# Business & Company Resource Center

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**Coloring options: replacing synthetic food coloring with "natural source" coloring is not as simple as it seems. Food developers are faced with a complex body of regulations in the U.S. and Europe regarding the usage of natural coloring agents.**

acceptable daily intakeUnited States. Food and Drug Administration

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A food's "look" is important and products that fail to make a good first impression are likely to stay on store shelves. Before Sir William Perkin discovered the first synthetic dye in 1856, natural colors from herbs, fruits and spices were used to enhance food appearance (1). Synthetic colors quickly replaced natural colors because they were less expensive, more stable and had eye-popping quality/intensity. Synthetic colors have dominated the color additive market for many decades, but that may be about to change. Consumers are showing renewed interest in natural colors as part of the natural ingredients trend and from lingering doubts about the safety of some synthetics. Manufacturers are responding to this increased consumer demand and benefiting from technological advances that have made natural colors less expensive, more stable and more vibrant than the first generation predecessors. Another reason for the move towards natural colors is that currently permitted artificial colors may be approaching the acceptable daily intake (ADI) limits permitted in the U.S. and/or Europe.

Colors derived from "natural sources" are not exempt from regulation, even though they are natural constituents of foods. In both Europe and the U.S., colors derived from "natural sources" are still subject to existing regulations for color additives. The government agencies responsible for regulating color additives in Europe (EFSA) and the U.S. (FDA) both allow the use of a number of substances to impart color. The agencies sometimes differ on use restrictions, which color additives or concentrations of color additives are permitted or require different labeling or standards for the additives. Food manufacturers should keep abreast of regulatory actions by both agencies if they want to sell the same product in multiple markets, without reformulating.

Are All Colors "Color Additives"?

In the U.S., all ingredients deliberately added to food to provide color are considered "color additives," even if they are derived from natural sources (21CFR [section] 70.3(f) and 201(t) (1) of the Federal Food, Drug and Cosmetic Act (FDCA)). Under Title 21 of the U.S. Code of Federal Regulations (21 CFR) [section] 70.3(g), a material that otherwise meets the definition of color additive can be exempt from that definition on the basis that it is used (or intended to be used) solely for purposes other than as a coloring, as long as the material is used in a way that any color imparted is clearly unimportant insofar as the appearance, value, marketability or consumer acceptability is concerned. Based on these definitions, a substance such as naturally-derived lycopene would be categorized as a color additive if it was added to a food that was not originally red and the lycopene imparted a red color. However, if the lycopene was added for another reason (such as an antioxidant) to a food, such as ketchup, at a level that did not alter the color of ketchup, it would not be regulated as a color additive.

In the U.S., the only color additives that can be legally used in food must be approved for food use via a color additive petition. Color additives that have been approved only for drug or cosmetic use (i.e., D&C colors) cannot be added to food. Currently approved color additives for food, as well as their

into the browser.)

Color additives subject to batch certification include synthetic organic dyes, lakes or pigments, such as the Food, Drug and Cosmetic (FD&C) colors, and are known as "certified colors." Batch certification is required when the composition needs to be strictly controlled to ensure safety. Batch certification includes the process of taking a sample from each batch of a newly manufactured color and submitting it to the FDA for testing to determine whether it meets the color additive's requirements for composition and purity. If it does, the FDA "certifies" the batch and issues a certification lot number. Only then can that batch be used legally in FDA-regulated products (2).

Synthetic colors originally replaced natural colors because they were less expensive, more stable and had an eye-popping quality not matched by natural colors of the time. Certain shades of blue and green still remain out of the reach of colors from natural sources.


Color additives exempt from certification include, but are not limited to, naturally-derived colors, such as beta carotene (21CFR [section] 73.95), tomato lycopene extract or concentrate (21CFR [section] 73.585), annatto extract (21CFR [section] 73.30), dehydrated beets (21CFR [section] 73.40) and turmeric (21CFR [section] 73.600). Exemption from certification does not mean a color additive is exempt from requiring a color additive petition, only that the certification process is not required. Although color additives mentioned in Section 21CFR [section] 73 are not subject to batch certification requirements, they must comply with their specific regulation, which may be very restrictive regarding source, identity, solvent used for extraction, solvent residue, permitted diluents, heavy metal content, labeling and uses and restrictions. Additional requirements may also apply (e.g., a required method of analysis). Regardless of whether a color additive is subject to or exempt from certification, it is subject to strict regulations for identity and use.

