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Estimation of theoretical intake of synthetic food colours Azorubine, Erythrosine, Indigotine, and Ponceau 4R by the Brazilian population

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Abstract

There are very few studies evaluating the exposure of the general population to food colours. This study aimed to estimate the Theoretical Maximum Daily Intake (TMDI) by the Brazilian population of four rather seldom-used synthetic food colours: Azorubine, Erythrosine, Indigotine, and Ponceau 4R. The study was conducted using data from the two most recent National Household Budget Surveys (carried out in 2008/2009 and 2017/2018). The study covered the country's population, sorted into the following groups: gender, geographic region, and age (among people older than 10 years). The results show that the mean TMDI (mg/day) does not exceed the Acceptable Daily Intake (ADI) in any population group for any of the food colours. The highest values found were 12.5% of the ADI for Erythrosine in 2008/2009 and 4% in 2017/2018. A decrease in the mean TMDI was observed for all food colours comparing 2008/2009 and 2017/2018. Intake increases with decreasing age, adolescents being the group with the highest mean TMDI. When considering the prevalence of food consumption instead of the mean consumption, TMDI gets closer to the ADI, reaching 79% of the ADI of Erythrosine for adolescent females. The intake of these food colours proved to be within the recommended levels.

Keywords: additives; acceptable daily intake; surveillance; dietary intake; exposure assessment.

Practical Application: First study of the exposure of the Brazilian population to some artificial colours.

1 Introduction

During food and beverage processing, the addition of food colours is a common practice to enhance the sensory attributes of the final products. Synthetic food colours have many advantages compared to natural colours, such as high stability to light, oxygen, and pH, and colour uniformity (Beto et al., 2015). However, based on various scientific findings, several toxicity effects have been reported, including behavioural effects on children, effects on the respiratory system, connection with allergies, the development of attention deficit hyperactivity disorder (ADHD) in children, and neurodevelopmental effects at No-Adverse Effect Limit levels (Amchova et al., 2015; Oplatowska-Stachowiak & Elliott, 2017; Uysal et al., 2017; Vojdani & Vojdani, 2015).

In order to evaluate the possible effects that food additives can have on health, it is important to have data on exposure to these substances. To estimate the intake of a particular additive within a diet, the following information is necessary: 1) the food products that contain the additive, 2) the concentration of the additive in these food products, and 3) how much of this food is consumed. Furthermore, the consumer's body weight or the average value for the population studied is needed to check whether the intake exceeds the Acceptable Daily Intake (ADI) (Joint FAO/WHO Expert Committee on Food Additives, 2014). There are very few studies evaluating the exposure of the general population to food additives in Brazil, where the National Health Surveillance Agency (ANVISA) is responsible for regulation of the use of food additives such as dyes and allows the use of 14 synthetic dyes. In a study carried out on foods for children in Brazil, it was observed, from data on the presence of food colours in these food products, that Azorubine (INS 122), Erythrosine (INS 127), Indigotine (INS 132), and Ponceau 4R (INS 124) had a similar, relatively low frequency of use (Lorenzoni et al., 2012). However, there are no data in the literature on exposure of the Brazilian population to these dyes.

Azorubine (also known as Carmoisine) is an azo dye permitted as a food colour for several foods and drinks in Brazil and the European Union, within the limits of 50 to 500 mg/kg (Agência Nacional de Vigilância Sanitária, 2021; European Food Safety Authority, 2009a). The EFSA (European Food Safety Authority) Panel on Food Additives and Nutrient Sources Added to Food, in its latest evaluation of Azorubine, concluded that the range of information did not justify an ADI revision (4 mg/kg) (EFSA, 2009a). However, subsequent research indicates that the intake of this food colour has possible effects on health (Karatepe et al., 2017; Oyewole & Oladele, 2016; Salama et al., 2016). Erythrosine is a food colour that gives products a cherry-pink colour and has a xanthen-poly-iodine structure, with an ADI of 0.1 mg/kg (European Food Safety Authority, 2011). Erythrosine has also been shown to be an inhibitor of several important interactions, with possible effects on thyroid function and on the accumulation of tissue in humans (Ganesan et al., 2011). Indigotine is an indigoid food colour found as a dark blue powder or dark blue grains, with an ADI of 5 mg/kg. A periodic assessment made

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by the EFSA panel found that Indigotine is little absorbed and does not cause concern for genotoxicity (European Food Safety Authority, 2014). Ponceau 4R is an azo food colour in the form of a sodium salt that gives food a reddish colour, with an ADI of 4 mg/kg. The EFSA panel concluded that there was no evidence of carcinogenicity caused by Ponceau 4R (European Food Safety Authority, 2009b). As for the effects of Ponceau 4R on hyperactivity and ADHD, the same committee concluded that some sensitivity reactions after the consumption of this food colour have been reported, especially when mixed with other synthetic colours (European Food Safety Authority, 2009b).

