

# Color Additives Used in Animal Food



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# What are Color Additives?

- ▶ Defined in Federal Food, Drug, and Cosmetic Act (the Act)
  - ▶ Any dye, pigment or substance which when added or applied to a food, drug or cosmetic, or to the human body, is capable (alone or through reactions with other substances) of imparting color
  - ▶ Includes substances that when fed to animals, impart color to meat, milk, or eggs
  - ▶ Includes “chemical” and “food-like” substances
    - ▶ FD&C Blue No. 1, beet juice

# Regulation of Color Additives

- ▶ Who is responsible?
  - ▶ FDA's Center for Food Safety and Applied Nutrition (CFSAN)
    - ▶ Even for animal foods
- ▶ How are they regulated?
  - ▶ See 21 CFR 70 (human food regulation)
  - ▶ Color additive petition process
    - ▶ Described in 21 CFR 71
    - ▶ Defined separately from food additives in Act, so color additives cannot be generally recognized as safe (GRAS)

# Color Additives (cont)

- ▶ Color additives are, by definition, “artificial”
  - ▶ 21 CFR 501.22(a)(4)
    - ▶ The term *artificial color* or *artificial coloring* means any color additive as defined in 21 CFR 70.3(f)
    - ▶ For animal food, there are no “natural” color additives
- ▶ All approved color additives (colors) are in CFR
  - ▶ 21 CFR 73 or 21 CFR 74
  - ▶ No enforcement discretion
    - ▶ Some approvals are included in AAFCO Official Publication

# Use of Colors

- ▶ Colors approved for specific uses
  - ▶ Foods, drugs, cosmetics, and medical devices
    - ▶ Separate lists (subparts) for each
  - ▶ Cannot use colors for drugs, cosmetics, or devices in animal food
    - ▶ Except if approved as part of New Animal Drug Application (NADA)

# Three Classes of Colors

## ▶ Certified colors

- ▶ Synthetic manufacturing process ; used because impart intense, uniform color and blend more easily for different hues
- ▶ Approved ones are listed in 21 CFR 74
- ▶ Each batch of these colors must be certified by CFSAN's Color Certification Branch that batch has passed analyses of its composition and purity (21 CFR 80)
- ▶ If batch is not FDA-certified, it cannot be used
  - ▶ Concern with imported products

# Classes of Colors (cont)

- ▶ Certified provisionally listed colors
  - ▶ Synthetic manufacturing process, including salts
  - ▶ Pertinent regulations are 21 CFR 81 and 82
- ▶ Includes “Lakes” of certain colors in 21 CFR 74
- ▶ Use in food must conform to requirements of pertinent regulation in 21 CFR 74 and 82
- ▶ Each batch must be certified

# Classes of Colors (cont)

## ▶ Colors exempt from certification

- ▶ Pigments/ substances derived from sources, such as vegetables and other plants, minerals, algae, or animals
- ▶ Approved colors listed in 21 CFR 73
- ▶ Examples include:
  - ▶ Annatto extract (yellow), dehydrated beets (bluish-red to brown), caramel (yellow to tan), and tagetes meal and extract (enhance yellow color of chicken skin and eggs)



# Colors Approved for Food

- ▶ Colors approved for use in foods
  - ▶ 21 CFR 73, subpart A – Foods
  - ▶ 21 CFR 74, subpart A – Foods
    - ▶ 21 CFR 82 – refers back to 21 CFR 74
  - ▶ Regulations are very specific about:
    - ▶ Color composition, including diluents, preservatives
    - ▶ Use in what type of food
    - ▶ Maximum addition rate
    - ▶ Labeling requirements
  - ▶ Use in food must meet requirements of regulation

# Certified Colors

- ▶ 7 can be used in animal food
  - ▶ Only after each batch is certified by FDA
- ▶ Must be approved for coloring foods “generally”
  - ▶ 74.101 – FD&C Blue No. 1
  - ▶ 74.102 - FD&C Blue No. 2
  - ▶ 74.203 - FD&C Green No. 3
  - ▶ 74.303 - FD&C Red No. 3
  - ▶ 74.340 - FD&C Red No. 40
  - ▶ 74.705 - FD&C Yellow No. 5
  - ▶ 74.706 - FD&C Yellow No. 6

