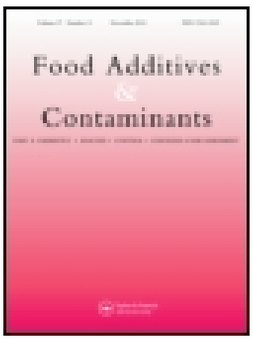

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Estimate of the theoretical maximum daily intake of Sunset Yellow FCF by the Brazilian population

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ABSTRACT

This study estimated the theoretical maximum daily intake (TMDI) of Sunset Yellow (SY) synthetic food dye by the Brazilian population through food consumption data from the Household Budget Survey (HBS) of the Brazilian Institute of Geography and Statistics (IBGE, 2008/09). The study covered the population in urban and rural areas in the five regions of the country, and from different age groups, in order to verify if it were possible to exceed the acceptable daily intake (ADI) of SY, which is 4.0 mg kg^{-1} body weight. This was assessed by cross-checking food products containing this dye from the largest supermarket chains in Brazil with data from the HBS-IBGE 2008/09. These data showed that the average consumption of SY per capita did not exceed the ADI in any of the aforementioned population groups. However, when considering food consumption in urban and rural areas (279 and 260 mg of SY day^{-1}), in the five regions of the country (260–338 mg of SY day^{-1}), and for adolescents (332 mg SY day^{-1}), it is noted that part of the population could be exceeding the recommended ADI, which may pose health risks. Although it is unlikely that individuals will exceed the SY ADI, this may occur in some cases, especially for younger people.

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Sunset Yellow FCF; acceptable daily intake; dye; additive

Introduction

It is estimated that in the year 2020, non-communicable chronic diseases will account for 75% of deaths worldwide. The human diet has been on the international research agenda as one of the main determining causes of these diseases (Machado et al. 2012).

Due to changes in the eating habits of Brazilians and the replacement of fresh food with processed foods, the diet of the population has become increasingly poorer. This habit has resulted in changes in global patterns of disease in the second half of the 20th century, contributing to the onset of non-communicable chronic diseases, mainly of the circulatory system, diabetes and cancer (Pinheiro & Abrantes 2012).

In addition to diet changes throughout the years, the technology used by the food industry has raised questions regarding the safety of food additives, primarily when it comes to artificial food colouring (Moutinho et al. 2007). The use of dyes in food has always been a controversial subject since the main reason for its use is to make the product aesthetically more attractive in many cases. In addition, studies have shown the occurrence of short- and long-term adverse reactions due to the consumption of food products containing these additives (Beseler 1999; Ortolani et al. 1999). Azo-dyes can provoke urticaria, aggravation of atopic eczema, pupura, vaculitis, asthma and possibly severe anaphylactic reactions (Ortolani et al. 1999).

With regard to protecting the health of consumers, principles for risk analysis have been applied in the framework of the Codex Alimentarius (FAO/WHO Codex Alimentarius Commission 2014). A reliable evaluation of food additives at a global level is based on the control of the acceptable daily intake (ADI) developed by JECFA. The ADI, expressed in mg kg^{-1} of bw day^{-1}, is defined as 'the maximum amount of a substance ingested by a person on a daily basis over their life span, without causing any harmful effects', according to the toxicological

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knowledge available (WHO, 1987). This value incorporates a 100-fold safety factor. JECFA evaluates the estimated dietary exposures and, in the risk characterisation step, compares the probable exposure to the food additive with the relevant ADI (FAO/WHO Codex Alimentarius Commission, 2014).

For the artificial dye Sunset Yellow FCF (INS 110) (SY), an azo-dye, the ADI was established as 2.5 mg kg^{-1} bw day^{-1} in 1982 (JECFA, 1982). The EFSA ANS Panel (The Panel on Food Additives and Nutrient Sources of the European Food Safety Authority) re-evaluated the safety of SY as a food additive in 2009 (EFSA ANS Panel, 2009) and decided to reduce the ADI to 1 mg kg^{-1} bw day^{-1} temporary for 2 years. This decision was based on the effects observed in the testis of rats in a study where SY of unknown purity bought in a local market in India was used as the testing material (Mathur et al. 2005; EFSA ANS Panel, 2014). In its latest evaluation, JECFA concluded that the ADI for SY should be increased from 2.5 to 4 mg kg^{-1} bw day^{-1} (JECFA, 2011).