Proper Labeling is Essential

The Nutritional Labeling and Education Act of 1990 (NLEA) and regulations emanating therefrom, require that food labels contain the names of any color additives subject to certification (21CFR [section] 101.22(k) (1)). Exempt color additives must appear in the ingredients declaration by name, as

color" is not. An example of a compliant soup label contains the terms "natural flavoring (egg, soy, sesame)" or "natural smoke flavoring," but specifies beta carotene as providing color (as "beta carotene (color)"). If beta carotene or any other substance is added to provide color, but is not added to the ingredient label, the FDA would consider the soup to be mislabeled and would take appropriate corrective action, such as issuing a warning letter or detaining the product.

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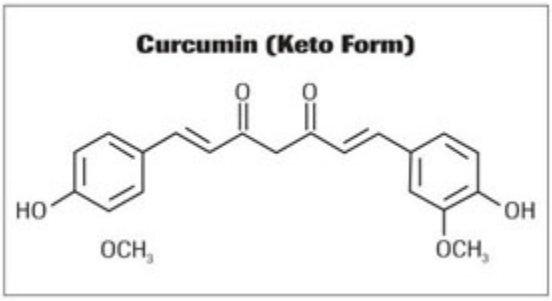


In the U.S., all ingredients that are added to provide color to food are considered to be "color additives," even if they are derived from natural sources, such as turmeric. Turmeric's colorful component, curcumin, is shown here.

The FDA is vigilant about use and declaration of approved colors in the U.S., and not all colors can be used in all foods. Some FDA regulations only allow certain colors to be used in certain foods. A recent FDA import alert (3) indicates that inclusion of illegal or undeclared food color additives in foods imported into the U.S. is a common cause of detention. The vast majority of the foods in this above-cited FDA alert were detained because of the use of undeclared certified colors (e.g., FD&C Yellow #5 (Tartrazine), FD&C Yellow #6 (Sunset Yellow FCF), or FD&C Red #40 (Allura Red)), or colors that have been banned in the U.S., but still are used in other countries (e.g., FD&C Red #2 (Amaranth), Ponceau 4R, or Carmoisine (Azorubine)). Some of these colors also have been associated with adverse reactions in certain individuals.

For example, FD&C Yellow #5 has been suspected as the cause of some allergic reactions, including asthma and urticaria (hives). Additional food products have been detained due to detection of unknown colors, undeclared colors that are exempt from certification (e.g., sodium copper chlorophyllin) or unpermitted colors from natural sources that are permitted in other countries (such as safflower extract) (4). FDA personnel also scrutinize ingredient labels for mislabeled color additives identified with their European name (or E number designation), color index number, INS number, or trade or common name (e.g., tartrazine), telltale signs that the color additives may not be approved for use in the U.S. (4) Food manufacturers that want to successfully import food into the U.S. should, without exception, only use color additives designated in Sections 21CFR [section] 73 or 21CFR [section] 74 (even if they are derived from "natural sources"), and identify the additive on the label according to current labeling guidelines.

Existing Color Regulations are Changing

Food manufacturers must keep current on color additive regulations because certain regulations have been revised in the U.S. and Europe, and more

labels as "artificial color" or "color added." In response to reports of severe allergic reactions, including anaphylaxis, to foods containing cochineal extract or carmine, the FDA issued a final rule on January 5, 2009 (74 FR207), amending the regulations for these color additives. Effective January 5, 2011, labels of all foods containing cochineal extract or carmine must refer to these substances by name, to allow consumers who are allergic to these color additives to avoid their consumption. It is expected this labeling requirement will lead to decreased usage of cochineal extract and carmine as food colorants.

As part of the review of the safe use of a color additive, the petitioner must indicate the Acceptable Daily Intake (ADI) of the additive, defined as an estimate of the amount of a food additive that can be ingested daily over a lifetime, without appreciable health risk. EFSA recently reduced the ADIs for Quinoline Yellow (E104), Sunset Yellow FCF and Ponceau 4R (5), three of six synthetic color additives that, when used in combination, have been shown in the commonly cited "Southampton study" to be associated with development of hyperactivity in children (6). As of July 2010, EFSA will require products containing Quinoline Yellow (E104), Sunset Yellow (E110), Ponceau 4R (E124), Allura Red (E129), Tartrazine (E102) and Carmoisine (E122) to carry a warning label mentioning this association (7). Three of these color additives, Allura Red, Tartrazine and Sunset Yellow FCF, are currently permitted for use in the U.S. Although the FDA has not issued new regulations for these three additives, it is expected that use of these colors will also decrease in the U.S., due to EFSA's actions.

