l) 87.105 FD&C Red No 40.
- m) 87.106 FD&C Yellow No 6.
- n) 87.107 FD&C Yellow No 5.
- o) 87.110 Annatto Extract
- p) 87.112 Astaxanthin dimethyldisuccinate
- q) 87.114 Astaxanthin
- r) 87.116 Caramel
- s) 87.118 Carmine
- t) 87.120 Carrot Oil
- u) 87.122 Cochineal Extract
- v) 87.124 Corn Endosperm Oil
- w) 87.126 Dehydrated Beets
- x) 87.128 Fruit Juice
- y) 87.130 Haematococcus algae meal
- z) 87.132 Paprika Oleoresin
- aa) 87.134 Paprika
- bb) 87.136 Paracoccus pigment
- cc) 87.138 Riboflavin
- dd) 87.140 Saffron
- ee) 87.142 Synthetic Iron Oxide
- ff) 87.144 Tagetes (Aztec Marigold) Extract



- gg) 87.145 Tagetes (Aztec Marigold) Meal
 - hh) 87.146 Titanium Dioxide
 - ii) 87.148 Toasted Partially Defatted Cooked Cottonseed Flour
 - jj) 87.150 Tomato Lycopene Concentrate
 - kk) 87.152 Tomato Lycopene Extract
 - ll) 87.154 Turmeric Oleoresin
 - mm) 87.155 Turmeric
 - nn) 87.156 Ultramarine Blue
 - oo) 87.158 Vegetable Juice
 - pp) 87.160 β -Apo-8'-carotenal
 - qq) 87.164 β -Carotene
 - rr) ++++++
 - ss) Renumber section 73 transfers – Richard Steve Gramlich moved to transfer the proposed ingredients into section 73 in the AAFCO OP, and to leave the cross-reference to the old number there for 2 years and then remove reference. Mark LeBlanc seconds. Motion passes.
Many questions about these feed ingredients. Mika Alewynse thinks that the acidifiers list may be incomplete (e.g., benzoic acid is not listed).
 - tt) 60.73- Salts of Volatile Fatty Acids- editorial change –Dave Dressler moves to approve this change; Mark LeBlanc seconds. Motion passes. Kristi Smedley pointed out that some definitions include the entire regulation and other definitions contain more limited text. What is the correct approach for the approved Food Additives? Charlotte Conway said that the specifications (heavy metals, etc) are missing from this definition. Richard Ten Eyck said that he will add the CFR reference and dates as now in the AAFCO OP.
4. Discussions:
- a) Hemp in Feed – Presentation on industrial hemp products, how they are made, how used, and typical product specifications was made by Timothy Bonnar of Hemp Oil Canada. Charlotte Conway said that FDA is working on what is the appropriate regulatory path for hemp products. In Oregon, hemp is an undefined ingredient not allowed in animal food.
 - ~~b) Values in Footer on Vitamin Table ; original source? Use human or animal bio-availabilities? – Tom~~
 - ~~c) Montmorillonite update for Industry – Tom~~
 - d) Fabricated Meat background information. Is a Feed Term needed? – Susan Thixton (TAPF) informed that this is commonly used as non-meat product in human food. Technology has progressed tremendously. They would like AAFCO to develop a definition to address that this product is used in pet foods and that consumers want to find out what is in it. Does AAFCO want to develop a definition? They need industry to provide comment. Susan Thixton will get together with Ali Kashani to discuss this matter and put



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together a path forward.

- e) Materials NOT suitable for animal feed list in the BIN or website. Richard Ten Eyck explained that the goal here is to assemble a list of what ingredients are not allowed. If it is not listed, does this mean that it is not allowed? Rather the point here is to include those substances that have been reviewed by the IDC and found to be not suitable for use in feed. Per Kristi Smedley, some of these ingredients are already listed in section 589 (?? Not in the OP) (Maybe this is in CFR but is not in the AAFCO). Both Kristi and Mika Alewynse pointed out that very few ingredients have been determined to be disallowed. Often ingredients are tabled pending further information requested from the Sponsor.

Richard Ten Eyck is considering holding another IDC meeting at the end of April, prior to the AAFCO Board Meeting in early May.

Needs Vice Chair.

Needs Investigators for NPN and for Collective Terms.

Meeting was adjourned 10 AM Pacific.

Minutes were accepted on 4/8/16 by evote

Attachment A for the 2/12/16 IDC meeting:

T33.21 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 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." 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."

