

Feature Article

Establishing Standards on Colors from Natural Sources

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Abstract: Color additives are applied to many food, drug, and cosmetic products. With up to 85% of consumer buying decisions potentially influenced by color, appropriate application of color additives and their safety is critical. Color additives are defined by the U.S. Federal Food, Drug, and Cosmetic Act (FD&C Act) as any dye, pigment, or substance that can impart color to a food, drug, or cosmetic or to the human body. Under current U.S. Food and Drug Administration (FDA) regulations, colors fall into 2 categories as those subject to an FDA certification process and those that are exempt from certification often referred to as “natural” colors by consumers because they are sourced from plants, minerals, and animals. Certified colors have been used for decades in food and beverage products, but consumer interest in natural colors is leading market applications. However, the popularity of natural colors has also opened a door for both unintentional and intentional economic adulteration. Whereas FDA certifications for synthetic dyes and lakes involve strict quality control, natural colors are not evaluated by the FDA and often lack clear definitions and industry accepted quality and safety specifications. A significant risk of adulteration of natural colors exists, ranging from simple misbranding or misuse of the term “natural” on a product label to potentially serious cases of physical, chemical, and/or microbial contamination from raw material sources, improper processing methods, or intentional postproduction adulteration. Consistent industry-wide safety standards are needed to address the manufacturing, processing, application, and international trade of colors from natural sources to ensure quality and safety throughout the supply chain.

Keywords: adulteration, food additives, food safety, natural colors, synthetic colors

Introduction

Current regulations for colors exempt from certification, also referred to as “natural” colors, noncertified colors, or exempt colors because they are not subject to certification testing by the FDA prior to use, lack consistent definitions and universally accepted quality control and product safety specifications that typically comprise a harmonized regulatory framework (Burrows 2009; Scotter 2011; Oplatowska-Stachowiak and Elliott 2017). Additionally, there is a lack of agreement on standard testing methods that would help to insure the safety, quality, and purity of these color additives. A survey conducted by Innova Database reported that 31% of American consumers surveyed were very or extremely

concerned about food colorings (Innova Database 2013). This survey highlights the growing importance of natural colors and the opportunities for the natural colorings industry to address both safety and consumer concerns.

Even a single product safety incident involving natural color additive could adversely impact consumer confidence and alter the marketplace. History has shown that problems with adulterants or contaminants in foods, perceived safety and side-effects of synthetic colors, and even the revelation that cochineal red was an insect-based color have resulted in public demand for clarity that has changed FDA rulings on ingredient labels (Burrows 2009). To ascertain a need for consistent standards for the manufacture and application of natural colors, scientists from the fields of plant biology, food chemistry, food toxicology, food product development and manufacturing, and food quality and regulatory affairs organized to address quality attributes and potential safety hazards. This paper arose from those multidisciplinary discussions, with a focus on understanding potential hazards through the perspective of manufacturers, importers, and end-users of natural colors. This work proposes standards for testing natural colors to ensure their quality and safety. The objective of this review is to outline current issues involving natural color additives in the marketplace and propose solutions that lead to recommendations for establishing industry standards for colors from natural sources. Our intent for this work is to initiate discussion among members of the academic, regulatory, and industrial communities who are responsible for realistic, practical approaches to define standards for natural colors. This work was initiated by Sensient Technologies Corp. (Sensient; Wisc., U.S.A.) in collaboration with the U.S. Pharmacopoeial Convention (USP), but the content of this work does not

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Certification: An Expert Committee Report

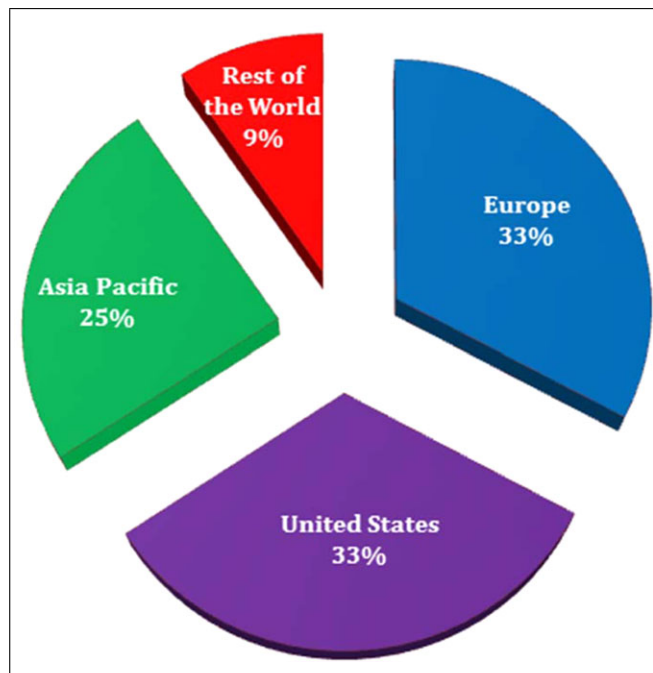


Figure 1—Global percentage of food colors market by country/region in 2014.

Source: Markets and Markets Research.

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Why We Use Color Additives

Since ancient times, cultures of the world have used colors for a wide variety of purposes including dyeing textiles, coloring food and beverages, and coloring the body in religious and ethnic ceremonies and rituals. Their use in enhancing visual appeal has served to enrich all aspects of life and culture. There appears to be basic connection between human perception and the role of color in our lives, despite limited research that would explain genetic and environmental responses to color stimuli (Elliot and Maier 2014), how colors can modulate one's affective experiences (Strauss and others 2013), and why a person prefers one color over others (Palmer and Schloss 2010). Color additives are a part of our daily lives around the world, with Europe, United States, and Asian countries the predominant users (Figure 1) in products that range from pet foods to cosmetics and foods consumed every day. A current trend with food color additives is to find a suitable naturally derived color to replace synthetic colors (Sigurdson and others 2017) in effort to present a more wholesome ingredient label. While social scientists study the basic psychology of color and discuss differential evolutionary or cultural influences related to human responses to color, there appears to be agreement that color can impact our affect, cognition, and behavior (Meyers-Levy and Peracchio 1995; Elliot and Maier 2014). A 2015 report from the Color Marketing Group (Alexandria, Va., U.S.A.) highlights that a significant portion of consumer buying decisions is influenced by color, and is indicative of the universal role color has on our lives. As with food flavor, the relationship between color and flavor perceptions is an emerging field and development efforts are currently directed at how flavor affects the brain as related to vision, taste, odor, and touch (Lewis and others 2008; Krishna 2012). In many

cases, the visual perception of color can supersede the perception of taste and smell, since colors may impact emotions which are an influencing factor in food purchasing decisions. In the human response to color, it has been reported that people “see” flavors (Lewis and others 2008; Kurtz and others 2013; Acree and others 2014), which is an indication that opinions about food flavor or attributes are based largely on their color. An effective use of color is presumed to drive consumer interest and eventually consumer acceptance and use (Grossman and Wisenblit 1999; Sable and Akcay 2010). Color impression was reported to account for 62% to 90% of the acceptance/rejection of an object (Singh 2006) with consumers making their decisions within 90 s of their initial reaction to a product. Since color can impact flavor perception and acceptance, alteration to food color plays a critical role in product development and product improvements (Sable and Akcay 2010). Coupled with a perceived difference in natural versus synthetic pigments and their associated health risks (Delgado-Vargas and others 2000), a food product developer must decide which color system to use to insure finished product quality, consistency in manufacturing, and the complex nature of consumer acceptance.