Future Outlook for New Colors

The new regulations in the U.S. and Europe will likely diminish usage of some synthetic colors previously employed to color food yellow, orange and red. It is probable there will be a corresponding increase in the use of natural source color additives to impart these hues. New colors should not be derived from known allergenic sources like milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans or cochineal beetles, or a warning label will be required.

Several naturally-derived color additives that can be used to color food yellow, orange or red (such as 6-carotene, turmeric or lycopene) are also generally recognized as safe (GRAS) in food for other purposes. As inferred from the color additive regulations, other food ingredients that have received GRAS (or food additive) status could potentially be considered color additives, when used to impart color. As such, a color additive petition must be filed for any GRAS substance (or food additive) that fits the definition of a color additive (i.e., if it will be used as an intentional color additive when used at higher concentrations and/or in additional foods than those stated in the original GRAS determination or food additive petition). Fruit extracts or powders that are GRAS for flavorings may be considered color additives, under either one of these scenarios.


As natural source color additives replace synthetic colors, their usage may increase to the point where the additives are consumed at levels above currently demonstrated safe levels. This fact is not going unnoticed by regulatory agencies. In January, 2010, EFSA announced it was reviewing the maximum allowable levels of lycopene in a number of food categories, because the increasing use of lycopene in foods could increase consumption over the currently recommended ADI (8). The EFSA is proposing 3-10-fold reductions in quantities of lycopene used in biscuits and cakes, edible ices, desserts, jams, jellies and marmalades, sauces and pickles, non-alcoholic flavored beverages (except dilutable drinks) and confectionery (excluding surface coating). In Europe and the U.S., it is altogether possible the use of lycopene as a coloring agent may not be allowed in new foods or that new sources of lycopene may not be approved as food ingredients (due to concerns over its over consumption). This scenario may occur with other non-certified, naturally derived colors, as the public demands more food products that only contain natural-sourced ingredients.

What Should Be Done?

Food manufacturers have a lot to consider these days, as the regulation of synthetic and natural source food colors undergoes review and modification in the U.S. and Europe. Existing regulations vary across borders. Wise manufacturers will consult the rules of all the countries they seek to market to, in order to avoid unnecessary reformulation. In response to new regulations, it is expected that there will be an increased demand for natural sources of yellow, orange and red food colors. Developers can use currently approved colors from natural sources to fill this void. However, because the use of existing natural source colors may increase to levels that are not known to be safe, colors from new sources should be developed and approved for use in food. In the U.S., substances that have been determined GRAS for another purpose could be used as colors, but only after a color additive petition has been approved. The fact that all colors, regardless of source, must be properly declared on labels and that the term "natural color" is not recognized by the FDA should be forefront in the minds of food manufacturers when they are developing new products for market in the U.S. Something as seemingly innocuous as color may make the product a success or a failure.

Website Resources:

www.PreparedFoods.com--Type "colors" into the search field

References:

(1) Henry, BS. (1996). Natural Food Colors (Chapter 2). In Natural Food Colorants (Hendry GAF and Houghton JD, Eds.). Blackie, Academic & Professional, London, England.

(2) www.fda.gov/ForConsumers/ConsumerUpdates/ ucm048951.htm or http://tinyurl.com/2g3mjph (Accessed 5/17/2010).

(3) www.accessdata.fda.gov/cms_ia/importalert_118.html or http://tinyurl.com /282lej6. Note: Site may be very slow to load.

(4) www.fda.gov/downloads /Food/GuidanceComplianceRegulatoryInformation/ ComplianceEnforcement/ucm073305.pdf or http://tinyurl.com/2856asd (Accessed 5/17/2010).

(5) www.efsa.europa.eu/en/press/news/ans091112.htm or http://tinyurl.com /2fk8h9y (Accessed 5/17/2010).

(6) McCann D, et al. 2007. Lancet. 370:1560-1567.

(7) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do? uri=OJ:L:2008:354:0016:0033:en:PDF {Annex V} or http://tinyurl.com /25a6hp7.

(8) www.efsa.europa.eu/en/efsajournal/doc/1444.pdf or http://tinyurl.com /26vond5 (Accessed 5/17/2010).

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