

## STATEMENT OF EFSA

### Refined exposure assessment for Brilliant Black BN (E 151)<sup>1</sup>

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#### ABSTRACT

The European Food Safety Authority (EFSA) carried out an exposure assessment of Brilliant Black BN (E 151), taking into account new information on its use as a food additive in foods. In 2010, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) adopted a scientific opinion on the re-evaluation of Brilliant Black BN and concluded that dietary exposure in 1- to 10-year-old children at the high level may exceed the Acceptable Daily Intake (ADI) for Brilliant Black BN of 5 mg/kg body weight (bw)/day at the upper end of the range. Following this conclusion, the European Commission requested that EFSA performs a refined exposure assessment for this food colour. Data on the presence of Brilliant Black BN in foods were requested from relevant stakeholders through a call for usage and concentration data. Usage levels were provided to EFSA for 11 out of 37 food categories in which Brilliant Black is authorised. In addition, 4 337 analytical results were also reported to EFSA, with the majority of values being below the limit of detection (LOD) or limit of quantification (LOQ). Exposure assessment was performed using the EFSA Comprehensive Food Consumption Database. Three scenarios were considered: (1) exposure estimates based on Maximum Permitted Levels (MPLs), (2) a refined brand-loyal exposure scenario, and (3) a refined non-brand-loyal exposure scenario. Considering the first scenario, high exposure levels (95<sup>th</sup> percentile) exceeded the ADI for toddlers and children in four dietary surveys. In comparison with the previous assessment, for both children and adults, the current mean exposure estimates are of the same order of magnitude, whereas the 95<sup>th</sup> percentile exposure is lower, particularly in adults. The mean and high-level exposure estimates of Brilliant Black BN are below the ADI for all population groups when considering the refined scenarios (brand-loyal and non-brand-loyal).

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#### KEY WORDS

Brilliant Black BN, E 151, dietary exposure, EFSA Comprehensive European Food Consumption Database, food colours

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## SUMMARY

Following a request from EFSA, the Food Ingredients and Packaging (FIP) Unit was asked to deliver a refined exposure assessment for Brilliant Black BN (E 151) in food taking into account new information on its use in foods and beverages.

Brilliant Black BN (E 151) is a synthetic bis-azo dye authorised as a food additive in the European Union (EU) for use in foods in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives, as amended.

It was previously evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1975, 1978 and 1981, and by the EU Scientific Committee for Food (SCF) in 1984. The JECFA and SCF committees have established different ADIs of 1 and 5 mg/kg body weight (bw)/day, respectively. In 2010, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) adopted a scientific opinion on the re-evaluation of Brilliant Black BN (E 151) as a food additive. The ANS Panel concluded that at both the maximum permitted levels (MPLs) and the maximum reported levels of use of Brilliant Black (E 151), mean intake estimates were generally below the ADI of 5 mg/kg bw/day. However, in 1- to 10-year-old children, the high percentiles of exposure (95<sup>th</sup>/97.5<sup>th</sup> percentiles) can exceed the ADI at the upper end of the range.

Recently, new data on the actual uses of Brilliant Black BN (E 151) in foods and beverages as consumed were submitted to EFSA by industry following a call for data. In addition, analytical results reported by competent national authorities after a call for data were also obtained. Moreover usage levels were retrieved from the report submitted to EFSA by FoodDrinkEurope (FDE) in 2012. The present statement provides the exposure assessment of Brilliant Black BN (E 151) based on current MPLs, reported information on usage levels, reported analytical results and individual consumption data from the EFSA Comprehensive European Food Consumption Database. Three exposure scenarios were considered: (1) exposure estimates based on MPLs (MPL scenario), (2) a brand-loyal exposure scenario assuming long-term exposure to Brilliant Black BN (E 151) at the maximum reported use/analytical level for one food category, and (3) a non-brand-loyal exposure scenario assuming long-term exposure to Brilliant Black BN (E 151) at the mean reported use/analytical levels for all foods.

The scenario used for the exposure assessment of the total population based on MPLs (MPL scenario) resulted in an exceedance of the ADI of 5 mg/kg bw/day at the high exposure level (95<sup>th</sup> percentile) for toddlers and children in four dietary surveys. The refined exposure scenarios based on reported usage and analytical data showed considerably lower exposure for all population groups with both mean and high-level estimates below the ADI of 5 mg/kg bw/day. For the brand-loyal and non-brand-loyal scenarios, the highest mean dietary exposure to Brilliant Black BN (E 151) was observed in toddlers—up to 0.84 and up to 0.17 mg/kg bw/day, respectively—whereas the highest 95<sup>th</sup> percentile exposure for brand-loyal scenario was in children—up to 1.83 mg/kg bw/day—and in toddlers for non-brand-loyal scenario—up to 0.30 mg/kg bw/day.

For the MPL scenario, the mean exposure estimates of the current exposure assessment of Brilliant Black BN (E 151) are in line with the evaluation carried out in 2010, whereas the 95<sup>th</sup> percentile exposure is estimated to be lower, particularly in adults. For refined scenarios, the current exposure estimates of Brilliant Black BN (E 151) based on usage levels and analytical results (with majority of values below the limit of detection (LOD) or limit of quantification (LOQ)) are lower than the previous assessment for both the mean and the high exposure levels. These differences are the result of the different approaches used for refined scenarios, the different usage level data submitted, more food consumption data being available and a detailed nomenclature of foods categories, thus allowing a detailed selection of foods that can contain Brilliant Black BN (E 151).

In conclusion, using MPLs for calculations, high-level (95<sup>th</sup> percentile) exposure estimates are above the ADI for toddlers and children (totally in four surveys), whereas mean total population exposure estimates are below the ADI for all age groups. Considering the refined exposure scenarios based on

reported usage/analytical levels, the mean and high-level exposure estimates of Brilliant Black BN (E 151) are below the ADI for all population groups.