Historical Perspective on Color Regulations

The use of colors has a long history, dating back to the beginning of civilizations from ancient Egypt, India, and China where minerals, soils, insects, and plants were used to color foods, cosmetics, the body, textiles, paintings, and more (McKone 1991). Throughout history, foods have also been enhanced with color additives to make them brighter and more attractive, to appear fresher, and to mask deterioration and decay in a manner that today might be considered adulteration. Roman naturalist Pliny the Elder noted in the 1st century that winemakers used aloe to adulterate the flavor and color wine (McKone 1991). From the European perspective, laws were introduced as early as 1155 to prevent bread from being adulterated. In what may be the earliest recorded pure food law, Europe enabled laws in 1292 against the adulteration of beer (McKone 1991). In 1396, the 1st decree prohibiting the use of color additives such as chalk, lime, and crushed bones in milk and the coloration of butter with flowers, herbs, and drugs was issued in Paris (McKone 1991; Burrows 2009). Until the middle of the 19th century, colors used in foods, drugs, and cosmetics were mostly from natural sources including animals, insects, vegetables, and minerals. In 1856, English chemist Sir William Henry Perkin accidentally discovered the 1st organic synthesized dye, an aniline-based pigment from a coal-tar source that exhibited a mauve or purple color. This discovery led to a revolution in synthetic pigments, which eventually replaced natural colors as the price decreased (Burrows 2009). Today, coal-tar colors are the foundation of many synthetic colors, although the starting materials for their synthesis have changed. By the mid-1800s, food adulteration in England had reached an apex and many processed foods were assumed to be contaminated. Due to illness and death from additives that contained various heavy metals such as arsenic, copper, lead, and mercury, public pressure contributed to the passing of the Adulteration of Food and Drink Act of 1869 (McKone 1991). In the United States, food color legislation also occurred in response to adverse events and public debate about safety and fraud. In 1886, Congress passed the 1st bill allowing colorants in butter and in 1896 recognized color additives for use in cheese (U.S. Congress 1896). The rise of synthetic color use was precipitated by improvements in food processing technologies that expanded shelf life through the use of preservatives, refrigeration, and harsh processing techniques such as canning that altered the natural appearance of foods. Consumers

demanded restoration of the inherent colors of foods along with assurance of the safety of these additives. In the United States, individual states passed their own laws on food safety and the food industry as a whole demanded consistent national safety and purity standards. Some of the earliest functions of the FDA in 1883 mandated the protection of the purity of the nation's food supply (Barrows 2014). In 1899, the Natl. Confectioners' Assn. issued a circular that enumerated 21 coal-tar colors it considered harmful and unfit for human consumption. In the 1906 Pure Food and Drug Act, a food was declared adulterated "if it be colored, powdered or polished with intent to deceive or to make the article appear of better quality than it really is." Subsequent studies were conducted on hundreds of color additives to determine safety and application to foods. A list of 7 color additives was eventually approved and a procedure established for the certification of these and future colors (Burrows 2009). Through the early 1900s the quality of color additives was generally poor, but work by individual companies such as H. Kohnstamm & Co., which on April 1, 1908 voluntarily certified the 1st batch of colors, improved the purity and safety of synthetic colors. Thirty years later, Congress passed the Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act), which gave the U.S. government the responsibility and legal authority to enforce violations related to food additives (Burrows 2009). The FD&C Act was amended in 1960 with the Color Additive Amendments, which provided the FDA with a mandate to regulate food color additives. This regulatory change led to the listing of over 200 colorings for which the industry, rather than the federal government, had the burden to prove safety. Under these amendments, FDA was given the authority to accept, reject, or remove a color from the approved list and industry was required to submit formal applications for any new color additives proposed for use in food. As consumers demand transparency and the demand for safe, effective, and affordable color additives increases, improved standards will be needed to ensure consumer confidence and safety. As this review will illustrate, there are still many areas of concern related to food color additives, especially those from natural sources.

Current Regulatory Definitions

A color additive is defined as any dye, pigment, or other substance that can impart color to a food, drug, or cosmetic or to the human body (21 Code of Federal Regulations [CFR]). In contrast to food additives, there is no "generally recognized as safe" (GRAS) exemption that applies to color additives. Any substance used to impart color is considered a color additive and is subject to premarket approval requirements in the form of a listing regulation in the CFR unless the substance is used solely for a purpose other than coloring. Color additive listing regulations containing specifications and use restrictions are located at Title 21 CFR Parts 70–82. The use of an unlisted color additive, or a listed color additive that does not conform to the specifications or use restrictions of the applicable listing regulation, may cause a product to be considered adulterated and subject to enforcement action by the FDA.

Colors that are exempt from certification are often derived from plant, mineral, or insect sources and thus from inherently natural origins; but not all exempt colors are from nature such as chemically modified copper chlorophyllin or are synthesized to be nature-identical in the case of β -carotene. Noncertified colors are also subject to FDA regulations and must comply with identity and purity specifications and use limitations described in their CFR listing regulations. However, exempt colors do not

Table 1—A list of common exempt colors and their FDA^a and INS^b numbers.

Natural colorant	FDA	E number
Curcumin	73.600	100
Tumeric Oleoresin	73.650	None
Riboflavin	73.450	101(i)
Carmine/Cochineal	73.100	120
Chlorophylls	None	140i to ii
K-Cu-chlorophyll	None	141ii
Na-Cu-chlorophyll	73.125	141ii
Cu-chlorophylls	None	141i
Caramel I	73.85	150a
Caramel II	73.85	150b
Caramel III	73.85	150c
Caramel IV	73.85	150d
Vegetable Carbon	None	153
Carotenes	None	160(a) iv
Carrot Oils	73.300	None
b-carotene	73.950	160(a)i to iii
b-apo-8'-carotenoic acid (caroteneal)	73.900	160e
Annatto-bixin	73.300	160(b)i
Annatto-norbixin	73.300	160(b)ii
Paprika	73.340	None
Paprika oleoresins	73.345	160(c)
Lycopene	73.585	160(d)I, ii, iii
Lutein	None	161(b)i
Canthaxanthin	73.750	161g
Beet red	73.40	162
Anthocyanins	None	163
Grape color extract	73.169	None
Fruit juice	73.250	None
Vegetable juice	73.260	None
Enocianin (Grape skin extract)	73.170	163ii
Saffron, crocetin, and crocin	73.500	None
Titanium dioxide	73.575	171
Iron Oxides	73.200	172
Spirulina Blue	73.530	None
Spirulina Green	None	None
Gardenia Blue	None	None
Gardenia Yellow	None	None
Gardenia Red	None	None
Monascus Red	None	None
Monascus Yellow	None	None
Carthamus Yellow	None	None
Carthamus Red	None	None
Flavoanthin	None	None
Huito (<i>Genipa americana</i>)/ Jagua	None	None

^aFood and Drug Administration from the Federal Food, Drug, and Cosmetic Act, 21 C.F.R. §73.

^bIntl. Numbering System (European Union) by Codex Alimentarius.

undergo any certification process by FDA to assure their quality and safety before they may be marketed. By contrast, colors subject to certification, typically synthetic dyes and lakes, require individual batch certification by the FDA against strict purity and quality requirements to confirm compliance with the listing regulation before they may be marketed. After each batch of a color subject to certification is certified by FDA as meeting the required purity and quality specifications, it receives an individual batch registration number and is provided an "FD&C" name to reflect its status as a certified color that may be legally used for its approved uses. A list of the common exempt color additives with their associated FDA and Intl. Numbering System (INS) numbers is presented in Table 1. Cochineal extract and carmine are color additives derived from insects, both with the same FDA and INS number. Although every batch is tested by the FDA against a toxicological reference, neither are considered a certified color additive and its nomenclature changes after the lots are evaluated and an FDA lot number is assigned. In this way, each color additive is unique relative to identity, specifications, uses and

Table 2—Comparison of specifications and limits outlined in FDA's code of Federal Regulations and the European Union legislation.

Color	FD&C Yellow #6 Sunset Yellow	Fruit juice	Anthocyanins
Cited regulations	21CFR 74.706	21CFR 73.250	EC Directive E163
Process	Azo reaction of Schaffer salt and sulfanilic acid	Expression of juice from fresh fruit or a water infusion of dried fruit	Extraction with sulfated or acidified water, carbon dioxide, methanol, or ethanol of edible fruits and vegetables with subsequent concentration and/or purification
Total color	87% min	None	None
Sum of volatile matter (at 135 °C) and chlorides and sulfates	13% max	None	None
Water insoluble matter	0.2% max	None	None
Unreacted Intermediates			
Na-salt of 4-aminobenzenesulfonic acid	0.2% max	None	None
Na-salt of 6-OH-2-naphthalenesulfonic acid	0.3% max	None	None
Disodium salt of 6,6'-oxybis [2-naphthalenesulfonic acid]	1% max	None	None
Disodium salt of 4,4'-(1-triazene-1,3-diyl)bis[benzenesulfonic acid]	0.1% max	None	None
Sub-dyes			
Sum of the Na-salt of 6-hydroxy-5-(phenylazo)-2-naphthalenesulfonic acid and the Na-salt of 4-[(2-hydroxy-1-naphthalenyl)azo]benzenesulfonic acid	1% max	None	None
Sum of the trisodium salt of 3-hydroxy-4-[(4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid and other higher sulfonated subsidiaries	5% max	None	None
Potentially carcinogenic contaminants			
4-Aminoazobenzene	50 ppb	None	None
4-Aminobiphenyl	15 ppb	None	None
Aniline	250 ppb	None	None
Azobenzene	200 ppb	None	None
Benzidine	1 ppb	None	None
1,3-Diphenyltriazene	40 ppb	None	None
1-(Phenylazo)-2-naphthalenol	10 ppb	None	None
Sulfur dioxide	None	None	<1000 ppm
Residual solvents	None	None	Methanol <50 ppm Ethanol <200 ppm
Heavy metals			
Lead (as Pb)	10 ppm	None	2 ppm
Arsenic (as As)	3 ppm	None	3 ppm
Mercury (as Hg)	1 ppm	None	1 ppm
Cadmium (as Cd)	1 ppm	None	1 ppm

restrictions, labeling requirements, and whether the materials is certified or exempt (Burrows 2009). Basic standards are described in Title 21 Parts 70–82 for each listed color additive such as chemical specifications and restrictions. The use of an unlisted color additive or if the color additive does not conform to the specification of the listing regulation may cause a product to be considered adulterated and subject to action by the FDA. While the FD&C Act allows for food ingredients to be exempt from the definition of a food additive if they are GRAS, such an exemption does not apply to color additives. However, there are examples of GRAS ingredients that are also listed as color additives such as ferrous lactate listed under 21 CFR 184.1311 and 21 CFR

73.165. However, if a substance is listed as a GRAS substance it requires a premarket approval by the FDA as a color additive if used for the purpose of coloring a food (Barrows and others 2003).

