COMPREHENSIVE REVIEWS IN FOOD SCIENCE AND FOOD SAFETY

Palette of Our Palates: A Brief History of Food Coloring and Its Regulation

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ABSTRACT: Food color additives are vital to how we taste and perceive food, yet they generally remain mysterious to the public. This article examines food color additives from historical and regulatory perspectives. First, it uses recent examples to illustrate the importance of colors to our enjoyment of food. It then recounts the early history of food colors and the emergence of regulation to prevent their unsafe and fraudulent uses. The margarine war of the late 19th and early 20th centuries is described, as well as the 1906 and 1938 Food and Drug Acts. The article then enters the modern era of color additive regulation, beginning with the Color Additive Amendments of 1960. The debate over the Delaney anti-cancer clause is assessed, as well as other recent safety and regulatory controversies. The article asserts that this string of incidents has gained public notoriety for color additives. The article concludes by discussing the future of food coloring and the move towards more natural dyes.

The Power of Color: Tasting With Our Eyes

It looked like 1993 would be the year of clear. Color was out; clear was in. Pepsi launched a huge national rollout of its brand new clear soda, Crystal Pepsi. In ads, as Van Halen's hit song "Right Now" played, the drink was touted as the "Clear Alternative to Cola."[1] One survey rated it as the best new grocery product of 1992 (it had already been sold in several test markets).[2] The product was certain to be such a hit that Coca-Cola planned to unveil a competing product, Tab Clear.[3] The beer industry was surely not going to be left out, with Miller prepared to begin test-marketing a clear beer.[4] Clear beverages were going to be a surefire success. After all, Amoco's "crystal clear" gasoline had been a hit for years, and cosmetics companies were cleaning up with clear versions of soaps and deodorants.[5]

But a funny thing happened to transparent beer, Tab Clear, and most notably Crystal Pepsi: they flopped. Miserably. Obviously, nobody wants to drink a clear, carbonated soft drink, right? Well, not quite; 7-Up has been clear since 1929 and is an American institution. (Ironically, 7-Up was originally colored dark and went clear 77 y ago to separate itself from competitors.) But despite differing only in color, Americans just could not accept their cola (or beer) in clear form. One analyst offered this prophetic comment at the beginning of 1993: "The companies have spent 100 years convincing people that colas are dark. They're dark because they put coloring in them, but that's beside the point. People will ultimately go back to the darker sodas because they will decide they prefer colas that are 'real'."[6]

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Experts have long known that color plays a crucial role in the taste and perception of food. Alongside flavor and texture, color is considered by food scientists to be a major quality factor of food. In fact, it might be the most important of the 3. "If you don't have the color right, I think you can forget about the other two," says Jack Francis, food scientist at the Univ. of Massachusetts. "If it isn't the color you expect it to be, you don't like it."[7]

This was likely the downfall of Crystal Pepsi; the actual taste did not coincide with what its color (or lack thereof) suggested. Subconsciously, consumers probably expected a lemon–lime or slightly fruity taste and were thrown off when they tasted traditional cola. According to Nicki Engeseth, food scientist at the Univ. of Illinois, "People are strongly influenced by perception based on sight. If you put yellow food coloring in vanilla pudding, before they even taste it, they will think it will be lemon or banana. They will tell you it is lemon or banana even after tasting it because they are so strongly perceiving it as lemon or banana."[8]

Our reaction to the appearance of our food is often visceral and ingrained in us through millennia of habit. According to food researchers, when early humans searched for food, they had to learn to avoid toxic or spoiled objects. Color was the most readily accessible clue, and such inedible items are often blue, black, or purple. Blue has long been one of the most popular colors in human decoration, but it is known to be one of the least appetizing. Studies have shown that people actually lose appetite when fed food dyed blue.[9]

Food manufacturers have dealt with this limitation of their palettes in an ingenious way: they have kept blue away from "real" foods, and relegated it to the realm of "fun": candy, kids cereals, and sports drinks. "You can do candy in any color and people will eat it because it is fun," says Engeseth. "But put that color on somebody's plate and people don't typically associate

blue with an edible product. You very rarely see anything blue on a plate."[10]

This boundary between fun and serious foods faced a serious test earlier this decade. To appeal to kids, food companies unveiled an array of traditional foods in unconventional colors. Ore-Ida put out "Kool Blue Funky Fries" and Parkay marketed margarine in "Electric Blue" and "Shocking Pink."[11] The trend was kicked off by Heinz's EZ Squirt ketchup, which in 2000 first appeared in green.[12] The condiment was such a hit (it actually increased the company's total sales of ketchup by more than 5%)[13] that other colors followed. The trend peaked with the introduction of Kellogg's Mickey's Magix cereal, which launched a full-scale assault on one of the most wholesome and natural of foods: it promised to turn milk pastel blue.[14]

Despite the early success of these colorful products, they are all, predictably, now defunct. Consumers may initially be intrigued by the novelty of a colored version of a "real food," but ultimately they want unnatural hues limited to the perceived "fun foods." Blue M&Ms and yellow Gatorade may be around forever, but do not expect to see green meat for any more than a fleeting moment.

This does not mean that distinct coloring is only used for novelty or excitement; colors are an integral part of our most cherished staple foods. One look through any ordinary pantry or refrigerator reveals the incredible variety of colors we have come to expect from "real foods." From the creamy yellow of margarine to the deep greens of pickles, from the seductive ruby red of grapefruit juice to the wholesome brown look of cereals and crackers, our diet could be mistaken for a painter's canvas. And what do each of the aforementioned foods have in common? Besides from being typical foods in the average American diet, there is a good chance that each of them includes an ingredient with no other purpose than to impart color.

The FDA characterizes these ingredients as "color additives," but they are more popularly known as food colorings or dyes. And while the intense scrutiny given to each food component is a relatively recent development, color has been added to food since time immemorial.

While Ancient Egyptian writings tell of drug colorants, archaeologists believe food colors likely emerged around 1500 B.C.[15] Saffron is mentioned as a colorant in Homer's *Iliad*, and Pliny the Elder remarks that wines were artificially colored in 400 B.C.[16] Until recently, food coloring could only be obtained from what people readily found in nature.[17] For instance, saffron has long been used to give a yellow tint to rice, and squid ink gives pasta a black appearance[18]. Other popular natural colorants have included paprika, turmeric, beet extract, and petals of various flowers.[19]

By medieval times, chefs had discovered a selection of natural dyes for each color. However, most of these colors were hard to come by and so were reserved only for the upper classes.[20] This led to the belief in early Renaissance Europe that color in food indicated nutritional value and an inherent medicinal power.[21] Eating deep red colors produced full, rich blood, and golden colorings promoted divine solar healing.[22]

Unfortunately, most of the exotic plant extracts used were neither brilliant nor consistent enough for today's standards.[23] Diets filled with specially colored foods were unknown to all but the most well-to-do of our ancestors, as the known colorants of the past were lacking in both availability and potency.

Copper Pickles and Lead Candy: The Run-Up to Regulation

The only encounter with food color that a peasant of the middle ages might have had was with poisoned bread. As true refined white flour and bread were preferred by the elite, manufacturers often produced cheap versions for the peasantry that used lime, chalk, or even crushed bones to attain the desired effect.[24] The proliferation of bread tainted with deleterious white colorings spawned one of the oldest surviving instances of food adulteration regulations, from the time of King Edward I (1272 to 1307).

> *If any default shall be found in the bread of a baker in the city, the first time, let him be drawn upon a hurdle from the Guildhall to his own house through the great street where there be most people assembled, and through the streets which are most dirty, with the faulty loaf hanging from his neck; if a second time he shall be found committing the same offence, let him be drawn from the Guildhall through the great street of Cheepe to the pillory, and let him be put upon the pillory, and remain there at least one hour in the day; and the third time that such default shall be found, be shall be drawn, and the oven shall be pulled down, and the baker made to foreswear the trade in the city for ever.*[25]

Other early coloring laws include a 1396 French edict against coloring butter, and a 1574 French law that forbade coloring in pastries to simulate the presence of eggs.[26] Despite the threat of punishment, laws like these were generally ignored due to the difficulty of enforcement and the simple fact that there was, and still is, a lot of money to be made by deceiving consumers. This became an even more rampant problem in the late 18th century, as the development of modern chemistry introduced new food dyes and the industrial revolution provided the manufacturing processes to easily deliver them to consumers.