## TABLE OF CONTENTS

Abstract .....	1
Summary .....	2
Background and Terms of reference as provided by EFSA .....	5
1. Additional information .....	5
2. Data and methodologies .....	7
2.1. Data.....	7
2.1.1. Use and use levels of Brilliant Black BN (E 151) .....	7
2.1.2. Maximum Permitted Levels of use.....	7
2.1.3. Reported use levels and analytical levels of Brilliant Black BN (E 151).....	9
2.1.4. Food consumption .....	11
2.2. Methodologies.....	13
2.2.1. Regulatory maximum level exposure assessment scenario .....	14
2.2.2. Refined exposure assessment scenario .....	15
3. Assessment .....	16
3.1. Exposure to Brilliant Black BN (E 151) from its use as a food additive .....	16
3.2. Main food categories contributing to exposure to Brilliant Black BN (E 151) .....	16
3.3. Discussion.....	19
3.4. Uncertainty analysis.....	21
4. Conclusions .....	22
Documentation provided to EFSA .....	22
References .....	23
Appendices .....	24
Appendix A. Summary of the reported use levels (mg/kg) of Brilliant Black BN (E 151) provided by industry .....	24
Appendix B. Summary of analytical results (middle-bound mg/kg) of Brilliant Black BN (E 151) provided by Members States .....	26
Appendix C. Concentration levels of Brilliant Black BN (E 151) used in the refined exposure scenarios (mg/kg or mL/kg) .....	28
Appendix D. Summary of total estimated exposure of Brilliant Black BN (E 151) from its use as a food additive for the MPL scenario and refined exposure scenarios per population group and survey: mean and high level (mg/kg bw/day) .....	30
Appendix E. Main contributors to the total mean dietary exposure to Brilliant Black BN (E 151) for the brand-loyalty scenario. The number of surveys where the food category was ranked as the most important contributor and the total number of surveys are also presented.....	32
Abbreviations .....	33

## BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY EFSA

In its letter of 26 May 2011 to the European Food Safety Authority (EFSA), the European Commission requested clarification on the outcomes of the exposure calculations undertaken by the ANS Panel in the opinions on the so-called Southampton colours (quinoline yellow<sup>4</sup>, sunset yellow<sup>5</sup>, ponceau 4R<sup>6</sup>). The Member States and stakeholders had informed the European Commission that the figures used in these exposure assessments required possibly some updating.

On 1 August 2011, EFSA responded by a letter indicating that following the discussions which took place on 27 May 2011 between EFSA, the Commission, and Member States representatives, where the possibility to make refined exposure assessments in the future was discussed, further exchanges between the Commission and EFSA have shown an interest for performing such refined assessments.

Once the necessary preparatory work to enable the realisation of the foreseen refined exposure assessments e.g. the establishment of a correspondence table between the food categorisation system (FCS) of the new European legislation (Regulation (EU) No 1129/2011<sup>7</sup>) and of the EFSA Comprehensive Food Consumption Database (FoodEx) had been finalised, in its letter of 26 April 2012, EFSA has requested information on the priorities set by the Commission.

On 23 May 2012, the European Commission sent a letter to EFSA setting the priorities for the refined exposure assessments of twelve food colours (Priority 1: caramel colours (E 150a, E 150c and E 150d); Priority 2: curcumin (E 100), amaranth (E 123), brown HT (E 155); Priority 3: azorubine/carmoisine (E 122), allura red AC (E 129), brilliant black BN (E 151); Priority 4: quinoline yellow (E 104), sunset yellow (E 110), ponceau 4R (E 124)) and indicating that revised data on use and use levels for food colours under priorities 2 and 3 were currently being collected by FoodDrinkEurope and should be provided to EFSA once they were available. Similar revised use data for the caramel colours (E 150a, E 150c and E 150d) have been provided by the Commission to EFSA.

EFSA is asked to provide refined exposure assessments for food colours already re-evaluated taking into account the restrictions/exceptions listed in Regulation (EU) No 1129/2011, especially in the case of main contributors.

Furthermore, it is requested that following the establishment of a correspondence table between the food categorisation system of Regulation (EU) No 1129/2011 and of the EFSA Comprehensive Food Consumption Database (FoodEx), EFSA will use the FoodEx system in order to provide refined exposure assessments and exclude non relevant food subgroups from the intake calculations. The list of priorities, as provided by the European Commission, is set as follows:

Priority 1 – caramel colours (E 150a, E 150c, E 150d)

Priority 2 – curcumin (E 100), amaranth (E 100), brown HT (E 155)

Priority 3 – azorubine/carmoisine (E 122), allura red AC (E 129), brilliant black BN (E 151)

Priority 4 – quinoline yellow (E 104), sunset yellow (E 110), ponceau 4R (E 124)

### 1. Additional information

Brilliant Black BN (E 151) is a bis-azo dye authorised as a food additive in the European Union (EU) under Annex II of Regulation (EC) 1333/2008, as amended, for use in 37 food categories, at MPLs between 50 and 500 mg/kg or mg/L.

<sup>4</sup> EFSA, 2009. Scientific Opinion on the re-evaluation of Quinoline Yellow (E 104) as a food additive, ON-1329.

<sup>5</sup> EFSA, 2009. Scientific Opinion on the re-evaluation of Sunset Yellow FCF (E 110) as a food additive, ON-1330.

<sup>6</sup> EFSA, 2009. Scientific Opinion on the re-evaluation of Ponceau 4R (E 124) as a food additive, ON-1328.

<sup>7</sup> OJ L 295, 12.11.2011, p. 1.