Quality requirements for certified and noncertified colors

The use of synthetic dyes and lakes in foods and beverages is common. Their legal definitions and labeling requirements are easier to define and apply than those for noncertified, or natural colors. For example, Table 2 compares the FDA's specification for FD&C Yellow #6 (Sunset Yellow) in 21 CFR § 74.206 with FDA's specification for natural colors from fruit juice in 21 CFR § 73.250 and compares to anthocyanins from the European



Figure 2—Trends toward colors from natural sources as the proportion of consumers that report trying to avoid artificial food colors. Source: Nielsen Global Health & Ingredient Survey, January to March, 2016.

Community (EC) Directive E163. Whereas extensive testing for quality and safety is mandated for FD&C color additives, minimal regulations exist for the noncertified colors. The FDA's specifications for FD&C Yellow #6 describe the process method, total color, sum of volatile matter and chlorides and sulfates, water insoluble matter, unreacted intermediates, sub-dyes, potentially carcinogenic contaminants, sulfur dioxide, residual solvents, and heavy metals. A survey of synthetic or unauthorized colors in 1 urban and 1 rural area in India by Tripathi and others (2007) found that of 1199 samples analyzed 31% contained nonpermitted colors by the Prevention of Food Adulteration Act of India. Even when the color was permitted, some exceeded legal limits with 1 beverage sold in an urban area with Sunset Yellow FCF and Tartrazine at levels 8 to 20 times above the permissible limits while in rural areas Sunset Yellow FCF, Tartrazine, and Carmoisine exceeded permissible limits by 23, 16, and 15 times, respectively. Nonpermitted colors such as Rhodamine B, Metanil Yellow, Orange II, Malchite Green, Auramine, Quinoline Yellow, Amaranth, and Sudan dyes were also identified. In contrast, the regulations for fruit juice include only the method of extraction. While these generic specifications may control gross composition of the resulting color, it does not preclude the possibility of impurities or contaminants that could enter into the product during processing, storage, or blending and represents a significant gap in the current regulatory regime.

Color Trends

Demand for natural food products and colors from natural sources has seen tremendous market growth with many multinational companies announcing moves toward removing all certified colors from their product lines. Global consumption patterns are trending away from synthetic colors (Figure 2) with Europe, Africa, Middle-Eastern, and Asian-Pacific countries reporting higher avoidance than North America and Latin America. The desire for a clean label, one that is free of artificial ingredients, is a major market and product development driver (Hunter 1999; Burrows 2009; Moloughney 2014). A 2016 Nielsen Global Health and Ingredient survey (Figure 3) revealed that artificial

flavors, preservatives, and colors were among the food ingredients most avoided by consumers overall, trends that were consistent for consumers across various regions of the world. As reported in the June 2013 issue of *Food Navigator*, economic value of natural colors surpassed certified colors according to data from Mintel and Leatherhead Food Research (2013), which also estimated a global color market equivalent to \$1.45 billion per year in 2009, an increase from the \$1.2 billion in 2007. In the same year, 31% of the market was attributed to colors from natural sources at a 5% annual growth, while certified colors grew by only 1%. According to this report, the global market for natural colors increased by almost 35% from 2005 to 2009, led by the EU marketplace at 36% and followed by the United States with an increase of 28%.

With an increased demand for natural colors comes a requisite need and expectation for a reliable and consistent supply of raw materials from nature. Unreliable ingredient supplies may occur due to many factors ranging from environmental degradation, increased urbanization, infrastructure limits in developing countries, competition for food production, political instability, and the effects of climate and population change (Figure 4). Increased market demands and high prices can create a situation where individuals or companies intentionally adulterate natural colors for economic gain. These illegal practices exist for other high-value crops such as medicinal and aromatic plants and these issues were addressed by the World Health Organization (WHO) in a series of publications to serve as a guideline for wild crafting, collection, and cultivation of plants (WHO 2003). Guidelines like these can also serve as a framework for raw materials traceability through the value chain and can be used to prove ethical sourcing. However, intentional adulteration along the value-added color processing chain is difficult to determine, so a need for an advanced color analysis system is needed to detect both intentional and unintentional adulteration and to determine if finished products meet their own label claims. Lack of quality standards and the possibility of intentional adulteration are daily concerns for the industries in the natural products sector, including natural color additives. Adulterants have become so commonplace that industry, academic, and government sectors often know in advance of what to look for and must verify purity

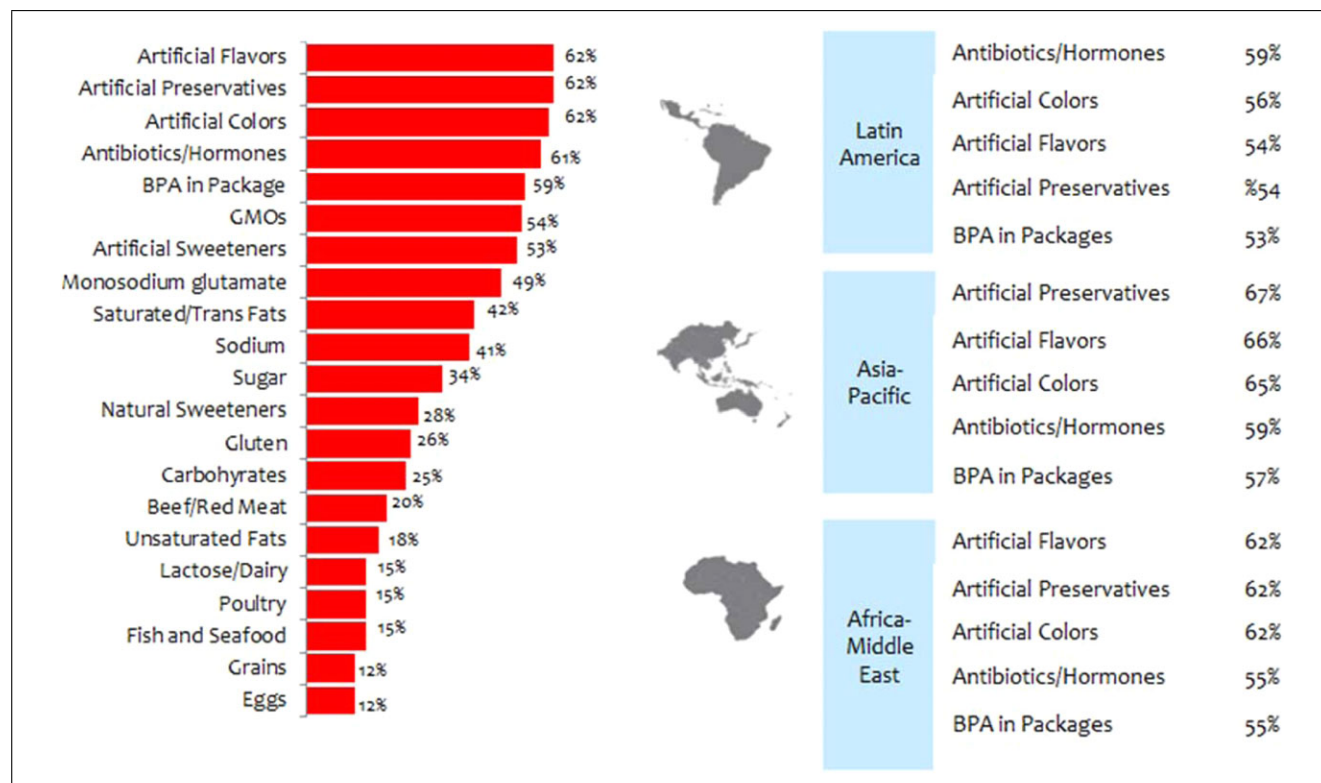


Figure 3—Percentage of global consumers avoiding certain foods or food ingredients. Source: Nielsen Global Health & Ingredient Survey, January to March, 2016.

and quality in routine screenings of their suppliers. In the case of natural colors, adulterants may include synthetic dyes, high solvent residues, microbial contamination, or less expensive colors or filler materials that have been blended into the product for fraudulent economic gain.