The aim of this work was to estimate the Theoretical Maximum Daily Intake of these four food colours by the Brazilian population, using procedures recommended by the World Health Organization (WHO) and Food and Agriculture Organization of the United Nations (FAO) to evaluate additive intake. It is expected to portray a global panorama of the intake of artificial colours that serves as a basis for public policies for monitoring intake.

2 Materials and methods

This study was carried out following the methodology proposed by Feitosa et al. (2017). Initially, a database was created for all processed food products whose labels indicated that they contained the artificial food colours Azorubine (INS 122), Ponceau 4R (INS 124), Erythrosine (INS 127), and Indigotine (INS 132). This information was obtained from one of the largest supermarket chains in Brazil. It was chosen because it was the only supermarket chain that, at the time of data collection, sold products in the five regions of Brazil and with all information needed on the internet (ingredient list). The data were then correlated with the results from the 2008/2009 and 2017/2018 Household Budget Surveys (HBS) (Instituto Brasileiro de Geografia e Estatística, 2010, 2020) to estimate the Theoretical Maximum Daily Intake (TMDI) of each artificial food colour, using the maximum concentration allowed by Brazilian legislation (Agência Nacional de Vigilância Sanitária, 2021).

2.1 Presence of Azorubine, Erythrosine, Indigotine, and Ponceau 4R in food products

An initial screening of the labels was carried out on the website of one of the largest supermarket chains. The data were gathered in the period between July 2016 and June 2017. Some of the products which were not considered included: products whose labels did not contain a list of ingredients on the website; fresh foods; and products that are marketed in bulk, such as fresh meat, fresh fish, and fruit, which cannot contain any food colouring. When the same product was sold in packages of different sizes, it was counted only once. This resulted in a total of 1510 labels that were sorted into the different food categories as defined in the HBS. The manual published by the Codex Alimentarius Committee in 2014 suggests that all food products which contain food additives permitted by legislation (Joint FAO/WHO Expert Committee on Food Additives, 2014) should be considered for the calculation of TMDI. In this study, only the categories with food products that contained the artificial food colours mentioned above were considered in the calculation, thus yielding more precise values. The survey of products was carried out to select the food categories to be used in the intake estimate.

2.2 Food consumption based on the HBS

The Brazilian Institute of Geography and Statistics (IBGE) conducts the HBS periodically in Brazil. The HBS obtains general information on the households, families, and individuals, consumption habits, expenses, and income of the families surveyed (Instituto Brasileiro de Geografia e Estatística, 2010, 2020). Consumption values of foods were extracted from the HBS taken in 2008/2009 and 2017/2018 and published in 2010 and 2020, respectively (Instituto Brasileiro de Geografia e Estatística, 2010, 2020). In these surveys, a representative sample of households in the country is visited, and residents over 10 years of age report their food consumption at home and out on two non-consecutive days. Data were collected in 2008/2009 through food records and, on this occasion, the age, gender, and body mass of each individual were also recorded (Instituto Brasileiro de Geografia e Estatística, 2010). Data collection in 2017/2018 was performed with a 24-hour recall, and the body mass of the individuals was not collected (Instituto Brasileiro de Geografia e Estatística, 2020). The HBS classifies food into categories (around 100), which have undergone minor modifications from one survey to another. For each of these categories, it was checked whether there was any product containing any of the dyes Azorubine, Erythrosine, Indigotine, and Ponceau 4R in its formulation.

WHO and FAO guidelines recommend the use of methods of screening and consumption to overestimate dietary exposure, as this will prevent situations that may indicate that there are no safety concerns with the intake of the additive being studied (Joint FAO/WHO Expert Committee on Food Additives, 2014). To comply with these guidelines, in this study, it was considered that, whenever one category contained a product with Azorubine and/or Erythrosine and/or Indigotine and/or Ponceau 4R, all food products within that category would contain the food colour(s). In addition, all food products were considered to contain the highest concentration permitted by legislation.

2.3 Estimation of TMDI

There are different approaches to estimating the probable daily dietary exposure to food additives. The WHO and FAO recommend TMDI as a simple method for estimating exposure. The TMDI is calculated by multiplying the average daily intake of food by the maximum amount of the additive permitted by legal regulation. The resulting value, after adding up the quantity of additive in all food products in the individual's diet, is equal to the total dietary exposure and thus can be compared to the determined ADI (Joint FAO/WHO Expert Committee on Food Additives, 2014).

Data on the mean food consumption per capita from the HBS (g of food per day) were used to calculate the mean intake per capita of Azorubine, Erythrosine, Indigotine, and Ponceau 4R (mg of food colour per day), considering the maximum values for each food colour permitted by the Brazilian legislation (Agência Nacional de Vigilância Sanitária, 2021). The mean TMDI per capita was obtained for each of the food colours by adding up their quantities in all food products. In this study we also present the TMDI considering the prevalence of food consumption (PFC), recalculating the TMDI by redistributing the total amount consumed only among interviewees who reported consuming the food products under investigation (eaters only).