Brilliant Black BN (E 151) has previously been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1975, 1978 and 1981, and by the EU Scientific Committee for Food (SCF) in 1984. The JECFA and SCF committees have established different Acceptable Daily Intakes (ADI) of 1 and 5 mg/kg body weight (bw)/day, respectively. In 2010, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) re-evaluated Brilliant Black BN (E 151) as a food additive (EFSA ANS Panel, 2010). The safety of Brilliant Black BN (E 151) was assessed on the basis of uses and use levels authorised in the legislation<sup>8</sup> and reported use levels provided by industry. The ANS Panel concluded that the database did not give reason to revise the ADI of 5 mg/kg bw/day that was previously established by the SCF, based on a long-term carcinogenicity and toxicity study in rats. The ANS Panel concluded that, at the maximum reported levels of use of Brilliant Black BN (E 151), refined intake estimates were generally below the ADI of 5 mg/kg bw/day. However, intake estimates for 1- to 10-year-old children at the high percentiles of exposure (95<sup>th</sup>/97.5<sup>th</sup> percentiles) can be up to 6.9 mg/kg bw/day and thus exceed the ADI at the upper end of the range.

Table 1 presents the dietary exposure to Brilliant Black BN (E 151) as estimated by the ANS Panel in 2010 for two population groups: children and adults (EFSA ANS Panel, 2010).

**Table 1:** Summary of anticipated exposure to Brilliant Black BN (E 151) in children and the adult population as calculated in the previous ANS Panel opinion (EFSA ANS Panel, 2010) (mg/kg bw/day)

	Adult UK population <sup>(a)</sup> (> 18 years old)	Pre-school UK children <sup>(a)</sup> (1.5–4.5 years old, 15 kg bw)	Children EXPOCHI population (1–10 years old, 15.8–29 <sup>(b),(c)</sup> kg bw)
<b>Estimated exposure using MPLs</b>			
Mean exposure	0.9	3.1	0.4–3.5
Exposure 95 <sup>th</sup> or 97.5 <sup>th</sup> percentile	3.3	7.2	1.5–7.6
<b>Estimated exposure using reported use levels</b>			
Mean exposure	0.4	1.2	0.3–2.8
Exposure 95 <sup>th</sup> or 97.5 <sup>th</sup> percentile	2.6	2.1	1.1–6.9

(a): For the UK, estimates are based on the UNESDA report which gives the 97.5<sup>th</sup> percentile intake from beverages plus *per capita* average from the rest of the diet (Tennant, 2006).

(b): For EU children, estimates are based on the EXPOCHI report, which gives the 95<sup>th</sup> percentile intake.

(c): Except for the Cypriot children, where the reported body weight was 54 kg for 11- to 14-year-old children.

Refined exposure estimates have been performed for both children and the adult population according to the Tier 2 and Tier 3 approaches described in the SCOOP Task 4.2, which combines detailed individual food consumption information from the population with the MPL as specified in Directive 94/36/EC on food colours (Tier 2) with the maximum reported use levels of Brilliant Black BN (E 151), as identified by the Panel from the data provided by industry (Tier 3). Data were made available by the Confederation of the Food and Drink Industries of the EU (CIAA) for some of the authorised uses of Brilliant Black BN (E 151) (confectionery, decorations and coatings, fine bakery wares, edible ices, and desserts including flavoured milk products). In addition, analytical data on confectionery products were made available from a survey of the UK Food Standard Agency (FSA, 2002). Owing to a lack of information for other food categories, the maximum reported use levels used to estimate dietary exposure were at the level of MPLs. For estimating the exposure of the adult population, only food consumption data from the UK were available, whereas, for children, additional food consumption data were available from the EXPOCHI report (Huybrechts et al., 2010). The EXPOCHI report provides detailed food consumption data on children from 10 European countries: Belgium, France, the Netherlands, Spain, Italy, Finland, Greece, Cyprus, Sweden and Germany.

The main contributors (> 10 %) to the total anticipated mean exposure of the adult population to Brilliant Black BN (E 151) were fine bakery wares, sauces and seasonings, non-alcoholic flavoured

<sup>8</sup> European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs. OJ L 237, 10.9.1994, p.13.

drinks, and desserts including flavoured milk products. For children, the main contributors to the total anticipated exposure to Brilliant Black BN (> 10 %) were fine bakery wares, desserts including flavoured milk products, sauces and seasonings, non-alcoholic flavoured drinks, candied fruits and vegetables and mostarda di frutta, confectionery and savoury snack products.

## 2. Data and methodologies

### 2.1. Data

#### 2.1.1. Use and use levels of Brilliant Black BN (E 151)

The use of Brilliant Black BN (E 151) as a food additive is permitted in a wide range of foods.

Brilliant Black BN (E 151) is an authorised food colour in the EU for single use in processed fish and fishery products including molluscs and crustaceans (fish paste and crustacean paste, pre-cooked crustaceans and smoked fish). In addition, Brilliant Black BN (E 155) is included in Group III of the food additives authorised with a combined maximum limit, as defined in Commission Regulation (EC) No 1333/2008 on food additives, and may therefore also be used in the food categories in which Group III food additives are allowed.

The use of Brilliant Black BN (E 151) is authorised in the EU at *quantum satis* (QS)<sup>9</sup> levels only in edible cheese rind and casings, coatings and decorations for meat (only edible casings).

Brilliant Black BN (E 151) may also be used in the form of colour lakes.<sup>10</sup>

#### 2.1.2. Maximum Permitted Levels of use

MPLs of use of Brilliant Black BN (E 151) have been defined in Annex II of Regulation (EC) No 1333/2008<sup>11</sup> of the European Parliament and of the Council by establishing a Union list of food additives, as amended (Table 2).

