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Exposure estimate for FD&C colour additives for the US population

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Abstract

Dietary exposures to the seven food, drug, and cosmetic (FD&C) colour additives that are approved for general use in food in the United States were estimated for the US population (aged 2 years and older), children (aged 2–5 years) and teenage boys (aged 13–18 years) based on analytical levels of the FD&C colour additives in foods. Approximately 600 foods were chosen for analysis, based on a survey of product labels, for the levels of FD&C colour additives. Dietary exposure was estimated using both 2-day food consumption data from the combined 2007–10 National Health and Nutrition Examination Survey (NHANES) and 10–14-day food consumption data from the 2007–10 NPD Group, Inc. National Eating Trends – Nutrient Intake Database (NPD NET-NID). Dietary exposure was estimated at the mean and 90th percentile using three different exposure scenarios: low exposure, average exposure and high exposure, to account for the range in the amount of each FD&C colour additive for a given food. For all populations and all exposure scenarios, the highest cumulative eaters-only exposures in food were determined for FD&C Red No. 40, FD&C Yellow No. 5 and FD&C Yellow No. 6. In addition, the eaters-only exposure was estimated for individual food categories in order to determine which food categories contributed the most to the exposure for each FD&C colour additive. Breakfast Cereal, Juice Drinks, Soft Drinks, and Frozen Dairy Desserts/Sherbet (also referred to as Ice Cream, Frozen Yogurt, Sherbet (including Bars, Sticks, Sandwiches)) were the major contributing food categories to exposure for multiple FD&C colour additives for all three populations.

Keywords

Dietary exposure; food consumption; FD&C Blue No. 1; FD&C Blue No. 2; FD&C Green No. 3; FD&C Red No. 3; FD&C Red No. 40; FD&C Yellow No. 5; FD&C Yellow No. 6

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Supplemental data for this article can be accessed [here](#).

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Introduction

Synthetic organic dyes are widely used as colour additives in processed foods. The use of these dyes has come under increased scrutiny in the past few years because of their use in food consumed by children, and their suggested link to effects on behaviour. Currently in the United States there are seven synthetic organic dyes that, when batch-certified by the USFDA for identity and purity, are approved as FD&C colour additives. These colour additives – FD&C Blue No. 1 (dye and lake), FD&C Blue No. 2 (dye and lake), FD&C Green No. 3 (dye and lake), FD&C Red No. 3 (dye only), FD&C Red No. 40 (dye and lake), FD&C Yellow No. 5 (dye and lake), and FD&C Yellow No. 6 (dye and lake) – are approved for general use in food at levels consistent with good manufacturing practice (GMP), meaning that no more of the additive should be used than is needed to achieve the intended technical effect (Table 1).

A study conducted by McCann et al. (2007) reported a connection between consumption of six colour additives and possible behavioural effects in children. The colour additives evaluated were Tartrazine, Sunset Yellow, Ponceau 4R, Carmoisine, Quinoline Yellow, and Allura Red AC. Three of these colour additives (i.e., Tartrazine, Sunset Yellow and Allura Red AC) that are batch-certified as FD&C colour additives are approved for use in food marketed in the United States; the other three colour additives (i.e., Ponceau 4R, Carmoisine and Quinoline Yellow) are not approved for use in food marketed in the United States.

The USFDA convened its Food Advisory Committee (FAC) in March 2011 to consider the available relevant data on the possible association between children's consumption of the certified colour additives in food and hyperactivity or other behavioural effects (USFDA FAC 2011). The FAC was tasked to advise the USFDA on what action, if any, was warranted to ensure the safety of these colour additives. As part of the materials presented to the FAC, a per capita exposure was estimated for each FD&C colour additive based on the total pounds of each FD&C colour additive batch-certified by the USFDA in 2010 (USFDA 2010), as well as the US population from the 2010 Census (United States Census 2010). After considering the information presented by the USFDA, experts and other stakeholders, the FAC concluded that a causal link between children's consumption of FD&C colour additives and behavioural effects had not been established, and that additional label information (i.e., a warning label) to ensure the safe use of FD&C colour additives was unnecessary. One recommendation from the FAC was for the USFDA to conduct a comprehensive exposure assessment for the FD&C colour additives approved for use in food, with a particular focus on children.

There have been studies conducted in other countries to estimate the exposure to colour additives in the diet. EFSA has provided a refined exposure assessment for Sunset Yellow (EFSA 2014) and Allura Red AC (EFSA 2015). In addition, exposure assessments were provided as part of the scientific opinion on the re-evaluation of Tartrazine (EFSA 2009), Brilliant Blue FCF (EFSA 2010) and Erythrosine (EFSA 2011). Furthermore, a scientific report submitted to EFSA provided dietary exposure estimates for different food additives, including colour additives, for young children (Huybrechts et al. 2010).

Studies conducted in Australia (FSANZ 2008), Korea (Ha et al. 2013), Japan (Yamada & Ishiwata 2000) and India (Dixit et al. 2010) have estimated exposure to various colour additives for multiple populations. Studies conducted in India (Rao et al. 2004; Dixit et al. 2011), Hong Kong (Lok et al. 2010), Germany (Diouf et al. 2014), Kuwait (Husain et al. 2006; Sawaya et al. 2008), Ireland (Connolly et al. 2010) and Brazil (Toledo et al. 1992) have focused on exposure to colour additives in children and/or adolescents. Finally, there have been studies in other countries that are specific for a certain colour additive. In Italy, the exposure to Allura Red AC from the consumption of red juice-based and red soft drinks was estimated for various populations. In this study, the highest exposure was found in a 'health' juice-based drink (Fallico et al. 2011). In addition, a study in France estimated the exposure to Tartrazine as part of a risk assessment for this colour additive (Elhkim et al. 2007).

Although there have been studies conducted in the United States that discussed the levels of FD&C colour additives in commonly consumed beverages (Stevens et al. 2014, 2015b) and in foods commonly consumed by children (Stevens et al. 2015a), a comprehensive exposure estimate considering all foods containing FD&C colour additives has not been conducted. Based on the recommendation of the FAC, the USFDA conducted an exposure assessment of the seven FD&C colour additives approved for general use in food in the United States. This exposure estimate is based on food consumption data, as well as the analytically determined levels of FD&C colour additives in food.

Materials and methods

Compilation and sources of FD&C colour additives in foods

In order to estimate the exposure to each FD&C colour additive, the foods that contain these colour additives and the amount of each FD&C colour additive in those foods first had to be determined. Three different sources were used to identify those foods that contain FD&C colour additives.

Food Essentials LabelBase

The FoodEssentials LabelBase database (<http://labelbase.foodessentials.com/>) was used to compile a list of foods containing each of the seven FD&C colour additives. This proprietary product label database provides access to greater than 250 000 labels sourced from data contained in the Gladson and Mintel databases for US products. This database was used to determine the foods that list FD&C colour additives as ingredients. The Gladson Nutrition Database (GND) (<http://www.gladson.com/Our-Services/Nutrition-Database>) contains information from over 90% of products in most major consumer packaged goods categories. It includes information such as product images, ingredient lists, nutrition facts and universal product codes (UPCs). The Mintel Global New Products Database (GNPD) (<http://www.mintel.com/global-new-products-database>) monitors product innovation and retail success in the consumer packaged goods market. It contains data similar to that in the Gladson database for 62 countries in 32 food categories from 1996 to the present.

Websites

Websites were also used to obtain information regarding those foods that contain FD&C colour additives. Some food manufacturers list ingredient label information on their websites. In addition, other publicly available websites such as Walmart, Food Facts and Shop Well provide ingredient lists. Therefore, these websites were also used to gather information regarding the use of FD&C colour additives.