In Brazil, the National Health Surveillance Agency (ANVISA) is responsible for the regulation of the use of food additives such as dyes, and allows the use of 14 synthetic dyes. Among these, SY (INS 110) can be used in many different food products, including yoghurts, biscuits, cakes, soft drinks and other beverages, ice creams, gelatins and other desserts, candies, soups, ready-to-eat culinary preparations etc. (ANVISA, 2011).

The use of food dyes has raised a number of questions such as whether the amounts used by the industry are suitable, so that the consumption of certain food products does not exceed ADI parameters. In Brazil there is no legal obligation to declare the amount of food colouring present in a given food product, but only a general list of the additives used (Schumann et al. 2008).

In order to evaluate the possible effects that food additives can cause to health, it is important to have data on the exposure to these substances. The first step to estimate the consumption of additives and their potential risks is to obtain appropriate estimates for the presence and the amount of a particular substance both in the food product and in the general diet (Kroes et al. 2002).

There are different methods for estimating probable dietary exposure to a food additive. Three elements must be taken into account: (1) the concentration of the food additive in food; (2) the amount of food consumed; and (3) the average body weight of the population. The FAO/WHO Codex Alimentarius Commission proposed two approaches for a simple evaluation of dietary exposure to food additives: theoretical maximum daily intake (TDMI) and estimated daily intake (EDI) (FAO/WHO Codex Alimentarius Commission, 2014).

The TDMI can be calculated by multiplying the average per capita daily food consumption for each food by the maximum use level of the food additive established by national regulations and summing the resulting exposure values to give total dietary exposure. This value only approximates the dietary exposure since it does not take into consideration the food consumption by special populations groups (FAO/WHO Codex Alimentarius Commission 2014).

The Brazilian Institute of Geography and Statistics (IBGE) periodically conducts data collection on food purchases via the Household Budget Survey (HBS). In the latest edition of the survey HBS 2008–09, the study was based on 55,970 households, which included the individual consumption of food by consumers aged 10 years old or above, inside and outside the household (IBGE 2010).

This study aimed to estimate from the Brazilian legislation and the food consumption data of HBS-IBGE/2008–09, the maximum value for the TMDI of SY by the Brazilian population in order to establish if it is possible to exceed the ADI.

Materials and methods

This study was conducted in three stages. The first stage was the development of a database with the processed food products which had the artificial dye SY on their label and had been sold by one of the largest supermarkets in Brazil. The assessment of food intake by the Brazilian population was subsequently done through data obtained from the HBS 2008/09 (IBGE 2010). The third stage was estimation of the TMDI of SY by the Brazilian population carried out via the correlation of the data obtained.

Synthetic dye Sunset Yellow in food

Using data available on the website of one of the largest supermarket chains in Brazil, it was possible

Table 1. Products with Sunset Yellow FCF (SY) classified according to the categories of the Household Budget Survey (HBS) 2008–09.

Category/subcategory category	Maximum permitted level (g/100 g or g/100 ml)[a]	Number of available products	Number of products with SY	Percentage of products with SY
Cakes	0.005	112	3	2.7
Sandwich cookies	0.005	127	1	0.8
Yoghurts	0.01	122	2	1.6
Chocolate	0.05	170	4	2.4
Fruit-based sweets	0.005	104	2	1.9
Other sweets	0.01	128	12	9.4
Spirits	0.02	100	5	5.0
Juices	0.01	74	10	13.5
Soft drinks	0.01	24	4	16.7
Milk beverages	0.005	33	3	9.1
Other non-alcoholic beverages	0.01	51	6	11.8
Fried and baked pastries	0.005	38	2	5.3
Industrialised snacks	0.005	54	2	3.7
Ready meals	0.005	443	13	2.9
Total		1580	69	4.4

Note: [a]According to Brazilian Legislation (Agência Nacional de Vigilância Sanitária – ANVISA, 2011).

to find out the food products that contained the synthetic colouring SY.

Initially, data on food were sorted according to the 98 different food groups established in the HBS 2008/09 (IBGE 2010). Based on this division, the records were sorted into 14 food groups (Table 1) in which at least one food product contained the SY in its composition.