In 1820, English chemist Friedrich Accum was the first to bring this growing problem to the public's attention with his publication of A Treatise on Adulterations of Food and Culinary Poisons.[27] The book lists countless examples of contemporary foods that either using poisonous dyes or any colorant that masked the true nature of the product.

Among those using color to deceive were coffee and tea merchants. They often took used or fake tealeaves and coffee grounds, treated and colored them, then sold them as genuine and new.[28] Other merchants also made common use of toxic colorants, as Accum illustrated with the following example:

> "Vegetable substances, preserved in a state called pickles, whose sale frequently depends greatly upon a fine lively green color, are sometimes intentionally colored by means of copper. A young lady amused herself by eating pickles impregnated with copper. She soon complained of a pain in the stomach. In nine days after eating the pickle, death relieved her of her suffering."[29]

Bakers were still up to their old tricks in Accum's time, adding chalk to whiten bread, only now they were also adding alum[30] (one of a variety of metallic salts, known for use in styptic, or shaving pencils[31]). Perhaps the most reprehensible use of toxic colorings was in the manufacture of candies and jellies. Manufacturers loaded up confections with poisonous chemicals, seeking to appeal to children through bright colors. Accum documented sweets colored with vermilion (contains mercury), red lead, white lead, verdigris (a copper salt), blue vitriol (contains copper), and Scheele's green (contains copper and arsenic).[32]

Understandably enraged (even in 1820 it was known that these chemicals were toxic[33]), Accum sought to enact change. With no sign of government regulation in sight, Accum published the names and addresses of those selling the products.[34] This made him some powerful enemies, and he was the subject of a public smear campaign. His landmark exposé was forgotten in England

and food adulteration continued unimpeded.[35] Apparently, however, other countries took notice. Denmark listed colors permitted for food coloring in 1836, and Germany banned harmful colors in food with its Color Act of 1887.[36]

About 35 y after Accum, Dr. Arthur Hill Hassall published the following grim account of the state of English food.

> From morning to night (the Englishman) is the subject of perpetual fraud. . . he drink chicory and beans in his coffee, water in his milk, alum in his bread, disgusting parasites, flour and gypsum in his sugar, meal in his mustard, turmeric in his ginger, sulfuric acid in his vinegar, lead in his cayenne, copper in his pickles.[37]

Like Accum before him, Hassall took particular exception to the practice of selling brightly colored poisonous candy to children. Here he describes a candy bird cake decoration:

> The pigments employed for colouring the pigeon are light yellow for the beak, red for the eyes, and orange-yellow for the base or stand. The yellow color consists of the light kind of chromate of lead or pale chrome; for the eyes, bisulfuret of mercury, or vermillion, and for the stand, the deeper variety of chromate of lead or orange chrome.[38]

Descriptions like these finally ignited the move for government regulation. Parliament formed a Committee of Inquiry to investigate Hassall's reports. Witnesses were called that confirmed the extent of food adulteration in the marketplace. Thomas Blackwell, the owner of a major food manufacturer, admitted that his company "greened" preserved fruits and vegetables with copper salts and colored red sauces for meats with iron compounds. He explained that his firm did not realize these additives were so objectionable.[39]

This inquiry resulted in the 1st modern law respecting food or color additives, the Food Adulteration Act of 1860.[40] However, this law was largely toothless, and critics argued that it did little more than acknowledge food adulteration and frighten the public.[41] Individuals were left on their own to stay clear of toxic foods.

A popular English household book, Enquire Within Upon Everything,[42] published regularly after 1856, advised housewives how to avoid commonly adulterated foods. Among a variety of recipes and other information, Enquire described simple home tests that could detect adulteration. For example, bread could be tested for alum by "soaking a piece of the bread in an ammoniaca tincture of logwood. If alum be present the bread will be turned *blue*, whereas pure bread will remain *pink*." In addition, the book suggested that the housewife should grind her own pepper, flour, and coffee, bake her own bread, and avoid items nearly certain to be toxic such as sweets and jellies.[43]

Dissatisfaction with the 1st Food Adulteration Act led to a series of amendments and updated laws. Parliament passed the Sale of Food and Drugs Act of 1875, which attached criminal sanctions to food adulteration. The act decreed, "No person shall mix, colour, stain, or powder any article of food with any ingredient or material, so as to render the article injurious to health, with the intent that the same may be sold in that state, and no person shall sell such article under a penalty not exceeding £50."[44] Along with subsequent amendments and the culminating Food Adulteration Act of 1899, a regime was created, not unlike our own, of active oversight and stiff penalties to ensure that nothing known to be an active poison would be used in food manufacturing.[45]

In America, it was even longer before toxic colorants were yanked off the shelves. In 1880 in Boston, it was found that 46% of the candy sampled contained at least 1 toxic mineral pigment, predominately lead chromate.[46] The government began investigating color additives in 1881,[47] but you would still have to be extremely fortunate to find a pickle not bathed in copper sulfate at that time.[48] Throughout the 19th century, it was nearly impossible to find any food, drink, or drug that had escaped contamination. It was so common to find milk tinged yellow with lead chromate that many people refused to purchase white milk, thinking it had been adulterated. Toxic colored metal salts containing arsenic, mercury, lead, chromium, and copper remained in common use in the United States as late as 1905.[49]

As the 20th century approached, public awareness and outcry over the potential dangers of colors additives grew. Many individual states had limited and vague regulations in place, but these were inconsistent and largely ineffective. Even the industry knew it had a problem, and in 1899, the Natl. Confectioners Assn. advised its members to stop their use of 21 specific colors additives.[50] At the 1904 St. Louis Exposition, "pure food" advocates caused a sensation by setting up a display of colored silks made with dyes used by food manufacturers in their products.[51] Finally, the federal government intervened and outlawed colored metal salts and other injurious pigments with the sweeping reforms of the Wiley Act of 1906.[52]

Fortunately for food manufacturers and consumers, they no longer had to rely on toxic colorants. New technology had been invented to create dyes that were generally safer, brighter, and more stable. In 1856, English chemist Sir William Henry Perkin discovered the 1st synthetic organic dye, which he called mauveine. The purplish color he produced became known as mauve, and it was an instant success. Prior to his discovery, the only known purple dye was Tyrian purple, laboriously extracted from the glandular mucus of certain mollusks. Perkin derived mauveine from aniline ($C_6H_5NH_2$), an organic compound, synthesized from benzene (C_6H_6), which comes from petroleum or coal. Perkin got his aniline by taking advantage of the abundance of coal tar, a waste product of the production of coal gas and coke.[53]

Perkin's discovery led to the creation of many more dyes derived from aniline and other organic compounds. These came to be known as "coal-tar colors," owing their name to the origin of Perkin's raw material. These new chemically synthesized colors were less expensive, easier to produce, and superior in coloring ability to natural organic and even mineral dyes. Their potency meant that only tiny amounts were needed and the taste of the food would not be altered.[54] By the turn of the century, some 695 of these new, coal-tar colors had been synthesized, and over 80 were on the market.[55] And while they were generally safer than the metal salts they replaced and used in less quantity, they were still basically unregulated. Aniline in its pure form is toxic, so the synthesis of truly safe pigments requires special processes. Until 1906, there was nothing to prevent manufacturers from using industrial dyes in food.[56]

Early regulation: the margarine war

The federal government did not get into the business of protecting the public from poisonous colorants until 1906. However, it had already acknowledged the importance and impact of food coloring in an earlier set of laws dealing with margarine. In this context, the problem with color was not safety, but alleged fraud.

