Letter to the Editor

Theoretical Risk Assessment of Dietary Exposure to Brilliant Blue FCF in Chinese Population*

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Brilliant blue FCF is a dye and synthetic colorant with a triphenylmethane base structure. It is permitted as a food additive in many countries and regions. In recent years, Codex Alimentarius Commission[1], the European Union[2], Australia, New Zealand[3], the United States[4], China, and other countries have allowed the use of brilliant blue FCF as a food colorant. Criteria of use in various food categories and relevant maximum use level have been established in different countries. The maximum use level for brilliant blue FCF in various food categories is specified in China National Food Safety Standard-Standards for Use of Food Additives (GB 2760-2014)[5], and specification GB 1886.217-2016 is provided to ensure safety and quality.

According to the working principle of Joint FAO/WHO Expert Committee on Food Additives (JECFA), when new data are available or acceptable daily intake (ADI) is revised, the safety of food additives that have been approved and listed in the standard should be reviewed[6]. In 2010, the European Commission issued Regulation No. 257/2010, which established a program to reevaluate approved food additives[7]. Similarly in China, reassessing a food additive is necessary when scientific findings or emerging evidence indicate a potential risk or when using a food additive no longer has technical justification. JECFA evaluated the use of brilliant blue FCF as a food colorant at its 13th meeting in 1969; ADI of 0-12.5 mg/kg body weight (BW) was established based on a no-observed-adverse-effect level (NOAEL) of 5% in the diet (equivalent to 2,500 mg/kg BW per day) derived from a chronic 200-fold uncertainty factor. Answering to the request of the 48th session of the Codex Committee on Food Additives, brilliant blue FCF was evaluated by JECFA again using the available data. Based on a 15% decrease in mean terminal BW and decreased survival of females at 1,318 mg/kg, a NOAEL of 631 mg/kg BW per day was identified. JECFA established an ADI of 0-6 mg/kg BW on the basis of this NOAEL, applying uncertainty factors of 10 for interspecies and 10 for intraspecies differences[8].

In light of the preceding adjustment, this theoretical risk assessment of brilliant blue FCF was conducted based on the food consumption data in China and the maximum level of the colorant in various food categories that allow its use under the China National Food Safety Standard-Standard for Uses of Food Additives (GB 2760-2014). The purpose of the assessment is to know the dietary intake level of brilliant blue FCF and the potential health risk according to the current China National Food Safety Standards, as well as to provide scientific advice to risk managers on how to regulate the future use of this food additive.

The assessment is mainly designed for the population above 2 years old in China. According to consumption patterns and habits, the population was divided into the following age groups: 2-3, 4-9, 10-17, 18-59, and over 60 years old.

In this study, the concentration of brilliant blue FCF in food was identified based on the hypothesis that its use would comply with the provisions of GB 2760-2014. Food consumption data were obtained from the Nutrition and Health Survey of Chinese Residents in 2002.

Based on the actual food consumption and weight of the respondents as indicated in the aforementioned Nutrition and Health Survey, and the maximum use level of brilliant blue FCF in various food categories, a simple distribution model was used to calculate the intake of brilliant blue FCF per kilogram per day for each individual[9]. The calculation formula was as follows:

$$EXP = \sum_{i=1}^{n} \frac{(F_i \times C_i)}{1000 \times BW}, \quad (1)$$

where EXP is the dietary exposure to brilliant blue FCF per kilogram per day of one individual (mg/kg BW), F_i is the consumption of food category i (g/day or mL/day), C_i is the maximum use level in food category i (mg/kg), and BW is the actual weight of one individual (kg).

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The frequency distribution of dietary exposure to brilliant blue FCF for all the subjects was obtained on the basis of the intake of each individual. The average dietary exposure to brilliant blue FCF for all population and the intake level in high exposure population (P97.5) were calculated.

Dietary exposure to brilliant blue FCF was calculated based on the maximum level in various food categories which allow the use of this additive according to GB 2760-2014 and the consumption data on brilliant blue FCF in these food categories, with consideration that the ADI is 6.00 mg/kg BW per day. Detailed assessment results are shown in Tables 1 and 2.