Product label survey

Since foods are continuously being reformulated and are being introduced or removed from the market, there can be a delay in updating the food product databases and websites to reflect these changes. Therefore, a product label survey was conducted at local grocery stores in the greater Washington, DC, area from June 2012 to May 2014. Stores surveyed included Giant, Safeway, Shoppers Food Warehouse, Harris Teeter, Target and Walmart. Over 7300 private label and brand name products were surveyed. This was intended to be a comprehensive survey of those food categories that were known currently or previously to contain FD&C colour additives. The following information was collected from each surveyed food: (1) the name of the food; (2) whether the food contained a FD&C colour additive; and (3) if the food contained a FD&C colour additive, which FD&C colour additives were included in the ingredient list.

FD&C colour additive use levels in foods

Once the foods that contain FD&C colour additives were identified, the amount of each FD&C colour additive in those foods was determined analytically, as this information is not disclosed on the label.

Selection of foods for analysis

In order to choose specific foods for analysis, those foods that contain FD&C colour additives were grouped into 52 broad food categories (e.g., Breakfast Cereal, Hard Candy, Juice Drinks, Soft Drinks, Sports Drinks) (Table 2), not all of which contained every FD&C colour additive. Table 2 lists those food categories that include foods that contain at least one FD&C colour additive. Although other food categories not included in Table 2 were surveyed, they were determined to not contain FD&C colour additives, and were therefore not included in the exposure estimate. For each FD&C colour additive, representative foods from those food categories, based on the results of the product label survey and the information obtained from the available databases and websites, were chosen for laboratory analysis.

Analysis of samples

Approximately 600 private label and brand name foods were identified for analysis. Information from labels, including the name of the food, nutrition information and ingredient list, was captured for each of the analysed foods. Prior to analysis, all foods were prepared as they would be consumed. For example, cake mixes were prepared according to package directions and then baked, and frozen concentrates were reconstituted prior to

analysis. Samples were analysed by a contract laboratory to determine the levels of FD&C colour additives based on a high-performance liquid chromatography (HPLC) method with photodiode array (PDA) detection developed by the USFDA (Petigara Harp et al. 2013). This method allows for the quantitative determination of all seven FD&C colour additives in a single run for a variety of food matrices.

The method involves extracting the colour additives from a food and isolating them from the non-coloured components that co-extract. The colour additives are then separated and identified by HPLC. In general, every 20th sample was analysed in triplicate and a known quality control sample was also run every 20th sample to ensure the analyses were being performed correctly. The HPLC apparatus used an Xterra RP18 column and gradient elution with aqueous ammonium acetate and methanolic ammonium acetate. The PDA wavelengths used for analysis were 429 nm (FD&C Yellow No. 5), 487 nm (FD&C Yellow No. 6), 510 nm (FD&C Red No. 40), 530 nm (FD&C Red No. 3), 620 nm (FD&C Blue No. 2), 626 nm (FD&C Green No. 3) and 626 nm (FD&C Blue No. 1). The limit of detection (LOD) for these analyses was 1 mg kg⁻¹. The total run time for each analysis is 50 min, and all samples were analysed by HPLC within 24 h of sample preparation. The contract laboratory provided the results for each FD&C colour additive in mg kg⁻¹. Samples intended to serve as negative controls (i.e., a corresponding food that did not contain FD&C colour additives) were also purchased and analysed. In addition, validation samples were analysed.

Table 2 contains the range of levels of each FD&C colour additive for a given food category. The levels found in a specific food that was analysed can be found in the supplemental data online.

General considerations

The product label survey is a snapshot in time due to the fluid nature of the use of FD&C colour additives in the marketplace. Therefore, our exposure estimate reflects those foods that were available in the marketplace across the United States at the time of the survey.

Dietary exposure estimates for FD&C colour additives from their use in food were performed using two different sets of food consumption data: (1) the combined 2007–10 NHANES 2-day dietary intake survey; and (2) the 2007–10 NPD Group, Inc. National Eating Trends – Nutrient Intake Database (NPD NET-NID) 10–14-day data using the proprietary Foods Analysis and Residue Evaluation – National Eating Trends (FARE-NET) programme. The use of 2-day food consumption data to assess chronic exposure can lead to an overestimation of exposure, especially for foods not commonly consumed. For this reason, food consumption data collected from a longer survey are considered to be more representative of actual consumption patterns in the United States (Lambe et al. 2000). Therefore, the dietary exposure to the seven FD&C colour additives was estimated using 2-day food consumption data, as well as 10–14-day food consumption data.

Three population groups were chosen for the exposure estimate: US population aged 2 years and older, children 2–5 years and teenage boys aged 13–18 years. Children 2–5 years old were chosen because they are known to have the highest exposure reported on a body weight

basis, and that there are certain food categories (e.g., Juice Drinks, Breakfast Cereal) that would be more commonly consumed by children. Teenage boys were chosen because this population tends to consume greater quantities of food, and in particular foods that could be coloured with FD&C colour additives (e.g., Soft Drinks, Toaster Pastries). Therefore, this population is intended to represent the exposure to FD&C colour additives at the ‘high end’ of the exposure spectrum.

All exposures were estimated on an ‘eaters-only’ basis, meaning that the estimate represents the dietary exposure to FD&C colour additives from the consumption of foods containing FD&C colour additives by the individuals in the population who consumed one or more of those foods over the survey period. Dietary exposures were estimated at the mean and at the 90th percentile for each population for each food category, where the 90th percentile represents those individuals who are the ‘high intake’ consumers of a given food.

The exposure estimate based on 2-day food consumption data was performed as follows. Foods that contained at least one of the FD&C colour additives were identified and grouped into one of 52 broad food categories (e.g., Breakfast Cereal, Hard Candy, Juice Drinks, Soft Drinks, Sports Drinks) (Table 2). Next, the foods identified as containing at least one FD&C colour additive were matched with food codes from the combined 2007–10 NHANES survey. Over 300 NHANES food codes were assigned to the identified foods.

This mapping of the NHANES food codes was performed for each of the seven FD&C colour additives, resulting in a list of food codes, grouped by broad food category, for each FD&C colour additive. The NHANES food codes vary in the level of granularity. For some foods, the food codes are very specific (e.g., cereals are indicated by brand name). However, for other foods, the NHANES food codes are more general (e.g., the NHANES food codes for the soft drink category are not specific to brands; therefore, the ‘soft drink, fruit-flavoured, caffeine containing’ food code would represent all fruit flavoured soft drinks that contain caffeine). Therefore, a given NHANES food code could represent one of the identified foods or a number of them, depending on the specific NHANES food code.

For each NHANES food code identified as containing a particular FD&C colour additive, a use level for that FD&C colour additive, which was based on the results of the analytical data, was assigned to that food code. It was not possible to analyse all foods listing a specific FD&C colour additive. Therefore, for some foods, analytical data for one food were used as a surrogate for another food (e.g., one brand of cookies and cream cereal was used as a surrogate for another brand’s cookie cereal). If a given FD&C colour additive was not found to be present in foods represented by a given NHANES food code (*i.e.*, that particular FD&C colour additive was not identified on the ingredient list for the foods represented by that NHANES food code), then that food code was not included in the exposure estimate for that particular FD&C colour additive.

For the exposure estimate based on 10–14-day food consumption data, an additional mapping step had to be performed. The NHANES food codes identified as containing each FD&C colour additive were mapped to the NPD NET-NID food codes. The NPD NET-NID data provide food frequency data from 10–14-day food diaries for over 5000 respondents.

The FARE-NET programme provides food consumption data based on the food frequency data from the NPD NET-NID combined with the mean food intake from NHANES.

For both the exposures estimated using 2- and 10–14-day food consumption data for each FD&C colour additive, three different exposure scenarios were performed: (1) a low-exposure scenario, where the lowest analytical value for a given FD&C colour additive was assigned to each food code; (2) an average-exposure scenario, where the analytical results were averaged for a given food code; and (3) a high-exposure scenario, where the highest analytical value for a given FD&C colour additive was assigned to each food code. These scenarios represent the lowest, average and highest exposure to each FD&C colour additive, respectively. For those food codes where only one food was represented by a given food code, the same level for that FD&C colour additive was used for all three scenarios.