However, the FAO/WHO guidelines consider that consumers who eat food products from one category do not necessarily eat products from other categories, so the guidelines suggest an approach that accounts for the two categories most consumed on average (Joint FAO/WHO Expert Committee on Food Additives, 2014; World Health Organization, 2011). This work also presents the values obtained using this approach in the results section.

3 Results and discussion

3.1 ADI of Azorubine, Erythrosine, Indigotine, and Ponceau 4R

Table 1 shows the ADI of Azorubine, Erythrosine, Indigotine, and Ponceau 4R for male and female adolescents, adults, and seniors. It is worth noting that the HBS only studies the food consumption of Brazilians older than 10 years; therefore, there are no data for children younger than that age. Still, the HBS considers that adolescents are people aged between 10 and 18 years old, adults between 19 and 54, and seniors over 55 years old. It is worth mentioning that in the 2008/2009 HBS, the body mass (weight) of the individuals was collected, which was not done in the 2017/2018 HBS. Thus, the ADI calculations in this study are based on the average weights presented in the oldest research. The ADI for each group was calculated by multiplying the weighted mean for the population in each group (provided by the 2008/2009 HBS) by the ADI (in mg/kg bw) of each food colour. The ADI established by JECFA (World Health Organization, 2019) is 0.1 mg/kg bw for Erythrosine, 4 mg/kg bw for Azorubine and Ponceau 4R, and 5 mg/kg bw for Indigotine. Thus, the values for Erythrosine are much lower because the ADI of this food colour is about 45 times smaller than that of the other food colours.

3.2 Presence of Azorubine, Erythrosine, Indigotine, and Ponceau 4R in food products

The 1510 labels studied were sorted into approximately 100 food categories present in the HBS. Two of these categories comprised products whose formulation contained Azorubine; one had Erythrosine, three had Indigotine, and three had Ponceau 4R. Table 2 lists these categories, the number of products within the category available at the supermarket chain website, and the number and percentage of products containing the food colours in the ingredient list.

Considering the total number of products assessed in this study (1510), there is a very low incidence of the presence of these food colours: six products (0.4%) for Indigotine and Ponceau 4R, three (0.2%) for Azorubine, and only one product (0.07%) for Erythrosine. The category 'Other sweets', which encompasses products such as sweets, jelly, confectionery, and chewing gums, contained three of the four artificial food colours in this study. In the 'Yoghurt' category, yoghurt with red fruit pulp is classified in both the Indigotine and Ponceau 4R product groups. In the 'Other dairy' category, which comprises 25 products such as heavy cream, fermented milk, whipped cream, and dairy beverages, there were three dairy beverages containing Ponceau 4R, representing 12% occurrence. It is, therefore, the food colour with the highest percentage within a category.

In the 2017/2018 HBS, the category 'Diet/light sweets' showed a consumption frequency lower than 0.5% and did not appear in the results. Due to their characteristics, the products in this study that were in the category 'Diet/light sweets' in the 2008/2009 HBS were transferred to the 'Other sweets' category in the 2017/2018 HBS. Because of this, the number of products in the category 'Other sweets' increased from 58 in the 2008/2009 HBS to 83 in the 2017/2018 HBS (Table 2).

Ahmed et al. (2021) studied the food types consumed by 6–17-year-old school-going children in Saudi Arabia and found that the most commonly used artificial food colour additives were Brilliant Blue (E133) (54.1%) and Tartrazine (E102) (42.3%), followed by Sunset Yellow (E110) (39.1%), Allura Red (E129) (33.9%), Carmoisine (17.5%), and Fast Green FCF (16.2%).

3.3 Estimated intake of Azorubine, Erythrosine, Indigotine, and Ponceau 4R

The value of mean food consumption was used to obtain results for the mean intake of Azorubine, Erythrosine, Indigotine, and Ponceau 4R, i.e., the total amount of food consumed divided equally among all the interviewees (consumption per capita). In addition to the consumption per capita, the HBS also provides data on the percentage of the population that claimed to have

Table 1. ADI of Azorubine, Erythrosine, Indigotine, and Ponceau by gender and age group considering mean body weight obtained from 2008/2009 HBS.

Gender	Age range (years)	Average weight (kg)	ADI of Azorubine (mg/day)	ADI of Erythrosine (mg/day)	ADI of Indigotine (mg/day)	ADI of Ponceau 4R (mg/day)
Male	Adolescents (10–18)	51	204	5.1	255	204
	Adults (19–54)	72	288	7.2	360	288
	Seniors (over 55)	70	280	7	350	280
Female	Adolescents (10–18)	48	192	4.8	240	192
	Adults (19–54)	61	244	6.1	305	244
	Seniors (over 55)	63	252	6.3	315	252

Source: Adapted from IBGE (2010).

Table 2. Categories, number of products in the category, number of products containing Azorubine, Erythrosine, Indigotine, and Ponceau 4R, and percentage of products containing these food colours.

