Synthetic Food Dyes
and the Link with Serious Health Consequences

Overview

One group of synthetic and industrialized food chemicals extensively studied and linked with adverse health reactions is artificial food dyes. This becomes particularly problematic when one considers just how prevalent synthetic food dyes have become in the U.S. diet. Unless consumers carefully examine the ingredients labels, they are likely unaware just how many products they bring home to their families contain synthetic food dyes. The dyes are present in hundreds of processed food items in U.S. grocery stores in everything from breakfast cereals, pickles, salad dressings, and pie crusts, to sports drinks. A 2014 report released by the FDA estimates that at least 96 percent of children aged 2-5 years are exposed to synthetic food dyes Red 40, Yellow 5, Yellow 6 and Blue 1.

The FDA has approved these synthetic dyes, so should consumers even be concerned? A recent review of the empirical studies on food dyes revealed: “The food industry dumps over 15 million pounds of the dyes studied into the food supply each year. Three of the dyes carry known carcinogens, and four can cause serious allergic reactions in some consumers. New studies show that seven of them

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contributed to cancer in lab animals, including brain and testicular tumors, colon cancer, and mutations” (Curran, 2010).

“Approximately 10,000 new processed food products are introduced every year in the United States. Almost all of them require additives not required by the FDA to be explicitly named in all ingredient lists, and may sometimes be represented under “natural coloring” or “added coloring.” It has been known to cause severe allergic reactions and anaphylactic shock in some people.”

~ Brenda Watson & Leonard Smith, M.D., food additive authors

A closer look

**Yellow Dye #5, Tartrazine**

The food dye Tartrazine (FD&C Yellow dye #5) appears to cause the most adverse reactions of all azo dyes (azos are nitrogen-based compound derivatives of diazene and azobenzene or diphenyldiazene). Over 70 years of scientific, empirical studies and clinical trials on humans have linked this dye to numerous negative health outcomes and as leading to a particular problem for those with asthma and aspirin intolerance. More specifically, Yellow 5 dye/Tartrazine has been linked in empirical studies and clinical trials to respiratory problems, bronchospasms and asthma, urticaria/skin reactions, anaphylactic shock, irritability, restlessness, and insomnia/sleep disturbances, and in children, behavioral problems including ADHD and learning difficulties. Animal studies have found a link with Tartrazine and generalized toxicity/genotoxicity, as well as adverse immunosuppressive effects. Clinical trials have suggested a link between Yellow Dye 5/Tartrazine and hyperactivity disorders/ADHD symptoms and learning difficulties in children, especially when it is combined with the preservative sodium benzoate.
Decades of clinical and consumer reports also reveal a litany of problematic reactions to Yellow 5 dye including allergies, asthma, breathing difficulties, feelings of suffocation, skin reactions including urticaria (hives), itching, swelling/edema/fluid retention (and subsequent weight gain), blurred vision, swollen lymph nodes, earaches, headaches, migraines, difficulty concentrating, depression, anxiousness, anxiety, irritability, general weakness, rhinitis, sinus problems, heat waves, restlessness, sleep disturbances/insomnia, cancer (especially thyroid tumors), sperm abnormalities, lymphomas, chromosomal damage and anaphylactic shock.

The FDA’s position on Tartrazine is that it prompts only minor adverse reactions in some people. In response to the FDA’s failure to protect the public from the potential dangers of this food dye in 2008 the Center for Science in the Public Interest filed a regulatory petition with the FDA requesting that this food dye be removed from the permitted food coloring list. To date, Tartrazine (FD&C Yellow dye #5) remains a permitted food dye in U.S. foods and, while like other food dyes it is required to appear on ingredients listings, there are no consumer warning labels on products containing it.

The food dye Yellow 5 (Tartrazine) is widely used in processed foods and can be commonly found in breakfast cereals, snack foods, candies, sodas, sports drinks, sauces, dips, salad dressings, pickles, pepperoncini, baked goods, pastry, pie crusts, cookies, prepared boxed and frozen meals, and condiments, among many others. This dye is also commonly found in conventional, catered and fast food restaurant items, a variety of personal care products such as mouthwash, and over the counter vitamins and medicines and prescription drugs. It may also be in pet food.
Caramel Coloring Food Dye

Several recent studies on caramel food coloring suggest this food dye may pose serious health consequences for consumers. Caramel food dye (an exempt-from-certification color additive) is common in many processed foods such as soda, baked goods and candy. Synthetic caramel coloring is processed with the use of sulfites which are recognized by the medical and research community as potentially dangerous to people with asthma and other health conditions. Toxicological data from clinical trials and animal research studies indicate this food dye is an immunosuppressive and can trigger allergic reactions in some people. Further, it is a known hidden source of gluten which can trigger serious adverse reactions in people with certain autoimmune disorders.