The low-exposure scenario represents the absolute lowest exposure for a given FD&C colour additive, presuming that an individual always consumes those products containing the lowest levels of that FD&C colour additive. Conversely, the high-exposure scenario represents the absolute highest exposure for a given FD&C colour additive, presuming that an individual always consumes those products containing the highest levels of that FD&C colour additive. The average-exposure scenario represents the exposure to a given FD&C colour additive for a 'typical' consumer that consumes a varied diet where the individual may be loyal to a particular brand, but that brand may not always contain the lowest or the highest level of that FD&C colour additive. Other studies have also performed exposure estimates for colour additives using various scenarios (FSANZ 2008). These studies have indicated that the maximum-exposure scenario would tend to overestimate the exposure to a given FD&C colour additive as it is not likely that an individual would consume foods containing the maximum amount of that FD&C colour additive on a daily basis, and that the mean-exposure scenario represents the most realistic exposure.

For the exposure estimated using 2-day food consumption data, an eaters-only exposure to each FD&C colour additive for the three populations was estimated for each broad food category that contained the given FD&C colour additive, as well as a cumulative eaters-only exposure for each FD&C colour additive that takes into account all food categories containing the given colour additive. For the exposure estimated using 10–14-day food consumption data, a cumulative eaters-only exposure for each FD&C colour additive that takes into account all food categories containing the given colour additive was estimated for the three populations. Cumulative exposure estimates for each FD&C colour additive were also performed on a body weight basis for both the 2-day NHANES and 10–14-day NPD NET-NID food consumption data, using the reported body weights for the members of the sample populations.

Specific considerations

There were some specific considerations that were used in preparing the exposure estimates.

Using the modified USFDA method, the contract laboratory provided analytical data for all seven FD&C colour additives for each food analysed, regardless of whether the FD&C

colour additive was declared on the ingredient list. Results below the LOD were indicated as $< 1.0 \text{ mg kg}^{-1}$. If a given FD&C colour additive was not included in the ingredient list, then it was presumed that FD&C colour additive was not present in the food, and the data were not considered further. However, if a FD&C colour additive was declared on the label, but the results for that colour additive were below the LOD, the colour additive was presumed to be present in the food at the LOD (*i.e.*, 1.0 mg kg^{-1}).

For fountain drinks obtained from fast food restaurants and convenience stores, there were no labels listing ingredients. Therefore, it was not possible to know if a food contained a particular FD&C colour additive if the results were below the LOD. For these foods, a particular FD&C colour additive was presumed to be present in that food only if the results were above the LOD.

If a particular food was analysed in triplicate, the three replicates were averaged to obtain a single value for that FD&C colour additive for that particular food. If the NHANES food code was represented by several foods, the average value for the foods analysed in triplicate was used to estimate the use level for the average-exposure scenario for that NHANES food code. However, the lowest- and highest-use levels for that NHANES food code were determined from the individual replicates, so that the lowest- and highest-use levels for the NHANES food code represent the absolute lowest- and the absolute highest-use levels. If an NHANES food code were represented by only a single food, the lowest value of the replicates was used to represent the low-exposure scenario, the average of the three replicates was used for the average-exposure scenario, and the highest replicate value was used for the high-exposure scenario.

For the pancakes category, pancakes could be purchased as a premade frozen pancake or made from a mix. However, the NHANES food codes for pancakes do not differentiate between frozen pancakes and those from a mix. Therefore, the NHANES food codes for pancakes were included in both the 'Pancakes and Waffles' category, as well as the 'Frozen Breakfast Foods' category. When estimating the overall exposure to a particular FD&C colour additive that included the pancake NHANES codes, the highest value of either the pancake made from mix or frozen pancake was used in order to provide a conservative estimate.

There is no NHANES food code for decorating gels. Therefore, these foods were considered under the food code for 'Icing, white'. This food code includes decorating gels in addition to all non-chocolate frosting. The analytical data indicate that the levels of FD&C colour additives in decorating gels can be quite high, and this is reflected in the values for the 'Icing, white' food code.

When estimating exposure to a frosted cake, the amount of FD&C colour additive in the cake component was added to the amount of FD&C colour additive in the frosting to yield the value used in the exposure estimate. As noted above, the 'Icing, white' food code encompasses frosting as well as decorating gels. Since decorating gels are not used on most cakes, only the amount of FD&C colour additive in frostings was used in the estimation of exposure for frosted cakes. Therefore, for the low-exposure scenario, the use level was

estimated using the lowest analytical value for a frosting containing a particular FD&C colour additive plus the lowest cake value. The use levels for the average- and high-exposure scenarios were similarly calculated using the average and high analytical values for frosting and cake, respectively.

Finally, not all NHANES food codes for frosted cakes were included in the exposure estimate. If the cake itself contained a FD&C colour additive, then the NHANES food code was included in the exposure estimate. However, if the cake component did not contain a FD&C colour additive, then it was excluded. A majority of frostings did not contain FD&C colour additives. Therefore, presuming all frosted cakes contain FD&C colour additives would overestimate the exposure to a given FD&C colour additive.

Results

The results of the cumulative eaters-only exposure estimate based on 2-day food consumption data and 10–14-day food consumption data are summarised in Tables 3, 4, and 5 and 6, 7, and 8, respectively.

The results of the exposure estimate based on 2-day food consumption data for the individual food categories for the three population groups are summarised for each FD&C colour additive in the supplemental data online.

Discussion

The results of the 2-day exposure estimates indicate that greater than 90% of individuals in all three populations consume at least one food containing FD&C Blue No. 1, FD&C Red No. 40, FD&C Yellow No. 5 and FD&C Yellow No. 6, whereas fewer individuals in all three populations consume FD&C Blue No. 2, FD&C Red No. 3 and FD&C Green No. 3. Based on the exposure estimated using the 10–14-day food consumption data, over 90% of the individuals in all three populations consume at least one food containing FD&C Blue No. 1, FD&C Blue No. 2, FD&C Red No. 40, FD&C Yellow No. 5 and FD&C Yellow No. 6, whereas fewer individuals in all three populations consume FD&C Red No. 3 and FD&C Green No. 3 (Tables 3–8).

The percent eaters are greater for the exposures estimated using the 10–14-day food consumption data than for those estimated using the 2-day data for all three populations (Tables 3–9). This is because an individual only needs to consume the food containing the colour additive once over the survey period to be included as an ‘eater’ of that food in the survey. Since there are more days in the 10–14-day food consumption survey, there are likely to be more individuals that will be included with at least one eating occasion over the survey period, therefore, contributing to the higher percent eaters.

In order to determine which FD&C colour additives a ‘typical’ consumer would most likely be exposed to, we considered the mean eaters-only exposures for the average-exposure scenario for all three populations (Tables 3–8). FD&C Blue No. 2 had the lowest mean eaters-only exposure for all three populations using 2-day food consumption data, whereas

FD&C Red No. 40 had the highest mean eaters-only exposure for all three populations. The mean eaters-only exposures for the average-exposure scenario based on 10–14-day food consumption data can also be compared. FD&C Green No. 3 had the lowest exposure for the US population aged 2 years and older and children aged 2–5 years, and FD&C Blue No. 2 had the lowest exposure for teenage boys aged 13–18 years. As with the exposure based on 2-day food consumption data, FD&C Red No. 40 also had the highest exposure for all three populations based on 10–14-day food consumption data.