Quality control for natural colors

Consumers may seek foods with natural colors over those that are artificially colored in the belief that those foods are of premium quality, healthier, and safer. Consumers expect safe products, truth in labeling, and for food ingredients to be free of adulteration (Hunter 1999). The impact of a single food safety incident with natural colors could expose an industry that lacks quality standards and safety testing and may result in loss of consumer confidence. According to Mintel GNPD in 2015–2016, natural colors were used in over 66% of global food or beverage launches, compared to artificial colors in 16 to 37% of the launches and whole foods that add color in 2% to 14% of the launches (Figure 5), highlighting the urgent need for safety and quality control of natural color additives. The color industry can look to the experiences of botanical product use in the dietary supplement industry to avoid a similar market impact and loss of consumer confidence (Foster and Blumenthal 2012). The consequences of failing to act as an industry can lead to increased consumer risk, economic loss, and potentially stricter government regulations and/or interventions. Prior to the passage of the Dietary Supplement Health and Education Act (DSHEA) of 1994, herbal products or dietary supplements had a good reputation and market enthusiasm by consumers. Following passage of the DSHEA, the industry grew at an accelerated rate since the FDA had clearly stated regulations by which suppliers must comply. However, the Federal Trade

Commission was widely considered slow to provide guidelines for marketing and claims, and did not provide sufficient oversight as products of questionable quality were allowed to enter the market (Bent 2008). The FDA also found it difficult to introduce standards such as GMP regulations to give credibility to suppliers, which resulted in critique of the industry, negative publicity, and the deeming of some products as ineffective or potentially hazardous (FDA 2004).

Natural colors and natural products in general still have a persistent problem with quality relative to adulteration and contamination across the field of products. Issues may range from sourcing to product labeling or product claims (Betz 2007; Ho and others 2006). For example, evaluations of quality of botanical ingredients and finished products have discovered numerous examples of product adulteration or failure to meet label claims of purity (Wang and others 2006; Sun and others 2007; Rebane and others 2010; Zacharis and others 2011; Haneef and others 2013; Li and others 2013; Posadzi and others 2013; Masada-Atsumi and others 2014; Vaclavik and others 2014). To correlate the significance of these studies to the field of natural color additives, research was conducted internally by Sensient over a 4-y period during which it evaluated 650 samples that were collected from various natural color suppliers intended for direct sale to the food, drug, or cosmetic industry. Basic product specifications were tested against internal limits set by Sensient (Table 3) with evaluations conducted for the purpose of product safety and quality determination. Results of these tests indicated that 25% of the samples failed to meet these basic specifications, resulting in rejection from the supply chain. Among the primary reasons for failure included excessive residual solvents, heavy metals, pesticides, microbiological contamination, and adulteration. In the case of fruit, vegetable, or spice color extracts the presence of residual

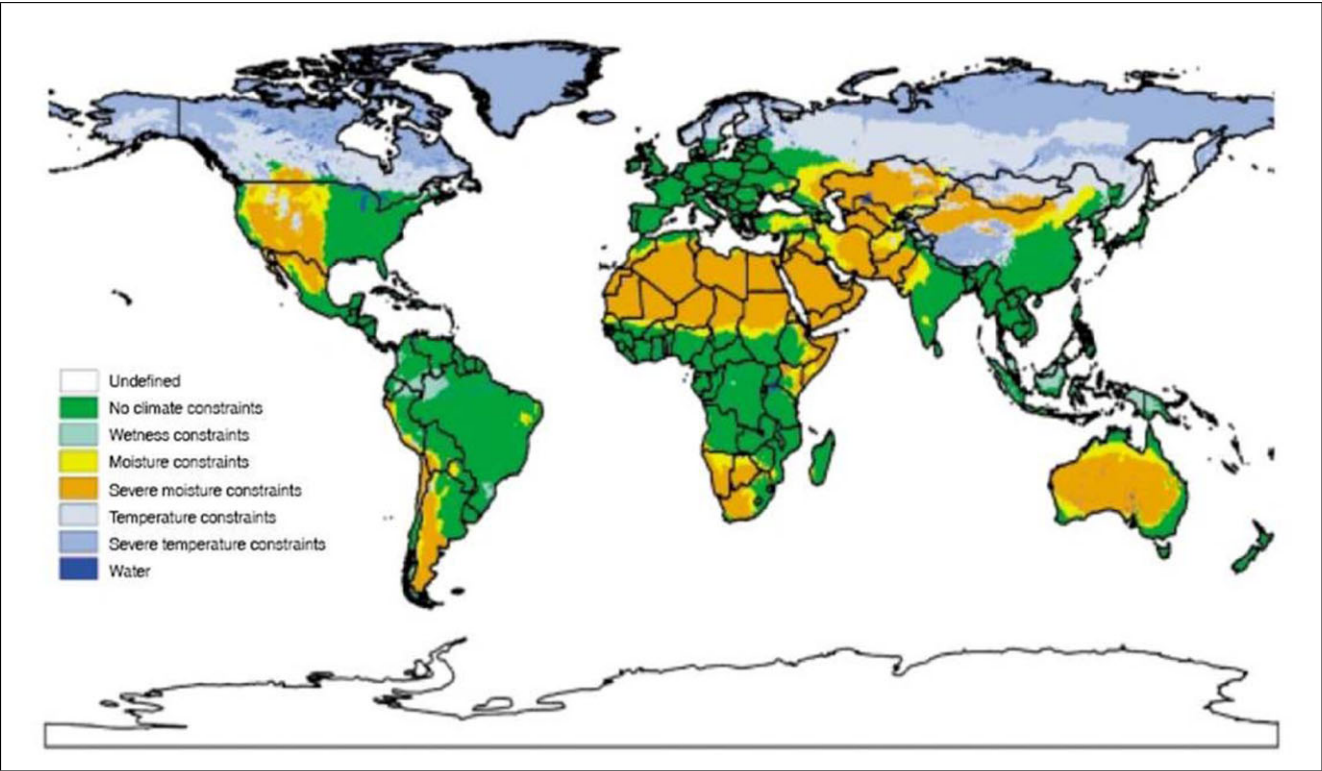


Figure 4—Climate constraints illustrate that the regions of the world from which natural colors could originate have environmental constraints, which must be considered for procurement of a reliable supply of raw materials.^a
^aReproduced with permission from the Intl. Inst. for Applied Systems Analysis (IIASA).

	Asia Pacific	Europe	North America	Latin America	Middle East & Africa
					
Natural Colors*	66%	73%	68%	72%	54%
Artificial Colors*	32%	16%	29%	37%	32%
Coloring Foods*	2%	14%	4%	2%	4%

Figure 5—Penetration of ingredients in global food and drink launches with a food coloring or colored food ingredient by world region (September 2015 to August 2016).
Source: Mintel GNPD, 2016.

solvents was the primary reason for rejection, followed by heavy metals in vegetable extracts and carmine and pesticide residues in solvent extracted colors. Specific examples of contaminations found in the survey included residual solvents in excess of >1000 ppm in color extracts, excessive lead and mercury in carmine, high pesticide residues in paprika, presence of dioxin in paprika, high levels of pathogenic bacterial, and extraction solvents not approved for use in natural colors for a specific country. Examples of specific adulterants found included *Carthamus tinctorius* (safflower)

adulterated with Orange II, paprika adulterated with finely ground red bricks, saffron adulterated with *C. tinctorius*, synthetic dyes adulterated with natural colors, Sudan dyes adulterated with turmeric and paprika, natural colors such as huito fruit extract not approved for use in the U.S. and Europe, and FD&C dyes adulterated with dyes not approved for foods, drugs, or cosmetics. The FD&C Act provides the FDA the authority to inspect and, when appropriate, detain or block a regulated product from coming into the U.S. if it is not in compliance with the Act. An import

Table 3—Example safety specification for exempt or natural colorants.