For the TDMI calculation, the Codex Alimentarius Commission suggests considering all foods in which a food additive is permitted (FAO/WHO Codex Alimentarius Commission 2014). However, as we had the dye usage data, we preferred to consider only foods where the dye was used. It was verified that in some food categories where the use of SY is allowed we did not find foods on the market with the presence of SY (e.g., ice creams, soups, sauces, among others).

Food consumption according to the HBS-IBGE 2008/09

The data source used was the HBS 2008/09. The basic information of the HBS used in this study refers to the consumption of food and drink inside and outside the household. Each resident aged 10 years or above recorded their individual food consumption for 2 non-consecutive days. Other data collected included age, sex and body weight of each individual in the household (IBGE 2010).

In this study, we considered the location of the sectors – urban and rural areas – in the five regions of the country as well as age group – adolescents, adults and seniors – from the HBS 2008/09.

Estimate of the theoretical maximum daily intake (TMDI)

Information about the presence of SY in food was correlated with data on the prevalence of food consumption per capita obtained by the HBS 2008/09.

In order to estimate the TMDI of SY, the maximum concentration of the dye allowed by Brazilian legislation for each food category was considered, according to the compendium of ANVISA (2011). Furthermore, since the objective of the study was to estimate the maximum possible consumption, it was considered that all food consumed of one category containing at least one product with SY contained this dye. This assumption represents a hypothetical worst case where all of the foods in Table 1 contain the highest yellow colour permissible with SY. In fact fewer than 5% of foods overall contain SY.

Results and discussion

Synthetic dye Sunset Yellow in food

Table 1 presents the food groups according to the classification of the HBS-IBGE 2008/09, where at least one product contained SY in its composition. The maximum permitted level of SY for each category of food allowed in Brazil is also shown.

A total of 4503 labels of foods sold on the website of the largest supermarket chain in Brazil were

analysed. According to the data obtained, labels of 69 foods assessed show this dye.

The categories of food products with the highest occurrence of products with SY in relation to the total number of products in the category were soft drinks (16.7%), juices (13.5%), other non-alcoholic beverages (11.8%) and other sweets (9.4%). These products may be widely consumed by children who can have higher intakes compared with adults because of higher food consumption in combination with lower body weights.

Acceptable daily intake of Sunset Yellow FCF

Table 2 shows the ADI of SY for adolescents, adults and seniors, male and female. To obtain the ADI, the average weights by age group were calculated using the data of the average body weight, which was given by the HBS-IBGE 2008/09.

These data were correlated with the ADI for SY, which is 4.0 mg kg^{-1} of body weight. From the data, in order not to exceed the ADI, the maximum consumption of SY must be from 192 to 288 mg day^{-1}, depending on gender and age.

Estimates of intake

In order to obtain the average intake per capita, the average food consumption (obtained from HBS) was used. All ingested food products within the category of products with SY and which contained the dye were considered and their concentration in the food product were set as the maximum permitted by law.

Since the average consumption is based on the assumption that all people in the study had consumed the food product, in order to evaluate the possibility that only part of the population may be exceeding the ADI, it was more appropriate to consider the prevalence of food intake, i.e., the percentage of the population that claimed to consume certain food product (data obtained from the HBS). However, the consumer of one category does not necessarily also consume the others. The FAO/WHO guidelines apply 'eaters only' food consumption for the two highest contributing food categories only (FAO/WHO Codex Alimentarius Commission 2014). In this work we decided to show results for the two possible approaches.

Table 2. Acceptable daily intake (ADI) of Sunset Yellow (SY) by age group and gender considering the average body weight from the Household Budget Survey (HBS) 2008–09.

Gender	Groups	Average weight (kg)	ADI of SY (mg day^{-1})
Male	Adolescents (10–18 years old)	51	204
	Adults (19–54 years old)	72	288
	Seniors (over 55 years old)	70	280
Female	Adolescents (10–18 years old)	48	192
	Adults (19–54 years old)	61	244
	Seniors (over 55 years old)	63	252

Source: Adapted from IBGE (2010).

Intake estimates in urban and rural areas

Table 3 presents data on the population average intakes of SY in urban and rural areas, as well as the intake for consumers only considering the prevalence of consumption within each category. Results for the FAO/WHO approach are also shown, in this case values for the average ADI of SY were considered except for the categories of 'fruit-based sweets' and 'juices' in which intake for 'eaters only' was considered (bold values in Table 3).

