ESTABLISHING STANDARDS ON COLORS FROM NATURAL SOURCES*

SENSIENT®

Background

Food and beverage colors are used in a wide range of different products. Numerous studies have concluded that color is at least as important as flavor in determining consumer preference for a given food product.

Color additives are defined by the Food and Drug Administration (FDA) as any dye, pigment, or substance that can impart color to a food, drug, cosmetic or to the human body. Under the present regulations, color additives fall into two categories:

1 Certified colors, subject to the FDA certification process

2 Colors exempt from certifications, often referred to as 'natural' colors

In recent years, consumer interest and demand for "natural" colors has led to growing use of exempt plant extracts and other materials as food colorants.

Natural Sources

Current regulations for colorants from "natural sources" lack a consistent definition as well as publicly available quality control and product safety specifications. There is also a lack of agreement regarding appropriate methods for testing the purity of these colorants. A survey conducted by Sensient Colors in 2015 reported that 34% of American consumers surveyed were either very or extremely concerned about synthetic or artificial food colorings and 66% were at least somewhat concerned. This represents a significant and growing market share that has been undervalued and underserved.

To address the pressing need for consistent standards for generation and application of colors from natural sources, a panel of experts in plant biology, food chemistry, food toxicology, food product development and manufacturing, as well as food quality and regulatory affairs was created. The focus of this expert panel was to discuss and deliberate quality attributes and potential safety hazards affecting food colorants from natural sources. This effort was sponsored by Sensient Technologies in collaboration with the U.S. Pharmacopeial Convention.

Historical Perspective on Color Regulations

Colorants have a long history, dating back to ancient Egypt, where they were used to color food and cosmetics. Foods have also long been adulterated with colorants, such as chalk in milk. In 1396, the first decree prohibiting the use of colorants in milk was issued in Paris (Burrows 2009). Until the middle of the 19th century, all colorants used in foods, drugs and cosmetics were from animals, vegetables and minerals - all natural sources. In 1856, Sir William Henry Perkin discovered the first synthetic organic dyestuff, and artificial colors took off (Burrows 2009).

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In 1886, the U.S. Congress passed the first bill allowing colorants in butter and in 1896 Congress recognized colorants in cheese (U.S. Congress, 1896). The rise of the use of colorants was prompted by changes in food technology—more processed foods, use of preservatives, refrigeration and canning, all of which altered the natural

appearance of foods. Consumers then began demanding that something be done to restore the natural color of foods.

Dr. Harvey Wiley took over the Division of Chemistry (the early Food and Drug Administration) in 1883, with a major goal of protecting the purity of the nation's food supply. States were passing their own laws, which prompted a demand from industry for consistent standards. In 1899, the National Confectioners' Association issued a circular that enumerated 21 coal-tar colorants found in foods that they 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." Dr. Bernhard Hesse, who was hired as an outside consultant by the Division in 1906, conducted extensive studies on hundreds of colorants to determine which ones could be safely added to food. He proposed a list of 7 colorants and established a procedure for the certification of these and future colorants. Up until then, quality had been poor and some firms took up the challenge to make purer colorants. One of these companies was H. Kohnstamm & Co. On April 1, 1908, the first batch of colorants produced by the company was certified. Then the Food, Drug and Cosmetic Act was passed in 1938—giving teeth to the 1906 Act (Burrows 2009).

As this white paper will illustrate, there are similar areas of concern with colorants from synthetic and natural sources and, as demand for natural colorants increases, better standards will be needed to ensure they are safe for consumption.

Current Regulatory Situation

The FDA oversees color additives in foods, drugs, cosmetics and medical devices. All color additives that are required to be listed by the FDA fall into two categories: Those subject to the FDA's certification process, and those that are exempt. Those that are exempt are generally those derived from plant or mineral sources.

In 1960, the FDA passed the Color Additive Amendment, which also included the "Delaney Clause." The amendment defined the term "color additive" and required that only color additives listed as "suitable and safe for a given use could be used in foods, drugs, cosmetics and medical devices." The amendment outlined the procedural regulations for the petition process for a color to be listed. Also included through the Delaney Clause, was a prohibition of listing a color if it was shown to be a carcinogen.

Certification-exempt color additives must comply with identity and purity specifications and use limitations described in their listing regulations (in Section 401 of the Act), establishing some basic standards for these

substances. In Title 21 of the CFR, parts 70 to 82, the FDA issued certain regulations for color additives. In these sections, the identity of each listed color additive, its chemical specifications and identified uses and restrictions are described. The use of an unlisted color additive, or the use of a color additive that doesn't conform to the purity and identity specifications of the listing regulation may cause a product to be considered adulterated, according to the provisions of the FD&C Act, and the FDA may take enforcement action against such products.