Table 9 compares the cumulative eaters-only exposure estimates based on either 2-day or 10–14-day food consumption data for the average-exposure scenario for the US population aged 2 years and older. The exposure estimates based on 10–14-day food consumption data are lower than those based on 2-day food consumption data. This is due to the fact that most foods are not consumed every day. If the FD&C colour additive is not consumed daily, then the average daily consumption would be lower when more days are considered. Therefore, by using longer term food consumption data, an individual's consumption is averaged over more days. Consequently, the exposures estimated using the 10–14-day food consumption data are more representative of chronic intake than those estimated using the 2-day data.

Although the focus of this exposure estimate was to model chronic exposure, there are certain occasions where an individual may have a high short-term consumption of foods that may contain FD&C colour additives (e.g., holidays, birthday parties). Of the two food consumption data sets used in the exposure estimate, the use of 2-day food consumption data would be more appropriate than the 10–14-day food consumption data to represent these types of eating occasions.

It is also possible to consider the exposure estimates by food category to determine which food categories are the major contributors to exposure for each FD&C colour additive for each population (see the supplemental data online). In order to compare the food categories, the mean eaters-only exposure for each food category needs to be converted to a total sample mean basis by multiplying the eaters-only mean exposure by the percent eaters for each food category. Figures 1–7 show the 10 food categories that are the major contributors to mean exposure for the average-exposure scenario for each FD&C colour additive for each population. If there is no bar for a particular population for a given food category, it does not indicate that there was no exposure for that food category; it just indicates that food category was not in the top 10 food categories contributing to exposure for that population for that particular FD&C colour additive.

Figure 1 shows the 10 food categories that are the major contributors to exposure (mean; average-exposure scenario) for FD&C Blue No. 1 for each population. Juice Drinks was the food category that contributed the most to exposure for all three populations. The Decoration/Chips for Baking, Soft Drinks, Ice Cream Cones, Frostings and Icings, Breakfast Cereal, and Soft Candy/Gummies categories were also major contributors for all three populations for FD&C Blue No. 1.

Figure 2 shows the 10 food categories that are the major contributors to exposure (mean; average-exposure scenario) for FD&C Blue No. 2 for each population. Breakfast Cereal was

the food category that contributed the most to exposure for all three populations. The Decoration/Chips for Baking, Frozen Dairy Dessert/Sherbet, Toaster Pastries, Cakes and Cupcakes, Chocolate, and Frostings and Icings categories were also major contributors for all three populations, while Pudding was also a major contributor for the US population aged 2 years and older and children aged 2–5 years for FD&C Blue No. 2

Figure 3 shows that FD&C Green No. 3 was only found in four food categories. Of these categories, over 99% of the exposure (mean; average-exposure scenario) to FD&C Green No. 3 was from the Frozen Dairy Dessert/Sherbet food category for all three populations. Breakfast Cereal is the only other food category in which there is exposure to FD&C Green No. 3 for all three populations. The US population aged 2 years and older is the only population group in which there is exposure to FD&C Green No. 3 for all four food categories.

Figure 4 shows the 10 food categories that are the major contributors to exposure (mean; average-exposure scenario) for FD&C Red No. 3 for each population. Decoration/Chips for Baking was the food category that contributed the most to exposure for the US population aged 2 years and older. While this food category was a major contributor to exposure for the other two populations, the food category contributing the most to exposure for children aged 2–5 years and teenage boys aged 13–18 years was Ice Cream Cones. Frostings and Icings, Frozen Dairy Dessert/Sherbet, Soft Candy/Gummies, Meal Replacement Drinks/Bars, Cookies, Toaster Pastries, and Ice Pops, Frozen Fruit Bars were also major contributing categories for all three populations for FD&C Red No. 3.

Figure 5 shows the 10 food categories that are the major contributors to exposure (mean; average-exposure scenario) for FD&C Red No. 40 for each population. Soft Drinks was the food category that contributed the most to exposure for the US population aged 2 years and older and teenage boys aged 13–18 years. While this food category was a major contributor to the exposure for children 2–5 years, the food category contributing the most to exposure for this population was Juice Drinks, which was also a major contributor to the exposure for the other two populations. Frozen Dairy Dessert/Sherbet, Breakfast Cereal, and Cookies were also major contributing categories for all three populations for FD&C Red No. 40.

Figure 6 shows the 10 food categories that are the major contributors to exposure (mean; average-exposure scenario) for FD&C Yellow No. 5 for each population. Juice Drinks was the food category that contributed the most to exposure for the US population aged 2 years and older and children aged 2–5 years. While this food category was a major contributor to exposure for teenage boys aged 13–18 years, the food category contributing the most to exposure for this population was Soft Drinks, which was also a major contributor to the exposure for the other two populations. Snack Foods, Cake and Cupcakes, and Frozen Dairy Dessert/Sherbet were also major contributing categories for all three populations for FD&C Yellow No. 5.

Figure 7 shows the 10 food categories that are the major contributors to exposure (mean; average-exposure scenario) for FD&C Yellow No. 6 for each population. Soft Drinks was the food category that contributed the most to exposure for the US population aged 2 years

and older and teenage boys aged 13–18 years. While this food category was a major contributor to the exposure for children aged 2–5 years, the food category contributing the most to exposure for this population was Snack Foods, which was also a major contributor to the exposure for the other two populations. Sports Drinks, Juice Drinks, and Breakfast Cereal were also major contributing categories for all three populations for FD&C Yellow No. 6.

As noted previously, there have been other estimates regarding the amount of FD&C colour additives in beverages (Stevens et al. 2014), and in foods (Stevens et al. 2015a) commonly consumed by children in the United States. The per capita exposure for FD&C colour additives presented in the Stevens et al. (2014) paper was higher than the per capita estimate presented to the FAC for the same year (2010) (FAC 2011). This is because the exposure estimate presented to the FAC had been adjusted to reflect the amount of each FD&C colour additive used only in human food and beverages. According to one source (SRI Consulting 2005), 95–97% of the total amount of the certified colour additives are used to manufacture US products (e.g., food, pharmaceuticals, and cosmetics), with the remaining 3–5% being exported. Of the 95–97% of the certified colour additives used in US products, 10% are used in pharmaceuticals, 3% are used in cosmetics, 14% are used in pet food, and the remaining 73% are used in human food and beverages (SRI Consulting 2005). Therefore, only 73% of the total poundage of each certified FD&C colour additive was used in the per capita exposure estimate to reflect the amount of each FD&C colour additive used in human food and beverages. The per capita estimate presented in Stevens et al. (2014) includes all uses of FD&C colour additives, including use in pharmaceuticals, cosmetics, human food and beverages, pet food, as well as that exported for use in other countries, thus overestimating human dietary exposure. The use of the adjustment factor in the per capita exposure presented to the FAC explains the difference in that presented in Stevens et al. (2014).

The analytical results used in the exposure estimate described in this paper were typically lower than those reported by Stevens et al. (2014, 2015a), when the same foods were analysed. It was noted by Stevens et al. that several samples contained mixtures of FD&C Blue No. 1 and FD&C Blue No. 2, of FD&C Red No. 3 and FD&C Red No. 40, or of FD&C Yellow No. 5 and FD&C Yellow No. 6. For each pair of FD&C colour additives, the wavelength of the colour additive with the greater concentration was used to calculate the amount of FD&C colour additive in the sample. Therefore, individual FD&C colour additives in each pair were not always quantitated. Moreover, the authors also stated that natural dyes that could be present in the food have maximum absorbance wavelengths similar to some of the FD&C colour additives and therefore, the estimated amounts of FD&C colour additives for those foods containing natural dyes are higher than if the FD&C colour additives were isolated and measured without the natural dyes. The authors indicated that such a separation was not possible for their study.