It should be noted that the TMDI data represent the consumption of all food products in the aforementioned categories, which also consider the prevalence of food consumption (PFC). The TMDI will overestimate average intakes because it is assumed that all food in every category will be coloured with SY at its maximum concentrations and that individuals who consume foods from any category containing SY will also consume foods from all other categories containing SY. Not all foods will contain the maximum permitted levels of SY because different colour shades correspond to different flavours. The TMDI will therefore tend to overestimate intakes.

From the location data of urban and rural areas, it is possible to estimate that the average consumption of SY is 39% higher in urban areas then in rural areas. This result had been expected due to the proximity of points of sale, as well as to the different eating habits of this population. According to Coelho et al. (2009), in rural areas there is a higher probability of the purchase of basic commodities, especially beans, sugar and rice; therefore, the role of home-grown food products, which certainly influences this result, should also be evaluated.

Table 3. Estimate of theoretical maximum daily intake (TMDI) per capita of Sunset Yellow (SY) (mg day^{-1}) in urban and rural areas.

	Urban				Rural			
Food	Average consumption of food (g day^{-1})	Average intake of SY (mg day^{-1})	PFC (%)[a]	Average intake of SY (mg day^{-1}) CPFC[b]	Average consumption of food (g day^{-1})	Average intake of SY (mg day^{-1})	PFC (%)[a]	Average intake of SY (mg day^{-1}) CPFC[b]
Cakes	13.1	0.7	13.1	5.0	18.1	0.9	14.8	6.1
Sandwich cookies	5.0	0.3	4.5	5.6	2.5	0.1	2.3	5.5
Yoghurts	10.8	1.1	4.5	24.1	4.6	0.5	1.9	24.5
Chocolate	3.9	1.9	4.3	8.4	1.3	0.7	1.8	1.2
Fruit-based sweets	2.2	0.1	2.9	**44.9**	2.6	0.1	3.6	**38.4**
Other sweets	7.6	0.8	11.6	3.8	8.4	0.8	12.4	3.5
Spirits	1.3	0.3	0.6	6.6	1.9	0.4	0.8	6.7
Juices	151.0	15.1	41.1	**47.1**	115.1	11.5	33.1	**49.9**
Soft drinks	105.0	10.5	25.2	36.8	42.7	4.3	11.4	34.8
Flavoured and sweetened milk beverages	22.2	1.1	7.9	41.6	8.4	0.4	3.2	37.6
Other non-alcoholic beverages	3.0	0.3	0.9	14.1	1.4	0.1	0.5	13.3
Fried and baked pastries	11.3	0.6	13.7	32.9	4.3	0.2	6.3	30.0
Industrialised snacks	0.7	0.0	0.8	4.1	0.6	0.0	0.7	3.4
Ready Meals	3.2	0.2	5.1	4.3	1.4	0.1	2.9	4.6
TMDI (mg day^{-1})	–	**33**	–	**279** 110 (FAO/WHO approach)	–	**20**	–	**260** 97 (FAO/WHO approach)

Notes: [a]PFC, Prevalence of food consumption (%).
[b]CPFC, considering the prevalence of food consumption (i.e., consumers only, average daily intake in mg day^{-1}).

The average consumptions obtained were below the ADI, representing 11% and 14% of the ADI for adults, males and females, respectively (for urban areas).

However, considering the data on the prevalence of food intake – which range from 260 mg of SY day^{-1} in rural areas to 279 mg of SY day^{-1} in urban areas – part of the population could be exceeding the ADI in both regions, with values representing up to 145% of the established ADI for SY (for female adolescents from urban areas). But considering the FAO/WHO approach, the ADI is not exceeded (considering food consumption based on 'eaters only' just for the two highest contributors). To calculate the EDI for high consumers, the FAO/WHO guidelines suggest multiplying by three the food additive intake from the food category that is the major contributor (in this case, 'juice' category). Doing that, values obtained are 167 and 158 mg of SY day^{-1} for urban and rural areas, respectively.

The food products that represented the most significant contribution to these results were juices and soft drinks, which together accounted for more than 75% of the total SY consumed (considering average ingestion and not 'eaters only').