While the FD&C Act allows food ingredients to be exempt from the definition of a "food additive" if they are GRAS (generally recognized as safe), such an exemption does not apply to color additives.

There are examples of GRAS ingredients that are also listed as color additives, such as ferrous lactate (21 CFR 184.1311 and 21 CFR 73.165). Therefore, even if a substance is listed as a GRAS substance, it would still require pre-market approval by the FDA as a color additive.

Trends

With increasing demand for natural colorants comes the requisite need and expectation of a reliable and consistent supply of defined raw materials. In the future, global food and food ingredient shortages could occur due to many factors, ranging from environmental degradation, loss of agricultural areas due to increasing urbanization, infrastructural limitations in developing countries, competition for food production and even political instability, to the effects of climate change and population growth.

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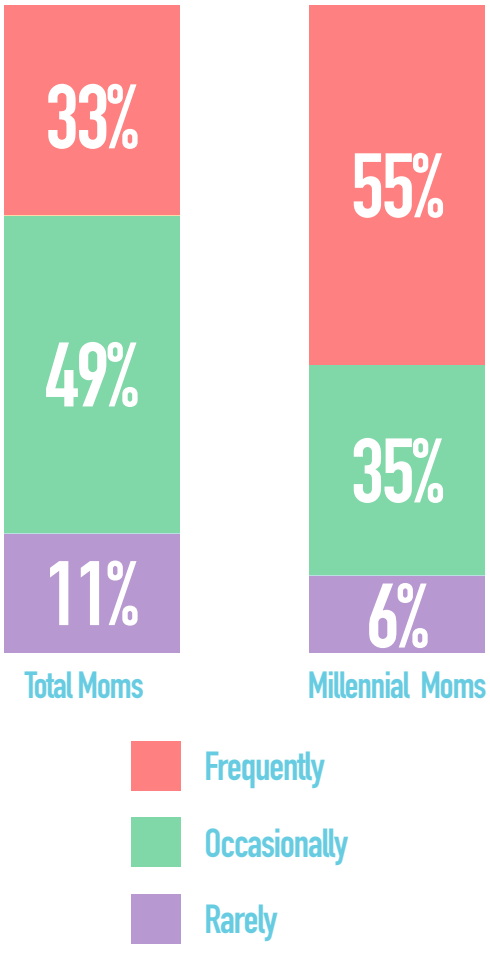
All of these factors contribute to a supply of inferior plant pigments, creating a climate in which some individuals may compensate with the addition of adulterants. The field of medicinal and aromatic plants is challenged by a similar concern. As a consequence, the WHO drafted a series of publications that serve as guidelines for the wild crafting/collection and cultivation of medicinal and aromatic plants (WHO 2003). Such guidelines are now used around the world and help provide the framework for traceability from the origin of the plant through the value chain into a final processed product and can be used if/when needed for ethical sourcing and provide established guidelines for

How often do other people ask your opinion when making purchase decisions?



the documentation of non-adulterated and non-contamination of raw materials.

The Consequences to an Industry with a Lack of Controls

The natural food colors industry can look to the experiences of the herbal products industry to avoid similar fates. As noted, natural colors are enjoying annual sales growth and increased consumer demand. People are seeking food products with natural colors over those that are artificially colored in the belief that those foods are safer. One food safety incident, coupled with media exposure of the lack of standards and food safety testing, is all it takes for natural colors to be abandoned by consumers. The industry would experience a significant drop in sales as a result. This statement is not made from conjecture, but from direct experience with the history of herbal products.

Prior to the passage of the Dietary Supplement Health and Education Act (DSHEA) of 1994, herbal products (now called dietary supplements) enjoyed a good reputation with, and enthusiasm from, consumers. Prior to passage, Congress received the most correspondence from consumers since the Vietnam War (wanting the FDA to NOT restrict the sale of herbal products). When DSHEA was passed, in fact, the industry grew at an even faster rate, as the FDA had clearly laid out the 'rules' or regulations to which companies needed to adhere (and they were not strict), so that companies now had the confidence to invest in product development and marketing. In the 4.5 years after the passage of DSHEA, the industry grew exponentially to an estimated US$12 billion.

However, the FDA was slow in developing the final key standards needed (the GMP regulations, namely) to lend credence to the industry, and this became the material the critics used to 'debunk' the industry, especially as a controversy was building with the herbal supplement ephedra. Since then, the industry has ridden the rising and falling tides of consumer distrust.

