



CLEAN LABEL CONFERENCE

Natural Color in the USA: The Process to Natural Color Approval – What Product Developers Need to Know

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Thank you for the opportunity to speak to you today.

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If you would like to receive additional information regarding Burdock Group's capabilities in natural colors, cosmetics, personal care, food & feed ingredients, claims and dietary supplement safety or international regulations, please contact Amanda Roche (aroche@burdockgroup.com).

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Color Additives

- Food colors are food additives that are added to foods, mainly for the following reasons:
 - To make up for color losses following exposure to light, air, moisture and variations in temperature
 - To enhance naturally occurring colors
 - To add color to foods that would otherwise be colorless or colored differently



Nestle and FDA-certified Colors

- Nestle commits to removing FDA-certified colors from all Nestle chocolate candy by end of 2015

“We know that candy consumers are interested in broader food trends around fewer artificial ingredients.”

- More than 250 products/10 brands
- Labels: “No artificial flavors or colors” claim
- Annatto replacing Red #40 and Yellow #5

History of Color Additives in the US

Legal Framework

- Colors are food additives under 1958 Food, Drug, and Cosmetics Act
 - Any dye, pigment or substance which imparts color when added or applied to a food, drug or cosmetic, or to the human body
- All color additives require pre-market approval *via* color petition process
- Colors listed in US Code of Federal Regulations (CFR), Part 21, Section 73 & 74

US Regulations on Color Additives

“color additive” [21 CFR 70.3(f)]

- The term “artificial color,” as defined in 21 CFR 101.22, includes any “color additive” as defined in 21 CFR 70.3(f)
- Where a food substance such as beet juice is deliberately added for its color, it is a color additive
- However, food ingredients which contribute their own natural color when mixed with other foods are not regarded as color additives
- Even though a substance like beet juice is a natural substance, it is an “artificial color” when added to a food deliberately for its color

Certified & Exempt Colors

Colors can be generally divided into “certified” and “exempt from certification” categories

- Certified: Testing of each batch by FDA confirms safety
 - Synthetically produced (or human made) and used widely because they impart an intense, uniform color, are less expensive, and blend more easily to create a variety of hues.
 - There are nine certified color additives approved for use in the United States
 - *Certified colors: FD&C colors*
- “Exempt” colors: no batch testing required
 - Pigments derived from natural sources such as vegetables, minerals or animals.



Certified Colors (21 CFR § 74)

Certified Color	EU Number	Uncertified Name
FD&C Red No. 40	E 129	Allura Red AC
FD&C Red No. 3	E 127	Erythrosine
FD&C Blue No. 1	E 133	Brilliant Blue FCF
FD&C Blue No. 2	E 132	Indigotine
FD&C Yellow No. 5	E 102	Tartrazine
FD&C Yellow No. 6	E 110	Sunset Yellow FCF
FD&C Green No. 3	E 143	Fast Green FCF
Orange B		
Citrus Red No. 2		

Dyes: Water soluble form of color
Lakes: Water insoluble form of the dye

Exempt Colors (21 CFR § 73)

- Annatto extract
- Astaxanthin
- Dehydrated beets (beet powder)
- Ultramarine blue
- Canthaxanthin
- Caramel
- beta-Apo-8'-carotenal
- beta-Carotene
- Cochineal extract; carmine
- Sodium copper chlorophyllin
- Toasted partially defatted cooked cottonseed flour
- Ferrous gluconate
- Ferrous lactate
- Grape color extract
- Grape skin extract (Enocianina)
- Haematococcus algae meal
- Synthetic iron oxide
- Fruit juice
- Vegetable juice
- Dried algae meal
- Tagetes (Aztec marigold) meal and extract
- Carrot oil
- Corn endosperm oil
- Paprika/oleoresin (extract)
- Phaffia yeast
- Riboflavin
- Saffron
- Titanium dioxide
- Turmeric/oleoresin



US Approved Colors Permitted in the EU

Colorant	E Number	FD&C #	Color Index #	Alternate Names
Turmeric	E100		75300	Curcumin
Tartrazine	E102	Yellow 5	19140	Yellow 5
Sunset Yellow FCF	E110	Yellow 6	15985	Orange Yellow S
Carmine	E120		75470	Cochineal, Carmine 40, Carminic acid
Carmoisine	E122		14720	Azorubine
Amaranth*	E123		16185	FD&C Red #2
Ponceau	E124		16255	Conchineal Red A
Erythrosine**	E127	Red 3	45430	Red 40
Allura Red AC	E129	Red 40	16035	