For the general population, the findings showed that mean dietary exposure to brilliant blue FCF was estimated at 0.05 mg/kg BW per day (0.83% of ADI). At 97.5%, exposure was estimated at 0.29 mg/kg BW per day (4.83% of ADI). The maximum exposure (99%) was estimated at 0.48 mg/kg BW per day (8% of ADI). The ADI was not exceeded when all the maximum exposures for all the food categories that may contain brilliant blue were added up, and the ADI was not exceeded even at the maximum exposure for individual food categories when the calculations for each individual food category were conducted separately.

When only the population consuming foods containing brilliant blue FCF was considered, the dietary exposure was higher than that of the general population but still below the ADI. For this population, the exposure of different food categories to brilliant blue FCF was estimated in this study. The mean and 97.5% dietary exposure in the individual food category did not exceed the ADI. Among the various categories, jams, jellies, and marmalades had the highest exposure, and the average and 97.5% exposure were 0.29 mg/kg BW and

Table 1. Dietary Exposure of Chinese General Population and Consumer Only (mg/kg BW per day)

Food Category	General Population		Consumer	
	Mean	P97.5	Mean	P97.5
Flavored fermented milk	0.00094	0.0000	0.0677	0.2659
Modified condensed milk	0.00001	0.0000	0.0139	0.0930
Frozen drink	0.00013	0.0000	0.0339	0.1432
Jams, jellies, and marmalades	0.00017	0.0000	0.2920	1.0805
Preserved surface-drying fruit	0.00019	0.0000	0.0405	0.1819
Decorations on pastries	0.00045	0.0000	0.0209	0.0703
Decorative fruits	0.00001	0.0000	0.0704	0.1825
Pickled vegetables	0.00225	0.0250	0.0154	0.0656
Cooked bean products	0.00383	0.0489	0.0413	0.1327
Processed nuts and seeds	0.00099	0.0142	0.0159	0.0555
Cooked nuts and seeds	0.00101	0.0131	0.0301	0.1045
Cocoa products, chocolate, and chocolate products and candies	0.00040	0.0000	0.2187	1.1205
Starch-based balls	0.00406	0.0418	0.1334	0.5287
Instant cereals	0.00006	0.0000	0.0091	0.0303
Fillings and topping syrups for bakeries (fillings of crackers only)	0.00005	0.0000	0.0182	0.0641
Fillings and topping syrups for bakeries (filling of flavor pie only)	0.00011	0.0000	0.0364	0.1281
Flavoring syrup	0.00002	0.0000	0.0089	0.0563
Fruit flavoring syrup	0.00044	0.0000	0.1781	1.1253
Herbs, spices, seasonings, and condiment powder	0.00005	0.0004	0.0006	0.0031
Semi-solid blended condiments	0.01812	0.2097	0.1557	0.7223
Fruit and vegetable juice (nectar) drinks	0.00024	0.0000	0.0540	0.2219
Milk-containing drinks	0.00005	0.0000	0.0857	0.5723
Carbonated drinks	0.00064	0.0000	0.0599	0.2006
Powdered drinks	0.00005	0.0000	0.2815	0.9484
Flavored drinks	0.00010	0.0000	0.0450	0.1558
Integrated alcoholic beverages	0.00001	0.0000	0.0635	0.1143
Jelly	0.00000	0.0000	0.0109	0.0297
Puffed food	0.01071	0.1131	0.0601	0.4165

Note. P, percentile.

1.08 mg/kg BW, which accounted for 4.83% and 18.00% of ADI, respectively. Cocoa products, chocolate, chocolate products, and candies followed with the average and 97.5% exposure at 0.22 mg/kg BW (3.67% of ADI) and 1.12 mg/kg BW (18.67% of ADI), respectively.

The results show that neither the average nor the highest percentile exposures to brilliant blue FCF exceeded the JECFA ADI of 0-6 mg/kg BW in any age group and that the average daily exposure decreased with increasing age. According to the estimation, the average intake of 2-3 years old children was the highest, followed by that of 4-9 years old children. Detailed results are presented in Table 2.