Safety risk	Specification
Heavy metals	
Lead (as Pb)	<2 ppm
Arsenic (as As)	<3 ppm
Mercury (as Hg)	<1 ppm
Cadmium (as Cd)	<1 ppm
Total Heavy Metals	<20 ppm
Microbiological Properties	
Total plate count	<1000 cfu/g
Yeast	<100 cfu/g
Mold	<100 cfu/g
Total coliforms	<3 cfu/g
<i>Escherichia coli</i>	Negative in 10 grams
<i>Salmonella</i>	Negative in 10 grams
<i>Staphylococcus aureus</i>	Negative in 10 grams
<i>Listeria monocytogenes</i>	Negative in 10 grams
Total mycotoxins	<20 ppb
Pesticide residues	
Complies with EPA	Concentration factor based on plant material
Complies with EU	
Solvent residues	
Methanol	<50 ppm
Ethanol	<250 ppm

alert with regard to colors is issued when foods enter the U.S. with mislabeled or disallowed colors based on a review of required documentation. The FDA maintains a list on its website for industry to review under the heading “Import Alert and Refusals Involving Color Additive Violations” and defines the purpose of an import alert as a means to identify and disseminate information on problem commodities and/or shippers, to provide guidance for import coverage, and to identify products and/or shippers that have met a

criterion for detention but without physical examination. Import refusals and alerts are also listed according to product category and by country of origin. For example, Import Alert 45-02 includes both certified and exempt colors and provides guidance to FDA field personnel regarding both manufacturers and/or product issues. The FDA tracking system and the reporting of countries found to be in violation (Figure 6) highlight concerns regarding undeclared and/or illegal coloring agents in the food supply. This Import Alert also illustrates areas for potential research relative to the problems facing natural colors from the detection of adulterants, illegal color additives, and extraneous matter in food products.

Proposed solutions

We propose the implementation of industry-driven standards that will translate to both safety and quality solutions for issues facing the natural color markets. By utilizing the historical and applied knowledge of the impacted industries with respect to the identification of hazards and associated risk assessment strategies, the resultant standards should mitigate risk, increase consumer and industry confidence, and provide a framework for self-regulation (Figure 7). These approaches are similar to other industries including herbal products and nutraceuticals and follow best practices adopted from both food and flavor processors.

The raw materials for natural color production are a logical starting place for self-regulation and are the 1st source of potential contamination or adulteration. Typical to the trade of raw materials in the food and botanicals industry is the development of detailed specification sheets that would be confirmed with a certificate of analysis from a 3rd-party laboratory. However, these analyses commonly report on quality characteristics (that is, color intensity, pH, and acidity) or contaminants (that is, pesticides, yeast, mold, and pathogens) and lack focus on adulterants or contaminants that

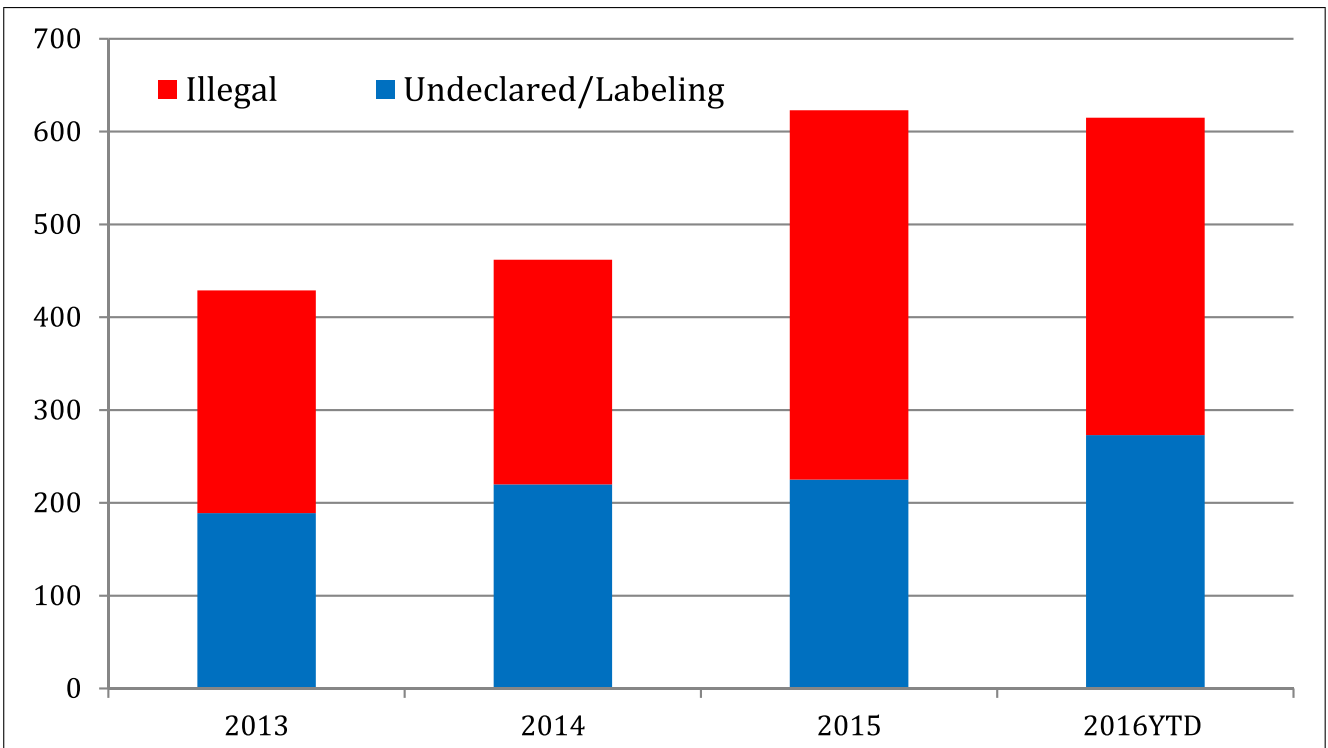


Figure 6—Number of incidents of FDA imported detentions between 2014 and 2016 (Jan-Sept 2016) for undeclared or illegal and/or mislabeled colors.

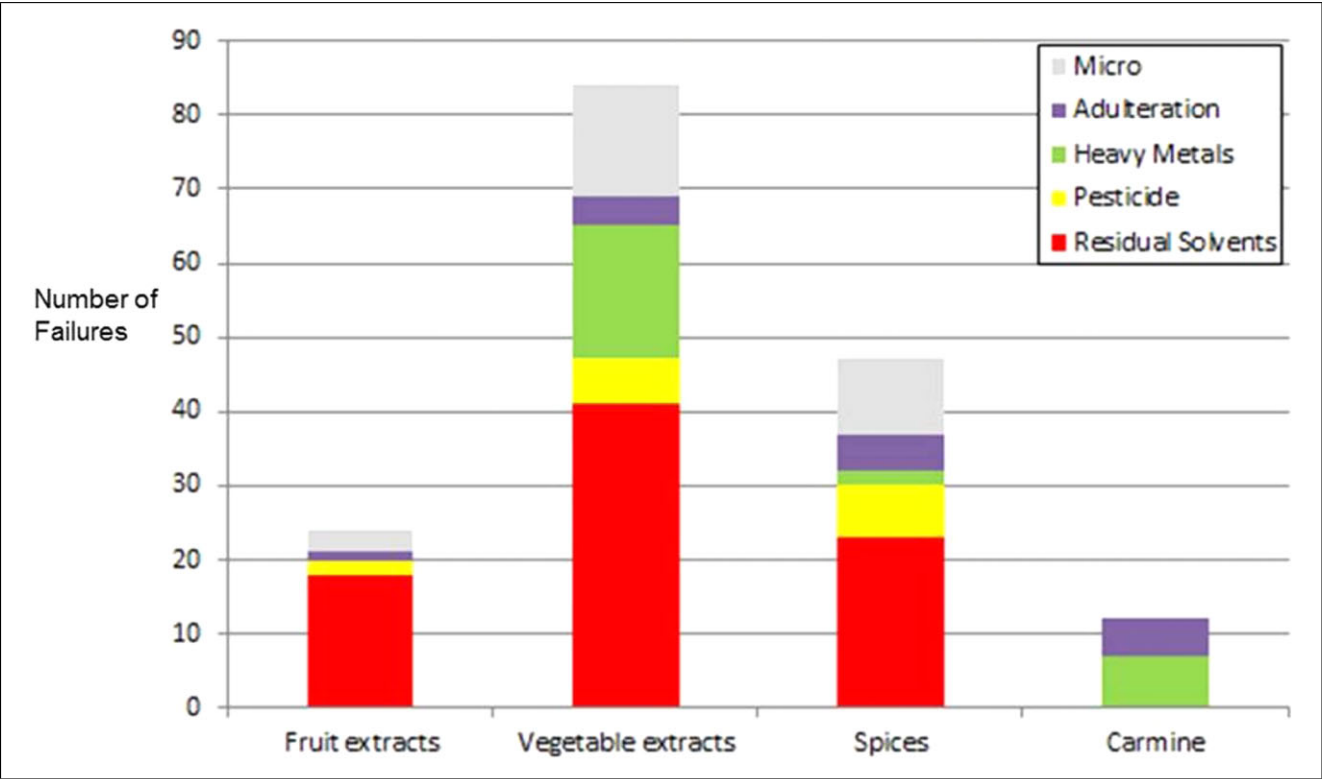


Figure 7—Prevalence of failures of natural colors in the marketplace from fruit,^a vegetable,^b spice,^c and carmine sources.
^aFruit extract is the juice expressed from the fresh fruit or water infusion from dried fruit. ^bVegetable extracts are the juice expressed from the fresh vegetable or water infusion from dried vegetables. ^cSpices include annatto, turmeric, and paprika.

can adversely impact the natural color industry. Therefore, closer tracking of potential adverse factors influencing natural colors and the development of safety standards throughout the supply chain are an absolute requirement.