Category	Number of products in category	Number/ percentage of products containing Azorubine	Number/ percentage of products containing Erythrosine	Number/ percentage of products containing Indigotine	Number/ percentage of products containing Ponceau 4R	Number of products in category	Number/ percentage of products containing Azorubine	Number/ percentage of products containing Erythrosine	Number/ percentage of products containing Indigotine	Number/ percentage of products containing Ponceau 4R
	HBS 2008/2009					HBS 2017/2018				
Yoghurt	43	1/2%	0/0%	1/2%	2/5%	43	1/2%	0/0%	1/2%	2/5%
Other dairy products	25	0/0%	0/0%	0/0%	3/12%	25	0/0%	0/0%	0/0%	3/12%
Chocolate	75	0/0%	0/0%	2/3%	0/0%	75	0/0%	0/0%	2/3%	0/0%
Ice cream/ ice pop	17	0/0%	0/0%	0/0%	1/6%	17	0/0%	0/0%	0/0%	1/6%
Other sweets	58	2/3%	1/2%	3/5%	0/0%	83	2/2%	1/1%	3/4%	0/0%

consumed a certain food product. With this percentage, it is possible to recalculate the TMDI by redistributing the total amount consumed only among interviewees who reported consuming the food products under investigation (eaters only). Thus, it is more suitable to consider this percentage, i.e., the prevalence of consumption, to assess whether a portion of the population may be exceeding the ADI. In this study, results will be presented for both 'mean' intake (TMDI) and intake 'weighted by the prevalence of consumption' (TMDI PFC).

Intake by gender

The results for mean TMDI and TMDI PFC of Azorubine, Erythrosine, Indigotine, and Ponceau 4R in the 2008/2009 and 2017/2018 HBS divided by males and females are shown in Table 3. The range of ADI values for each food colour (Table 1) is presented to facilitate comparison.

It should be noted that TMDI totals represent the sum of the values for food products within the categories. This study assumes that all food colours were used at their maximum concentrations permitted by legislation.

The results for the FAO/WHO approach are also shown; using this framework, the number of categories is equal to or less than two for Azorubine and Erythrosine, so the total values are identical to those for the FAO/WHO approach. The average values for Indigotine in the categories 'Chocolate' and 'Other sweets' were replaced by the values for eaters only (highlighted in bold in the table). For Ponceau 4R, the same replacement was made in the categories 'Yoghurts' and 'Ice cream/ice pop' (in bold).

Mean TMDI was below ADI for all food colours in the distribution by gender. Even for Erythrosine, which has the lowest ADI among the four artificial colours analysed, the highest mean TMDI (0.4 mg/day, in 2008/2009) corresponds to only 8% of the lowest ADI (4.8 mg/day, for female adolescents). For the other food colours, TMDI corresponds to 1.8% of the lowest ADI (for female adolescents) for Indigotine and 0.5% for Azorubine and Ponceau 4R (all for HBS 2008/2009). Comparing the data from 2008/2009 and 2017/2018, a decrease in the average TMDI for all dyes is noted. Females show higher consumption of 'Yoghurts', 'Chocolate', and 'Other dairy products' (g per day) than males. For this reason, mean TMDI is the same or slightly higher for women for all food colours evaluated. Ansari et al. (2012) analysed the eating behaviour of a total of 2402 first-year undergraduates from universities in Germany, Denmark, Poland, and Bulgaria and showed that women consumed significantly more sweets, cakes, fruits, salads, and vegetables, and less fast food, meat, and fish than men.

When the TMDI is weighted by the prevalence of consumption for Azorubine, Indigotine, and Ponceau 4R, the levels are also below the ADI, but significantly higher. For each food colour, the values closest to the ADI represent 7.9% of the ADI for Azorubine (for female adolescents and HBS 2008/2009), 15.8% of the ADI for Ponceau 4R (for male adolescents and HBS 2017/2018), 24.5% of the ADI for Indigotine (for female adolescents and HBS 2008/2009), and 76.5% of the ADI for Erythrosine (for male adolescents and HBS 2017/2018). It should be noted that, in this study, a low incidence of Erythrosine was observed on the labels analysed, so the values used for the calculations come from a single source (a strawberry-flavoured ice cream topping sauce).

Intake by region in Brazil: North, Northeast, Midwest, Southeast, and South

The results for TMDI of Azorubine, Erythrosine, Indigotine, and Ponceau 4R in different regions of Brazil are shown in Figure 1.

The mean TMDI of all food colours is below the ADI in all regions of the country. In most cases, the values are higher in the South Region and lower in the North Region. When comparing with the ADI, the maximum value is observed for Erythrosine, reaching 10.4% of the ADI for female teenagers from the Northeast Region in 2008/2009. There were decreases in the average consumption of all dyes and in all regions over the period of about 10 years between the two HBS used in this study. In general, considering all regions, the greatest reductions in the period studied are observed for the intake of Indigotine and Erythrosine. In particular, the mean TMDI for Indigotine dropped about 84% from 2008/2009 to 2017/2018 in the North Region. This reduction is due to a reduction in consumption of all foods in the categories containing Indigotine (yoghurts, chocolates, and other sweets).