According to the results, the major food that contributed to brilliant blue FCF dietary intake for the general population were semi-solid blended condiments (40%), puffed food (24%), starch-based balls (9%), cooked bean products (9%), pickled vegetables (5%), and others (including jelly and integrated alcoholic beverages) (5%). For children, the major food that contributed to brilliant blue FCF dietary intake were semi-solid blended condiments (40%), puffed food (16%), starch-based balls (15%), and cooked bean products (7%). For adults, top contributors were semi-solid blended condiments (42%), puffed food (27%), starch-based balls (9%), and cooked bean products (7%). In summary, semi-solid blended condiments, puffed food, starch-based balls, and cooked bean products were the main contributors to the dietary intake for the Chinese population.

Following the international assessment principle and methods for food additives, the study conducted the theoretical risk assessment for brilliant blue FCF in the Chinese population on the basis of the food consumption data in China and the maximum use level of the colorant in various food categories in accordance with GB 2760-2014. The assessment results indicated that estimated dietary exposure to brilliant blue FCF in the Chinese population was low, both for the general population and for all age groups, and no health concern was observed when estimated high exposures were compared with the health-based guidance value established by JECFA. In this assessment, the average dietary exposure to brilliant blue FCF decreased with increasing age. The reason was the increase of BW with age, and not because of higher consumption of typical foods containing brilliant blue FCF (e.g., semi-solid blended condiments) by children.

This study involves the following uncertainties: (1) The study assumed that the concentration of brilliant blue FCF in foods was equal to the maximum level of the additive allowed for use in all food categories; however, the actual use level may be lower than that, thereby resulting in likely overestimation of the risk of brilliant blue FCF. (2) The food categories indicated in the China National Food Safety Standard (GB2760-2014) were general, thereby causing difficulty in identifying specific food subcategories and calculating food consumption levels. (3) The consumption data used in this evaluation were generated from the Nutrition and Health Survey in 2002. However, an increasing variety of food types have become available and economic prosperity has spread in recent years. Consequently, the recent dietary structure and habits of the Chinese population have changed greatly compared with those in 2002 and food contribution to brilliant blue FCF dietary intake for the Chinese population may also change. The aforementioned uncertainties should

Table 2. Detailed Estimated Dietary Exposure to Brilliant Blue FCF in Chinese Population

Age Group (year)	*N*	Dietary Exposure (mg/kg BW per day)			% ADI	
		Mean	P97.5	P99	P97.5	P99
2-3	1,351	0.08	0.66	1.11	11.00%	18.50%
4-9	5,833	0.07	0.48	0.78	8.00%	13.00%
10-17	8,381	0.05	0.31	0.49	5.17%	8.17%
18-59	43,398	0.04	0.26	0.43	4.33%	7.17%
≥ 60	9,996	0.04	0.23	0.37	3.83%	6.17%
General	68,959	0.05	0.29	0.48	4.83%	8.00%

Note. P, percentile; High exposure intake accounting for proportion of ADI(%) = 97.5% dietary intake or 99% dietary intake. The calculation formula was as follows: $x = \frac{A}{B} \times 100\%$. *x*, High exposure intake accounting for proportion of ADI. A, 97.5% dietary intake or 99% dietary intake (mg/kg BW); B, ADI (mg/kg BW).

be considered when applying the results and conclusions of this assessment to actual management decisions.

This study was a theoretical evaluation based on currently available data. According to the principle of risk assessment for food additives, when no abuse has occurred, a detailed evaluation is unnecessary if the theoretical evaluation results show minimal health risk. Through the theoretical evaluation of brilliant blue FCF, the current China National Food Safety Standard-Standards for Uses of Food Additives (GB2760-2014) provides sufficient health protection for the general population in China, including all age groups. However, some studies have reported several cases of abuse of brilliant blue FCF during food manufacturing and processing in China[10]. The results of this assessment indicated that the strict implementation of the current national food safety standard for the use of brilliant blue FCF in food provides sufficient protection for Chinese consumers. This food dye is one of the artificial colors that might be easily abused. Therefore, we highly recommend that foods comply with the current national food safety standards in food manufacturing and processing in China. Furthermore, monitoring by competent authorities should be improved to prevent risks that may arise from abuse of brilliant blue FCF in food.

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