**Table 2:** MPLs of Brilliant Black BN (E 151) in foods according to Annex II of Regulation (EC) No 1333/2008

FCS category No	Food category	Restrictions/exceptions	MPL (mg/L or mg/kg as appropriate)
1.4	Flavoured fermented milk products including heat-treated products		150
1.6.3	Other creams	Only flavoured creams	150
1.7.1	Unripened cheese excluding products in category 16	Only flavoured unripened cheese	150
1.7.3	Edible cheese rind		<i>Quantum satis</i>
1.7.6	Cheese products (excluding products in category 16)	Only flavoured unripened products	100
3	Edible ices		150
4.2.4.1	Fruit and vegetable preparations excluding compote	Only <i>mostarda di frutta</i>	200

<sup>9</sup> According to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, '*quantum satis*' shall mean that no maximum numerical level is specified and substances shall be used in accordance with good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose and provided the consumer is not misled.

<sup>10</sup> Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 354, 31.12.2008, p. 16.

<sup>11</sup> Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 354, 31.12.2008, p. 16.

FCS category No	Food category	Restrictions/exceptions	MPL (mg/L or mg/kg as appropriate)
5.2	Other confectionery including breath-freshening microsweets <sup>(a)</sup>	Except candied fruit and vegetables	300
5.2	Other confectionery including breath-freshening microsweets <sup>(a)</sup>	Only candied fruit and vegetables	200
5.3	Chewing gum		300
5.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	Only decorations, coatings and sauces, except fillings	500
5.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	Only fillings	300
6.6	Batters	Only batters for coating	500
7.2	Fine bakery wares		200
8.2.3	Casings, coatings and decorations for meat	Only decorations and coatings, except edible external coating of <i>pasturmas</i>	500
8.2.3	Casings, coatings and decorations for meat	Only edible casings	<i>Quantum satis</i>
9.2	Processed fish and fishery products including molluscs and crustaceans <sup>(a)</sup>	Only <i>surimi</i> and similar products and salmon substitutes	500
9.2	Processed fish and fishery products including molluscs and crustaceans <sup>(a),(b)</sup>	Only fish paste and crustacean paste	100 <sup>(c)</sup>
9.2	Processed fish and fishery products including molluscs and crustaceans <sup>(a),(b)</sup>	Only pre-cooked crustaceans	250 <sup>(d)</sup>
9.2	Processed fish and fishery products including molluscs and crustaceans <sup>(b)</sup>	Only smoked fish	100 <sup>(e)</sup>
9.3	Fish roe	Except sturgeons' eggs (caviar)	300
12.2.2	Seasonings and condiments <sup>(a)</sup>	Only seasonings, for example curry powder, tandoori	500
12.4	Mustard		300
12.5	Soups and broths		50
12.6	Sauces <sup>(a)</sup>	Including pickles, relishes, chutney and piccalilli; excluding tomato-based sauces	500
12.9	Protein products, excluding products covered in category 1.8 <sup>(a)</sup>	Only meat and fish analogues based on vegetable proteins	100
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)		50
13.3	Dietary foods for weight-control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)		50
14.1.4	Flavoured drinks <sup>(a)</sup>	Excluding chocolate milk; malt products	100
14.2.3	Cider and perry	Excluding <i>cidre bouché</i>	200
14.2.4	Fruit wine and made wine	Excluding <i>wino owocowe markowe</i>	200

FCS category No	Food category	Restrictions/exceptions	MPL (mg/L or mg/kg as appropriate)
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	Except spirit drinks as defined in Article 5(1) and sales denominations listed in Annex II, paragraphs 1–14, of Regulation 110/2008 and spirits (preceded by the name of the fruit) obtained by maceration and distillation, London gin, sambuca, maraschino, <i>marrasquino</i> or <i>maraskino</i> and <i>mistrà</i>	200
14.2.7.1	Aromatised wines <sup>(a)</sup>	Except <i>americano</i> , <i>bitter vino</i>	200
14.2.7.2	Aromatised wine-based drinks <sup>(a)</sup>	Except <i>bitter soda</i> , <i>sangria</i> , <i>claria</i> , <i>zurra</i>	200
14.2.7.3	Aromatised wine-product cocktails <sup>(a)</sup>		200
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol <sup>(a)</sup>	Only alcoholic drinks with less than 15 % of alcohol and <i>nalewka na winie owocowym</i> , <i>aromatyzowana nalewka na winie owocowym</i> , <i>nalewka na winie z soku winogronowego</i> , <i>aromatyzowana nalewka na winie z soku winogronowego</i> , <i>napój winny owocowy lub miodowy</i> , <i>aromatyzowany napój winny owocowy lub miodowy</i> , <i>wino owocowe niskoalkoholowe</i> and <i>aromatyzowane wino owocowe niskoalkoholowe</i>	200
15.1	Potato-, cereal-, flour- or starch-based snacks	Excluding extruded or expanded savoury snack products	100
15.1	Potato-, cereal-, flour- or starch-based snacks	Only extruded or expanded savoury snack products	200
15.2	Processed nuts	Only savoury-coated nuts	100
16	Desserts excluding products covered in categories 1, 3 and 4		150
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms		300
17.2	Food supplements supplied in a liquid form		100
17.3	Food supplements supplied in a syrup-type or chewable form	Only solid food supplements	300
17.3	Food supplements supplied in a syrup-type or chewable form	Only liquid food supplements	100

(a): This food category was linked to (a) specific FoodEx category/categories for the exposure assessment, as explained in Section 3.2.

(b): Single use of Brilliant Black BN (E 151) for this food category (combined use of Group III food additives for other food categories).

(c): Maximum individually or for the combination of E 100, E 102, E 120, E 122, E 142, E 151, E 160e and E 161b.

(d): Maximum individually or for the combination of E 100, E 102, E 120, E 122, E 129, E 142, E 151, E 160e and E 161b.

(e): Maximum individually or for the combination of E 100, E 102, E 120, E 151 and E 160e.