Table 3. Estimated TMDI per capita and weighted by Prevalence of Food Consumption (PFC) of Azorubine, Erythrosine, Indigotine, and Ponceau 4R (mg/day) for males and females.

Food products	MALE						FEMALE					
	HBS 2008/2009			HBS 2017/2018			HBS 2008/2009			HBS 2017/2018		
	Mean food consumption per capita (g/day)	Mean TMDI[1] (mg/day)	Weighted TMDI PFC[2] (mg/day)	Mean food consumption per capita (g/day)	Mean TMDI (mg/day)	Weighted TMDI PFC (mg/day)	Mean food consumption per capita (g/day)	Mean TMDI (mg/day)	Weighted TMDI PFC (mg/day)	Mean food consumption per capita (g/day)	Mean TMDI (mg/day)	Weighted TMDI PFC (mg/day)
AZORUBINE (ADI ranging between 192 and 288 according to Table 1**)**												
Yoghurt	8.5	0.4	12.0	6.5	0.3	12.0	11.0	0.5	12.1	9.7	0.5	11.0
Other sweets	7.3	0.4	3.6	2.2	0.1	3.9	8.1	0.4	3.1	2.0	0.1	2.8
TOTAL	*15.9*	*0.8*	*15.6*	*8.7*	*0.4*	*15.9*	*19.1*	*1.0*	*15.2*	*11.7*	*0.6*	*13.8*
FAO/WHO approach[3]		*15.6*			*15.9*			*15.2*			*13.8*	
ERYTHROSINE (ADI ranging between 4.8 and 7.2 according to Table 1**)**												
Other sweets	7.3	0.4	3.6	2.2	0.1	3.9	8.1	0.4	3.1	2.0	0.1	2.8
TOTAL	*7.3*	*0.4*	*3.6*	*2.2*	*0.1*	*3.9*	*8.1*	*0.4*	*3.1*	*2.0*	*0.1*	*2.8*
FAO/WHO approach		*3.6*			*3.9*			*3.1*			*2.8*	
INDIGOTINE (ADI ranging between 240 and 360 according to Table 1**)**												
Yoghurt	8.5	0.4	12.0	6.5	0.3	12.0	11.0	0.5	12.1	9.7	0.5	11.0
Chocolate	2.7	0.8	**24.3**	1.1	0.3	**14.3**	4.2	1.3	**28.3**	1.7	0.5	**17.0**
Other sweets	7.3	2.2	**21.8**	2.2	0.7	**23.6**	8.1	2.4	**18.3**	2.0	0.6	**16.7**
TOTAL	*18.6*	*3.4*	*58.1*	*9.8*	*1.3*	*49.9*	*23.2*	*4.2*	*58.7*	*13.4*	*1.6*	*44.7*
FAO/WHO approach		*46.5*			*38.2*			*47.2*			*34.2*	
PONCEAU 4R (ADI ranging between 192 and 288 according to Table 1**)**												
Yoghurt	8.5	0.4	**12.0**	6.5	0.3	**12.0**	11.0	0.5	**12.1**	9.7	0.5	**11.0**
Other dairy products	0.7	0.0	3.9	0.8	0.0	4.4	1.2	0.1	4.1	1.4	0.1	4.7
Ice cream/ice pop	5.0	0.5	**14.4**	3.0	0.3	**15.8**	4.2	0.4	**11.9**	2.8	0.3	**13.3**
TOTAL	*14.2*	*1.0*	*30.3*	*10.3*	*0.7*	*32.2*	*16.4*	*1.0*	*28.1*	*13.9*	*0.8*	*29.0*
FAO/WHO approach		*26.4*			*27.9*			*24.1*			*24.4*	

[1]TMDI: Theoretical Maximum Daily Intake. [2]PFC: Prevalence of Food Consumption (i.e., considering eaters only). [3]FAO/WHO approach: the two categories with the highest consumption levels are considered on average, i.e., the mean total levels replacing the levels of the two categories with the highest mean consumption by the levels weighted by the corresponding prevalence of consumption.

When considering TMDI PFC, the lowest value with respect to ADI is observed for Azorubine for male adults from the NE Region in 2017/2018 (4.7% of the ADI) and the highest value for Erythrosine for female adolescents from the MW region in 2008/2009 (79% of the ADI). For HBS 2017/2018, the highest value is also for Erythrosine, but for female adolescents from the Southeast and South Regions (73% of the ADI). The levels calculated using the FAO/WHO approach also do not exceed the ADI in any region of the country for both HBS.

In a study conducted in the United States, Bastaki et al. (2017) concluded that the exposure to food colour additives in the United States for average and high-intake consumers is well below the ADI. In a study conducted in Iran, Zahedi et al. (2020) concluded that the population is being exposed to slight potential health risks and suggested that more attention should be directed toward the ingestion of synthetic food dyes.