Stevens et al. remeasured the levels of FD&C colour additives in many of the beverages originally reported in Stevens et al. (2014) using a modified version of the method developed by Petigara Harp et al. (Stevens et al. 2015b). The levels of the FD&C colour additives in all beverages in the new analysis were lower by 10–36% compared with the levels in the

original publication. The authors noted that this change was mostly due to a lack of correction for standard purity in the previously published results. The authors further noted that the levels of the FD&C colour additives in some orange beverages were more than 50% lower than the previously published levels. The stated reasons for this discrepancy are: (1) an overlap of the absorbance range for FD&C Yellow No. 6 and FD&C Red No. 40, which was not corrected for in the previous study; and (2) interference from other coloured ingredients in the beverage sample (e.g., a proportion of real fruit juice), which elevates the absorbance. These errors were accounted for and corrected in the new study for beverages (Stevens et al. 2015b), but the same correction has not been performed for all sampled beverages and for all foods analysed by Stevens et al. (2015a). Therefore, it may not be appropriate to make a direct comparison between the analytical results presented in this paper and those by Stevens et al.

Conclusions

This comprehensive dietary exposure assessment of FD&C colour additives in foods in the United States addresses a recommendation of the 2011 FAC to understand better children's exposure to these colour additives. The approach used in this study provides an assessment of the current exposure to the seven FD&C colour additives based on actual levels of these colour additives in foods. Eaters-only exposures were estimated for each FD&C colour additive for the US population aged 2 years and older, children aged 2–5 years, and teenage boys aged 13–18 years. Exposure was estimated using both 2- and 10–14-day food consumption data. The use of 10–14-day food consumption data versus 2-day food consumption data allows for the estimation of an exposure that is more representative of chronic exposure to FD&C colour additives. For all populations and all exposure scenarios, the highest cumulative eaters-only exposures were determined for FD&C Red No. 40, FD&C Yellow No. 5, and FD&C Yellow No. 6. Breakfast Cereal, Juice Drinks, Soft Drinks, and Frozen Dairy Desserts/Sherbet were the major contributing food categories to exposure for multiple FD&C colour additives for all three populations. This exposure estimate is the first to address the exposure to the seven FD&C colour additives for multiple US populations based on the analysis of representative foods combined with food consumption data.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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References

- Connolly A, Hearty A, Nugent A, McKeivitt A, Boylan E, Flynn A, Gibney MJ. Pattern of intake of food additives associated with hyperactivity in Irish children and teenagers. *Food Add Contam.* 2010; 27:447–456.

- Diouf F, Berg K, Ptok S, Lindtner O, Heinemeyer G, Heseker H. German database on the occurrence of food additives: application for intake estimation of five food colours for toddlers and children. *Food Add Contam B*. 2014; 31:197–206.
- Dixit S, Purshottam SK, Gupta SK, Khanna SK, Das M. Usage pattern and exposure assessment of food colours in different age groups of consumers in the State of Uttar Pradesh, India. *Food Add Contam*. 2010; 27:181–189.
- Dixit S, Purshottam SK, Khanna SK, Das M. Usage pattern of synthetic food colours in different states of India and exposure assessment through commodities preferentially consumed by children. *Food Add Contam*. 2011; 28:996–1005.
- EFSA. Scientific Opinion on the re-evaluation of Tartrazine (E102). *EFSA J*. 7:1331. 2009. Available from: <http://www.efsa.europa.eu/en/efsajournal/pub/1331>
- EFSA. Scientific Opinion on the re-evaluation of Brilliant Blue FCF (E133) as a food additive. *EFSA J*. 8:1853. 2010. Available from: http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1853.pdf
- EFSA. Scientific Opinion on the re-evaluation of Erythrosine (E127) as a food additive. *EFSA J*. 9:1854. 2011. Available from: http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1854.pdf
- EFSA. Reconsideration of the temporary ADI and refined exposure assessment for Sunset Yellow FCF (E110). *EFSA J*. 12:3765. 2014. Available from: http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3765.pdf
- EFSA. Refined exposure assessment for Allura Red AC (E129). *EFSA J*. 13:4007. 2015. Available from: http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/4007.pdf
- Elhkim MO, Héraud F, Bemrah N, Gauchard F, Lorino T, Lambré C, Frémy JM, Poul J-M. New considerations regarding the risk assessment on Tartrazine. An update toxicological assessment, intolerance reactions and maximum theoretical daily intake in France. *Regul Toxicol Pharmacol*. 2007; 47:308–316. [PubMed: 17218045]
- Fallico B, Chiappara E, Arena E, Ballistreri G. Assessment of the exposure to Allura Red colour from the consumption of red juice-based and red soft drinks in Italy. *Food Add Contam*. 2011; 28:1501–1515.
- [FSANZ] Food Standards Australia New Zealand. Survey of added colours in foods available in Australia. 2008. Available from: <http://www.foodstandards.gov.au/science/surveillance/pages/surveyofaddedcolours5519.aspx>
- Ha M-S, Ha S-D, Choi S-H, Bae D-H. Exposure assessment of synthetic colours approved in Korea. *Food Add Contam A*. 2013; 30:643–653.
- Husain A, Sawaya W, Al-Omair A, Al-Zenki S, Al-Amiri H, Ahmed N, Al-Sinan M. Estimates of dietary exposure of children to artificial food colours in Kuwait. *Food Add Contam*. 2006; 23:245–251.
- Huybrechts, I.; Sioen, I.; Boon, P.; De Neve, M.; Amiano, P.; Arganini, C.; Bower, E.; Busk, L.; Christensen, T.; Hilbig, A., et al. Long-term dietary exposure to different food colours in young children living in different European countries. 2010. Available from: <http://www.efsa.europa.eu/en/supporting/pub/53e>
- Lambe J, Kearney J, Leclercq C, Zunft HFJ, De Henauw S, Lamberg-Allardt CJE, Dunne A, Gibney MJ. The influence of survey duration on estimates of food intakes and its relevance for public health nutrition and food safety issues. *Eur J Clin Nutr*. 2000; 54:166–173. [PubMed: 10694789]
- Lok KY-W, Chung W-Y, Benzie IFF, Woo J. Colour additives in snack foods consumed by primary school children in Hong Kong. *Food Add Contam B*. 2010; 3:148–155.
- McCann D, Barrett A, Cooper A, Crumpler D, Dalen L, Grimshaw K, Kitchin E, Lok K, Porteous L, Prince E, et al. Food additives and hyperactive behaviour in 3-year-old and 8/9-year-old children in the community: a randomised, double-blinded, placebo-controlled trial. *Lancet*. 2007; 370:1560–1567. [PubMed: 17825405]
- Petigara Harp B, Miranda-Bermudez E, Barrows JN. Determination of seven certified color additives in food products using liquid chromatography. *J Agric Food Chem*. 2013; 61:3726–3736. [PubMed: 23528012]

- Rao P, Bhat RV, Sudershan RV, Krishna TP, Naidu N. Exposure assessment to synthetic food colours of a selected population in Hyderabad, India. *Food Add Contam.* 2004; 21:415–421.
- Sawaya W, Husain A, Al-Otaibi J, Al-Foudari M, Hajji A. Colour additive levels in foodstuffs commonly consumed by children in Kuwait. *Food Control.* 2008; 19:98–105.
- SRI Consulting. Specialty Chemicals Update on Food Additives. 2005
- Stevens LJ, Burgess JR, Stochelski MA, Kuczek T. Amounts of artificial food colors in commonly consumed beverages and potential behavioral implications for consumption in children. *Clinical Pediatrics.* 2014; 53:133–140. [PubMed: 24037921]
- Stevens LJ, Burgess JR, Stochelski MA, Kuczek T. Amounts of artificial food dyes and added sugars in foods and sweets commonly consumed by children. *Clinical Pediatrics.* 2015a; 54:309–321. [PubMed: 24764054]
- Stevens LJ, Burgess JR, Stochelski MA, Kuczek T. Amounts of artificial food colors in commonly consumed beverages and potential behavioral implications for consumption in children: revisited. *Clinical Pediatrics.* 2015b; 54:1228–1230. [PubMed: 25876924]
- Toledo MCF, Guerchon MS, Ragazzi S. Potential weekly intake of artificial food colours by 3–14-year-old children in Brazil. *Food Add Contam.* 1992; 9:291–301.
- United States Census. Available from: <http://www.census.gov/2010census/popmap/>
- USFDA Color Certification Reports. Fiscal Year 2010. 2010. Available from: <http://www.fda.gov/ForIndustry/ColorAdditives/ColorCertification/ColorCertificationReports/default.htm>
- USFDA Food Advisory Committee (FAC). 2011. Available from: <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/FoodAdvisoryCommittee/ucm149740.htm>
- Yamada, T.; Ishiwata, H. Daily intake study of food additives by age cohort based on the market basket method. 2000. Available from: <http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/DI-study>

*Also referred to as Ice Cream, Frozen Yogurt, Sherbet (including Bars, Sticks, Sandwiches)

Figure 1.
Major contributors to exposure to FD&C Blue No. 1 based on the 2-day mean average-exposure scenario.

