

The Scoop on Synthetic Colorants – by Sarah A. Codrea, Executive Director, IACM

As both a parent and a person trying to be health conscious, I am always considering the potential health impacts of the many food and drink products my family consumes. What's okay to eat, and what should be avoided? There is a large amount of data available to today's consumers, with everything from the caffeine in my morning cup of coffee to the occasional evening chocolate indulgence under the microscope. Sometimes, this data can seem contradictory—one day something is declared “healthy!”, and the next day, its reputation has shifted to “potentially harmful.” In general, moderation seems to be key.

The focus of this particular article is food colorants. Is there a difference between natural and synthetic food dyes, and is it possible that too much of either could have an effect on my health? With the prevalence of available research on the subject, it can be difficult to sift through the sometimes contradictory studies to differentiate validated facts from persistent myths. For instance, the question of whether synthetic colorants are the cause of ADHD in children or cause cancer has been studied, debated and recently re-evaluated. What is the outcome?

Currently, the regulatory landscape in most regions is of the opinion that claims linking synthetic colorants with possible negative health, genotoxicity, or behavior effects have not been scientifically sound enough to make blanket changes to the rules governing how manufacturers can incorporate these additives into food and beverage products. So, just as I will continue to enjoy the caffeine in my coffee in moderation, my family will continue to enjoy the appeal that vibrant colorants can lend to some of my favorite foods and beverages as a part of a normal, balanced diet.

Safety & Regulatory Considerations Colorants are governed by their own unique set of regulations. Unlike many other food additives and processing aids, there is no “generally recognized as safe” (GRAS) exception for colorants in the US. Every batch of synthetic colorants produced in the US must be certified to meet the standards set by the 1938 FDA Food, Drug, and Cosmetics (FD&C) Act. Global regulatory agencies, mandating usage standards for colorants, have looked to re-evaluate the full breadth of available artificial colors and determine if there is any particular health risk, with consideration for recent studies focusing on synthetic azo dyes. These agencies not only looked to evaluate potential risk, but also set Acceptable Daily Intake (ADI) levels based on toxicological data. ADI is set with the top 10% of most sensitive individuals in mind and assumes that humans are 10 times more sensitive than test species, therefore incorporating a large factor of conservative assumptions. Estimates of intake or actual exposure to food additives are made to assure that estimated daily intake (EDI) falls below ADI. (The GFSA currently recommends ADIs for 38 of the 46 colorants it categorizes.)

In general, synthetic colorants are present in very low concentration with use levels in parts per million, which represents a miniscule of the dietary portion for the average American. In addition, per capita consumption data for colorants presented by the FDA's special Food Advisory Committee in 2011 showed that they fall well below set ADIs, which was affirmed by a 2015 longer exposure study by the FDA that also evaluated intake by age group and diet.^{1,2} The study considered variability in the level of colorants within each type of food (low, average and high exposure scenario) and level of consumption of foods containing colorants among consumers – those that consumed the average (or mean), and those that consumed the most of those foods (90th percentile) over the 10-14 day period – see chart below. *These data show that an adult or child would need to consume anywhere from 10 to 100 times or more of the estimated daily intake to reach the acceptable daily intake level in their diet (ADI/EDI > 10).*

For the average consumer, the number of recent studies examining synthetic colors combined with the fact that many of them seem to contradict one another can be befuddling. In addition, many of these studies have been met with varying degrees of reception for different markets, such as the US and the EU.

Published Studies – What's been discovered? The European Commission Regulation 257/2010 is currently re-evaluating permitted food colorants with consideration of risk assessment and ADI, with hopes to complete the assessment in 2020. The commission has spent particular time looking at the azo dyes that have been the subject of recent studies in order to extract meaningful conclusions. For example, Sunset Yellow was linked with testicular toxicity and changes in lipid profiles in male rats in two 2005 studies by the same research group in India.^{3,4} However, the EFSA considered the study and subsequently found that the results of those studies were questionable due to the colorant having been purchased at a street vendor; the colorant was not tested for its characteristics and purity prior to conducting the toxicological study, therefore making both the purity of the dye and conclusions of the study