Intake by age groups: adolescents, adults, and seniors

Table 4 shows the results of mean TMDI and TMDI PFC of Azorubine, Erythrosine, Indigotine, and Ponceau 4R for the Brazilian population by age group.

It is observed that the mean TMDI is also below the ADI for the studied food colours. For Azorubine, Indigotine, and Ponceau 4R, all mean TMDI values represent, at most, 2.5% of the ADI in 2008/2009 and 0.8% for 2017/2018 (for Indigotine). For Erythrosine, the highest mean TMDI in 2008/2009 was observed in female adolescents (0.6 mg/day), representing 12.5% of the ADI. However, the average consumption decreased to 0.1 mg/day in 2017/2018, representing 2.1% of the ADI for female adolescents. It is interesting to note that the mean TMDI values increase as group age decreases for all food colours for the two HBS (except for Erythrosine for 2017/2018 where it was 0.1 mg/day for the three age groups). Feitosa et al. (2017), in their study on the intake of the Sunset Yellow food dye by the Brazilian population using the 2008/2009 HBS, also observed that the younger the age group, the higher the intake.

For the TMDI weighted by the prevalence of consumption, the results come close to the ADI. The intake of Indigotine by adolescents (60.7 mg/day) reached 25% of the ADI in 2008/2009 and dropped to 19% of the ADI in 2017/2018 (45.7 mg/day). The intake of Erythrosine by seniors reached 63% of the ADI in 2008/2009 (4.0 mg/day) and 67% in 2017/2018 (4.2 mg/day). However, as previously mentioned, the intake of Erythrosine is

NO – North

HBS 2017/2018	Azor.[4]	Eritr.[5]	Indig.[6]	P.4R[7]
Mean TMDI (mg/day)[1]	0.3	0.0	0.6	0.5
TMDI WPFC (mg/day)[2]	16.6	2.7	53.5	32.5
FAO/WHO (mg/day)[3]	16.6	2.7	52.6	30.0
HBS 2008/2009				
Mean TMDI (mg/day)	0.7	0.4	3.8	0.9
TMDI WPFC (mg/day)	17.3	3.4	66.2	29.5
FAO/WHO (mg/day)	17.3	3.4	52.6	26.5

NE – Northeast

HBS 2017/2018	Azor.	Eritr.	Indig.	P.4R
Mean TMDI (mg/day)	0.4	0.1	1.0	0.7
TMDI WPFC (mg/day)	13.4	2.6	45.3	31.9
FAO/WHO (mg/day)	13.4	2.6	34.8	24.5
HBS 2008/2009				
Mean TMDI (mg/day)	0.9	0.5	3.9	0.9
TMDI WPFC (mg/day)	16.5	3.7	68.9	33.2
FAO/WHO (mg/day)	16.5	3.7	56.5	25.7

MW – Midwest

HBS 2017/2018	Azor.	Eritr.	Indig.	P.4R
Mean TMDI (mg/day)	0.4	0.1	1.3	0.6
TMDI WPFC (mg/day)	13.7	2.5	40.6	32.1
FAO/WHO (mg/day)	13.7	2.5	29.7	24.0
HBS 2008/2009				
Mean TMDI (mg/day)	0.8	0.3	3.6	1.0
TMDI WPFC (mg/day)	14.9	3.8	75.0	32.0
FAO/WHO (mg/day)	14.9	3.8	64.4	23.2

SE – Southeast

HBS 2017/2018	Azor.	Eritr.	Indig.	P.4R
Mean TMDI (mg/day)	0.6	0.1	1.7	0.8
TMDI WPFC (mg/day)	14.6	3.5	47.0	31.4
FAO/WHO (mg/day)	14.6	3.5	36.3	25.2
HBS 2008/2009				
Mean TMDI (mg/day)	0.9	0.3	3.6	1.1
TMDI WPFC (mg/day)	14.7	3.0	52.4	31.6
FAO/WHO (mg/day)	14.7	3.0	41.2	25.7

SO – South

HBS 2017/2018	Azor.	Eritr.	Indig.	P.4R
Mean TMDI (mg/day)	0.8	0.2	1.1	1.1
TMDI WPFC (mg/day)	15.4	3.5	50.6	31.6
FAO/WHO (mg/day)	15.4	3.5	39.3	29.8
HBS 2008/2009				
Mean TMDI (mg/day)	1.0	0.4	4.6	1.1
TMDI WPFC (mg/day)	15.3	3.1	57.5	26.7
FAO/WHO (mg/day)	15.3	3.1	45.9	24.0