Hazard Analysis

The origin of raw material sources is an area of serious concern, largely due to the presence of heavy metals, which is more common in material originating from some countries. Some safety issues are indigenous to each raw material and it is unclear to what degree blending and other practices contribute to violations.

As raw material is the starting place for any natural product, and is a source of adulteration, this is where the standard-setting process should begin. Typical to the trade of raw materials and natural products is the development of 'specification sheets,' which would be crosschecked with a 'certificate of analysis.'

Botanical Authentication

There are several models and practical approaches to botanical authentication that can be used for natural colorants. Without such authentication, there is an increased risk that the material from which the natural colorant originates may be purposefully or inadvertently sourced from plant materials other than what is disclosed on the label or combined with other improperly labeled plants or synthetic materials. Some of these adulterants, even when from natural sources, may contain other allergenic and/or potentially toxic materials or lower cost plant materials not easily discovered, especially if the colorant is screened only for the concentration of a particular color compound.

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Adulteration from Raw Materials

Many of the starting points for the development of natural colors for foods include the use of raw material from botanicals. The problem of adulteration within the herbal industry prompted a study by several industry organizations to take an in-depth look at commercial plants and their common adulterants. The natural colorant, saffron, has been particularly vulnerable to adulteration, because it is expensive and difficult to obtain. Although the adulteration of this favored spice has been a

Managing the Key Risk Factors for Natural Colors

Hazards	Mitigation Strategy
Microbiological	Test all incoming raw materials for pathogens. Test all finished products for pathogens and spoilage organisms
Heavy Metals	Test for most common heavy metals (FDA, EU & Codex)
Pesticides	Test for pesticides that are not allowed (FDA, EU & Codex)
Adulteration	Test for synthetic dyes or other additives that adulterate product. Screening established for unknown adulterants
Unauthorized Solvents	Map all supplier process and detail solvents used to ensure they meet all local regulations. Test for the presence of solvents.
Supplier Reliability	All vendors should be "certified" by the manufacturer
Raw Material Traceability	Need full traceability for all ingredients

problem for hundreds of years, it will continue until the industry accepts standards to easily check for the presence of the raw material on a routine basis. A recent import alert for saffron adulterated with unauthorized tartrazine food coloring is evidence of the problem. Other adulterants and risk factors to colors from natural sources include microbial contamination, solvent residues, and pesticide residues. A comprehensive testing protocol to identify these risk factors is required.

Benefits and Conclusion

We are all aware of the food safety incidents that have occurred with products supplied out of several countries, notably China. The key benefit to this initiative is to ensure safe colorants in the marketplace, to build consumer confidence, to convince more manufacturers and processors to use natural colors by facilitating a strong, agreed-upon approach in their use and definition and, perhaps most importantly, to preempt a future, serious, adverse reporting incident resulting from purposeful or inadvertent adulteration and/or contamination. The crops that provide the raw materials from which natural colorants are produced come from similar growing regions across the globe. It will take only one major product safety incident involving natural colors to change the entire landscape of the industry. Reaching an industry-wide agreement on the proper collection and harvesting of plants for their

natural colors could easily follow the WHO-accepted guidelines now in place for medicinal plants. The WHO Guideline on GACP for Medicinal Plants (2003) could be used as a template to ensure traceability, beginning with the collection of the plant and ending with what consumers put on their plates, which is required of other foodstuffs.

The advantages of development and publishing the proposed standards include:

- Higher quality color sources available to processors, therefore raising the quality bar across the industry
- Developing and harmonizing standards will stimulate trade
- Ensuring a practical system relative to botanical authentication
- Ensuring consumer product safety
- Better definition of product quality
- Guidance for sourcing
- Brand protection of all companies in the supply chain
- Availability and reference by all in the industry
- Stimulating industry "self-policing," thus preventing the FDA from establishing further enforcement or restricting trade in natural colors

CERTASURE™

The Certasure™ Program

Until either Food Industry trade groups or the FDA itself defines a specific set of standards for natural-sourced colorants, there is a risk of a similar outcome to the herbal supplement market. For this reason, Sensient has created a comprehensive certification program for colors from plant sources that combines stringent quality testing, comprehensive vendor certification, full raw material traceability and best manufacturing practices to ensure that colors from natural sources meet all safety and authenticity requirements. Backed by Sensient, the global leader in food and beverage colors, Certasure™ provides food manufacturers full brand protection.

* Source: The Committee on Standards for Natural Colors, 2015

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