*Also referred to as Ice Cream, Frozen Yogurt, Sherbet (including Bars, Sticks, Sandwiches)

Figure 2.
Major contributors to exposure to FD&C Blue No. 2 based on the 2-day mean average-exposure scenario.

*Also referred to as Ice Cream, Frozen Yogurt, Sherbet (including Bars, Sticks, Sandwiches)

Figure 3.
Major contributors to exposure to FD&C Green No. 3 based on the 2-day mean average-exposure scenario.

*Also referred to as Ice Cream, Frozen Yogurt, Sherbet (including Bars, Sticks, Sandwiches)

Figure 4.
Major contributors to exposure to FD&C Red No. 3 based on the 2-day mean average-exposure scenario.

*Also referred to as Ice Cream, Frozen Yogurt, Sherbet (including Bars, Sticks, Sandwiches)

Figure 5.
Major contributors to exposure to FD&C Red No. 40 based on the 2-day mean average-exposure scenario.

*Also referred to as Ice Cream, Frozen Yogurt, Sherbet (including Bars, Sticks, Sandwiches)

Figure 6.
Major contributors to exposure to FD&C Yellow No. 5 based on the 2-day mean average-exposure scenario.

Figure 7.
Major contributors to exposure to FD&C Yellow No. 6 based on the 2-day mean average-exposure scenario.

Table 1

Structures and certified and common names for the seven general use FD&C colour additives.

Structure	Certified colour additive	Code of Federal Regulations citation	Common name
FD&C Blue No. 1	21 CFR 74.101	Brilliant Blue FCF
FD&C Blue No. 2	21 CFR 74.102	Indigotine
FD&C Green No. 3	21 CFR 74.203	Fast Green FCF
FD&C Red No. 3	21 CFR 74.303	Erythrosine
FD&C Red No. 40	21 CFR 74.340	Allura Red AC
FD&C Yellow No. 5	21 CFR 74.705	Tartrazine

Structure	Certified colour additive	Code of Federal Regulations citation	Common name
FD&C Yellow No. 6	21 CFR 74.706	Sunset Yellow

Table 2

Range of analytical results (mg kg⁻¹) for each FD&C colour additive in the food categories considered in the exposure estimate.

Food category	FD&C Blue No. 1	FD&C Blue No. 2	FD&C Green No. 3	FD&C Red No. 3	FD&C Red No. 40	FD&C Yellow No. 5	FD&C Yellow No. 6
Baby Foods	< 1.0 ^a	n.f. ^b	n.f.	8.4–8.8	2.8–13.2	n.f.	18.7
Biscuits	n.f.	< 1.0	n.f.	n.f.	n.f.	1.1	1.3
Breakfast Cereal	< 1.0–63.1	< 1.0–41.5	< 1.0	< 1.0–8.5	7.4–231.9	< 1.0–147.2	< 1.0–227.2
Cakes and Cupcakes	< 1.0–44.4	< 1.0–28.1	1.2	1.0–3.0	< 1.0–1268.7	< 1.0–168.2	< 1.0–3.9
Candied Fruit	n.f.	n.f.	n.f.	n.f.	161.0	n.f.	n.f.
Canned Fruits (Applesauce)	n.f.	n.f.	n.f.	n.f.	15.1	n.f.	n.f.
Cereal or Granola Bars	< 1.0–26.1	< 1.0–10.0	n.f.	n.f.	< 1.0–163.3	< 1.0–134.6	< 1.0–90.8
Cheese Spreads and Cream Cheese	8.7–23.2	< 1.0	n.f.	n.f.	7.6–133.6	n.f.	n.f.
Chewing Gum	< 1.0–73.5	< 1.0–130.8	n.f.	< 1.0–8.2	< 1.0–184.9	5.4–19.0	4.4–288.7
Chocolate	1.1–55.5	< 1.0–99.6	n.f.	n.f.	< 1.0–86.5	< 1.0–52.0	3.0–98.9
Cocoa Mix	< 1.0–1.2	n.f.	n.f.	n.f.	8.1–30.3	2.1	4.6
Condiments	< 1.0	n.f.	n.f.	n.f.	9.0–72.5	36.9–335.9	< 1.0–178.7
Cookies	< 1.0–11.9	< 1.0–2.0	n.f.	2.8–64.9	< 1.0–1062.9	< 1.0–142.5	1.3–100.3
Covered Nuts	< 1.0	< 1.0	n.f.	< 1.0	n.f.	5.4	n.f.
Crackers	< 1.0–1.2	n.f.	n.f.	n.f.	< 1.0–17.4	1.0–87.8	1.9–359.8
Decoration/Chips for Baking	< 1.0–148.5	< 1.0–33.8	n.f.	7.7–183.2	< 1.0–187.8	< 1.0–338.0	8.1–171.6
Dessert Toppings	2.2–9.6	n.f.	n.f.	< 1.0	< 1.0–225.6	2.0–5.1	< 1.0–17.3
Dips	n.f.	n.f.	n.f.	n.f.	< 1.0	< 1.0–60.0	13.9–17.6
Dried Fruit (Leathers)	1.0–46.8	n.f.	n.f.	2.0–2.2	31.3–170.0	< 1.0–29.6	< 1.0–115.7
Drink Mixers	< 1.0	n.f.	< 1.0	n.f.	< 1.0–181.1	< 1.0–4.2	n.f.
Energy Drinks	< 1.0–1.6	n.f.	n.f.	n.f.	1.2–17.6	4.8–5.4	n.f.
Fillings (e.g., pie fillings)	n.f.	n.f.	n.f.	n.f.	214.0	1.4–1.7	n.f.
Flavored Milk	n.f.	n.f.	n.f.	n.f.	8.2–8.3	n.f.	n.f.
Flavored Water/Enhancer ^c	16.1–96.8	n.f.	n.f.	n.f.	479.5–4704.4	78.8–1499.1	14.3–242.4
Frostings and Icings	< 1.0–11 664.7	< 1.0–1283.2	n.f.	< 1.0–23 562.8	< 1.0–906.5	3.9–1080.0	1.7–10 151.4
Frozen Breakfast Foods	< 1.0–4.6	3.5–26.4	n.f.	8.3–73.7	< 1.0–61.6	2.9–20.1	< 1.0–168.9
Frozen Meals and Snacks	< 1.0	n.f.	n.f.	n.f.	2.3–8.7	3.8–321.1	2.1–12.3