FCS, Food Categorisation System.

### 2.1.3. Reported use levels and analytical levels of Brilliant Black BN (E 151)

Most food additives in the EU are authorised at a specific MPL. However, a food additive may be used at a lower level than the MPL. Therefore, information on actual use levels is required for performing a

more realistic exposure assessment, especially for those food additives for which no MPL is set and which are authorised according to QS.

In the framework of Regulation (EC) No 1333/2008 on food additives and of Commission Regulation (EU) No 257/2010<sup>12</sup> regarding the re-evaluation of approved food additives, EFSA issued a public call<sup>13</sup> for food additives concentration data (usage level and/or analytical data) on Brilliant Black BN (E 151).

Data on Brilliant Black BN (E 151) including present use and use patterns (i.e. the food categories and subcategories and the actual use levels (typical and maximum use levels), especially for those uses which are limited only by QS) were requested from relevant stakeholders. European food manufacturers, national food authorities, research institutions, academia, food business operators and any other interested stakeholders were invited to submit analytical data on Brilliant Black BN (E 151) in foods and beverages. The data submission to EFSA followed the requirements of the EFSA Guidance on Standard Sample Description for Food and Feed (EFSA, 2010a).

#### 2.1.3.1. Summarised data on reported use levels of Brilliant Black BN (E 151) in foods provided by industry

Industry provided EFSA with data on use levels (n = 20) of Brilliant Black BN (E 151) in foods for 11 out of the 37 food categories in which Brilliant Black BN (E 151) is authorised.

Reported use levels of Brilliant Black BN (E 151) in foods were provided to EFSA by three different industries stakeholders: the International Chewing Gum Association (ICGA), FoodDrinkEurope (FDE) and a private company. Usage data (n = 10) were provided for the following food categories: edible ices (Food Categorisation System (FCS) food category 3) chewing gum (FCS food category 5.3), decorations, coatings and fillings (FCS food category 5.4), flavoured drinks (FCS food category 14.1.4) and desserts (FCS food category 16). For all other food categories in which the use of Brilliant Black BN (E 151) is authorised, no reported use levels have been provided through the call for data.

Additional information on use levels of Brilliant Black BN (E 151) was retrieved from the report submitted to EFSA by FDE in 2012 (FDE, 2012), including the updated information on Brilliant Black BN (E 151) for nine food categories: edible ices (FCS food category 3), confectionery (FCS food category 5.2), decorations and coatings (FCS food category 5.4), fine bakery wares (FCS food category 7.2), fish roe (FCS food category 9.3), cider and perry (FCS food category 14.2.3), fruit wines (FCS food category 14.2.4), spirit drinks (FCS food category 14.2.6) and desserts (FCS food category 16). In total, 10 usage levels were retrieved from the FDE report (FDE, 2012).

All usage data provided on Brilliant Black BN (E 151) in foods by industry across the food categories are summarised in Appendix A.

#### 2.1.3.2. Summarised data on analytical levels of Brilliant Black BN (E 151) in foods provided by Member States

Additionally, analytical results from Member States were collected through the EFSA call for concentration data. It should be noted that complete information on the methods of analysis was not made available to EFSA. In total, 4 337 analytical results were reported to EFSA by five countries: Austria (n = 996), Czech Republic (n = 312), Germany (n = 2 868), Hungary (n = 81) and Slovakia (n = 80). The data were mainly on flavoured drinks (FCS food category 14.1.4), fine bakery wares (FCS food category 7.2) and other confectionery including breath-freshening microsweets (FCS food

<sup>12</sup> Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L 80, 26.3.2010, p. 19.

<sup>13</sup> Call for food additives usage level and/or concentration data in food and beverages intended for human consumption. Published: 27 March 2013. Deadline 15 September 2013. Available online: <http://www.efsa.europa.eu/en/data/call/130327.htm>

category 5.2). In total, 19 out of the 20 FoodEx level 1 food categories were covered. Foods were sampled between 2004 and 2013 and were analysed in the same year of collection.

Data from non-authorised uses<sup>14</sup> (n = 475) observed in several food categories were all values that were not detected/not quantified, with the exception of one sample on 'other sugars and syrups' (FCS food category 11.2) and one sample on fruit juice (FCS food category 14.1.2) with quantified middle-bound values of 0.7 and 0.3 mg/L, respectively. Data from non-authorised uses were not considered in the exposure assessment. The 685 samples expressed as qualitative results were also not used in the exposure assessment, as they give only binary results (i.e. an indication of the presence or absence of the food additive in the food analysed).

Overall, 3 177 out of the 4 337 total analytical results reported for Brilliant Black (E 151) in foods were included in the exposure estimates after discarding analytical results on foods in which Brilliant Black BN (E 151) is not authorised and values are expressed as qualitative results. Out of this cleaned dataset, analytical results of Brilliant Black BN (E 151) were not quantified (less than the limit of quantification (LOQ)) in 507 samples and not detected (less than the limit of detection (LOD)) in 2 566 samples, and 104 samples were numerical values (quantified). Only eight of these samples come from a non-accredited laboratory.

Only 104 out of the 3 177 concentration data results reported were numerical values (above the LOD/LOQ). These data were measured in the following food categories: edible ices (FCS food category 3), other confectionery including breath-freshening microsweets (FCS food category 5.2), processed fish and fishery products (FCS food category 9.2), fish roe (FCS food category 9.3), flavoured drinks (FCS food category 14.1.4), alcoholic beverages (FCS food category 14.2), desserts (FCS food category 16) and food supplements (FCS food category 17). For all remaining food samples analysed (n = 3 071), the concentration of Brilliant Black BN (E 151) was not detected or not quantified (i.e. left-censored).