A hazard analysis conducted by natural color manufacturers and suppliers would need to 1st prioritize likely sources of hazards, including historical data on prior hazards common to a country of origin or for a specific raw material (Table 4). Potential hazards may include presence of heavy metals, pesticides, residual or unaccepted solvents, and microbiological contaminations. An illustration of how evaluation criteria used for developing a hazard analysis may be applied to a HACCP plan for several exempt color sources is presented in Table 5. For example, the origin of a raw material grown in rich soils or volcanic soils may present a heavy metals hazard. Such a safety concern is indigenous to the raw material, but can be remedied by blending with other raw materials prior to processing or used for nonfood applications. Other hazards are more common to international trade, with both intentional and unintentional adulterations impacting the safety of the natural colors supply. For example, Food Sentry, LLC (2013) reported that the top 10 countries where food safety violations were recorded included (in order) India, China, Mexico, France, United States, Vietnam, Brazil, Dominican Republic, Turkey, and Spain. This illustrates the importance of considering country of origin in risk assessment and a recognition that raw materials and finished ingredients from certain countries may have increased risk of noncompliance. Among the hazards identified, excessive and/or illegal pesticides residues (33%), pathogen contamination (22%), filth or unsanitary conditions (16%), mycotoxin contamination (10%), illegal chemical and/or additive contamination

Table 4—Proposed risks and mitigation strategies for natural and exempt colors.

Risk	Mitigation strategy
Microbiological	Test all incoming raw materials for wholesomeness and spoilage. Test all finished products for pathogens, spoilage organisms, and mycotoxins.
Heavy metals	Test most common heavy metals based upon FDA, ^a EU, ^b and JECFA ^c guidelines.
Pesticides	Test for presence of pesticides that are not allowed (EPD ^d and EU)
Adulteration	Test for synthetic dyes or known additives that physically or chemically adulterate. Screen for unknown adulterants.
Extraneous/foreign materials	Botanically identify source materials. Screen for extraneous materials including soil, insects, and physical hazards. Use ASTA ^e and FDA guidelines.
Solvents and solvent residues	Evaluate supplier process for approved and unapproved solvents. Test finished products for unapproved solvents and solvent residue.

^aU.S. Food and Drug Administration.

^bEuropean Union.

^cJoint FAO/WHO Expert Committee of Food Additives.

^dEnvironmental Product Declaration.

^eAmerican Spice Trade Assn., Inc.

tion (4.5%), and heavy metal contamination (3.4%) were the most common.

Botanical authentication

The natural products industry uses an array of quality control and quality assurance procedures for proper identification of botanicals

Table 5—Evaluation criteria for developing a HACCP plan for natural coloring sources.

Color	Turmeric	Paprika	Vegetable juice	Cochineal
Country of origin	India or China	India or China	India or China	Peru or Mexico
Natural/Crop/Botanical	Yes	Yes	Yes	Yes
Import alert or known food safety incident	Sudan dyes and pathogens	Sudan dyes	Multiple	Synthetic dyes and pathogens
Kill step part of supplier HACCP	No	No	No	No
Is a preservative present?	No	No	No	No
Are nutrients present	Protein ~10%	Protein ~1%	Protein ~10%	Protein ~20%
Is Aw > 0.86	<0.86	<0.86	>0.86	<0.86
pH between 4 and 10	Yes	Yes	No	Yes
Risk assessment	High	High	High	High
Is identity confirmation possible	Yes	Yes	Yes	Yes
Heavy metals	Yes	Yes	Yes	Yes
Microbiological	Yes	Yes	Yes	Yes
Pesticides	Yes	Yes	Yes	Yes
Residual solvents	Yes	Yes	Yes	Yes
Adulterants	Yes	Yes	Yes	Yes

used in dietary supplements, which highlights the importance of using raw materials for natural colors that are properly authenticated through the use of genetic, taxonomic, and/or chemical approaches that verify the identity of the raw materials. Proper authentication is a step toward eliminating many safety, adulteration, and contamination issues relevant to processing of natural colors, especially since botanical sources are commonly used as raw materials. The need to authenticate botanical materials began after the passage of DSHEA in 1994, which opened the U.S. market to new plant-based dietary supplements. A meta-analysis examining the contamination and adulteration of herbal medicinal products found that the most common issues for herbs were dust, pollens, insects, rodents, parasites, microbes, fungi, molds, toxins, pesticides, heavy metals, and even prescription drugs (Posadzki and others 2013). This study also highlights the temptation for suppliers to adulterate products for economic gain. The natural colors industry is susceptible to similar safety and quality issues in the absence of a system of routine monitoring. There are several models and practical approaches to botanical authentication that can be used for natural colors (Brinckmann 2011). Traditional methods include visual or macroscopic taxonomic identification of the plant part used for pigment processing (Upton and others 2011) or microscopic evaluations at the cellular level (Applequist 2006). Other methods include chemical profiling of target pigments or evaluating genetic markers, although this technology is expensive and the reference databases are not fully developed. However, all raw material evaluations need to be validated for a particular color source to accommodate genetic variability and environmental variations to prevent use of nonspecified sources or synthetic materials in natural color manufacture. Source confirmation also reduces the potential risk of allergenic and/or toxic materials or lower quality plant materials that are not easily discoverable, especially if the color additive is only evaluated for the concentration of the coloring agent. For example, bilberry provides a natural red color from its anthocyanin content but may be adulterated with synthetic pigments, anthocyanins from other species, or other natural pigments such as amaranth dye (Penman and others 2006; Foster and Blumenthal 2012). To address these adulteration problems, several different chemical characterization protocols would need to be developed to confirm the identity of the raw material. However, in today's markets there are no standardized criteria for quality or safety. Thus, colors used in commerce now only need to meet their own self-reported label claims.

Raw materials adulteration

Many of the starting points for the processing of natural colors for foods and beverages rely on authentic raw material from botanical sources that are prone to intentional adulteration. Examples include annatto, a common natural carotenoid extract used as a color additive in foods, where adulterations have been reported dating back to 1856. In one report, annatto adulteration was so extensive that its actual concentration was only 30% of the product being sampled (Hogg 1856), with extraneous matter that included flour, chalk, salt, red earth, turmeric, and copper comprising the balance. Adulteration of turmeric with starch and artificial colors has been reported, and turmeric may also include extraction of different *Curcuma* spp. instead of *Curcuma longa*, the official species of commerce (Dixit and others 2009). Due to its exorbitant price, saffron (*Crocus sativus*) has been particularly vulnerable to adulteration. Saffron is the stigma of crocus flower, of which approximately 85000 are needed to produce a single kilogram, and has been the target of economic adulteration for centuries including blending with other raw materials or, more recently, the addition of synthetic dyes such as Tartrazine (Yellow #5) food coloring (Saffron Import Alert August 2013). Tartrazine is a synthetic food coloring used extensively in the food industry, but may cause allergic reactions or intolerance in asthmatics or people with an allergy to aspirin (Wuthrich 1993; Rowe and Rowe 1994; Rahman and others 2012). Thus, adulteration issues with natural colors may pose not only economic but potentially physical harm to unsuspecting consumers.

Approach to setting standards

Safety issues are among the greatest concerns to color suppliers, yet setting standards for the industry can be problematic since not all parties are likely to agree on methods of analysis or detailed specifications. However, suppliers also recognize the importance of ensuring their ingredients and consumer products are safe, despite any differences in sampling and protocols that may occur. While analysis methods are available that are reliable and accurate, a robust sampling plan that will gain the acceptance of use by the industry must also be implemented. A stepwise approach is proposed to develop standards that are widely available for the industry's common use and that consider health risks and public perception of contaminants (Lipp and Chase 2015). A successful approach will also encourage extensive monitoring of ingredient lots, producers and products, allow for random checks along the

value chain, and result in a systems approach for standards that contribute to solving both quality and safety problems.

Microbial contaminations

Natural colors are often processed from crop-based foods or food by-products and have an inherent risk for microbial contamination. These colors can be added at any time during a food processing operation, therefore it is paramount that the ingredient is safe to use in any application. A number of risk factors can dictate the level of microbial testing required for an ingredient, including the source of raw material, the type of process used to obtain the color, use of excipients or other additives, level of acidity, and water activity. Colors from natural sources should be tested for spoilage organisms, indicator organisms, and food borne pathogens. An example specification for microbiological and mycotoxin levels is presented in Table 3. While the presence of pathogenic bacteria should always have a zero-tolerance specification, other evaluations such as elevated yeast, mold, and total plate counts can be indicative of poor postharvest or postprocess handling, breached package seals, or conditions suitable for bacterial survival or growth. Mycotoxin tests are product-specific, and can reveal issues in the quality of raw materials prior to processing. Standard methods for microbial determination may also be problematic since natural colors are often highly concentrated and may contain natural or added microbial inhibitors or even solvent residues that interfere with evaluations. For some colors, new or modified methods may be required such as dilution, solvent removal, or neutralization, as well as inoculation trials and accelerated shelf life evaluations.