A Snapshot of Today's Food Color Industry

- Food coloring substances have been used for thousands of years. Today's food and beverage manufacturers rely on colorants to: help products to stand out to consumers, offset color loss during storage from exposure to heat, light, air, and moisture, and help a product to match an expected color, such as red for a strawberry-flavored item.
- The FDA certified nearly 24 million pounds of FD&C colorants in 2014 alone, compared to under 15 million in 1999.
- 46 colors currently have drafted or adopted provisions under the internationally recognized GSFA maintained by the UN and WHO's Codex Alimentarius
- Colorants may fall under two categories: natural (derived from plant, mineral, or insect sources and then processed) or synthetic (produced from other organic compounds or inorganic feedstocks).
- Synthetic colorants should not be confused with colorants labeled “artificial,” as in the U.S., all colorants that are not native to the food product are considered artificial. (Red coloring sourced from tomato extract must be labeled as artificial when it's used to lend a red hue to a strawberry smoothie.)
- Each colorant type has its own formulating considerations. Synthetic types are typically more vibrant, stable to heat and light, and economical, and thus can be used at lower levels to achieve a desired effect. When using natural colorants, the manufacturer may need to adjust the formulation to assure that taste is not altered and the product continues to taste the way it should. In some instances, both synthetic and natural colors are used.

¹ Codrea, Sarah. “Industry Activity: A Historical Perspective.”

International Association of Color Manufacturers (IACM). IFT 2015. Chicago, IL. July 2015.

² Doell, D. et al. “Updated Exposure Estimate for FD&C Color Additives for the U.S. Population.” U.S. Food and Drug Administration, College Park, MD 20740. 2015.

³ Mahur, Neera et al. “Effect of sunset yellow on testis in rats.” *J. Ecophysiol. Occup. Hlth.* 5 (2005): 1 – 3.

⁴ Mahur, Neera et al. “Sunset yellow induced changes in the lipid profile in male albino rat.” *Biochem. Cell. Arch.* 5.2 (2005): 197 – 200.

suspect.⁵ In an abundance of caution, the EFSA temporarily lowered the ADI in 2009 while more data could be requested and observed, then raised the ADI again after no sperm morphology effect could be reliably demonstrated as a result of Sunset Yellow ingestion, in a study conducted according to Good Laboratory Protocols (GLP).

However, there have been other recent studies that have also attempted to shed some additional light on whether synthetic food colors could be a health threat. How can one, as a consumer, sort out the conclusions that are scientifically sound from those contradictory studies that may be problematic? Notably, several studies have been published to examine the potential link between ingestion of synthetic dyes and hyperactive behavior, particularly in children.

The National Institute of Health first explored the relationship between hyperactivity and colorants in 1983, in what is known as the “Feingold hypothesis” finding “no consistent evidence of effect,” a conclusion that has since been echoed and supported by the Nutrition Foundation and National Research Council, as well as bolstered by certain hyperactivity studies such as the “Isle of Wight Study” of 2004 and parallel findings by Shulte-Korne et al in 1996.⁶ Despite this, the question of whether there could be some potential link persists. Some studies seem to hang on the question—some of the children tested did exhibit certain increases in hyperactive behavior. Why might this be?

Perhaps the most notable recent study alleging a link between hyperactivity and colorants is the “Southampton Study” conducted in 2007. This study involved two groups of children, age 3 or 8/9, who were given either placebos or a beverage containing a blend of various colorants over alternate weeks. This study used a combination of parent/teacher ratings, computerized testing, and classroom observations to determine whether the behavior of the children exhibited increased hyperactivity.