Figure 1. Map of Brazil with mean TMDI and TMDI weighted by the Prevalence of Food Consumption (WPFC) of food colours Azorubine, Erythrosine, Indigotine, and Ponceau 4R (mg/day) in the North (NO), Northeast (NE), South (SO), Southeast (SE), and Midwest (MW) regions of Brazil. [1]TMDI: Theoretical Maximum Daily Intake. [2]WPFC: Based on the prevalence of food consumption (i.e., considering eaters only). [3]FAO/WHO approach: the two categories with the highest consumption levels are considered on average, i.e., the mean total levels replacing the levels of the two categories with the highest mean consumption by the levels weighted by the corresponding prevalence of consumption. [4]Azor. = Azorubine (ADI ranging between 192 and 288 mg/day according to Table 1). [5]Eryth. = Erythrosine (ADI ranging between 4.8 and 7.2 mg/day according to Table 1). [6]Indig. = Indigotine (ADI ranging between 240 and 360 mg/day according to Table 1). [7]P.4R = Ponceau 4R (ADI ranging between 192 and 288 as shown in Table 1).

based on a single product that had the colour in its ingredient list. The weighted TMDI for Erythrosine is notably higher for seniors, which seems an unexpected result. However, given that the mean consumption and the prevalence of consumption are low in this category, individual levels are high, since the amount of food is redistributed only among people who stated they had consumed the product.

Using the FAO/WHO approach, the TMDI values are always equal to or lower than those mentioned above; thus, they do not exceed the ADI for any of the age groups in this study.

Comparing consumption between the years 2008/2009 and 2017/2018, there was a decrease in average intake (TMDI) for all food colours, more significant in the adolescent group. There was a decrease in the consumption of foods that contribute to the intake of dyes. Adolescents decreased yoghurt consumption from 14 g to 10 g/day; chocolate from 6 g to 2 g/day; and 'Other sweets' (gelatines, candy, chewing gum, etc.) from approximately 11 to 3 g/day per capita (data not shown in Table 4). Some changes in consumption were observed between the two HBS. There was a decrease in the consumption of soft drinks (which would imply healthier habits), but at the same time, a reduction in the consumption of the traditional Brazilian diet (rice and beans) and an increase in the consumption of preparations (including sandwiches and ready-to-eat foods). There was also a reduction in the consumption of fruits and vegetables, remaining well below the recommended levels (Instituto Brasileiro de Geografia e Estatística, 2020). However, it should be taken into account that there has been a change in the procedure for collecting food consumption data in the HBS, as mentioned

Table 4. Estimated TMDI per capita and TMDI weighted by Prevalence of Food Consumption (PFC) of Azorubine, Erythrosine, Indigotine, and Ponceau 4R (mg/day) for adolescent, adult, and senior age groups.

Food products	ADOLESCENT				ADULT				SENIOR			
	HBS 2008/2009		HBS 2017/2018		HBS 2008/2009		HBS 2017/2018		HBS 2008/2009		HBS 2017/2018	
	Mean TMDI[1] (mg/day)	Weighted TMDI PFC[2] (mg/day)	Mean TMDI (mg/day)	Weighted TMDI PFC (mg/day)	Mean TMDI (mg/day)	Weighted TMDI PFC (mg/day)	Mean TMDI (mg/day)	Weighted TMDI PFC (mg/day)	Mean TMDI (mg/day)	Weighted TMDI PFC (mg/day)	Mean TMDI (mg/day)	Weighted TMDI PFC (mg/day)
AZORUBINE (ADI ranging between 192 and 288 according to Table 1)												
Yoghurt	0.7	12.8	0.5	12.1	0.5	11.9	0.4	11.3	0.3	10.9	0.3	10.8
Other sweets	0.6	2.9	0.1	2.5	0.4	3.4	0.1	3.4	0.3	4.0	0.1	4.2
TOTAL	*1.2*	*15.7*	*0.6*	*14.6*	*0.8*	*15.4*	*0.5*	*14.7*	*0.7*	*14.9*	*0.4*	*14.9*
FAO/WHO approach[3]		*15.7*		*14.6*		*15.4*		*14.7*		*14.9*		*14.9*
ERYTHROSINE (ADI ranging between 4.8 and 7.2 according to Table 1)												
Other sweets	0.6	2.9	0.1	2.5	0.4	3.4	0.1	3.4	0.3	4.0	0.1	4.2
TOTAL	*0.6*	*2.9*	*0.1*	*2.5*	*0.4*	*3.4*	*0.1*	*3.4*	*0.3*	*4.0*	*0.1*	*4.2*
FAO/WHO approach		*2.9*		*2.5*		*3.4*		*3.4*		*4.0*		*4.2*
INDIGOTINE (ADI ranging between 240 and 360 according to Table 1)												
Yoghurt	0.7	12.8	0.5	12.1	0.5	11.9	0.4	11.3	0.3	10.9	0.3	10.8
Chocolate	1.9	**30.6**	0.6	**18.5**	0.9	**25.7**	0.5	**15.5**	0.4	**18.5**	0.2	**13.6**
Other sweets	3.4	**17.3**	0.8	**15.0**	2.1	**20.5**	0.6	**20.7**	1.9	**24.1**	0.6	**25.0**
TOTAL	*5.9*	*60.7*	*1.9*	*45.7*	*3.5*	*58.2*	*1.4*	*47.5*	*2.6*	*53.5*	*1.1*	*49.4*
FAO/WHO approach		*48.59*		*34.04*		*46.70*		*36.60*		*42.95*		*38.98*
PONCEAU 4R (ADI ranging between 192 and 288 according to Table 1)												
Yoghurt	0.7	**12.8**	0.5	**12.1**	0.5	**11.9**	0.4	**11.3**	0.3	**10.9**	0.3	**10.8**
Other dairy products	0.1	5.6	0.1	7.1	0.0	3.2	0.0	4.5	0.1	5.2	0.1	2.6
Ice cream/ice pop	0.9	**13.2**	0.5	**14.2**	0.4	**13.2**	0.3	**14.4**	0.2	**11.1**	0.2	**13.8**
TOTAL	*1.7*	*31.6*	*1.2*	*33.5*	*0.9*	*28.4*	*0.7*	*30.2*	*0.6*	*27.2*	*0.6*	*27.3*
FAO/WHO approach		*26.1*		*26.5*		*25.2*		*25.8*		*22.0*		*24.7*