Estimates of intake by country region

In order to obtain the data of average consumption per capita of the SY in five different regions of the country, the same above-mentioned methodology was followed (Table 4).

The regions that showed the highest consumption of food products containing SY were the Southern region (35 mg SY day^{-1}), followed by the Southeastern region (33 mg SY day^{-1}) and the Midwestern region (32 mg SY day^{-1}).

By comparing the different regions of the country, it is possible to observe that the average intake per capita of SY was within the recommended ADI in all regions of the country, with values between 9–13% and 10–15% of the ADI for male and female adults, respectively.

However, when considering the prevalence of food intake ('eaters only' for all categories) is possible to observe that in all regions of the country (289–338 mg SY day^{-1}) part of the population might be exceeding the recommended ADI, which is 288 and 244 mg SY day^{-1} for male and female adults, respectively. This does not happen if the FAO/WHO approach is considered as the TMDI values are between 110 and 169 mg SY day^{-1} (considering 'eaters only' just for the two highest contributors, indicated by bold values in

Table 4. Estimate of theoretical maximum daily intake (TMDI) per capita of Sunset Yellow (SY) (mg day^{-1}) by region of the country.

	North		Northeast		Southeast		South		Midwest	
Food	AI[a] of SY	AI of SY CPFC[b]	AI of SY	AI of SY CPFC	AI of SY	AI of SY CPFC	AI of SY	AI of SY CPFC	AI of SY	AI of SY CPFC
Cakes	0.6	4.7	0.5	4.7	0.7	5.4	0.9	5.4	0.9	5.3
Sandwich cookies	0.2	6.0	0.3	7.5	0.2	4.8	0.3	5.1	0.1	4.1
Yoghurts	0.6	27.9	0.9	25.7	1.0	23.3	1.2	24.4	1.0	22.3
Chocolate	1.4	3.7	1.1	2.2	1.8	8.4	2.8	17.0	2.1	6.2
Fruit-based sweets	0.1	**53.5**	0.1	**56.5**	0.1	**37.7**	0.3	44.4	0.1	**68.5**
Other sweets	0.9	4.8	0.9	5.8	0.7	3.2	0.8	2.9	0.6	3.6
Spirits	0.4	6.7	0.4	7.4	0.2	6.0	0.4	6.2	0.2	7.6
Juices	15.7	**101.5**	13.5	**54.7**	14.7	32.5	15.3	**45.0**	14.6	**73.9**
Soft drinks	8.3	37.8	5.9	33.7	11.2	37.2	11.6	38.4	9.8	37.8
Flavoured and sweetened milk beverages	0.6	42.1	0.5	36.9	1.4	**41.4**	1.0	**45.9**	0.9	41.0
Other non-alcoholic beverages	0.2	13.3	0.4	14.5	0.3	14.1	0.1	14.2	0.3	12.5
Fried and baked pastries	0.4	28.8	0.3	31.1	0.6	37.0	0.5	25.6	0.7	33.7
Industrialised snacks	0.0	3.2	0.0	3.8	0.0	4.5	0.1	3.8	0.0	3.7
Ready meals	0.2	4.1	0.2	4.9	0.2	4.1	0.3	4.4	0.3	3.0
TMDI (mg day^{-1})	**30**	**338** 169 (FAO/WHO approach)	**25**	**289** 123 (FAO/WHO approach)	**33**	**260** 111 (FAO/WHO approach)	**36**	**283** 110 (FAO/WHO approach)	**32**	**323** 159 (FAO/WHO approach)

Notes: [a]AI, average intake of SY (mg day^{-1}).
[b]CPFC, considering the prevalence of food consumption (i.e., consumers only, average daily intake in mg day^{-1}).

Table 4 for each region). For high consumers, the EDI will be between 156 mg of SY day^{-1} in the Northeast and 239 mg of SY day^{-1} in the Midwest.

Estimates of intake by age group

In order to evaluate the average intake per capita of SY by age group, the classification established by the HBS 2008/09 was considered: adolescents (10–18 years old), adults (19–54 years old) and seniors (over 55 years old) (IBGE 2010).

Table 5 shows the average intake per capita and consumption per capita considering the prevalence of consumption for each age group.