Appendix B shows the analytical results of Brilliant Black (E 151) in foods as reported by Member States (whole set of analytical data reported and positive samples only).

#### **2.1.4. Food consumption**

##### **2.1.4.1. EFSA Comprehensive European Food Consumption Database**

Since 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been populated with national data on food consumption at a detailed level. Competent authorities in the European countries provide EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (see the Guidance of EFSA 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a)).

The food consumption data gathered by EFSA were collected by different methodologies and thus direct country-to-country comparisons should be interpreted with caution. Depending on the food category and the level of detail used for exposure calculations, uncertainties could be introduced owing to possible subjects' under-reporting and/or misreporting of the consumption amounts.

Consumption records were codified according to the FoodEx classification system (EFSA, 2011b). Nomenclature from the FoodEx classification system has been linked to the FCS categories, as presented in Annex II, part D, of Regulation (EC) No 1333/2008, for the exposure assessment.

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<sup>14</sup> Such results could be due to the use of multi-screen methods covering a large range of compounds from food control laboratories analysing the food samples and/or errors in the classification of the foods sampled and/or misuse.

#### 2.1.4.2. Food items selected for the refined exposure assessment of Brilliant Black BN (E 151)

The food categories in which the use of Brilliant Black BN (E 151) is authorised were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx classification system food codes), at a detailed level (up to FoodEx level 4) (EFSA, 2011b). For example, for FCS category 9.2 ‘Processed fish and fishery products including molluscs and crustaceans’, the MPL of 500 mg/kg of Brilliant Black (E 151) was combined with consumption data on ‘*surimi*’ and ‘fish products (unspecified)’, both at FoodEx level 3; the MPL of 250 mg/kg was combined with consumption data on ‘crustaceans’ at FoodEx level 2; and the MPL of 100 mg/kg was combined with consumption data on ‘fish paste’ and on fish species which can be consumed when smoked (e.g. herring, salmon) at FoodEx level 3.

Some food items are not referenced in the EFSA Comprehensive Database and therefore could not be taken into account in the present estimate. This results in an underestimation of the exposure. These are described below (in ascending order of the FCS codes):

- 1.6.3 Other creams, only flavoured creams;
- 1.7.1 Unripened cheese, excluding products in category 16, only flavoured unripened cheese;
- 1.7.3 Edible cheese rind;
- 1.7.6 Cheese products (excluding products in category 16), only flavoured unripened products;
- 4.2.4.1 Fruit and vegetable preparations excluding compote, only *mostarda di frutta*;
- 5.4 Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4 (decorations, coatings, sauces and fillings). This category covers confectionery products generally used for decorating, coating and filling of foodstuffs, e.g. fine bakery wares, edible ices, candy and confections. This food category is not available in the FoodEx nomenclature, but foodstuffs that are likely to be decorated, coated or filled (e.g. fine bakery wares) are included in the assessment;
- 6.6 Batters, only batters for coating;
- 8.2.3 Casings, coatings and decorations for meat;
- 14.2.4 Fruit wine and made wine;
- 14.2.7.2 Aromatised wine-based drinks except *bitter soda*, *sangria*, *claria*, *zurra*;
- 14.2.7.3 Aromatised wine-product cocktails.

For the following food categories, the restrictions that apply to the use of Brilliant Black BN (E 151) could not be taken into account, and therefore the whole food category listed below (in ascending order of the FCS codes) was considered for the exposure estimates. This results in an overestimation of the exposure:

- 9.3 Fish roe, except sturgeons’ eggs (caviar). This exception could not be taken into account in the present exposure assessment, as no distinction is made in the FoodEx nomenclature between sturgeons’ eggs and other fish eggs. Therefore, the whole food category was taken into account.
- 14.2.3 Cider and perry, excluding *cidre bouché*. No distinction was possible between cider and *cidre bouché*; therefore, the entire food category was accounted for in the exposure estimates.
- 14.2.7.1 Aromatised wines, except *americano*, *bitter vino*, and 14.2.7.2 Aromatised wine-based drinks, except *bitter soda*, *sangria*, *claria*, *zurra*. No distinction is possible between *americano* and other products or between *bitter soda* and other products of each food category; therefore, the entire food category was accounted for in the exposure estimates.

- 15.1 Potato-, cereal-, flour- or starch-based snacks. It was not possible within the FoodEx food classification to differentiate extruded or expanded savoury snack products. To be conservative, it was assumed that all cereal-, flour- or starch-based snacks are extruded or expanded and the highest MPL of 200 mg/kg and the highest use/analytical levels were considered.
- 17 Food supplements. It was not possible to differentiate solid, liquid or syrup-type, or chewable forms of food supplements within FoodEx codes; therefore, these three food categories were considered as a whole and the highest MPL of 300 mg/kg and the highest use/analytical levels were used.

Further refinements were made in the following food categories:

- 5.2 Other confectionery, including breath- refreshing microsweets:
  - The MPL of 200 mg/kg refers to only candied fruit and vegetables. It was not possible within the FoodEx classification to differentiate candied vegetables from other vegetables; therefore, the MPL of 200 mg/kg was applied to only candied fruits and candied vegetables could not be included in the assessment.
  - The MPL of 300 mg/kg was assigned to the remaining foods of this food category.
- 9.2 Processed fish and fishery products including molluscs and crustaceans:
  - For ‘only *surimi* and similar products and salmon substitutes’, consumption data on unspecified fish products and *surimi* were used.
  - For ‘only smoked fish’, consumption data on fish species usually consumed when smoked (e.g. herring, salmon, mackerel, sardine) were considered.
- 12.2.2 Seasonings and condiments; only seasonings, for example curry powder, tandoori. Only seasonings, including spices, herbs, seasonings and extracts, and herb and spice mixtures were considered for the exposure assessment.
- 12.6 Sauces, including pickles, relishes, chutney and piccalilli; excluding tomato-based sauces. Only condiments, chutney and pickles, savoury sauces and dressings, excluding tomato-based sauces and ketchup, were included in the exposure estimate.
- 12.9 Protein products, excluding products covered in category 1.8; only meat and fish analogues based on vegetable proteins. Only the food category ‘meat imitates’ was used for the exposure calculation. Fish analogues based on vegetable proteins are not included in the FoodEx nomenclature.
- 14.1.4 Flavoured drinks. Colourless soft drinks, which are not likely to contain Brilliant Black BN (E 151) (e.g. lime or lemon soft drinks), were excluded from the exposure assessment. Consumption of chocolate milk-based flavoured drinks was excluded from the assessment.