"There is no reason why consumers need to be exposed to this avoidable and unnecessary risk that can stem from coloring food and beverages brown."

-Consumer Reports' Dr. Urvashi Rangan, a toxicologist and lead investigator on the study.

Caramel Food Dye and 4-methylimidazole...

Scientists and Consumer Protection Groups Call on FDA to Require Limits & Consumer Warning Labels
Additionally, several recent studies have linked caramel food coloring to cancer. Following the release of one such study the Center for Science in the Public Interest, along with five independent food science experts, filed a regulatory petition with the FDA requesting that caramel coloring be removed from the permitted food coloring list, citing FDA policy which allows the use of colors the agency believes have “a reasonable certainty of no harm” while color additives that have been found to cause cancer in animals or humans are disallowed in FDA-regulated foods and drugs. The cancer risk of caramel coloring is associated with 4-methylimidazole (4-MEI) exposures (which occurs during the manufacturing process of caramel coloring) primarily through soda consumption. While there is currently no federal limit for 4-MEI in food or beverages, Consumer Reports (sponsors of one of the studies) petitioned the Food and Drug Administration to set limits for the potential carcinogen last year. There are typically four levels of color and chemical intensity that can be used with this food dye, the highest level (the darkest color and the highest levels of chemicals contained such as ammonia and sulfites—as well as producing the highest levels of 4-methylimidazole) has been determined by the state of California to be a carcinogenic risk and must be labeled as such on products sold in that state. Cola manufacturers, one of the most common users of caramel food dye, have responded by choosing to lower the level of caramel coloring in their products but recent testing by an independent laboratory found that at least one of the major cola producers was not in compliance with that requirement.

“Soft drink consumers are being exposed to an avoidable and unnecessary cancer risk from an ingredient that is being added to these beverages simply for aesthetic purposes. This unnecessary exposure poses a threat to public health and raises questions about the continued use of caramel coloring in soda.”

~Keeve Nachman, PhD, senior study author, Director of the Food Production and Public Health Program at the CLF, Assistant professor Johns Hopkins Bloomberg School of Public Health.
As a footnote to this topic, Nestlé Corporation has announced that in response to consumer preferences, by the end of 2015 the company would be removing synthetic dyes (including Yellow 5, Tartrazine and Red 40) and artificial flavoring from 250 items in its product line, including some best-selling chocolate candies. The company noted in the press release that they are also actively working to eventually eliminate 'Caramel Food Dye' from their products—a decision that, in conjunction with the choice to eliminate nonexempt synthetic dyes and flavorings, will no doubt eventually further enhance sales and customer loyalty, especially given the number of people currently avoiding food products containing caramel food dye.

The rest of the cast: Blue 1, Blue 2, Green 3, Red 2, Red 3, Red 40, Yellow 6

Previous studies on the other food dyes have been linked to adverse neurobehavioral effects. A recent public information report presented a review of the study findings on food dyes revealing to consumers that clinical studies and laboratory research examining the link between several FDA-approved food coloring and adverse consequences has been taking place for decades...

Blue Dye 1: Banned in at least two other countries, FD&C Blue #1 has been linked in animal studies to chromosomal damage. When ingested in food items FD&C Blue #1 has been linked with triggering hypersensitivity reactions in some people, and according to a 2003 U.S. Food and Drug Administration report, when used in enteral feeding tubes can lead to systemic toxicity and death. This synthetic food dye is found in a wide variety of processed food items including breakfast cereal, candies, soda, and baked goods, among others.
Blue Dye 2: Animal studies on FD&C Blue #2 first indicated a statistically significant incidence of tumors (including brain tumors) as far back as three decades ago and in 2003 was determined by the World Health Organization to have toxicity risks in patient feeding tubes, “FD&C Blue No. 2, may have similar if not greater toxicity potential than Blue No. 1 and would not be appropriate replacements”. This synthetic food dye is found in a wide variety of processed food items including breakfast cereal, candies, processed drinks, and baked goods, among others. Blue dye 2 may also be present in pet food.