Food category	FD&C Blue No. 1	FD&C Blue No. 2	FD&C Green No. 3	FD&C Red No. 3	FD&C Red No. 40	FD&C Yellow No. 5	FD&C Yellow No. 6
Fruit Based Desserts (Gelatins)	< 1.0–1.3	3.1	n.f.	n.f.	< 1.0–201.7	6.6–14.5	< 1.0–150.2
Hard Candy	< 1.0–28.6	< 1.0–11.0	n.f.	2.3–2.4	< 1.0–85.1	< 1.0–108.9	< 1.0–62.3
Ice Cream Cones	139.8–232.6	n.f.	n.f.	244.0–1101.6	319.7	158.1	153.1
Ice Cream, Frozen Yogurt, Sherbet (including Bars, Sticks, Sandwiches)	< 1.0–17.1	< 1.0–16.5	< 1.0–1.0	< 1.0–14.2	< 1.0–633.9	< 1.0–63.8	< 1.0–54.9
Ice Pops, Frozen Fruit Bars	< 1.0–23.6	n.f.	n.f.	< 1.0–3.9	15.3–108.5	< 1.0–16.2	< 1.0–14.3
Iced Tea	< 1.0	n.f.	n.f.	n.f.	< 1.0–9.1	< 1.0–9.0	1.7
Jams and Jellies	1.3–4.7	n.f.	n.f.	n.f.	52.6–97.3	7.6–10.7	1.1–7.5
Juice Drinks	< 1.0–8.8	n.f.	n.f.	n.f.	< 1.0–65.6	< 1.0–45.3	< 1.0–33.8
Marshmallows and Marshmallow Toppings	< 1.0–46.4	< 1.0	n.f.	n.f.	47.9–126.2	42.8–78.0	n.f.
Meal Replacement Drinks and Bars	< 1.0–20.7	n.f.	n.f.	< 1.0–26.9	8.0–14.5	44.2	< 1.0–3.1
Non-Dairy Toppings	6.5	n.f.	n.f.	n.f.	44.2	78.1	n.f.
Pancakes and Waffles	1.6	1.7	n.f.	n.f.	< 1.0–5.9	6.9	n.f.
Pasta-based Meals (from mix)	n.f.	n.f.	n.f.	n.f.	3.2–4.1	2.1–49.7	< 1.0–27.5
Pies	< 1.0–2.8	n.f.	n.f.	< 1.0	< 1.0–44.0	< 1.0–54.1	< 1.0–9.2
Potatoes (from mix)	n.f.	n.f.	n.f.	< 1.0	< 1.0	9.6–29.5	2.0–5.3
Pudding	< 1.0–11.8	19.0–161.1	n.f.	n.f.	20.8–450.1	< 1.0–396.5	< 1.0–45.6
Sauces	3.1	n.f.	n.f.	n.f.	84.7–122.3	n.f.	96.4
Snack Foods	< 1.0–3.1	< 1.0–1.7	n.f.	n.f.	< 1.0–50.4	< 1.0–516.8	< 1.0–290.9
Soft Candy/Gummies	< 1.0–124.6	3.4	n.f.	< 1.0–756.2	< 1.0–276.2	< 1.0–220.3	< 1.0–208.8
Soft Drinks	< 1.0–8.1	n.f.	n.f.	n.f.	1.8–69.9	1.6–37.0	2.2–33.7
Soups	n.f.	n.f.	n.f.	n.f.	n.f.	10.2	< 1.0–24.2
Sports Drinks	< 1.0	n.f.	n.f.	n.f.	1.2–3.7	1.9–32.0	28.3–28.5
Toaster Pastries	< 1.0–7.6	1.2–71.8	n.f.	7.7	3.9–117.9	< 1.0–1.7	6.2–11.4
Trail Mix	n.f.	< 1.0	n.f.	n.f.	31.5	2.5	1.0
Yogurt	< 1.0–14.5	< 1.0	n.f.	n.f.	1.5–65.5	1.2–14.7	5.7–58.5

^aNotes: A value of < 1.0 mg kg⁻¹ indicates that a particular FD&C colour additive was listed on the label for a food in that food category, but the results for that colour additive were below the LOD. Therefore, the colour additive was presumed to be present in the food at the LOD (*i.e.*, 1.0 mg kg⁻¹).

^b n.f., Not found. This FD&C colour additive was not listed on the label for any foods in this food category and was not detected at the LOD. Therefore, this food category was not considered in the exposure estimate for this FD&C colour additive.

The analytical values for some of the foods in this category are for concentrates. The values were adjusted on a ready to eat basis for the exposure assessment.

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Cumulative eaters-only exposure to FD&C colour additives in mg/person/day and mg kg⁻¹ bw day⁻¹ (in parentheses) for the US population aged 2 years and older based on NHANES 2-day food consumption data.

Table 3

Colour	% Eaters	Low-exposure scenario		Average-exposure scenario		High-exposure scenario	
		Mean	90th percentile	Mean	90th percentile	Mean	90th percentile
FD&C Blue No. 1	92	0.9 (0.01)	2.1 (0.03)	1.3 (0.02)	2.9 (0.05)	2.3 (0.04)	4.8 (0.09)
FD&C Blue No. 2	69	0.7 (0.01)	1.3 (0.02)	0.8 (0.01)	1.6 (0.03)	1.1 (0.02)	3.4 (0.05)
FD&C Green No. 3	15	1.3 (0.02)	2.6 (0.04)	1.3 (0.02)	2.6 (0.04)	1.3 (0.02)	2.6 (0.04)
FD&C Red No. 3	54	1.3 (0.02)	3.4 (0.05)	2.3 (0.04)	3.8 (0.06)	3.7 (0.07)	4.2 (0.06)
FD&C Red No. 40	94	4.3 (0.07)	11.6 (0.2)	9.3 (0.2)	22.5 (0.4)	20.9 (0.4)	53.0 (0.9)
FD&C Yellow No. 5	94	2.6 (0.05)	6.4 (0.1)	4.6 (0.08)	10.8 (0.2)	8.2 (0.1)	19.3 (0.3)
FD&C Yellow No. 6	91	4.4 (0.07)	11.3 (0.2)	6.3 (0.1)	15.8 (0.3)	8.3 (0.1)	20.5 (0.4)

Cumulative eaters-only exposure to FD&C colour additives in mg/person/day and mg kg⁻¹ bw day⁻¹ (in parentheses) for children aged 2–5 years based on NHANES 2-day food consumption data.

Table 4

Colour	% Eaters	Low-exposure scenario		Average-exposure scenario		High-exposure scenario	
		Mean	90th percentile	Mean	90th percentile	Mean	90th percentile
FD&C Blue No. 1	96	0.6 (0.04)	1.2 (0.07)	1.1 (0.07)	2.2 (0.1)	2.1 (0.1)	4.1 (0.2)
FD&C Blue No. 2	78	0.5 (0.03)	0.8 (0.05)	0.6 (0.04)	1.2 (0.07)	0.9 (0.05)	2.8 (0.2)
FD&C Green No. 3	15	0.8 (0.04)	1.6 (0.09)	0.8 (0.04)	1.6 (0.09)	0.8 (0.04)	1.6 (0.09)
FD&C Red No. 3	62	0.7 (0.04)	1.1 (0.07)	2.0 (0.1)	1.6 (0.1)	3.6 (0.2)	1.8 (0.1)
FD&C Red No. 40	97	2.6 (0.2)	5.6 (0.4)	6.8 (0.4)	16.4 (1.0)	15.3 (0.9)	38.8 (2.2)
FD&C Yellow No. 5	98	2.2 (0.1)	5.4 (0.3)	3.4 (0.2)	8.0 (0.5)	5.5 (0.3)	12.7 (0.7)
FD&C Yellow No. 6	97	2.5 (0.1)	6.5 (0.4)	4.2 (0.2)	9.9 (0.6)	6.2 (0.4)	14.2 (0.8)

Cumulative eaters-only exposure to FD&C colour additives in mg/person/day and mg kg⁻¹ bw day⁻¹ (in parentheses) for teenage boys aged 13–18 years based on NHANES 2-day food consumption data.