## 2.2. Methodologies

Dietary exposure to Brilliant Black BN (E 151) from its use as a food colour was estimated using the approach agreed by the Panel at its 52<sup>nd</sup> plenary meeting,<sup>15</sup> which is to be followed for the exposure assessment procedure as part of the safety assessment of food additives under re-evaluation with the use of the consumption data available within the EFSA Comprehensive Database, as presented in Section 3, and with the limitations described below.

Dietary exposure was estimated based on individual consumption over the total survey period, excluding surveys with only one day per subject, which are considered to be inadequate to assess

<sup>15</sup> <http://www.efsa.europa.eu/en/events/event/140701a-m.pdf>

chronic dietary exposure, as suggested by the EFSA Working group on Food Consumption and Exposure (EFSA, 2011a).

The exposure to Brilliant Black BN (E 151) was calculated for the following population groups: toddlers, children, adolescents, adults and the elderly. For the present assessment, food consumption data were available from 26 different dietary surveys carried out in 17 different European countries, as mentioned in Table 3.

**Table 3:** Population groups considered for the exposure estimates of Brilliant Black BN (E 151)

Population	Age range	Countries with food consumption surveys covering more than one day
Toddlers	From 12 up to and including 35 months of age	Belgium, Bulgaria, Finland, Germany, Italy, Netherlands, Spain
Children <sup>(a)</sup>	From 36 months up to and including 9 years of age	Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, Netherlands, Spain, Sweden
Adolescents	From 10 up to and including 17 years of age	Belgium, Cyprus, Czech Republic, Denmark, France, Germany, Italy, Latvia, Spain, Sweden
Adults	From 18 up to and including 64 years of age	Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Spain, Sweden, UK
The elderly <sup>(a)</sup>	From 65 years of age and older	Belgium, Denmark, Finland, France, Germany, Hungary, Italy

(a): The terms ‘children’ and ‘the elderly’ correspond, respectively, to ‘other children’ and the merge of ‘elderly’ and ‘very elderly’ in the Guidance of EFSA on the ‘Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment’ (EFSA, 2011a).

Consumption records were codified according to the FoodEx classification system (EFSA, 2011b). Nomenclature from the FoodEx classification system has been linked to the FCS, as presented in Annex II of Regulation (EC) No 1333/2008, part D, to perform exposure estimates. In practice, FoodEx food codes were matched to the FCS food categories and the exposure was calculated by multiplying MPLs reported in Table 2 and values reported in Appendix C for each food category with their consumption amount per kilogram body weight separately for each individual in the database. The exposure per food category was subsequently added to derive an individual total exposure per day. Finally, these exposure estimates were averaged over the number of survey days, resulting in an individual average exposure per day for the survey period. This was done for all individuals in the survey and per age group, resulting in distributions of individual average exposures per survey and population group (Table 3). Based on these distributions, the mean and 95<sup>th</sup> percentile exposures were calculated per survey for the total population and per population group.

High-level consumption was calculated only for those foods and population groups where the sample size was sufficiently large to allow calculation of the 95<sup>th</sup> percentile (EFSA, 2011a). Therefore, in the present estimate, high-level (95<sup>th</sup> percentile) consumption figures for toddlers from Belgium, Italy and Spain were not included.

The following values were considered for dietary exposure to Brilliant Black (E 151) from its use as a food additive: (1) MPLs set out in the EU legislation (the *regulatory maximum level exposure assessment* scenario); and (2) the availability of adequate use levels or analytical data (the *refined exposure assessment* scenario).

### 2.2.1. Regulatory maximum level exposure assessment scenario

The regulatory maximum level exposure assessment scenario is based on the MPLs set out in Annex II of Regulation No 1333/2008 and listed in Table 2.

The exposure estimates derived following this scenario should be considered as the most conservative estimates, as it assumes that the consumer will be continuously (over a lifetime) exposed to Brilliant Black BN (E 151) present in food at the MPLs.

### 2.2.2. Refined exposure assessment scenario

The refined exposure assessment scenario is based on reported use levels from industry and analytical results submitted to EFSA by Member States. This exposure scenario can consider only food categories where the above data were available.

Appendix C summarises the concentration levels of Brilliant Black BN (E 151) used in the refined exposure assessment scenario. Based on the available dataset, two estimates based on different model populations were calculated:

1. The brand-loyal consumer scenario. It was assumed that a consumer experiences long-term exposure to the food additive at the maximum reported use/analytical levels for one food category. This exposure estimate is calculated as follows:
  - Food consumption is combined with the maximum reported use levels or the maximum of the analytical results for the main contributing food category at the individual level.
  - The mean of the typical reported use levels or the mean of analytical results is used for the remaining food categories.
2. The non-brand-loyal consumer scenario. It was assumed that the population experiences long-term exposure to the food additive at the mean reported use/analytical levels in food. This exposure estimate is calculated using the mean of the typical reported use levels or the mean of analytical results for all food categories.