Green Dye 3: Scientific animal studies have linked the synthetic food dye Green 3 with bladder and testes tumors. Consumer and clinical reports indicate sensitivities and allergic reactions to this food dye may include gastrointestinal and digestive problems such as stomach distress and diarrhea, skin reactions, and breathing problems, among others. Green Dye 3 can be found in a wide variety of processed foods including baked goods, ice cream, candy, snack foods, condiments, and beverages (including green beer, milkshakes and other popular St. Patrick's Day offerings). This synthetic dye can also be found in numerous over the counter and prescription drugs, lipsticks and other cosmetics, and a variety of personal care products.

Red Dye 2: FD&C Red #2 (Citrus Red) is typically reserved for use on some orange peels. Red Dye #2 has been linked with allergic reactions including skin reactions such as urticaria, swelling, and angioedema. Scientific animal studies have linked this dye with carcinogenic tumors.

Red Dye 3: FD&C Red #3 (Erythrosine) has been linked to cancer and thyroid tumors in scientific animal studies and may be genotoxic, though the FDA has been clear that it does not agree that these findings are persuasive enough to reverse their position that these food dyes are safe for consumers.
Consumer and clinical reports indicate that Red Dye #3 may trigger breathing difficulties and other allergic reactions in sensitive individuals. This dye can be found in a variety of processed foods including candies, bakery goods, sausage casings, maraschino cherries, fruit roll-ups and other snack foods, frozen meals and desserts, to name a few. It may also be present in over the counter and prescription drugs and chewing gum.

Red Dye 40: FD&C Red #40 contains a known carcinogenic contaminant (aniline) and has been linked in animal studies to intrauterine developmental problems, behavioral and physical toxicity, genotoxicity, and colon DNA damage. Red Dye 40 has been linked in clinical trials with allergy-like hypersensitivity in a small number of adults (including skin reactions such as itching and hives, swelling/edema, digestion problems, earaches, swollen lymph nodes, and agitation, nervousness, and migraine headaches) and as a potential trigger for hyperactivity in children. This widely used food dye makes an appearance in numerous processed foods including breakfast cereals and toaster pastries, candies, chocolate, pudding mix, cake mixes, snack chips, desserts, bakery goods (including refrigerated and frozen dinner rolls), processed drinks such as orange soda and other flavored sodas and drink mixes marketed to children. It may also be present in over the counter and prescription drugs, as well as pet food.

Yellow Dye 6: FD&C Yellow #6 (Sunset yellow) has been linked in empirical scientific research studies to allergic reactions and gastroenteritis, adverse reproductive and neurobehavioral effects, and cancer. It has also be demonstrated in a case study to trigger anaphylactic shock in sensitive individuals. Despite their acknowledgment of the findings on FD&C Yellow #6:
“Industry-sponsored animal tests indicated that this dye, the third most widely used, may cause tumors of the adrenal gland and kidney. In addition, small amounts of several carcinogens, such as 4-aminobiphenyl and benzidine (or chemicals that the body converts to those substances) may contaminate dye Yellow #6”

after reviewing those data the FDA concluded that Yellow Dye 6 does not pose a significant cancer risk to humans. And while the FDA also acknowledges that Yellow Dye 6 “may cause occasional and sometimes severe hypersensitivity reactions in some people,” their final position is that this food dye is safe for public consumption sans warning labels.

Dye Yellow 6 (Sunset Yellow) is commonly found in a wide variety of processed foods including breakfast cereals, snack foods, candies, sodas, sports drinks, sauces, dips, salad dressings, baked goods, pastry, pie crusts, cookies, prepared boxed and frozen meals, and condiments, among many others. It can also be found in conventional and fast food restaurant food items.
“Our study (Weiss, et al., 1980) was funded by the FDA, and its results, along with a number of others from that period, definitively demonstrated adverse behavioral effects of synthetic food colors (Weiss 1982).

During the intervening years, with a plethora of confirmations, the FDA has remained blindly obstinate. It continues to shield food additives from testing for neurotoxicity and apparently believes that adverse behavioral responses are not an expression of toxicity.”

~Dr. Bernard Weiss

Why are these synthetic dyes in the U.S. food supply?

There have been numerous screenings, tests and reviews concerning the safety of a variety of food colorings over the years. The FDA has consistently concluded that the evidence weighs in favor of determining the aforementioned food dyes safe for consumers, maintaining that colors found to be potentially hazardous have already been purged from the list of permissible additives. Not everyone interprets the data the same way, however. Citing numerous research findings linking synthetic food dyes with serious adverse health consequences, in 2008 The Center for Science in the Public Interest filed a Citizens Regulatory Petition requesting that the FDA ban these food dyes. In March 2011 the FDA reviewed the data on several food dyes and again declared them safe for human consumption.

P. Carlisle, Ph.D., © CRS Institute, Research report, 2009, 2015

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