Table 5

Colour	% Eaters	Low-exposure scenario		Average-exposure scenario		High-exposure scenario	
		Mean	90th percentile	Mean	90th percentile	Mean	90th percentile
FD&C Blue No. 1	93	1.0 (0.02)	2.2 (0.03)	1.6 (0.02)	3.4 (0.05)	2.8 (0.04)	6.3 (0.1)
FD&C Blue No. 2	72	0.6 (0.01)	1.1 (0.02)	0.8 (0.01)	1.7 (0.03)	1.5 (0.03)	4.0 (0.07)
FD&C Green No. 3	14	1.7 (0.03)	3.8 (0.06)	1.7 (0.03)	3.8 (0.06)	1.7 (0.03)	3.8 (0.06)
FD&C Red No. 3	53	0.9 (0.01)	2.3 (0.04)	1.7 (0.03)	2.4 (0.04)	2.6 (0.04)	3.0 (0.05)
FD&C Red No. 40	94	5.9 (0.09)	14.2 (0.2)	12.9 (0.2)	29.7 (0.5)	28.7 (0.5)	70.2 (1.1)
FD&C Yellow No. 5	93	3.3 (0.05)	7.6 (0.1)	6.0 (0.09)	13.9 (0.2)	11.4 (0.2)	26.1 (0.4)
FD&C Yellow No. 6	94	8.3 (0.1)	22.2 (0.3)	11.2 (0.2)	26.4 (0.4)	13.9 (0.2)	34.5 (0.5)

Cumulative eaters-only exposure to FD&C colour additives in mg/person/day and mg kg⁻¹ bw day⁻¹ (in parentheses) for the US population aged 2 years and older based on NPD NET-NID 10–14-day food consumption data.

Table 6

Colour	% Eaters	Low-exposure scenario		Average-exposure scenario		High-exposure scenario	
		Mean	90th percentile	Mean	90th percentile	Mean	90th percentile
FD&C Blue No. 1	99	0.6 (0.01)	1.4 (0.02)	0.9 (0.02)	2.0 (0.04)	2.0 (0.04)	3.0 (0.06)
FD&C Blue No. 2	93	0.4 (0.01)	0.9 (0.02)	0.5 (0.01)	1.2 (0.02)	0.9 (0.02)	2.1 (0.04)
FD&C Green No. 3	51	0.4 (0.01)	0.9 (0.02)	0.4 (0.01)	0.9 (0.02)	0.4 (0.01)	0.9 (0.02)
FD&C Red No. 3	84	0.7 (0.01)	2.1 (0.03)	1.7 (0.03)	3.0 (0.05)	3.2 (0.07)	3.2 (0.05)
FD&C Red No. 40	100	2.7 (0.05)	6.2 (0.1)	6.1 (0.1)	13.1 (0.2)	16.3 (0.3)	36.6 (0.7)
FD&C Yellow No. 5	100	1.7 (0.03)	3.4 (0.07)	3.0 (0.06)	5.9 (0.1)	5.4 (0.1)	11.1 (0.2)
FD&C Yellow No. 6	99	2.3 (0.04)	5.1 (0.1)	3.7 (0.07)	8.2 (0.2)	5.3 (0.1)	11.0 (0.2)

Cumulative eaters-only exposure to FD&C colour additives in mg/person/day and mg kg⁻¹ bw day⁻¹ (in parentheses) for children aged 2–5 years based on NPD NET-NID 10–14-day food consumption data.

Table 7

Colour	% Eaters	Low-exposure scenario		Average-exposure scenario		High-exposure scenario	
		Mean	90th percentile	Mean	90th percentile	Mean	90th percentile
FD&C Blue No. 1	100	0.3 (0.02)	0.7 (0.04)	0.7 (0.04)	1.1 (0.07)	1.8 (0.1)	1.8 (0.1)
FD&C Blue No. 2	96	0.3 (0.02)	0.7 (0.05)	0.4 (0.03)	1.0 (0.06)	0.8 (0.05)	2.2 (0.1)
FD&C Green No. 3	47	0.2 (0.02)	0.5 (0.03)	0.2 (0.02)	0.5 (0.03)	0.2 (0.02)	0.5 (0.03)
FD&C Red No. 3	87	0.3 (0.02)	0.6 (0.04)	1.3 (0.09)	1.4 (0.09)	3.1 (0.2)	1.7 (0.1)
FD&C Red No. 40	100	1.6 (0.1)	3.6 (0.2)	3.8 (0.2)	7.7 (0.5)	9.9 (0.6)	21.9 (1.3)
FD&C Yellow No. 5	100	1.3 (0.08)	2.6 (0.2)	2.0 (0.1)	3.8 (0.2)	3.3 (0.2)	6.4 (0.4)
FD&C Yellow No. 6	100	1.6 (0.1)	3.2 (0.2)	2.6 (0.2)	5.2 (0.3)	4.2 (0.3)	7.1 (0.4)

Cumulative eaters-only exposure to FD&C colour additives in mg/person/day and mg kg⁻¹ bw day⁻¹ (in parentheses) for teenage boys aged 13–18 years based on NPD NET-NID 10–14-day food consumption data.

Table 8

Colour	% Eaters	Low-exposure scenario		Average-exposure scenario		High-exposure scenario	
		Mean	90th percentile	Mean	90th percentile	Mean	90th percentile
FD&C Blue No. 1	100	0.7 (0.01)	1.6 (0.03)	1.1 (0.02)	2.2 (0.04)	2.1 (0.04)	3.7 (0.06)
FD&C Blue No. 2	91	0.3 (0.01)	0.8 (0.01)	0.5 (0.01)	1.3 (0.02)	1.2 (0.02)	3.2 (0.06)
FD&C Green No. 3	48	0.6 (0.01)	1.3 (0.02)	0.6 (0.01)	1.3 (0.02)	0.6 (0.01)	1.3 (0.02)
FD&C Red No. 3	85	0.7 (0.01)	2.1 (0.04)	1.4 (0.02)	2.6 (0.04)	2.3 (0.04)	2.7 (0.05)
FD&C Red No. 40	100	3.6 (0.06)	7.8 (0.1)	8.0 (0.1)	16.3 (0.3)	21.7 (0.4)	49.0 (0.8)
FD&C Yellow No. 5	100	2.3 (0.04)	4.6 (0.07)	4.0 (0.07)	8.2 (0.1)	7.4 (0.1)	14.8 (0.2)
FD&C Yellow No. 6	100	3.6 (0.06)	8.0 (0.1)	5.4 (0.09)	11.5 (0.2)	7.3 (0.1)	14.7 (0.2)

Comparison of cumulative eaters-only exposure estimates for the average-exposure scenario for the US population aged 2 years and older based on 2- and 10–14-day food consumption data.

Table 9

Colour	Exposure based on 2-day food consumption data in mg/person/day and mg kg ⁻¹ bw day ⁻¹ (in parentheses)			Exposure based on 10–14-day food consumption data in mg/person/day and mg kg ⁻¹ bw day ⁻¹ (in parentheses)		
	% Eaters	Mean	90th percentile	% Eaters	Mean	90th percentile
FD&C Blue No. 1	92	1.3 (0.02)	2.9 (0.05)	99	0.9 (0.02)	2.0 (0.04)
FD&C Blue No. 2	69	0.8 (0.01)	1.6 (0.03)	93	0.5 (0.01)	1.2 (0.02)
FD&C Green No. 3	15	1.3 (0.02)	2.6 (0.04)	51	0.4 (0.01)	0.9 (0.02)
FD&C Red No. 3	54	2.3 (0.04)	3.8 (0.06)	84	1.7 (0.03)	3.0 (0.05)
FD&C Red No. 40	94	9.3 (0.2)	22.5 (0.4)	100	6.1 (0.1)	13.1 (0.2)
FD&C Yellow No. 5	94	4.6 (0.08)	10.8 (0.2)	100	3.0 (0.06)	5.9 (0.1)
FD&C Yellow No. 6	91	6.3 (0.1)	15.8 (0.3)	99	3.7 (0.07)	8.2 (0.2)