In the late 1800s, oleomargarine (margarine) was a new product that was seen as a threat to undercut the established dairy industry and replace butter. The dairy industry tried a variety of tactics to battle the burgeoning margarine trade. First, a few states passed laws requiring that oleomargarine be strictly labeled and branded, often under penalty of imprisonment. This did not do much, as a spokesman for margarine producers observed, ". . . As oleomargarine is a pure and wholesome

article of food, possessing all the qualities of good dairy butter, the people have overlooked the name and have decided to eat it."[57]

The next volley in the war against margarine was an all-out propaganda campaign. The dairy industry put out various publications designed to incite the public against margarine. One article called margarine "the slag of the butchershop. . . a compound of diseased hogs and dead dogs." Other reports claimed that margarine "contained the germs of cancer" and caused insanity. Political cartoons featured lurid depictions of margarine factories, showing margarine being made out of stray cats, soap, paint, arsenic, old boots and hats, animal intestines, wool, and sheep heads.[58]

The publicity campaign worked, and during 1884 and 1885, 7 dairy-producing states banned the manufacture and distribution of margarine. Within 2 mo of its enactment, a state court ruled that New York's law was an unconstitutional restraint of trade and struck it down.[59] In 1898, the Supreme Court invalidated all remaining laws that completely banned margarine.[60] However, other restrictions were left in place. In 1886, Congress had passed the Oleomargarine Act, which imposed hefty licensing fees of margarine manufacturers and retailers, as well as 2 cents per pound tax.[61] President Cleveland touted the law as a revenue measure, thereby seeking to avoid the constitutionality problems of the discriminatory state prohibitions.[62]

The sign on the wall in this 1886 political cartoon reflected the view that the Oleomargarine Act was passed by Congress only to "please the dairymen."[63]

Having already attacked the quality of margarine, the dairy industry turned its focus towards the color. Butter has a natural yellow tint, depending on the animal's diet. Butter manufacturers had long added color to their product to make its yellow hue consistent, and the public came to associate butter with this color. After margarine was introduced in 1874 as a substitute for butter, its producers sought to aggressively compete by copying the color (margarine is naturally white).[64]

New state laws took direct aim at the color of margarine, reasoning that a white spread would present no challenge to the golden yellow butter. States passed new laws banning the manufacture, distribution, and importation of artificially colored margarine. State courts looked more favorably upon this approach than the outright bans.[65] The Supreme Court also blessed this approach in 1894, upholding Massachusetts' law restricting yellow margarine in *Plumley v. Massachusetts*. The Court's reasoning was as follows:

"The suggestion that oleomargarine is artificially colored so as to render it more palatable and attractive can only mean that customers are deluded, by such coloration, into believing that they are getting genuine butter. If any one thinks that oleomargarine, not artificially colored so as to cause it to look like butter, is as palatable or as wholesome for purposes of food as pure butter, he is, as already observed, at liberty under the statute of Massachusetts to manufacture it in that State or to sell it there in such manner as to inform the customer of its real character. He is only forbidden to practise, in such matters, a fraud upon the general public."[66]

The Court in *Plumley* takes a very narrow view of food coloring, declaring it to serve no purpose in this case other than fraud. Fortunately for makers of fake crab, fake blueberries, and fruit-flavored anything, this was a view that would not stand the test of time. Society has come to accept coloring not as fraudulent, but as a permissible, even useful taste signal. Red coloring on the outside of fake crab lets the consumer know what taste to expect and thereby enhances the eating experience. Even though the federal government did require explicit labeling of margarine,[67] the Court apparently felt that consumers were still at risk of deception. Perhaps fraud was a more proximate fear in this era of limited and developing regulation. Or, as some critics suggested, the government was willing to do almost anything to placate the powerful dairy industry. Either way, restricting color was officially certified as a valid way to fight margarine.

At the turn of the century, 32 states and 80% of the country's population lived under colored margarine bans.[68] In 1902, Congress seized upon the effectiveness of the state color bans to curb margarine use in the other 20% of the country. That year, the 1886 Oleomargarine Act was amended to reduce the tax on regular margarine. However, margarine with "artificial coloration" that "causes it to look like butter of any shade of yellow" was slapped with a new 10 cents per pound levy.[69] The Act and tax were upheld in *McCray v. United States*,[70] in which the Supreme Court once again cited the potential for colored margarine to deceive the consumer. If states can ban its manufacture and sale, the Court reasoned, surely Congress can deter its use by taxing it.

There was a limit to the Supreme Court's tolerance of discrimination against margarine. A handful of states were not satisfied to merely ban yellow margarine, they wanted to force the spread to be another, more unappetizing hue. While some legislators suggested dying margarine red or black, 5 states ultimately passed laws requiring that all margarine be dyed pink.[71] It is suspected that pink was chosen because a cow that is ill with mastitis will give pink milk.[72] The Supreme Court finally drew the line in 1898, striking down New Hampshire's pink margarine law.

In *Collins v. New Hampshire*,[73] the Court held that requiring pink coloration against the desires of margarine producers and consumers was not allowable because it "necessitates and provides for adulteration."[74] The Court realized the huge effect that pink coloring would have on margarine sales. "To color the substance as provided for in the statute naturally excites a prejudice and strengthens a repugnance up to the point of a positive and absolute refusal to purchase the article at any price."[75] The Court then takes us down the slippery slope of forced adulteration. If a law could force margarine to be dyed pink, there would be nothing to stop a state from requiring the adulteration of food with any harmless foreign object designed to elicit revulsion from consumers. The Court decries an imaginary future law mandating that a food be tainted with a "most offensive smell."[76]

While these debates may seem like ancient relics, the battle over colored margarine continued well into the 20th century. While the state color prohibitions and 1902 federal tax put a severe burden on margarine firms, they soon figured out a way around them. Since restrictions were imposed only on margarine colored yellow "artificially,"[77] an opportunity existed if margarine producers could somehow generate a naturally yellow product.

Margarine was originally made out of animal fats, but new food processing technologies allowed the use of other oils. Specifically, hydrogenation of oils, which was introduced to the United States in 1909, proved to be the breakthrough the industry needed.[78] Soon, manufactures were experimenting with blends of vegetable and plant oils that would impart the desired yellow hue. They succeeded; usually palm oil was the magic ingredient.[79] In 1930, Congress closed the tax loophole by amending the Oleomargarine Act to include all non-white margarine,[80] and states followed suit. As of 1932, in addition to the federal tax and licensing fees, 27 states totally prohibited colored margarine, and many others imposed some sort of tax and/or licensing requirement.[81]

The next step taken by margarine manufacturers truly highlights the immense importance consumers attached to the yellow

coloring. Firms began selling their white margarine alongside packets of yellow dye, encouraging consumers to color-it-yourself. Due to pressure from consumers and the Natl. Assn. of Margarine Manufacturers, or perhaps just the realization of the absurdity of people kneading yellow dye into margarine, Congress repealed the margarine tax and licensing fees in 1950.[82]

That same year, as part of the Federal Food, Drug, and Cosmetic Act, Congress issued a new set of regulations governing colored margarine. The statute defines "colored margarine" as "margarine having a tint or shade containing more than one and six-tenths degrees of yellow, or of yellow and red collectively, but with an excess of yellow over red, measured in terms of Lovibond tintometer scale or its equivalent." The rest of the law deals with special packaging and labeling requirements, ostensibly to ensure that consumers would not confuse the product with butter.[83]

These 1947 ads from Delrich illustrate one of the later ways the margarine companies met consumer demand for a yellow product: consumers did not even have to get their hands dirty![84]

Following Congress' lead, by 1955 every state but 2 had repealed their anti-margarine color laws. Minnesota gave in in 1963, and 1967 finally saw the capitulation of "the Dairy State," Wisconsin.[85] Just before Wisconsin repealed its ban, state officials estimated that over a ton of colored spread was being smuggled over the Illinois border each week.[86] While the major American margarine war is over, a few legal remnants remain. The 1950 federal regulations are still in place. And a few states, like Wisconsin, have obscure laws that occasionally surface. For example, Wisconsin statute 97.18(4) bans "The serving of colored oleomargarine or margarine at a public eating place as a substitute for table butter. . . unless it is ordered by the customer."[87]

The battle still rages in the Great White North. While Canada's history of margarine regulation has largely mirrored that of the United States, Quebec has an especially strong dairy lobby. In 1987, over 20 y after all other antimargarine laws had ended, Quebec banned all colored margarine. Unilever, the giant food conglomerate and margarine producer, declared war on the prohibition in 1997. The case was in court all the way until March 17, 2005, when the Canadian Supreme Court upheld the statute.[88] As of this writing, Quebecers can still get only white margarine. If history is any guide, consumers will travel to other provinces or mix-in their own yellow coloring to get what they want. Because when it comes to margarine, like other foods, it is nothing without the right color.

