



2014 FDA/JIFSAN Food and Nutrition Webinar – Color Additives in Foods

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Outline

- Definition of color additive
- Color additives permitted in foods
- Declaration of color additives on food labels
- FDA's enforcement of the requirements for color additives
- Resources for color additives

Definition of color additive

- A color additive is a substance that imparts color to a food, drug, cosmetic, or medical device
- FDA has regulatory responsibilities for all of these products when they are marketed in the U.S.
- FDA must pre-approve the color additives used in FDA-regulated products



Types of color additives

- Water-soluble dyes
- Extracts, spices, and mineral compounds
- Lakes – insoluble pigments formed by chemically reacting water-soluble dyes with precipitants and substrata
- Mixtures – color additives combined with other components by simple mixing



Why do we use food coloring?



Purposes of food coloring

- To provide identity to foods
 - Red coloring of maraschino cherries (naturally beige)
 - Candy flavors
- For effect
 - Children's cereals
 - Green ketchup
 - Cake decorations
- To mask natural variations in color
 - Citrus Red No. 2 in orange skins
- To enhance naturally occurring colors
 - Astaxanthin in salmon feed
- To protect products from damage or color loss
 - Light, air, moisture
 - Temperature extremes, other storage conditions



Color additives in foods

- FDA does not consider any color additives to be “natural”
 - All color additives are artificially added to foods

- Food ingredients that contribute their own natural colors are not color additives
 - Examples: strawberries, green or red peppers, chocolate



Color additive approval

- Color additives must be petitioned for FDA approval
- FDA lists approved color additives in the Code of Federal Regulations
- Color additives are listed for specific uses
 - Foods generally or specific foods
- Four requirements for listing color additives
 - Probable exposure from use
 - Cumulative effect in the diet
 - Evaluation of safety by qualified experts
 - Analytical methods to assure purity



Color additives permitted in foods

- “FD&C” color additives
 - Synthetic organic dyes and pigments
 - “Synthetic” means man-made
 - “Organic” means made of carbon, hydrogen, nitrogen, oxygen, and sulfur
 - Required to be batch certified by FDA
 - Assures conformity to purity requirements
 - Strict limitations for lead, arsenic, and mercury
 - Not much dye needed to achieve desired coloring



Common names for FD&C color additives

Common name:

- Allura Red AC
- Brilliant Blue FCF
- Erythrosine
- Fast Green FCF
- Indigotine
- Sunset Yellow FCF
- Tartrazine

Certified as:

- FD&C Red No. 40
- FD&C Blue No. 1
- FD&C Red No. 3
- FD&C Green No. 3
- FD&C Blue No. 2
- FD&C Yellow No. 6
- FD&C Yellow No. 5























Other color additives permitted in foods

- Non-“FD&C” color additives
 - Generally derived from plant or mineral sources
 - One insect source
 - May be synthesized or chemically processed
 - Not required to be batch certified
 - Must conform to purity requirements
 - Strict limitations for lead, arsenic, and mercury
 - Relatively large amounts may be needed to achieve desired coloring



Non-“FD&C” color additives permitted in foods

- Extracts
 - Annatto extract 
 - Carrot oil 
 - Cochineal extract 
 - Grape color extract 
 - Tomato lycopene extract 
- Insoluble pigments
 - Carmine 
 - Mica-based  pearlescent pigments
- Spices
 - Paprika 
 - Saffron 
 - Turmeric 
- Others
 - Caramel 
 - Dehydrated beets 
 - Fruit juice    
 - Vegetable juice  

How many color additives are permitted in food products marketed in the U.S.?

Multiple Choice:

- A. 20
- B. 50
- C. 200



Nutrition Facts
Serving Size 1 Cup (28g)
Serving Per Container about 3

New listings for food color additives

- Mica-based pearlescent pigments
 - Titanium dioxide chemically bonded to mica
 - Sparkle effect with various shades
 - May be used in cereals, frostings, candies, chewing gum
 - New use in distilled spirits containing 18-23% alcohol
- Spirulina extract
 - New blue color additive
 - Aqueous extract of cyanobacterium
 - May be used in candy, chewing gum, yogurt, desserts²⁹



Color additive regulations

- Listed color additives
 - 21 CFR Part 73
 - Non-“FD&C” color additives
 - 21 CFR Part 74
 - “FD&C” color additives
 - 21 CFR Part 82
 - Most “FD&C” color additive lakes
- Other color additive regulations
 - 21 CFR Parts 70, 71, 80, and 81



Declaration of color additives on food labels

- Artificial coloring must be declared on food labels
 - 21 CFR 101.22(k)
- “FD&C” color additives must be declared by their listed names or appropriate abbreviations
 - FD&C Red No. 40
 - Yellow 5 Lake
- Alternative names may be declared in parentheses
 - European E numbers, Colour Index (C.I.) numbers
- Most non-“FD&C” color additives may be declared as “Artificial color” or “Color added” or by their listed names³¹



Some specific requirements for declaring color additives on food labels

- Color additives do not have to be declared on the labels of butter, cheese, and ice cream
 - Unless specifically required in 21 CFR parts 73 or 74
- Cochineal extract and carmine
 - Required to be declared by their listed names on all food labels
- FD&C Yellow No. 5
 - Required to be declared on all food labels
- These three are possible allergens or sensitizers



FDA's enforcement of color additive requirements

- Authorized by Federal Food, Drug, and Cosmetic Act and other applicable laws
- Adulteration provisions
- Misbranding provisions
- Apply to domestic and imported products
 - Imported products only need to have the “appearance” of a violation



Common color additive violations

- Adulteration
 - Uncertified material used in a product
 - Certified color additives declared as “permitted color,” “artificial color,” or “color added”
 - Non-permitted color additives

- Misbranding
 - Added color on ingredient label but not on finished product label
 - *Except:* Not declaring cochineal extract, carmine, or FD&C Yellow No. 5 always makes a product adulterated



Some non-permitted color additives permitted in food in other countries

- Amaranth (E123, C.I. 16185)
- Anthocyanins
 - In the U.S., fruit juice and grape extracts are permitted in food
- Azorubine/Carmoisine (E122, C.I. 14720)
- Curcumin (E100, C.I. 75300)
 - In the U.S., turmeric and turmeric oleoresin are permitted in food
- Green S (E142, C.I. 44090)
- Patent Blue V (E131, C.I. 42051)
- Ponceau 4R/Cochineal Red A (E124, C.I. 16255)
- Vegetable carbon (E153, C.I. 77266)
 - In the U.S., D&C Black No. 2 is permitted in cosmetics



FDA's enforcement tools

- **Domestic products**
 - Recalls
 - Warning letters
 - Untitled letters
 - Detentions
 - Seizures
 - Injunctions
 - Prosecutions
 - Civil money penalties
- **Imported products**
 - Detentions
 - Import alerts
 - Detention without physical examination (DWPE)



Summary:

Important color additive requirements

- Only approved and listed color additives may be used in foods, drugs, cosmetics, and medical devices marketed in the U.S.
- All color additives must comply with the requirements in their listing regulations
 - Including purity requirements
- Color additives must be used appropriately
 - Manufacturers must consult the listing regulations
- Certified material must be used in products when required

Resources for color additives

- FDA's web site
 - <http://www.fda.gov>
- Summary of Color Additives for Use in United States in Foods, Drugs, Cosmetics, and Medical Devices
 - <http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditiveInventories/ucm115641.htm>

Thank you for your attention!

I am happy to answer questions.

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