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 120 grams per head per day~~ *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 xxxx) Reg 21 CFR 573.914

Section 73 edits: (page 430 2015 OP revision 1)

73.001 (old 73.1) Technical Additives table

Acidifiers (73.020- 029)

73.020 (87.26) Ammonium Formate

73.025 (87.27) Formic Acid

Antimicrobial Agents (73.030-039)

73.030 (old 87.15) Formaldehyde

Anticaking Agents (73.040-060)

73.040 (old 87.12) Bentonite

73.042 (old 87.28) Castor Oil

73.044 (old 87.17) Perlite



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73.046 (old 87.3) Silicon Dioxide
73.048 (old 87.13) Sodium Bentonite
73.050 (old 87.4) Verxite (incl flake and grits)

Binders (73.106-130)

73.107 (old 87.2) Lignin Sulfonate
T73.109 (old T73.300) Sodium salts of Fatty Acids Stays in tentative section
T73.111 (old T73.301) Potassium Salts of Fatty Acids Stays in tentative section
....

Biofuel Production (73.090-104)

73.100 Yeast for Production of Distillers Products

Emulsifiers (73.200-220)

73.200 Xanthan gum

Floculants (73.221-240)

73.221 (old 87.16) Chitosan
73.223 (old 87.21) Kraft Lignin

Nutritional Diluents (73.241-249)

73.241 (old 87.18) Reed-Sedge Peat

Pelleting Aids (73.300-340)

73.305 (old 87.24) Hide Glue
73.307 (old 87.6) Rice By-Products Fractions
73.309 (old 87.19) Urea Formaldehyde Condensation Polymer
73.105 Sodium Hydroxide Lignin Dehydrated

Surfactants (73.341-360)

73.341 (old 87.10) Poloxalene

Thickening agents (73.370-390)

73.370 (old 87.23) Cassia Gum

moved 73.105,

can we double list in 2 or more use categories? –yes if the full definition is with it.



Delete the current language in 87.1 and replace it with:

87.1 Algae Meal – The color additive, 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 percent 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.

(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

Add these new Official Definitions:

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*.



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(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 percent.

(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 (adopted xxxxx)

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 percent.

Water-insoluble matter, not more than 0.2 percent.

Leuco base, not more than 5 percent.

Sum of o-, m-, and p-sulfobenzaldehydes, not more than 1.5 percent.

N-Ethyl,N-(m-sulfobenzyl)sulfanilic acid, not more than 0.3 percent.

Subsidiary colors, not more than 6.0 percent.

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 percent.

(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.

21 CFR 74.101



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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 percent.

Water insoluble matter, not more than 0.4 percent.

Isatin-5-sulfonic acid, not more than 0.4 percent.

5-Sulfoanthranilic acid, not more than 0.2 percent.

Disodium salt of 2-(1,3-dihydro-3-oxo-7-sulfo-2H-indol-2-ylidene)-2,3-dihydro-3-oxo-1H-indole-5-sulfonic acid, not more than 18 percent.

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 percent.

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 percent.

(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.



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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.

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 two molecules from a mixture consisting principally of 3-[(ethylphenylamino)methyl] benzenesulfonic 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:



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Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Water-insoluble matter, not more than 0.2 percent.

Leuco base, not more than 5 percent.

Sum of 2-,3-,4-formylbenzenesulfonic acids, sodium salts, not more than 0.5 percent.

Sum of 3- and 4-[[ethyl(4-sulfophenyl)amino]methyl] benzenesulfonic acid, disodium salts, not more than 0.3 percent.

2-Formyl-5-hydroxybenzenesulfonic acid, sodium salt, not more than 0.5 percent.

Subsidiary colors, not more than 6 percent.

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 percent.

(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.

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 imidinated 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:



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Volatile matter (at 135 °C.) and chlorides and sulfates (calculated as the sodium salts), total not more than 13 percent.

Water-insoluble matter, not more than 0.2 percent.

Unhalogenated intermediates, total not more than 0.1 percent.

Sodium iodide, not more than 0.4 percent.

Triiodoresorcinol, not more than 0.2 percent.

2(2',4'-Dihydroxy-3', 5'-diiodobenzoyl) benzoic acid, not more than 0.2 percent.

Monoiodofluoresceins not more than 1.0 percent.

Other lower iodinated fluoresceins, not more than 9.0 percent.

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 percent.

(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.

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:



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Sum of volatile matter (at 135 °C.) and chlorides and sulfates (calculated as sodium salts), not more than 14.0 percent.

Water-insoluble matter, not more than 0.2 percent.

Higher sulfonated subsidiary colors (as sodium salts), not more than 1.0 percent.

Lower sulfonated subsidiary colors (as sodium salts), not more than 1.0 percent.

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 percent.

Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid (Schaeffer's salt), not more than 0.3 percent.