Early Regulation: Setting the Standard

1906 marked the beginning of the modern food regulation period in the United States. That year's Pure Food and Drugs Act first put the issue of harmful color additives under federal control, imposing criminal penalties for selling "adulterated" food. Three provisions govern color additives. First, a "confectionery" is adulterated "if it contains terra alba, barites, talc, chrome yellow, or other mineral substance or poisonous color or flavor. . . ." More generally, any food is deemed adulterated if it contains "any added poisonous or other added deleterious ingredient which may render the article injurious to health." Finally, the act prohibits food from being "colored. . . or stained in a manner whereby damage or inferiority is concealed."[89]

The main champion of this act was Dr. Harvey Wiley, chief of the Bureau of Chemistry at the U.S. Dept. of Agriculture. In his honor, the statute is often referred to as "The Wiley Act." While the Bureau had been investigating color additives for a number of years, the 1906 Act gave it the muscle and Congressional authority to begin active regulation. The law was an important first step, but the broad language meant that Wiley's Bureau would have its work cut out for it. Among other problems, it was unclear at the time exactly which color additives were safe and which were "deleterious" or "injurious to health." Wiley hired a highly regarded outside consultant, chemist Dr. Bernard Hesse, to help study additives and promulgate regulations on the heels of the new law.[90]

Of the 80 dyes being used in foods at the time, Hesse began by selecting the 16 that had not yet received any unfavorable reports. He tested these on various animals and humans for mainly short-range effects. From his research, Hesse concluded that (1) coal-tar colors should not be used indiscriminately in foods, (2) only specified dyes should be used in foods, and (3) only tested and certified dyes should be used in foods. Based on this study, in 1907 the Bureau of Chemistry issued Food Inspection Decision nr 76, which officially deemed 7 colors safe for use in food. Amaranth, Ponceau 3R, Erythrosin, Orange 1, Naphthol Yellow S, Light Green S F yellowish, and Indigo disulfo acid.[91] Three of these are still in use today.[92] Slowly, new colors were added to the original list as the Bureau deemed them safe.[93]

As this 1906 cartoon illustrates, many in the canned food industry objected to the Wiley Act, feeling that their business would be hurt by the new bans on traditional preservatives and colorings, such as copper salts.[94]

At a public hearing on color additive regulations, the Natl. Confectioners Assn., seeking to avoid future liability and bad publicity, suggested that each batch of food color be tested and certified by a qualified chemist. Wiley assented, and an approval and certification system was announced in Food Inspection Decision nr 77, also in 1907. While the 1906 Act almost certainly provided no authority for the Bureau to implement mandatory certification, Wiley could induce manufacturers to voluntarily cooperate. As part of F.I.D. 77, the Bureau announced that uncertified colors were probably harmful, so manufacturers who did not cooperate "may render themselves liable to prosecution, and the dyes or foods colored with them, liable to seizure." All the leading color manufacturers complied. At first, the companies used their own chemists, but soon the Bureau of Chemistry conducted the certifications itself. The Bureau would receive a sample from each batch of coloring prior to its sale, test it, and certify it as safe.[95]

By 1938, responsibility for regulating and enforcing color additives had been transferred to the newly minted FDA. At this point, there were 15 synthetic colors approved for use in foods, 6 of which are still used today. Although the marketplace had been cleaned up significantly since the passage of the Wiley Act in 1906, there were still frequent instances of misbranded, adulterated, and toxic products being sold.[96]

Congress responded in 1938 by passing the 1st version of the Food, Drug, and Cosmetic Act.[97] Instead of the few vague lines in the 1906 Act, an entire section of the 1938 law was devoted to color additives. The act formalized the official listing and certification provisions that had been issued as unenforceable decisions in 1907. All coal-tar colors that were "harmless and suitable" had to be listed by the FDA, and the batch certification program was made mandatory, with associated fees.[98]

In subsequent regulations, the FDA created a nomenclature for what now were being called the "certifiable color additives" (that is, coal-tar colors). Colors were divided into 3 subcategories: FD&C Colors (acceptable for foods, drugs, and cosmetics), D&C Colors (for drug and cosmetic use only), and Ext. D&C Colors

(for external use only). Colors were also given numbers to make them more easily distinguishable. This was the origin of the now familiar and cryptic "FD&C Yellow No. 6" type names we find on ingredient labels.[99]

Early Regulation: Court Challenges

There were 2 main lines of litigation in response to the new regime of regulation created by the 1906 and 1938 acts. One dealt with safety, as the courts struggled with drawing the line between declaring a color safe or harmful. The other wrestled with the provisions preventing the use of color to conceal any "damage or inferiority"[100] and to make food "appear better or of greater value than it is."[101]

While the Supreme Court held that yellow coloring in margarine clearly served no purpose other than to deceive consumers[102], this jurisprudence is exceptional. Perhaps because margarine was such a statutorily disfavored food, courts have not cited this opinion in the subsequent analysis of the economic adulteration of other foods.

Courts have a history of acknowledging that coloring can serve the valid purpose of enhancing the appearance of a product under the Federal Food and Drug Acts. In *Lexington Mill & Elevator Co. v. U.S.*[103], the 8th Circuit held that it was not fraud to bleach flour white. A special conditioning and milling process was traditionally used to whiten flour, but the court ruled that this did not create a superior product. The court found that the flour whitened using the traditional method was more expensive than darker flour "not due to any superiority. . . from a nutritious standpoint, but due to the fact that bread baked from it is whiter in appearance, and hence more pleasing to the eye."[104] In other words, artificial coloring was a perfectly acceptable alternative method to achieving the ultimate end: whiteness. "Whiteness in flour is a desirable end in and of itself," said the court.[105]

Adding color to a food sends a signal about that food to the consumer. If a color does not make the food "better" in the eyes of the consumer, manufacturers would not use it. Thus, the legal prohibition of using color to make a food "appear better or of greater value than it is,"[106] if followed strictly, would ban the use of any and all color. Since this is not a result anyone wants, courts have had to draw the line of acceptability. Courts have appeared to adopt a practical approach: whether the use of the color significantly misleads consumers as to the actual quality of the food.

This was the analysis used in *Pennsylvania v. DiMeglio*.[107] The state law at issue in *DiMeglio* was nearly identical in wording to the federal FD&C Act. The case involved a lemon pie made with Sunset Yellow (Yellow nr 6), an approved coal-tar dye. The maker of a rival natural-yellow lemon pie believed that the use of Sunset Yellow constituted fraud.

Comparing the products, the court found that there was "no difference in the food value"[108] of the 2 pies. Moreover, there was no evidence that "any member of the public was deceived" into believing that the artificially colored pie had any other "nutritional element than it actually did."[109] The court then goes on to openly state the proposition implied by *Lexington Mill & Elevator*, "It is the use of color whereby an article of food is made to appear better than it actually is that is forbidden, not the use of color whereby the food is made more attractive or appealing to the eye."[110]

The *DiMeglio* court found that the yellow dye did not indicate that the pie had more lemons or eggs. If this is true, then what did the yellow color indicate? The fact that a lemon cake is yellow instead of white has to mean *something* to the consumer. Instead of conducting an inquiry into food psychology, the court creates a way out. If the color does not reach the threshold of signaling something materially false, its use can just be attributed to general "eye appeal." There is apparently no need for further analysis.

Perhaps wary from the margarine experience, courts have seemed reluctant to characterize any food coloration as fraud. The focus on consumer deception was further expounded on in a series of cases dealing with orange beverages. In *U.S. v. Nesbitt Fruit Products*,[111] the 5th Circuit held that a beverage labeled "orange juice sweetened" could legally add orange color. The product in question was a beverage concentrate to be diluted by a retailer in the customer's presence. It was made of a mixture of orange juice, sugar, fruit acid, benzoate of soda, and orange coloring. When diluted, the beverage "becomes of about the color of orange juice and simulates its taste."[112] The court determined that the beverage "is inferior to pure orange juice in its vitamin content, and the added color tends to conceal the weakness of the orange juice content."

The court all but admits that the color added to this beverage was "concealing inferiority," in violation of the 1906 Act. Yet the court still held that no violation occurred. Because the product did not claim to be actual orange juice, but "orange juice sweetened," and a list of ingredients was visible to the consumer, there was no fraud. The court takes this as evidence that the manufacturer intended "no concealment of the fact that there is used a synthetic mixture."[113] In the same paragraph that the court says "the added color tends to conceal the weakness of the orange juice content," it concludes "Every ingredient being pure and wholesome, color being openly added not to conceal anything but to make the final result more pleasing to the eye, we are unable to say that the Nesbitt product is adulterated."[114] The Nesbitt court seems to concoct a subjective color fraud test, a combination of the view of the consumer and the intent of the manufacturer.