US Approved Colors Permitted in the EU

Colorant	E Number	FD&C #	Color Index #	Alternate Names
Indigotine	E132	Blue 2	73015	Indigo Carmine
Brilliant Blue FCF	E133	Blue 1	42090	
Sodium Copper Chlorophyllin	E141			Copper complexes of chlorophyll and chlorophyllins
Caramel (Plain)	E150a			
Caramel -				
Caustic Sulphite	E150b			
Caramel -				
Ammonia	E150c			
Carotenes	E160a		75130	Alpha-carotene, Beta-carotene
i Mixed Carotenes	E160a(i)		75130	
ii Beta Carotenes	E160a(ii)		40800	

US Approved Colors Permitted in the EU

Colorant	E Number	FD&C #	Color Index #	Alternate Names
Annatto***	E160b		75120	Bixin, Norbixin
Paprika Extract	E160c			Capsanthin, Capsorubin
Beta APO-8				
Carotenal	E160e		40820	
Carotenoic	E160f			
Lycopene****	E160d		75125	
Canthaxanthin	E161g		40850	
Beet Root Red	E162			Betainin
Calcium Carbonate	E170		77220	
Titanium Dioxide	E171		77891	TiO ₂
Synthetic Iron Oxide	E172		77491/2	Iron Oxides and Hydroxides

Exceptions to Colors for Use in US

- **Amaranth:** (FD&C Red #2) was delisted by the FDA in the 1970's. It can no longer be used in foods in the USA.
- **Erythrosine:** (FD&C Red #3) is only approved for use in the EU for very specific applications (*i.e.* cocktail cherries).
It is not permitted for use in confectionery items and general food items (Directive 94/36EC).
- **Annatto:** Permitted usage levels in the EU varies by application (*i.e.* 10 mg/kg for margarine, 20 mg/kg for decorations and coatings).



<http://www.intlfoodcraft.com/food-color.html>

Caramel as a Color

- FDA considers caramel color GRAS ingredient exempt from certification for use as a coloring agent.
- Caramel production:
 - Reaction of sugars with ammonia or sulfites during heating
 - Formation of 2-methylimidazole (2-MI) and 4-methylimidazole (4-MI)
- National Toxicology Program (NTP):
 - Evidence of 2-MI and 4-MI as carcinogens when fed alone; however:
- FDA: “There is no evidence in the available information to show that caramel as a food ingredient constitutes a hazard to the general public when used at levels that are now current or might reasonably be expected in the future.”
- EFSA completed review of caramel colors – not of concern
 - Not carcinogenic or genotoxic
 - No adverse effects on human reproduction or developing child

Carmines as a Food Coloring

- May be considered from a “natural” source
- Concern with potential for allergic reactions
- FDA has not banned the use of carmine
 - Found no evidence of a "significant hazard" to the general population
- As of January 5, 2011, FDA regulation:
 - Requires all foods and cosmetics containing cochineal to declare it on their ingredient labels, due to objections from people who have concerns for reasons of health, ethics or religion.

Coloring Foods

- EU: Utilizing food extracts as coloring agents
 - Treated as ingredients rather than additives
- Ingredients made by mashing, cooking, or concentrating vibrantly colored foods
- Raw materials include carrots, sweet potatoes, elderberries, tomatoes, blueberries, grapes, and spirulina for blue and green confections
- Occurring in US without FDA guidance

Factors with Natural Color Ingredients

- Plant-based anthocyanins that start as purple may change to red, and red may change to brown if used in low-pH liquids or exposed to light.
 - Light-stable formulations are being introduced
- Heat-stable formulations for bakery/cooking applications
- Added Flavor
 - Colors such as paprika and turmeric may add distinct flavor profile when used at high concentrations



US Regulations on Food Colors

- All food color additives, including both certified color additives and certification-exempt color additives, are considered to be “artificial colors”
- Only color additives that are listed in the CFR and meet its requirements may legally be used in food products in the U.S.
- All other artificial colors are non-permitted