4-Amino-5-methoxy-o-toluenesulfonic acid, not more than 0.2 percent.

Disodium salt of 6,6'-oxybis(2-naphthalene-sulfonic acid), not more than 1.0 percent.

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 percent.

(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.

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



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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 percent.

Water insoluble matter, not more than 0.2 percent.

Sodium salt of 4-aminobenzenesulfonic acid, not more than 0.2 percent.

Sodium salt of 6-hydroxy-2-naphthalenesulfonic acid, not more than 0.3 percent.

Disodium salt of 6,6'-oxybis[2-naphthalenesulfonic acid], not more than 1 percent.

Disodium salt of 4,4'-(1-triazene-1,3-diyl)bis[benzenesulfonic acid], not more than 0.1 percent.

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 percent.

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 percent.

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 percent.

(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.



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(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.

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 percent.

Water-insoluble matter, not more than 0.2 percent.

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 percent.

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 percent.

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 percent.

Sum of 4,5-dihydro-5-oxo-1-phenyl-4-[(4-sulfophenyl)azo]-1H-pyrazole-3-carboxylic acid, disodium salt, and 4,5-dihydro-5-oxo-4-(phenylazo)-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylic acid, disodium salt, not more than 0.5 percent.

4-Aminobenzenesulfonic acid, sodium salt, not more than 0.2 percent.



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4,5-Dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylic acid, disodium salt, not more than 0.2 percent.

Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylate, sodium salt, not more than 0.1 percent.

4,4'-(1-Triazene-1,3-diyl)bis[benzenesulfonic acid], disodium salt, not more than 0.05 percent.

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 percent.

(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.

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



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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



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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 percent solution in chloroform, complete and clear.
- (3) Absorption maximum wavelength 484-493 nanometers (in chloroform).
- (4) Residue on ignition, not more than 0.1 percent.
- (5) Total carotenoids other than astaxanthin dimethyldisuccinate, not more than 4 percent.
- (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 percent.

(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 milligrams per kilogram (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.



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(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 percent solution in chloroform, complete and clear.

Absorption maximum wavelength 484-493 nanometers (in chloroform).

Residue on ignition, not more than 0.1 percent.

Total carotenoids other than astaxanthin, not more than 4 percent.

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 percent.

(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



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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.



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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 percent.

Ash, not more than 12.0 percent.

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 percent.

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.



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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 carotenoids 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



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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 percent.

Total solids, not less than 5.7 and not more than 6.3 percent.

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 percent.

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



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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 conforms to the following specifications:

Total fatty acids, not less than 85 percent.

Iodine value, 118 to 134.

Saponification value, 165 to 185.

Unsaponifiable matter, not more than 14 percent.

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

Editing note: The existing definition for corn endosperm oil in definition 33.6 should be deleted when this definition is added to the Official Publication. The current definition in the OP refers to an outdated regulation. The current regulation for corn endosperm oil can be found in 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



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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 percent.

Acid insoluble ash, not more than 0.5 percent.

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.



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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 percent.

(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



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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



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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.



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(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 percent.

(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

Editing note: The existing listing of Paracoccus pigment in Table 87.5 should be deleted when this definition is added to the Official Publication.



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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, 3d Ed. (1981), pp. 262-263, 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, 3d Ed. (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.



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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 percent 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



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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 percent 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 percent – 27 percent
- Hexane residue: not more than 25 p.p.m.

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 additives 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.



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(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

Editing note: The existing listing of Tagetes (Aztec Marigold) Meal and Extract in Table 87.5 should be deleted when this definition is added to the Official Publication.

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 percent 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

Editing note: The existing listing of Tagetes (Aztec Marigold) Meal and extract in Table 87.5 should be deleted when this definition is added to the Official Publication.

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 percent 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 percent.

Water soluble substances, not more than 0.3 percent.

Acid soluble substances, not more than 0.5 percent.

TiO_2 , not less than 99.0 percent 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 percent 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.



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(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 percent 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



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(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 percent 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



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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.



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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 sulfo-silicate having the approximate formula $\text{Na}_7\text{Al}_6\text{Si}_6\text{O}_{24}\text{S}_3$.

(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 percent 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



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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 percent solution in chloroform, clear.

Melting point (decomposition), 136 °C.-140 °C. (corrected).

Loss of weight on drying, not more than 0.2 percent.

Residue on ignition, not more than 0.2 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 1 part per million.

Assay (spectrophotometric), 96-101 percent.

(c) Uses and restrictions.



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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 percent solution in chloroform, clear.

Loss of weight on drying, not more than 0.2 percent.

Residue on ignition, not more than 0.2 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Assay (spectrophotometric), 96-101 percent.

(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.



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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