In a later case of another orange soft drink, the court elaborated on the importance of the view of the consumer. As in *Nesbitt*, the government argued in *U.S. v. 88 Cases Bireley's Orange Beverage*[115] that the drink was cloaking its inferiority compared to orange juice. The court held that the use of orange coloring in the drink was permissible, reasoning that orange-flavored soft drinks are a category of products recognized by consumers to be independent of orange juice. This was based on the standard of "the reaction of the ordinary consumer under such circumstances as attended retail distribution of this product."[116]

In its analysis, the 3rd Circuit directly addressed the problems with the statutory language that caused the seemingly contradictory reasoning in *Nesbitt*. The court acknowledges that certain products, such as sugared orange drinks, are nutritionally inferior to orange juice. And without question, coloring is added to conceal this inferiority. However, the court says that consumers do not confuse orange drinks with actual orange juice so prohibiting their use of color serves no point.[117]

The prohibition of coloring to conceal inferiority only makes sense, the court reasons, in cases where the inferior product might actually be mistaken for the more wholesome food. States the court, "Without a finding that a marketable inferior product is likely to be confused with a specified superior counterpart, we think there can be no appearing 'better than it is' within the scope of disapproval of a section patently concerned only with confusion."[118]

Based on the preceding line of cases, illegal coloration should be found only in cases of clear market dilution, such as the situation in *U.S. v. Two Bags* (*Poppy Seeds*).[119] In this case, a producer of white poppy seeds grown in India was coloring his seeds dark. Naturally dark poppy seeds, grown in Turkey and the Netherlands, are slightly larger than white seeds and significantly more expensive. The court held that darkening the white poppy seeds was clearly intended to confuse consumers who preferred the

other seed varieties, and thus was prohibited under the Food, Drug, and Cosmetic Act.[120]

The safety provisions of the 1906 and 1938 Acts also inspired with their share of controversies. These often dealt with the use of colorings that were toxic but only used in minute amounts.

The 1st case to arise under the 1906 Act was *U.S. v. 1,950 Boxes of Macaroni*.[121] The macaroni in this case was dyed with "Martius Yellow," an additive known to be "a poison which will kill."[122] The manufacturer argued that the dye was used in such a small amount as to be rendered harmless. However, Judge Kennesaw Mountain Landis rejected this argument. According to Landis, where "it clearly appears that a poisonous substance wholly foreign to the food product has been added. . . he court is under no duty to. . . indulge in hair-splitting speculation as to whether the amount of poison used may possibly have been so nicely calculated as not to kill or be of immediate serious injury."[123]

When the poisonous element was arsenic, however, a court was willing engage in such speculation. The court in *W.B. Wood Mfg. Co. v. U.S.*[124] concluded that there was no evidence that the amount of arsenic in the yellow dye at issue was harmful. The court observed that the amount of arsenic in the dye was infinitesimal, comparable to the amount found in ever-present air, water, food, dust, and smoke. Thus, the dye could not be prohibited as a "deleterious ingredient, injurious to health" under the 1906 Act.

The 1938 Act required the Secretary of Health, Education, and Welfare (acting through the FDA) to certify colors as "harmless."[125] Foods were then deemed adulterated if they contained a coal-tar dye that had not been certified.[126] Did this take courts out of the business of determining the legality of a dye? A series of cases involving certain orange and red additives presented exactly this question.

In 1955, 3 previously certified coal-tar colors, Orange nr 1, Orange nr 2, and Red nr 32 were de-listed by the Secretary.[127] Although the colors were certified since 1939 as "harmless," there were instances of children in the early 1950s becoming ill from eating heavily colored Halloween candy and popcorn. This called the safety of the colors used into question and new tests were ordered. It was soon shown that these 3 colors caused severe health problems in lab animals.[128]

In 1956, the 2nd Circuit deferred to the Secretary's decision to de-list these 3 colors.[129] As long as the Secretary can show that the color "might render the article of food injurious," the court said, his decision is final. While there was no proof that the colors would be harmful to humans, the animal data easily cleared the "might" threshold. The court also stated that the Secretary did not have to determine safety tolerances for these colors and allow their use in small quantity. The court deferred to the Secretary's judgment that controlling the intake of potentially harmful colorants was impossible.

The decision to de-list Red nr 32 presented a serious problem for the citrus industry. When mature oranges are harvested, their skins can often be green or uneven shades of yellow and orange. Because consumers may misinterpret this as a sign that the fruit is not yet ripe, oranges are "de-greened." For California oranges, a process that involves exposure to ethylene gas is sufficient. But oranges from Texas and Florida need to be sprayed with dye. After extensive testimony, House and Senate Committees decided that coloring oranges was an economic necessity. Congress responded by allowing the use of Red nr 32 for coloring orange skins for 3 more years (until 1959) while a suitable replacement could be found.[130] In 1959, this temporary reprieve was extended 2 more years, but was applied to a different and less toxic color, Citrus Red nr 2.[131]

In light of the initial emergency legislation, the Florida Citrus Exchange re-challenged the Secretary's original decision to de-list the Red nr 32. This time, the case made it all the way up to the Supreme Court, where the de-listing of the color was once again upheld.[132]

The Citrus Exchange argued that "harmlessness" should be determined by testing the color in the amount that it actually is used in foods. The Court found that Congress intended "harmless" to be an absolute term: it referred to the "toxicity of the coloring ingredient, rather than of the food product as a whole."[133] The fact that the test animals were fed unrealistically large quantities of color was immaterial.[134]

The Court goes on, "it [Congress] evidently took the view that unless coal-tar colors were harmless, the considerations of the benefits of visual appeal that might be urged in favor of their use should not prevail, in the light of the considerations of the public health."[135] The implications of the *Florida Citrus Exchange* decision were grave for food manufacturers. A food dye had to be absolutely harmless for use by any living creature in any quantity under any conditions.[136] This would clearly wipe out the legal use of most, if not all, existing colors.[137]

Modern Regulation: The Current System

The *Florida Citrus Exchange* decision sparked calls from both industry and consumers for an overhaul of the way the government regulated color additives. Industry wanted the FDA to have greater flexibility in certifying colors as safe in certain amounts and for certain uses. Coming on the heels of the harmful candy/popcorn incidents, consumers wanted better assurance that the colors they consumed would be safe. During the first 5 mo of 1960, Congress held extensive hearings about color additives, taking testimony from many scientific experts. The House of Representatives subsequently issued a report of its findings in June.[138]

The House concluded that there were 4 main problems with the existing statutory regime. First, the strict requirement that a color be "completely harmless" in any amount or use did not comport with the modern idea of consumer protection. The House adopted similar logic as the Florida Citrus Exchange and the color additive industry, suggesting that the FDA should have freedom to approve colors subject to certain limits of usage. This recommendation to allow tolerance regulations for colors was approved by a special committee convened by the Natl. Academy of Sciences. The Dept. of Agriculture and the President's Bureau of the Budget also lauded the plan, arguing that the tolerance provisions enacted for other food additives in 1958 should be made applicable to colorants.[139]

The House noted that the strict "completely harmless" requirement of the FD&C Act was leading to a related problem: a dwindling number of colors available for use.[140] Eleven colors had been banned between 1955 and 1960.[141] The House worried that the inflexible regulations in place at the time would drive color and food manufacturers out of business, as one by one the color additives became de-listed by the FDA. Consumers would then be deprived of the colors they needed and wanted. The House cited as precedent for more flexible regulations the 1956 and 1959 bills allowing temporary use of Red nr 32 and then Citrus Red nr 2 only in a certain quantities and only for coloring orange peels. The "safe-for-use" principle had also recently been enacted in the 1958 Food Additive Amendment, and the House saw no reason why this should not be extended to colors.[142]

While maligning the increasing number of colors being prohibited from use, the House admits in its report that many colors once thought safe have, in fact, been shown to be toxic by modern testing. This was the 3rd problem; many long-used colors listed by the FDA as "certifiable" were not as safe as once thought. As

the system existed, the burden was on the FDA to re-test all the existing colors for safety, a process that was both lengthy and expensive. The report considered it essential to find a way to more efficiently retest existing colors and find out which were truly safe and in what amounts.[143]

The final problem cited by the report was that existing testing and regulations were limited only to "coal-tar colors." Up to this point, consumers had no regulatory protection from so-called "natural" colors. According to its report, the House found that "there is no sound scientific basis for distinguishing between a color additive extracted from a plant, animal, or mineral source and one which is synthesized with a chemical structure which will bring it under the term 'coal-tar color'."[144]

On July 12, 1960, Congress passed what it believed to be a solution to these problems: the Color Additive Amendments to the Food, Drug, and Cosmetic Act.[145] The Amendments revolutionized the regulation of color additives, putting in place the basic system that remains today. First, the new law gave the FDA control over all color additives, a color additive being "Any material. . . that is a dye, pigment, or other substance made by a process of synthesis of similar artifice, or extracted, isolated, or otherwise derived. . . from a vegetable, animal, mineral, or other source and that, when added or applied to a food. . . is capable of imparting a color thereto. . . ."[146]