Color Additive Petition

- Identity
 - Common or usual name
 - Chemical formula, structures, molecular weights of all color components
 - Complete description of its source (i.e., segment of plant or animal, common name, genus/species)
 - Chemical, physical and biological tests to establish identity of the color additive (e.g., NMR, photo)

21 CFR §71.1(c) A.

Color Additive Petition

- Physical, Chemical and Biological Properties
 - Description of physical appearance, melting/boiling range, solubility in common solvents, odor, etc.
 - Chemical and spectrometric properties – effects of air, water, light, acid, base and temperature
 - Particle size (if important), shape, surface area, etc., as appropriate – Example of Titanium dioxide, a naturally occurring mineral

Color Additive Petition

- Chemical specifications
 - Define the article of commerce/reflects the composition of the color additive
- Volatile matter
- Soluble, extractable or insoluble matter
- Subsidiary colors (those structurally similar to main color components)
- Components included in the identity of the additive
 - Pesticide residues
 - Solvent residues
 - Ash
 - Heavy metals
 - Total color content
 - Particle size
 - Residual salts

Color Additive Petition

- Manufacturing process description
 - Methods, facilities and controls used in production of the color additive (show reproducibility)
 - List of all substances used in the synthesis, extraction, or preparation of color.
- Stability data
 - Data that establish the stability of the color additive
 - Reflect actual conditions of use and exposure.

Color Additive Petition

- Uses and restrictions
 - Products that will be colored / amount of color additive necessary to achieve desired effect
- Labeling
 - Example of the labeling for bulk containers
 - Statement of precautions to preserve stability, if necessary
 - Example of product labels

Color Additive Petition

- Analytical Methods for Specifications
- Qualitative and Quantitative Determination of Color Additive in Food Products
- Safety Studies
- Estimate of Probable Exposure /Chronic Daily Exposure
- Proposed Regulation

“Natural” on a Food Label in the US

- FDA has not developed a definition for use of the term natural or its derivatives.
 - However, the agency has not objected to the use of the term if the food does not contain added color, artificial flavors, or synthetic substances.
- USDA states that:
 - A product containing no artificial ingredient or added color and is only minimally processed.
 - Minimal processing means that the product was processed in a manner that does not fundamentally alter the product.
 - The label must include a statement explaining the meaning of the term natural (such as "no artificial ingredients; minimally processed").

Labeling of Color Additives in the US

- The label of a food to which any coloring has been added shall declare the coloring in the statement of ingredients
- Certified color additives:
 - Declaration by name of all color additives subject to certification on food labels in ingredients statement [21 CFR 101.22(k)(1)].
- Exempt color additives (listed in 21 CFR 73, Subpart A)
 - Required to appear in the ingredients declaration by name, as artificial color, as artificial color added, as color added, or by an equally informative term [21 CFR 101.22(k)(2)].

Labeling of Colors for US Products

Certified Colors

- Shall be declared by the name of the color additive listed in the applicable regulation [21 CFR, Part 74 or 82]
- It is not necessary to include the "FD&C" prefix or the term "No." in the declaration, but the term "Lake" shall be included in the declaration of the lake of the certified color additive (e.g., Blue 1 Lake).
- Manufacturers may parenthetically declare an appropriate alternative name of the certified color additive following its common or usual name as specified in 21 CFR, Part 74 or 82.

Labeling of Colors for US Products

Colors Exempt from Certification

- May be declared as "Artificial Color," "Artificial Color Added," or "Color Added" (or by an equally informative term that makes clear that a color additive has been used in the food), when not required by regulation to be declared by their respective common or usual name.
- Alternatively, such color additives may be declared as "Colored with _____" or "_____ color," the blank to be filled in with the name of the color additive listed in the applicable regulation in 21 CFR Part 73.

Conclusion

In the United States

- FDA has not defined the term “natural”, but does not object to the term if the food does not contain added color, artificial flavors, or synthetic substances.
- All substances added to foods to impart color other than what naturally occurs in the food are considered color additives
- All color additives are considered “artificial”, even if derived from a natural source.
- The word “natural” cannot be used in an ingredient statement to modify a color additive

Questions?

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