The age group that consumes the most food products containing SY is adolescents (40 mg SY day^{-1}). This result may be related to the particularities of adolescence, which especially influence their habits and dietary recommendations. The diet represents at this stage a major component of lifestyle that favours the development of obesity and its co-morbidities (Pinho et al. 2013).

Adolescence is the prime time for interventions in health and nutrition when it comes to adopting healthy eating habits and promoting health in adulthood. Habits acquired at this stage will form the

Table 5. Estimated theoretical maximum daily intake (TMDI) of Sunset Yellow (SY) (mg day^{-1}) by age group.

	Adolescents (10–18 years old)		Adults (19–54 years old)		Seniors (over 55 years old)	
Food	AI[a] of SY	AI of SY CPFC[b]	AI of SY	AI of SY CPFC	AI of SY	AI of SY CPFC
Cakes	0.7	5.2	0.7	5.3	0.7	4.8
Sandwich cookies	0.6	6.5	0.2	5.1	0.0	2.7
Yoghurts	1.4	25.7	0.9	23.9	0.7	21.7
Chocolates	3.1	19.0	1.5	5.5	0.7	1.7
Fruit-based sweets	0.1	51.0	0.1	42.9	0.1	30.9
Other sweets	1.1	3.9	0.7	3.9	0.6	3.0
Spirits	0.1	5.8	0.3	6.8	0.3	8.0
Juices	16.8	78.6	14.7	48.2	10.0	38.4
Soft drinks	12.4	38.4	9.8	36.6	3.5	32.0
Flavoured and sweetened milk beverages	2.2	43.9	0.8	41.4	0.3	30.9
Other non-alcoholic beverages	0.2	14.8	0.3	13.6	0.3	13.1
Fried and baked pastries	0.7	31.0	0.5	35.2	0.3	24.4
Industrialised salty snacks	0.1	4.0	0.0	4.1	0.0	4.2
Ready meals	0.2	4.4	0.2	4.2	0.3	5.2
TMDI (mg day^{-1})	40	332 152 (FAO/WHO approach)	31	276 107 (FAO/WHO approach)	18	221 75 (FAO/WHO approach)

Notes: [a]AI, average intake of SY (mg day^{-1}).
[b]CPFC, considering the prevalence of food consumption (i.e., consumers only, average daily intake in mg day^{-1}).

basis of future eating habits (Caroba & Silva 2005; Andrade et al. 2013).

According to data on consumption per capita day^{-1} by age group, the food products that contributed the most to these results are juices, soft drinks and chocolate, which together account for about 79% of the total SY consumed by adolescents.

It is worth mentioning that the HBS 2008–09 interviewed children as young as 10 years old, which can raise major concerns since this category represents one of the largest groups of consumers of these products (Polônio & Peres 2009).

According to Polônio and Peres (2009), children are more susceptible to adverse reactions caused by food additives. Another aspect that should be noted is their physiological immaturity, which affects their metabolism and excretion of these substances. Moreover, children have no cognitive ability to control regular consumption as effectively as do adults.

Considering the prevalence of food consumption per capita, one segment of the population of adolescents could be consuming up to 173% of the ADI, adults 113% and seniors 88%. However, considering the FAO/WHO approach, none of the age groups exceeds the ADI. If the EDI is calculated for high consumers, only adolescents exceed the ADI (259, 161 and 123 mg SY day^{-1} for adolescents, adults and seniors, respectively).

Conclusions

This study demonstrated that when considering the average intake per capita of foods containing SY by the Brazilian population, the TMDI of this food dye would not exceed the ADI. However, when considering the prevalence of consumption with the current eating habits of parts of the Brazilian population, it is possible that the TMDI for this specific dye exceeds its ADI. Foods that contribute the most to the excess consumption of SY are powder juices, soft drinks and chocolate.

The TMDI is a theoretical value based on average consumption. It is possible that some high-level consumers of certain products could exceed the ADI. According to the survey, adolescents are the most likely age group to have a high intake of SY. Also, children below the age of adolescence would be expected to have higher intakes when expressed on a body weight basis. Unfortunately the HBS/IBGE 2008–09 does not include data needed to evaluate these questions.

The results of this study show the importance of research in the area of food safety legislation in order to collaborate on the adoption of public health policies aiming to ensure not only the safety of food from the aspect of contamination but also the safety in the usage of food additives.

Disclosure statement

No potential conflict of interest was reported by the authors.

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