This meant that the FDA now had regulatory domain over "artificial" and "natural" dyes. However, while these are the popular terms used to divide the universe of colors, the FDA makes no inherent distinction between the two.[147] There's good reason for this, as the distinction between "natural" and "artificial" is not so clear: consider beta-carotene, an orange dye that is identical whether it be extracted from a plant or artificially synthesized.[148]

The 1960 Amendments immediately put all 200 or so colors in commercial use at the time (not all were used for food) on a provisional list for interim use. Industry then had 2.5 y to petition the FDA to accept the additive for "permanent listing." This meant that the color manufacturing industry had to foot the bill for a massive retesting of every single color additive, with safety data subsequently presented to the FDA. This also meant that in theory, the burden was on the industry to affirmatively prove the safety of each color.[149]

Once receiving the safety data, the FDA could accept the color onto its permanent list, reject and de-list it, or postpone a decision and keep the color provisionally listed. Only about ninety of the original 200 colors have been accepted as safe enough for the permanent list. The rest have either been withdrawn or de-listed.[150] Many colors were de-listed for economic reasons. Forced to bear the extensive cost of testing and petitioning the FDA, the color industry sought permanent listing only for those colors that were most widely used and had the fewest substitutes. Most color additives have small volumes, so manufacturers were reluctant to spend millions of dollars to justify the existence of each dye.[151]

Decisions on many of the provisionally listed colors were delayed for many years (meaning they could be used without being officially sanctioned as safe),[152] but all new colors will have to be preapproved by the FDA before they may enter the market.[153] For colors accepted onto the permanent list, an individual regulation for that color additive is drawn up. Each color listed by the FDA has its own federal regulation, divided into 5 parts[154]:

(1) Identity of the color additive
(2) Specifications in producing the additive
(3) Uses and restrictions[155]
(4) Labeling requirements[156]
(5) Whether the additive must be certified or is exempt from certification[157]

The 5th requirement, certification or exemption, is how the FDA separates those colors commonly though of as synthetic (subject to batch certification) and those viewed as natural (exempt). Because the former are chemically synthesized, and their production is more akin to baking a cake than mere extraction from nature, each batch is tested by the FDA.[158] During the final 3 mo of 2005, the FDA tested and certified over 4.7 million pounds of dye.[159]

Modern Regulation: The Delaney Debate

The 1960 Amendments include 1 final provision that has remained contentious ever since its initial proposal. The Delaney Clause commands that a color additive is to be deemed unsafe and not listed for use if it "is found. . . to induce cancer in man or animal."[160] So, while Congress was creating leniency by allowing tolerance levels for toxic colors, it was simultaneously drawing a bright line with respect to those colors that were carcinogenic.

The Clause, named after New York Congressman James Delaney, was first introduced as part of the 1958 Food Additive Amendments.[161] Then 2 y later, Congress revisited the debate as it pertained to colors, hearing testimony from numerous scientific experts on both sides of the issue.

Proponents of the Clause, led by the Secretary of Health, Education, and Welfare, emphasized the unknowns of cancer: "Our advocacy of the anticancer proviso. . . is based on the simple fact that no one knows how to set a safe tolerance for substances in human foods when those substances are known to cause cancer when added to the diets of animals." Given that people are inadvertently exposed to so many trace carcinogens, the Secretary argued, Congress should make sure that they are not deliberately exposed to any additional carcinogenic residues.[162]

Scientists against the Delaney Clause countered with many of the same arguments in favor of establishing general safety tolerances. One scientist suggested that colors ought to be banned only if shown to be carcinogenic in the amount and conditions of their intended use. Others argued more broadly that by establishing an absolute, the anticancer provision was infringing on the ability of FDA experts to exercise scientific judgment.[163]

Congress eventually decided to err on the side of safety, approving the Delaney Clause. The 1960 House Report makes much of the dangers of cancer, mentioning that it was the 2nd leading cause of death in America with hundreds of thousands of new cases being diagnosed annually. The report stresses the uncertainties surrounding cancer and cancer-causing agents, concluding that there is no recognized scientific basis to determine what would constitute a "safe dose" of carcinogenic material.[164]

The debate over the Delaney Clause has not relented since 1960. The debate roared to life in the 1980s as advances in science provided the capability to detect minute traces of carcinogens in substances. The Reagan Administration expressed its dislike for the Clause, and Senator Orrin Hatch, R-Utah, twice unsuccessfully introduced bills that would scrap Delaney in favor of a *de minimis* standard.[165]

Even 25 y later, the basic tenets of the argument remained the same. Peter Barton Hutt, a partner at Washington law firm Covington & Burling and former general counsel of the FDA, supported the elimination of the Delaney Clause. "There isn't anything in the food supply that isn't carcinogenic. Do you want to ban everything? If you don't ban it, how do you decide what to keep and what to ban? That isn't science, it's policy."[166]

At the time, the Delaney Clause applied to color additives, other food additives, and pesticides. Supporters of the Clause argued that the case against it was weak, especially when dealing with colors. "It doesn't make any difference how much or how little (of a carcinogenic additive) a particular substance contains,"

said Rep. Ted Weiss, D-N.Y, "especially when you've got a color additive that has no nutrient value and no therapeutic value."[167]

"The Delaney Clause is founded on the principle that it is good public policy to err on the side of public health," according to Rep. Henry Waxman, D-Calif. "Even if the risk to any person is small, a ban may prevent a few people from getting cancer."[168]

Advances in science plus an administration and FDA not friendly to Delaney led to a series of court showdowns over the future of the Clause. The 1st skirmish, *Scott v. FDA*,[169] went to the government. Scott challenged the FDA's listing of Green nr 5, a color used for medical devices. The color, while not shown to be carcinogenic in tests, did contain trace amounts of Green nr 6, which was a carcinogen.[170]

The court ruled that the Delaney Clause did not mandate a ban of Green nr 5 because the dye taken as a whole was not shown to cause cancer. In its decision, the court cited *Monsanto v. Kennedy*,[171] a landmark case that established the possibility of a *de minimis* exception to Delaney for food additives. In *Monsanto*, a carcinogenic chemical from the food packaging migrated to the food in very minute amounts. The court said that the FDA could determine that the amount of impurity was so negligible as to be *de minimis* and not a threat to safety.[172] The fact that *Scott* referenced *Monsanto* gave the FDA hope that courts might grant it a *de minimis* exception to Delaney for color additives as well.

The FDA got its chance to find out 3 y later, as an advocacy group, the Public Citizen Health Research Group, challenged the FDA's listing of Orange nr 17 and Red nr 19 under the Delaney Clause. The FDA had listed the colors for use in 1986, after tests revealed that they caused cancer in lab animals. The agency estimated that the lifetime cancer risks to humans were extremely small: 1 in 9 million for Red nr 19 and 1 in 19 billion for Orange nr 17, at worst. Marking a change in policy, the FDA declared that it would consider any risk lower than 1-in-1-million to be a *de minimis* exception to the Delaney Clause.[173]

Arguing for a literal interpretation of Delaney, Public Citizen pointed to the legislative history of the Clause and the extensive testimony that took place in Congress. Public Citizen asserted that Congress knew exactly what it was doing: leaving no tolerance for any color additive that could possibly cause cancer. Members of Congress gave quotes at the time of approving the Delaney Clause that indicated they had considered its implications. "The colors which go into our foods and cosmetics are in no way essential to the public interest or the national security. . . consumers will easily get along without (carcinogenic colors)," said Rep. King.[174]

Despite agreeing that the risks imposed by the 2 dyes were almost absurdly infinitesimal, the court ruled against the government. Congress intended an "extraordinarily rigid" position, the court held, and this left no room for a *de minimis* exception. Advised the court, "in the color additive context, Congress intended that if this rule produced unexpected or undesirable consequences, the agency should come to it for relief." While conceding that such a time may have come, the court was not willing to override Congress' directive.[175]

Peter Barton Hutt, who served at the time as counsel for the Cosmetic, Toiletry, and Fragrance Assn., a co-defendant in *Young*, noted what he called the "reluctance" of the court. "This is one of those difficult cases in which the court is caught between what it believes is rigid statutory language and common sense. It leaves out the common sense that this (getting cancer from one of the color additives) is a trivial risk, smaller than driving a car or sitting in an office."[176] The C,T,& F Assn. appealed the *Young* decision to the Supreme Court, but was denied certiorari. Despite the setback, Rep. King appeared to be right: the industry readily found noncarcinogenic substitutes.[177]