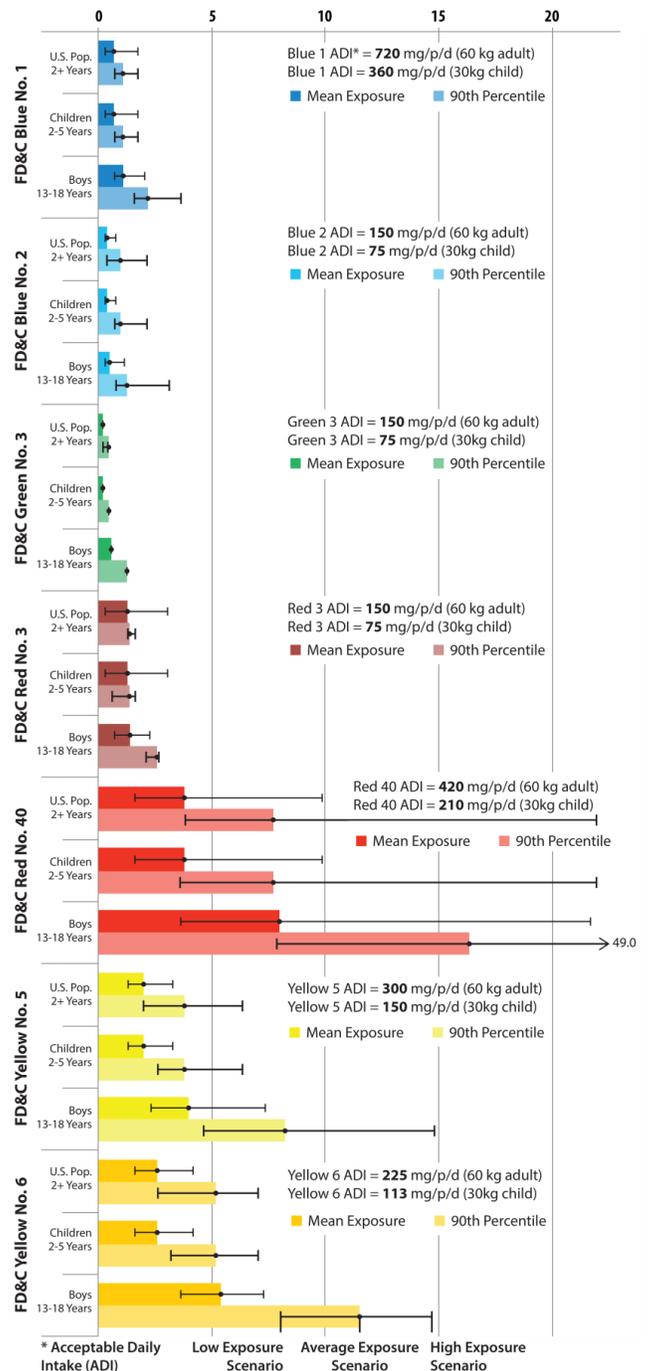
However, critics have suggested that the Southampton study lacked sufficient controls to validate the study’s conclusion. The study did not consider factors as the, time after consumption to record results, and body weight. The researchers’ method of recording observed effects has also been critiqued as non-standard, relevant only in regards to transient effects (i.e., such as that observed after a child consumes a sugary item) rather than long-term health, and lacking hard, statistical significance.

Regardless, the publication of the Southampton study led to some public concern. In Europe, the EFSA determined that data from the study only provided limited information that could not be extrapolated in order to pinpoint exact causes of small hyperactivity changes⁷, and the agency was unsure how widespread these changes could be since the samples used in the test were not representative of any existing food products on the market. However, to be cautious and respond to public concerns while allowing time for more data to be collected and examined, the EU parliament began requiring labeling of food colorants.

Response to the Southampton study outside of Europe differed. The U.S. FDA convened a food advisory committee of experts, consumers, and industry representatives to review available data in combination with the Southampton study, as well as invite public comment. Ultimately, the committee determined that no causal relationship exists between hyperactivity and food color additives, and the idea of a label like the EU label was rejected⁸. A label was also rejected in Canada, Australia, New Zealand, China, and Japan.

Claims linking synthetic colorants with possible negative health, genotoxicity, or behavior effects have not been scientifically sound enough to make blanket changes to the rules governing how manufacturers can incorporate these additives into food and beverage products. This position is supported by data that show that daily intake for the average person is far, far below the established conservative ADIs for safe consumption. The 10-100 fold gap between maximum safe intake levels and actual consumption are a comforting reassurance that moderation continues to be key when it comes to diet and health.

Cumulative Exposure to FD&C Color Additives (mg/p/d) Based on NPD NET-NID 10-14 Day Food Consumption Data



⁵ EFSA ANS Panel. (2014) “Scientific Opinion on the reconsideration of the temporary ADI and refined exposure assessment for Sunset Yellow FCF (E 110). EFSA Journal 12(7), 3765

⁶ Bateman, B et al. (2004) “The effects of a double blind, placebo controlled, artificial food colourings and benzoate preservative challenge on hyperactivity in a general population sample of preschool children.” *Archives of Disease in Childhood*, 89(6), 506-511.

⁷ EFSA AFC Panel (2008) Scientific Opinion of the AFC Panel on a request from the Commission on the results of the study by McCann et al. (2007) on the effect of some colours and sodium benzoate on children’s behaviour. The EFSA Journal 660, 1-54.

⁸ Food Advisory Committee (2011) Background Document for the Food Advisory Committee: Certified Color Additives in Food and Possible Association with Attention Deficit Hyperactivity Disorder in Children March 30-31, 2011; FDA/CFSAN Meeting Materials.