Solvent residues

Organic solvents are used extensively for extraction, purification, column chromatography, and concentration of a variety of natural colors (Delgado-Vargas and others 2000). Solvent removal is important due to the health risks associated with their consumption or exposure (USP 2013). FDA regulations limit the types of solvents that are acceptable for use for natural colors as well as the allowable concentration of residual solvents that may be present. Solvent monitoring is critical as it ensures the safety of the color extract and insures that only approved solvents are used as specified in the applicable FDA listing regulation. An example specification for residual methanol (<50 ppm) and ethanol (<250 ppm) is listed in Table 3; regulatory limits for other solvent residues by various countries are summarized in Table 6. However, limits for only a few organic solvents have been published for foods, with lack of harmonization among regulatory bodies. Moreover, these limits fail to provide information that encompasses the possible combinations of solvents used to produce the colors available in the marketplace. Although an emphasis is often placed on residual solvents or unspecified solvents, it must be recognized that solvent extractions can also concentrate nonpolar toxic compounds such as pesticides and fungicides that may pose a separate health risk to consumers. Residual solvents are typically determined using chromatographic techniques such as gas chromatography with static headspace sampling (Westmoreland and Rhodes 1989; Mulligan and McCauley 1995; Snow and Slack 2002; Hakkarainen 2007) using a flame ionization detector as standard analytical protocol for food additives (JECFA 2006). For identification of unknown solvents, chromatography coupled with mass spectrometry will allow for tentative identification and can be used in conjunction with manufacturing specifications to determine if unapproved solvents were used in manufacture.

Table 6—Allowable limits of residual solvents (mL/L) used to extract exempt or natural colors.

	United States ^a	European Union ^b	Japan ^c	Korea ^d
Acetone	30	50	30	50
1,3 Butylene glycol	MA ^e	n/a ^f	n/a	n/a
Ethyl acetate	MA	50	n/a	n/a
Ethyl chloride	30	n/a	n/a	n/a
Isopropyl alcohol	50	50	50	30–50
Methyl alcohol	50	50	50	50
Methylene chloride	30	10	n/a	10–30
Hexane	25	50	25	25
Trichloroethylene	30	n/a	30	n/a
n-Butanol	n/a	50	n/a	n/a
Methyl ethyl ketone	n/a	50	n/a	n/a
Ethyl alcohol	n/a	50	n/a	n/a

^a21 CFR 173 Subpart C. Solvents, lubricants, release agents, and related substances for spice oleoresins.

^bEC Commission directive 95/45/EC. Purity criteria concerning colors for use in foodstuffs.

^cSpecifications and Standards for Food Additives Section E, Ministry of Health Labor and Welfare.

^d2013 Korean Food Additive Code, Article 3.B. Standards and Specifications for Natural Additives.

^eMA = Minimum Allowance; used in the minimum amount required to perform its intended effect.

^fInformation not available.

Table 7—Current and proposed limits (mg/L) for heavy metals in exempt or natural colors.

	Mercury	Arsenic	Lead	Cadmium ^f	Total
FDA 21 CFR ^a	<1	<3	<10	n/a	n/a
Health Canada	n/a	<3	<10	n/a	<40
EC 231/2012 ^b	<1	<3	<2	<1	<40
JECFA ^c	<1		<2	n/a	<40
JFSA ^d	n/a	<2	<2	n/a	<20
GB Standards ^e	<1	<1	<10	n/a	<20
Proposed limits	<1	<3	<2	<1	<20

^aU.S. Food and Drug Administration.

^bEuropean Community.

^cJoint FAO/WHO Expert Committee of Food Additives.

^dJapanese Food Sanitation Act.

^eMandatory Natl. Standards for China.

^fInformation not available.

Heavy metals

Natural colors are similar to other value-added ingredients in their potential to contain naturally occurring contaminants such as heavy metals. Certain limits have been outlined by regulatory agencies in different countries. The proposed limits in Table 7 are an aggregate comparison among these regulators.

Adulterants and contaminants

Among the many risks associated with the color industry, the most alarming is the threat of intentional adulteration. For example, Figure 8 shows potential color adulterants that could be used to adulterate color additives from natural sources or food coloring materials based on their visible spectral wavelengths and color characteristics. Although private laboratories may have testing protocols established for color adulterants in certified colors, regulatory agencies would need to review, compare, validate, and publish these methods before their adoption as standard methods so that the ingredient industry can be assured of no intentional adulteration. Current FDA regulations exist that classify a color as adulterated if any such detectable contamination is present, and bars these products from entering commerce. Compared to certified colors, natural products analytical chemistry is more complex



Figure 8–Potential adulterants to colorants from natural sources or food coloring materials based on their visible spectrum and color characteristics.

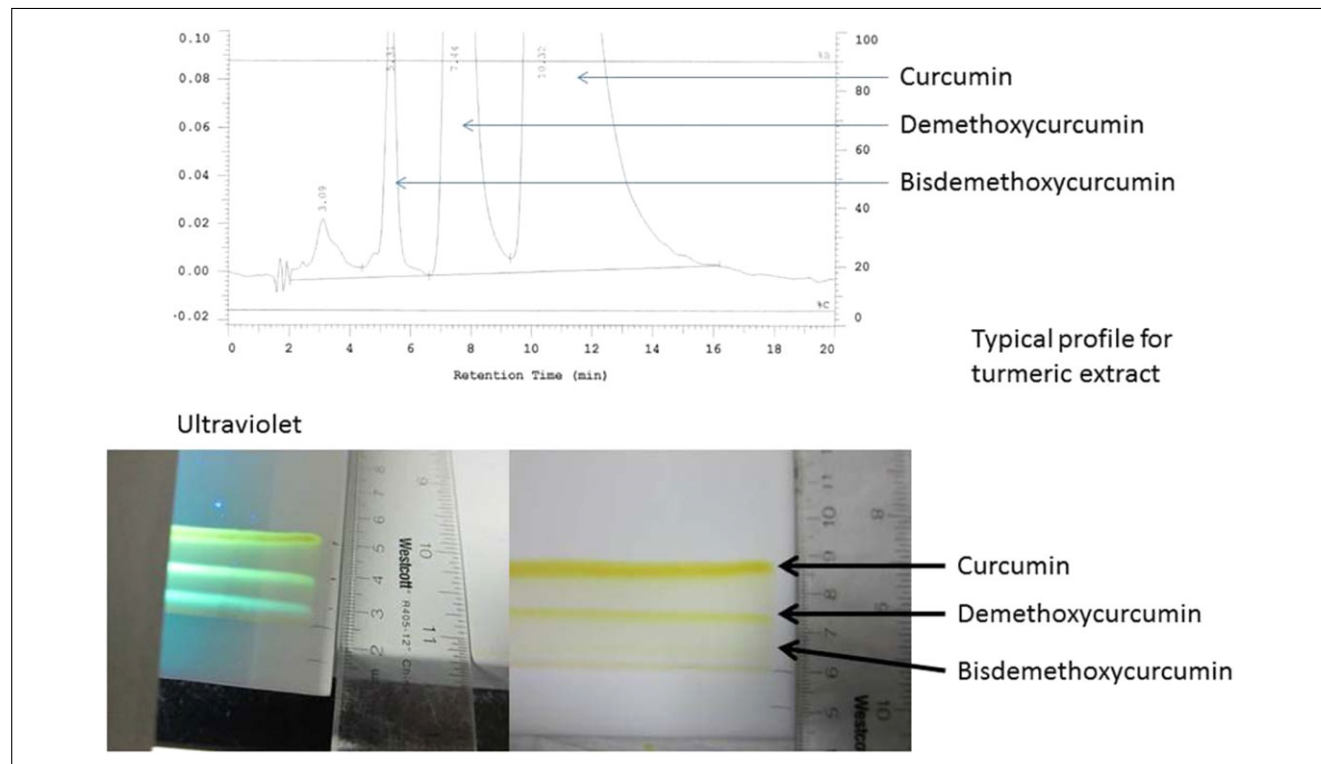


Figure 9–Representative quality control screen of turmeric extract using HPLC and ultraviolet illustrating 3 of the major marker compounds. Source: Sensient Technologies, LLC.