The strict interpretation of the Delaney Clause announced by the court in *Young* still stands with regard to color additives. Its controversial application was seen once again in 1990, as the FDA banned certain uses of Red nr 3, the dye used to make cherries pink in fruit cocktail. A small test revealed that male rats fed huge amounts of the color developed a high amount of thyroid tumors. The rats also turned pink, but it was the cancer that scientists cared about. The FDA concluded that fewer than 1 in 100000 people would develop cancer from a lifetime of Red nr 3 consumption, and it reluctantly applied the Delaney Clause by banning uses of the color that were still provisionally listed, mostly external cosmetics.[178]

In what was termed a "regulatory inconsistency," the agency did not immediately ban the colorant's use in food. The dye had been permanently listed for food use in 1969 after tests showed no safety concerns, and it is not an easy matter to de-list a "permanent" color.[179] Extensive studies and administrative requirements need to be satisfied to ban a permanent listing. In 1990, the FDA promised to "take steps" to ban Red nr 3 for all uses, but gave no timetable for such action.[180] Sixteen years later, the dye is still on the market and used in many foods; over 29 tons of the color was certified for use in the FDA's 2006 first fiscal quarter.[181]

Perhaps the ban's delay is partly owed to lobbying on the part of the fruit cocktail industry. With no adequate substitute available to dye cherries, fruit cocktail makers say that their sales would drop by 40%, with a resulting 246.7 million dollar negative impact on the economy.[182] This illustrates the fact that nobody wants to say: setting a tolerance level for carcinogenic food colorings is actually about putting a price on human life.

The Red nr 3 ban once again provoked the ire of critics who believed that the Delaney Clause is too inflexible and out of date. "Now it is possible to say something more than 'yes it is' or 'no it isn't' a carcinogen. We now have a methodology that allows us to be a little more discriminating. We can determine where risk is essentially trivial and where exposure could more easily be limited," said Richard Merrill, former FDA general counsel.[183]

The FDA made no secret of its feelings for the Delaney Clause in announcing the Red nr 3 ban. "Today's action is yet another reminder of the need for Congress to consider updating the law to reflect advances in the methods of scientific assessment that were not available when the law was originally passed in 1960," said Louis Sullivan, Secretary of Health and Human Services.[184] It remains to be seen if Congress will ever bow to this request. However, in 1996, Congress unanimously approved the Food Quality Protection Act[185], which eliminated the Delaney Clause as it applied to pesticides. The rigid no-tolerance approach was abandoned in favor of a standard of "reasonable certainty that no harm will result from aggregate exposure to pesticide residue."[186]

But to enact such a change with colors would have difficulty getting public support, as "supported cancer-causing food dyes" is not the kind of tag politicians want to be associated with, logical or not. Food coloring has always been seen as more of a luxury than pesticides, and its toxicity is less tolerated.

Because all current color additives have been extensively tested for carcinogenic effects, it is likely that the only future application of the Delaney Clause will be to any new colors seeking approval. Invocation of the Clause in this situation should raise less protest among industry, since any color affected will not have already been on the market.

Controversial Colors

Public perception of color additives, especially the certified (synthetic) ones, has continually been one of wariness. Foods with bright or strange coloration are seen as unnatural and alien, carrying a sense of suspicion that anything so strange is probably

harmful. It does not help that consumers see color additives listed on their food labels with cryptic names like "Red No. 40" and "Green No. 3."

Labels used to be even more mysterious. Before May 8, 1993, food manufacturers could just affix the mysterious "color added" tag to a product without actually having to specify the specific additive used.[187] In 1993, the FDA issued new labeling guidelines mandated by 1990's Nutritional Labeling and Education Act.[188] These new FDA rules required certified colors to be individually listed on product labels. Colors exempt from certification can still be listed on labels generally as "artificial color" or "color."[189] Regardless of their source, such color additives cannot be labeled "natural." The FDA considers "natural" only the color that naturally occurs in the food.[190]

Perhaps as a relic of the margarine war, makers of butter, cheese, and ice cream do not have to disclose if their product contains color, unless the regulation governing the specific additive used mandates its listing.[191] However, "voluntary declaration" of color additives used is officially "recommended."[192]

Confusing labels are not the only reason that the public has a negative perception of color additives. Public sentiment can be attributed to a series of high-profile incidents and negative publicity campaigns involving food coloring. As previously noted, the modern era of food coloring regulation was in part kick-started by incidents in the early 1950s involving Halloween candy and popcorn. Hundreds of children were hospitalized because they ate large quantities of food coloring that was considered safe at the time.[193]

The next major color controversy to hit the front pages dealt with Red nr 2, once the most widely used artificial color.[194] Red nr 2, also known as Amaranth, had long been considered one of the safest of all the coal-tar colors. It was 1 of the 7 original colors listed by the Bureau of Chemistry in 1907. It successfully passed safety tests required by the 1938 law and was exonerated in the Halloween candy and popcorn scare.[195]

The 1st sign of trouble was an inconclusive test in the early 1950s in which a small number of female rats fed Red nr 2 developed more breast tumors than the control group. In response, the FDA ordered a huge follow-up study with 800 rats, with an ultimate finding that the dye had "no significant influence on the formation of tumors." The agency conducted a similar test with 800 mice, reaching the same result.[196]

The Certified Color Industry Committee (the main industry group at the time) petitioned the FDA for permanent listing of Red nr 2 in 1965.[197] Due to a dispute with the CCIC over the filing requirements, the FDA did not announce a decision until 1969, when it stated in a memorandum that the dye was safe for general use in food, drugs, and cosmetics. Despite this declaration, the dye was still officially on the provisional list in January 1971, owing to the ongoing filing dispute.[198]

It was at this time that the FDA received word of Russian studies published in 1968 and 1970. The studies claimed that Red nr 2 caused rats to develop intestinal tumors and was toxic to the gonads and embryos. The studies were almost universally discredited, as the experiments were poorly designed and reported. Most significantly, there were serious questions as to whether the dye the Soviets tested was actually Red nr 2. But the news caught the attention of the public, and FDA officials scrambled to launch new tests to confirm the safety of the dye.[199]

After a series of tests examining the claims of gonad and embryonic toxicity, the FDA's Associate Commissioner for Science announced, "The question concerning reproduction toxicity can probably be closed." That left the cancer issue. The FDA conducted an experiment with 500 rats designed to put the issue to rest once and for all. Unfortunately, instead of being described as "definitive," the study is referred to by FDA scientists as the "botched" or "bungled" experiment. Rats that were fed the dye were mixed up with the control group, and rats that died in their cages were left to rot, rendering them unfit for pathological examination. After trying to decipher the study, the FDA concluded that Red nr 2 had "no apparent effect" on the rats. FDA Commissioner Alexander Schmidt was forced to defend this decision on CBS' "Face the Nation."[200]

Just a month after Schmidt's appearance on TV, another scientist ran a new statistical analysis on the data from the "bungled" experiment and concluded that Red nr 2 actually did cause an increase in the number of malignant tumors in female rats. Given the shakiness of the experiment and the competing earlier determination of safety by the FDA, the true nature of Red nr 2 was unclear.[201]

By this point, public pressure was mounting, and the FDA decided to de-list the color from the provisional list in 1976, stating that the color industry had not met its burden of proving Red nr 2's safety. Both the General Accounting Office and various Legislators publicly criticized the FDA for exposing the public to needless risk for over 15 y, as they quibbled over filing requirements and botched studies.[202]

The public reaction to the Red nr 2 controversy was so strong that many food companies pulled red versions of their products off the shelves for years, whether or not they contained the questionable dye. M&M's manufacturer Mars removed red candies from its packages, despite the fact that they were colored using the uncontroversial Reds nr 3 and nr 40. After public furor died down, red M&M's were reintroduced in 1987.[203] After the de-listing, Yellow nr 5 became the most widely used coal-tar color. It took years for red to regain consumer confidence, but Red nr 40 is now far and away the most popular synthetic dye.[204]

As the successor in popularity to Red nr 2, Yellow nr 5, also known as Tartrazine, also had its share of problems. It was one of the dyes singled out in 1977 by Ralph Nader's Public Citizen Health Research Group as unsafe. Public Citizen took the position that all coal-tar dyes should be banned, arguing that their safety is unproven over long periods of time. It pointed to the de-listing of Red nr 2 and Red nr 4 a year earlier as evidence that dyes we consider "safe" are often later shown to be toxic.[205]

While the FDA said that Public Citizen was "overstating the issue and causing public alarm that is simply not warranted," they simultaneously admitted that Yellow nr 5 caused severe allergic reactions in a small number of people.[206] Subsequently, in 1979, well before individual colors had to be listed on labels, the FDA ordered that products must disclose any presence of Yellow nr 5.[207]

The buzz around the dye took a strange turn in the 1990s, as a rumor spread among teens that the coloring, as used in the soft drink Mountain Dew, reduced sperm count and caused the testicles to shrink. The myth got to the point where some teens were allegedly using the soda as birth control. There have been no studies or incidents to indicate that there is any truth to this rumor, and its source remains a mystery.[208]

> The myth that the Yellow nr 5 in Mountain Dew reduces sperm count is a product of the mysterious public image of synthetic food coloring.[209]

Another popular, and slightly more substantiated claim about coal-tar colors is that they cause hyperactivity in children. This claim was introduced in 1973 as part of the Feingold Diet, a strict no-additive dietary plan designed for children. Dr. Benjamin Feingold's books caused quite a stir in the 1970s, but most studies have since shown no causal connection between food dyes and behavioral defects.[210] The FDA cites as the definitive word the 1982 report from the Consensus Development Panel of the Natl.