[1]TMDI: Theoretical Maximum Daily Intake. [2]PFC: Prevalence of Food Consumption (i.e., considering eaters only). [3]FAO/WHO approach: the two categories with the highest consumption levels are considered on average. i.e., the mean total levels replacing the levels of the two categories with the highest mean consumption by the levels weighted by the corresponding prevalence of consumption.

above. In 2008/2009, it was assessed through food records, and in 2017/2018 through 24-hour food recalls. These differences in procedures may influence the results for ingestion.

In this work, the estimated intake of four artificial dyes by the Brazilian population was evaluated. It is important to take into account the limitations and uncertainties of the study. Sources and types of uncertainty affecting areas of dietary exposure assessment were reviewed by the EFSA panel (European Food Safety Authority, 2006). In this case, we have uncertainties related to: 1) the presence of food colours in foods, 2) their concentration in foods, 3) the estimate of food consumption, and 4) the average weight of different population groups (to compare with the ADI). This work includes research performed with food products sold by one of the largest supermarket chains in Brazil to check which ones contained the food colours being studied. It is a more precise methodology than considering all foods to which the food colour is allowed – since it is not used in most cases, however, permitted. The fact of having used only one supermarket chain can bring some uncertainty that is minimized when considering the calculation of intake of the entire category where at least one product contained the food colour(s). As the maximum concentration allowed by legislation was used, there is no uncertainty about sampling measurement and sampling. However, food colourings may have been used in higher concentrations than allowed; there is therefore an uncertain relationship between maximum permitted levels and levels in the food/beverage available on the market (European Food Safety Authority, 2006). There are very few works quantifying these food colours in Brazil. However, for Erythrosine and Ponceau 4R, Prado & Godoy (2004) found concentrations above those allowed by legislation in foods (such as chewing gum and breakfast cereals) sold in the State of São Paulo. The database chosen to evaluate food consumption by the population was the HBS, performed by the Brazilian Institute of Geography and Statistics (IBGE), due to it being the only consumer research that encompasses the whole national territory. The HBS 2008/2009 and 2017/2018 were the two latest surveys conducted by IBGE on family budgets with available results. In the present study, a few aspects regarding time that pose some limitations must be considered: the HBS used in calculations were carried out in two distinct periods (2008/2009 and 2017/2018) and the data on the presence of food colours were gathered between July 2016 and June 2017. Regarding body weight, it should be taken into account that the data used in the study were obtained from the HBS 2008/2009, as body weight was not collected in 2017/2018. Finally, it is worth highlighting the possibility of the existence of 'high consumers' who may be exceeding the ADI for some of the studied food colours.

4 Conclusion

The results of this study show that the average consumption of the food colours Azorubine, Erythrosine, Indigotine, and Ponceau 4R by the Brazilian population does not exceed the ADI in any of the studied distributions: gender (male and female), regions of Brazil (North, Northeast, Midwest, Southeast, and South), and age groups (adolescents, adults, and seniors). Regarding the ADI, maximum percentages appeared for the colour Erythrosine, peaking at 12.5% of the ADI in 2008/2009. The mean TMDI increases as the group age decreases. When analysing TMDI weighted by PFC, the results do not exceed the ADI either for any of the populations studied, although the levels are close. For Erythrosine, values reached 79% of the ADI in 2008/2009 and 73% of the ADI in 2017/2018. Therefore, intake of the artificial food colours Azorubine, Erythrosine, Indigotine, and Ponceau 4R is within the limits of the ADI. Except for the category of special populations with peculiar eating habits, the Brazilian population (older than 10 years) does not appear to be facing any health risks from the excessive consumption of these artificial food colours.

Conflicts of interest

The authors declared that they have no conflict of interest.

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