# Colors Exempt from Certification

- ▶ Most commonly used in animal food
- ▶ Most can be used in animal food
- ▶ Animal food uses include:
  - ▶ Approved for coloring foods “generally”
  - ▶ Specific target animal food use stated
  - ▶ Are intended to color meat, milk, or eggs when fed
- ▶ Color and use must conform to requirements in regulation

# Colors Exempt from Certification (cont)

- ▶ Colors approved to color meat, milk, or eggs
  - ▶ Approved for specific animal classes and species
    - ▶ Salmonid fish (salmon, trout)
    - ▶ Chicken skin (broilers)
    - ▶ Eggs (layers)
  - ▶ Use in animal food must follow regulation due to human food safety concerns
    - ▶ Many of these colors have total maximum use rate from all sources
    - ▶ Human food product may also need to be labeled as containing color

# Labeling when Colors are Present

- ▶ Colors must be included in label's ingredients list in descending order of predominance by weight in product
- ▶ Labeling requirements are in 21 CFR 501.22
- ▶ Use of color must be disclosed
  - ▶ 21 CFR 501.22(c) - “A statement of ... artificial coloring ... shall be placed on the food, or on its container ... as may be necessary to render such statement likely to be read by the ordinary individual under customary conditions of purchase and use of such food”

# Changes to Labeling

- ▶ How colors are to be declared changed recently
  - ▶ Federal Register notice of final rule (76 FR 71248)
    - ▶ Effective date - November 18, 2013
  - ▶ New paragraph added
    - ▶ 21 CFR 501.22(k)
    - ▶ Reinforces colors must be declared as such

“The label of an animal food to which any coloring has been added shall declare the coloring in the statement of ingredients in the manner specified in paragraphs (k)(1) and (k)(2) of this section.”

# Declaring Certified Colors

## ▶ Certified colors

- ▶ Must be declared in accordance with name in CFR, except “FD&C” or “No.” may be omitted
  - ▶ FD&C Blue No. 1 may be declared as:  
FD&C Blue No. 1, FD&C Blue 1, Blue No. 1, or Blue 1
- ▶ If color is a Lake, it must be declared as such
  - ▶ FD&C Blue No. 1 Lake, FD&C Blue 1 Lake, Blue No. 1 Lake, or Blue 1 Lake

# Declaring Colors (cont)

- ▶ Colors exempt from certification
  - ▶ Must follow pertinent regulation for labeling
  - ▶ If permitted, may be declared as:
    - ▶ Coloring, artificial color, artificial color added, or color added
    - ▶ Another term that makes it clear color was added
    - ▶ “Colored with \_\_\_\_\_” or “\_\_\_\_\_ color” with blank filled in with name of color from 21 CFR 73



# Declaring Colors (cont)

- ▶ 21 CFR 501.22(a)(2) addresses spices used as colors
  - ▶ Paprika, turmeric, saffron and other spices that are also approved colors in 21 CFR 73, may be declared as:
    - ▶ “Spice and coloring”
    - ▶ Their common or usual name
      - ▶ “Colored with \_\_\_\_\_” or “\_\_\_\_\_ color”
- ▶ Another point
  - ▶ Some colors contain ethoxyquin, which must also be disclosed in ingredients list - 21 CFR 573.380

# More Information

- ▶ Guidance for Industry #223 Small Entity Compliance Guide, Declaring Color Additives in Animal Foods

<http://www.fda.gov/downloads/animalveterinary/guidance/complianceenforcement/guidanceforindustry/ucm369965.pdf>

# Thank You - Any Questions?



# Sections of a Color Regulation

- ▶ Astaxanthin – 21 CFR 73.35
  - ▶ Chemical identity
  - ▶ Specifications for minimum color, diluents, chemical composition, and impurities
  - ▶ Approved for use only in feed of salmonid fish to enhance pink/orange-red color of the fish itself
  - ▶ Color cannot exceed 80 mg/ kg feed
  - ▶ Labeling required to bear expiration dates
  - ▶ Labeling about presence of color required for feed and human food product (fish)