Inst. of Health, which concluded that there was no scientific support for the Feingold's assertion.[211]

Despite the general consensus, there have been a few studies that have suggested there is some truth to Feingold's claim. The Natl. Advisory Committee on Hyperkinesis and Food Additives, in a 1980 report for the Nutrition Foundation, concluded that a diet filled with artificial food coloring did not generally negatively affect the behavior of hyperactive children. But the report did admit that a small subset of hyperactive kids might be especially sensitive to food additives.[212] A more recent report from the Univ. of Melbourne has also indicated that certain children ingesting Tartrazine (Yellow nr 5) may experience irritability, restlessness, and sleep disturbances.[213] So, while the Feingold Diet is still promoted,[214] albeit with less fanfare and success than in the 1970s, its principles appear valid for a small subset of children at best.[215]

Coal-tar colors may be the targets of most criticism, but one natural color has also managed to stir up controversy. Cochineal extract, which is bright orange, and carmine, which is vivid red, are 2 different dyes derived from crushed female cochineal insects.[216] These scale insects (they are often erroneously called beetles),[217] which feed on cacti in Peru, Mexico, and the Canary Islands, have been used in dyes for hundreds of years. The dyes are not easy to make—70000 insects are needed for 1 pound of carmine—but they are potent and widely used.[218] Carmine can be found in popsicles, strawberry milk drinks, cheeses, artificial crab and lobster, and other foods. Among the uses of cochineal extract are coloring fruit drinks, candy, and yogurt.[219]

The FDA approved carmine and cochineal extract for permanent listing in 1967 and 1968, respectively.[220] Because they are natural dyes and exempt from certification, recall that they do not need to be individually listed on a food's ingredient label. Instead, they can be generally referred to as "color" or "artificial color."[221] There have been many anecdotal reports of Jews, vegetarians, and others with dietary restrictions becoming outraged after learning that they were unwittingly consuming an insect product. In addition, some people can suffer severe allergic reactions from consuming the dyes, including sneezing, asthma, and anaphylactic shock.[222]

> The dried bodies of cochineal insects, used to make carmine and cochineal extract, are extremely small.[223]

The Center for Science in Public Interest (CSPI) petitioned the FDA in 1998 to either ban cochineal-based dyes or require the colorings to be specifically listed on ingredient labels as: "carmine/cochineal extract (insect-based)."[224] Since the petition, some companies such as Pepsi and General Mills have voluntarily listed the colorants by name on labels. Others, such as Dannon, have replaced carmine with Red nr 40 or other colors.[225]

Earlier this year, the FDA finally weighed in by proposing a new rule. Responding directly the CSPI petition, the FDA agreed to require the specific listing of carmine and cochineal extract on food labels. But the agency sided with food industry lobbyists in declaring the listing of the insect/animal origin of the dyes to be unnecessary. "Information on the origin of these color additives is readily available to those consumers who want it," asserts the agency. According to the FDA, consumers can discern the nature of carmine and cochineal by consulting any standard dictionary or reading the color additive regulations.[226]

The proposed FDA rule makes sense for those with allergic reactions. Someone who is allergic to a cochineal-based dye can easily consult a label, spot the key words "carmine" or "cochineal extract," and know to avoid the food. Yet the agency's decision seems to give short shrift to others who may wish to avoid the dyes because of their insect origin. Given the complex and lengthy ingredient lists of many foods, it is unrealistic to expect that consumers will conduct research into each one. It is not unreasonable for a vegetarian to assume that her ruby red grapefruit juice or cherry popsicles do not contain an animal or insect product. If the food industry is worried about consumer reaction to the idea of eating an insect product, perhaps the dye should not be used. Food labeling laws are in place so consumers know what they are eating; the FDA's proposed rule lets manufacturers continue to hide the ball when it comes to cochineal-based color additives.

The Future of Color Additives

Despite the controversy and the public's general dislike for insect-based foods, carmine and cochineal extract could find an even larger market in the future. Demand for natural food coloring has been growing, sparked by a general demand among consumers for "all natural" products.[227] According to an executive at Warner-Jenkinson Co., a major color manufacturer, consumers attach a certain amount of magic to anything natural.[228] Companies place a high value on having a "clean label,"[229] believing that consumers would rather see "annatto extract" than Yellow nr 5 or Yellow nr 6. as a listed ingredient of their yellow food.[230]

Natural colors have long faced the same set of criticisms: they are more expensive, less stable, and less potent than their synthetic counterparts. But advances in technology have narrowed the gap in all 3 of these traditional shortcomings. In some cases, natural colors now have real advantages. With the list of allowable coal-tar colors whittled down over the years,[231] natural colors can yield hues otherwise unattainable. For example, annatto extract[232] excels at producing a golden yellow that consumers prefer for cheeses. Typical of synthetic colors, the coal-tar yellows produce hues that are too bright.[233] Natural colors provide for the more muted tones that are popular in Europe and Asia and gaining traction in the United States.[234]

Most significantly, many natural colors have been found to be nutraceuticals. Paprika[235] is a source of vitamin C, riboflavin[236] contains vitamin B, and many others are rich sources of antioxidants.[237] Says one industry executive, "It is a very new field for a lot of companies. We are still learning what the specific health benefits are and trying to quantify them. As the food industry works with the health industry, we will see them (natural colors) used more and more, not only for color, but also for the health benefits that could be great for children as well as adults."[238]

Natural colors provide the further benefit of generally being more internationally accepted. Every country has its own color additive regulations, and what is acceptable varies widely. For example, Red nr 40 is banned in many European countries, and Green nr 3 is illegal throughout the E.U. Conversely, E131 (Patent Blue V) and E142[239] (Green S), just to name 2, are coal-tar colors banned in the U.S. Regulations of natural colors also do not match up exactly between countries, but the differences are far less severe. The list of natural colorants permitted in the E.U. and the united States are very similar.[240]

Natural colors also provide the opportunity for innovation through mixing and different extraction techniques. FDA regulations broadly permit "Fruit Juice"[241] and "Vegetable Juice"[242] as color additives, and this flexibility allows manufacturers to be creative and personalize hues for their customers.[243]

As the list of approved synthetic colors has been shrinking, manufacturers have devoted more resources to the development of natural colors. The cost of product development and the FDA approval process is prohibitively expensive, especially given the move of consumer preferences away from coal-tar dyes.[244] While no new coal-tar colors have been created and submitted for FDA approval in many years, a new natural dye, tomato

lycopene extract, was approved in 2005.[245] There is no question that synthetic colors will continue to play a large role in coloring our foods. But the resurgent popularity of natural colors is an ironic and exciting twist that brings the color additive story full circle.

Often taken for granted or overlooked, food dyes play a crucial role in how we taste and enjoy what we eat. This has been shown time and again, from ancient history to the margarine war to Crystal Pepsi. While we may still view the certified coal-tar colors with a note of mystery, we can rest assured of their safety due to the complex regulatory regime in place. It is hard to believe that only a century ago, our ancestors were eating food dyed with highly toxic color additives. From that auspicious starting point, we have come to a time where a food colorant with a 1 in 19 billion chance of causing cancer is legally considered too dangerous. What we use to dye our foods and how we regulate it may continue to change, but there is no end in sight to the timeless practice of coloring our food.

Endnotes

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