and naturally diverse and the industry may not have expertise or instrumentation to conduct their own detailed chemical characterizations. Thin layer chromatography (TLC) and high performance liquid chromatography (HPLC) are two techniques for basic and sophisticated evaluations, respectively. Both are widely used in the development of international standards and in the identification

of natural color additives and their quality (Wu and others 2005; Cassinese and others 2007; Welch and others 2008; USP 2013). TLC is a qualitative tool for pigment identification and source verification that, when used against an authentic reference sample, allows the detection of a presumptive adulteration (Delgado-Vargas and others 2000). Use of HPLC alone or in combination with a

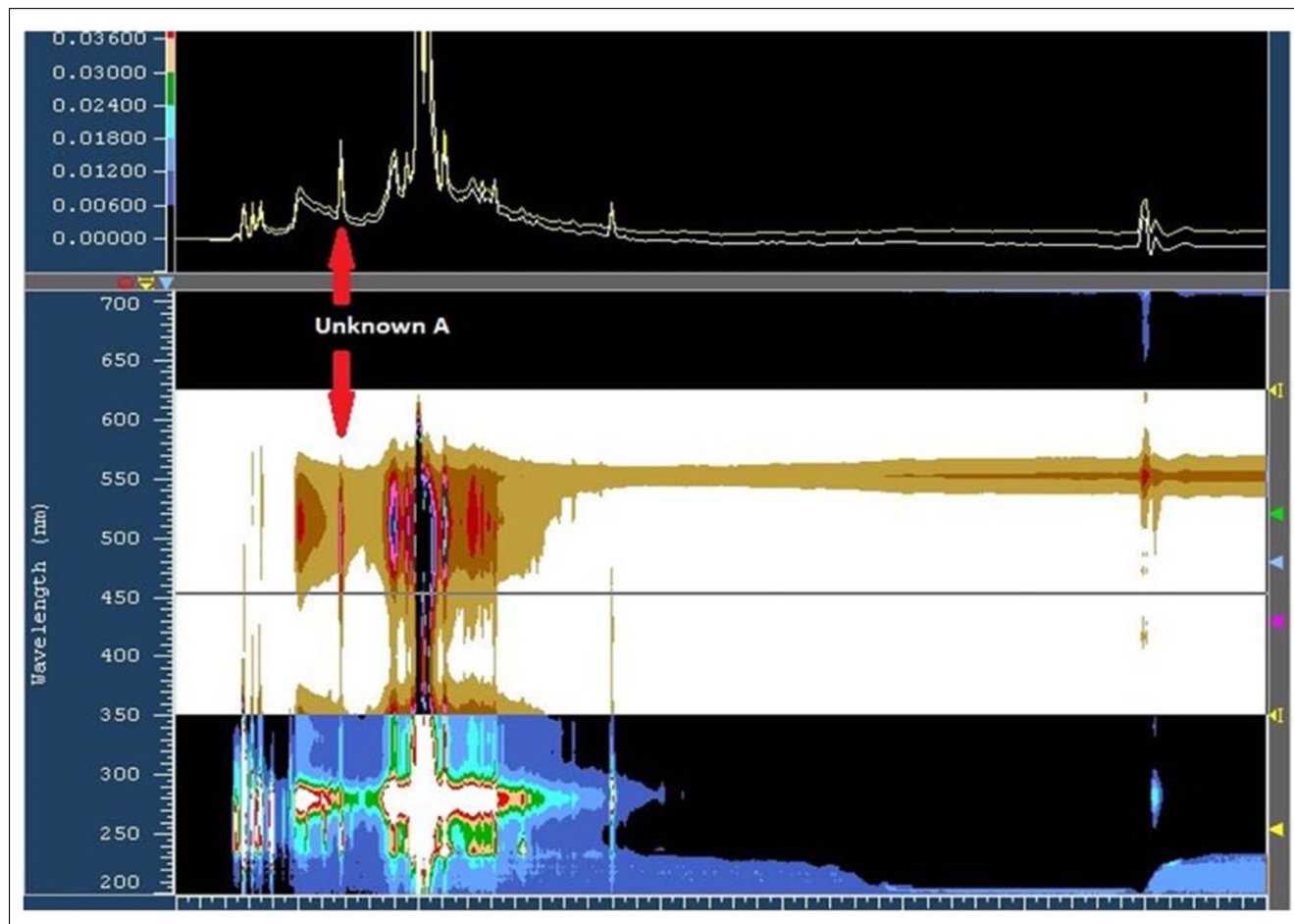


Figure 10—A sample HPLC chromatogram illustrating an analysis of carmine and an unknown contaminant/adulterant.

Source: Sensient Technologies, LLC.

range of detectors and/or TLC under visible or UV light is a classic approach of partition chromatography to separate individual compounds from a complex matrix and compare against a known chemical composition, as illustrated for yellow curcuminoids from turmeric root in Figure 9. The presence of an unknown compound on the TLC plate or chromatographic peak is an indication of a potential contaminant or adulterant. Likewise, as is illustrated in Figure 10 using an HPLC chromatogram and diode array spectra from 200 to 700 nm for carmine, the presence of an unknown compound presumptive of an adulteration is shown, later confirmed as the synthetic red color Ponceau 4R. Similar adapted techniques such as high performance TLC are commonly used for botanical identifications and can be adapted to screen colors for both known and unknown adulterants against a reference sample. Infrared spectroscopy (IR) has also been proposed as a rapid and cost-effective tool for food surveillance to deter economic adulteration and monitor for unintentional contamination. Powerful pattern recognition techniques can be used to screen raw materials and final products and to monitor food authenticity (Rodríguez-Saona and others 2016). Analytical chemistry is an effective tool to tentatively identify and even confirm the identity of compounds that should not be in either pure or mixed natural color additives, especially when compared against a database of known potential color adulterants.

Regulatory Environment

Development of uniform standards by an industry is an initial step toward insuring the quality and safety of its ingredients for the public. By contrast, electing a route of formal regulation and oversight by government sectors can lead to contentious debates and significantly lengthen the time to implement the desired standards. Some in industry may contend that a loosely regulated or unregulated field provides greater freedom for innovation and the ability to form strategic partnerships in the market. Others may see a lack of regulation as an open door that enhances risk and vulnerability to problems that could adversely impact the entire marketplace. Moreover, since some natural colors are processed from agricultural raw materials, it may be difficult to reach agreement on methods of identification, analysis methods, or reference standards due to their complex chemical composition. Similar to concerns with fruit juice authentication, some natural colors may vary considerably due to cultivar differences, environmental factors, handling conditions, and method of processing. If established, industry-wide standards imposed on a natural color may inadvertently limit accessibility to previously available and affordable source and unintentionally alter its market potential. However, wise selection of quality and safety standards should give added security to the sector for long-term growth and stimulate the inclusion of natural colors into more consumer products. As the food safety regulatory

landscape changes, most notably by the passing of the Food Safety Modernization Act, the natural colors industry should change as well and be proactive with its self-regulation policies to collectively solve some of its major issues such as intentional adulteration. A recommended approach is one of collaboration among regulators and the private sector to begin drafting a scientific and practical basis for robust standards that lead to an agreeable regulatory framework. All parties involved, especially consumers, expect at least minimum safety standards from a food product with natural colors. With the healthy halo surrounding foods with natural colors, these market suppliers have an added responsibility to ensure product safety and to ensure consumer and brand protection.

Benefits and Conclusion

This review outlines current safety and quality issues involving color additives for foods from natural sources, and calls upon the processors and suppliers of these colors to establish industry standards. By agreeing to a mutually beneficial approach in the use and definition of standards, perhaps the most serious adverse events, purposeful adulteration, and inadvertent contamination can be averted by the industry. We contend that a major product safety incident involving natural colors could alter the entire landscape of the natural color market and lead to shortages of supplies and a loss of consumer acceptance due to increased risk and liability. Reaching industry-wide agreements on the proper collecting, harvesting, handling, and processing of natural colors could easily follow the WHO-accepted guidelines now in place for medicinal plants. Guidelines could be used to ensure traceability from source and across the supply chain as required for other food ingredients and linked with predefined specifications and appropriate labeling. This would also help prevent an unscrupulous supplier from selling a rejected color through a different market channel. This benefits the industry, consumers, and prevents purposeful adulteration of natural colors with synthetic dyes, unspecified colors, or physical contaminants. The elimination of colors with pesticides, heavy metals, and microbial contamination at unacceptable levels and the exclusion unapproved pesticides and solvents can also be achieved. Although this approach to improve safety and quality is not new for the food industry, its application to the natural color market is timely to address the unique challenges of this market. Advantages to the development and implementation of standards may include higher quality raw ingredients, harmonized international standards, botanical authentications, consumer safety and confidence, and ultimately market and brand protection for the impacted industries. Establishing standards for colors from natural sources can facilitate their growth in the market and expand economic opportunities for the industry based on a science-based approach to provide the needed quality and safety assurances.

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