In the refined exposure assessment scenarios, the concentration levels considered by EFSA were extracted from the whole dataset received (i.e. reported use levels and analytical results). For analytical results, the mean middle-bound value ( $< \text{LOD}/\text{LOQ} = \text{half of the LOD}/\text{LOQ}$ ) is used for each food category, which takes into consideration left-censored data (i.e. analytical results  $< \text{LOD}$  or  $< \text{LOQ}$ ). The left-censored data were treated by the substitution method as recommended in the 'Principles and Methods for the Risk Assessment of Chemicals in Food' (WHO, 2009) and the EFSA scientific report 'Management of left-censored data in dietary exposure assessment of chemical substances' (EFSA, 2010b). The middle-bound concentrations of Brilliant Black BN (E 151) were used to estimate exposure in the present statement assigning half of the LOD or LOQ, respectively, for reported data below the LOD or below the LOQ. For the reported use levels, the mean typical reported use level for each food category is used.

If both reported use levels and analytical results were available for the same food category, the most reliable value was used. If the typical use level was reported as a range, a normal distribution of values within the food category was assumed and the mean of two values representing the lower and upper range was calculated without considering values reported as zero as the lower range.

Food categories for which no or inadequate reported use/analytical levels were available, including processed fish and fishery products other than *surimi* and similar products and salmon substitutes (FCS food category 9.2), mustard (FCS food category 12.4), protein products (FCS food category 12.9), dietary foods for weight-control diets (FCS food category 13.3) and processed nuts (FCS food category 15.2), were not considered in the exposure assessment.

### 3. Assessment

#### 3.1. Exposure to Brilliant Black BN (E 151) from its use as a food additive

Table 4 summarises the estimated exposure to Brilliant Black (E 151) from its use as a food additive in all five population groups (Table 3). Detailed results by population group and survey are presented in Appendix D.

**Table 4:** Summary of exposure to Brilliant Black BN (E 151) from its use as a food additive, using the regulatory maximum level exposure assessment scenario and refined exposure scenarios, in five population groups (minimum to maximum across the dietary surveys in mg/kg bw/day)

	<b>Toddlers (12–35 months)</b>	<b>Children (3–9 years)</b>	<b>Adolescents (10–17 years)</b>	<b>Adults (18–64 years)</b>	<b>The elderly (&gt; 65 years)</b>
<b>Regulatory maximum level exposure assessment scenario</b>					
Mean	0.86–3.88	0.78–2.92	0.23–1.63	0.28–1.17	0.14–0.57
High level (95 <sup>th</sup> percentile)	2.75–6.35	1.79–6.11	0.65–3.33	0.78–2.52	0.54–1.39
<b>Refined estimated exposure scenario</b>					
<b>Brand-loyal scenario</b>					
Mean	0.08–0.84	0.16–0.74	0.13–0.42	0.05–0.30	0.03–0.20
High level (95 <sup>th</sup> percentile)	0.25–1.71	0.42–1.83	0.41–1.04	0.23–0.69	0.11–0.60
<b>Non-brand-loyal scenario</b>					
Mean	0.03–0.17	0.03–0.13	0.01–0.05	0.01–0.05	0.01–0.04
High level (95 <sup>th</sup> percentile)	0.11–0.30	0.07–0.28	0.03–0.12	0.03–0.10	0.02–0.09

#### 3.2. Main food categories contributing to exposure to Brilliant Black BN (E 151)

The main food categories contributing to total mean exposure to Brilliant Black BN (E 151) (> 5 % of total exposure) calculated for the MPL scenario and the brand-loyal and non-brand-loyal refined scenarios, as well as the number of surveys in which each food category is a main contributor, are shown in Tables 5, 6 and 7, respectively.

The contribution of individual food categories to the total mean exposure to Brilliant Black BN (E 151) varies between age groups owing to different consumption patterns.

When considering the MPL scenario (Table 5), flavoured drinks and fine bakery wares were the main contributors for all age groups, except toddlers, for whom flavoured fermented milk products were the most important contributor to the total mean exposure to Brilliant Black BN (E 151).

For the brand-loyal scenario, the food categories that, at the individual level, had the highest contribution to the total individual exposure to Brilliant Black BN (E 151) were identified for each age group. Fine bakery wares and flavoured drinks were the main contributors in children, adolescents and adults. In toddlers, besides fine bakery wares, flavoured fermented milk products were also an important contributor and, in the elderly, alcoholic beverages made an important contribution to the total mean exposure Brilliant Black BN (E 151) (Table 6). More details by age group and food category are reported in Appendix E.

In the non-brand-loyal scenario (Table 7), fine bakery wares and flavoured fermented milk products were the most important contributors to the total mean exposure of Brilliant Black BN (E 151) in toddlers and children. In adolescents, besides fine bakery wares, flavoured drinks were also an important contributor. In adult population groups, exposure was mostly from flavoured drinks, fine bakery wares and soups and broths and, in the elderly, alcoholic beverages were also an important contributor.

**Table 5:** Main food categories contributing to exposure to Brilliant Black BN (E 151) using MPLs (> 5 % to the total mean exposure) and number of surveys in which each food category is a contributor

FCS category No	Foods	Minimum and maximum percentage contribution of food categories to total dietary exposure across dietary surveys (number of surveys) <sup>(a)</sup>				
		Toddlers	Children	Adolescents	Adults	The elderly
01.4	Flavoured fermented milk products including heat-treated products	6.5–79 (7)	8.4–43 (13)	5.6–16 (9)	5.0–36 (11)	6.9–33 (6)
03	Edible ices	5.1–17 (2)	5.2–15 (10)	5.0–11 (5)	6.3–8.1 (3)	5.6–7.4 (2)
05.2	Other confectionery including breath-freshening microsweets	–	5.2–13 (6)	7.1–12 (2)	9.6–11 (2)	5.6–6.7 (2)
07.2	Fine bakery wares	11–54 (6)	13–50 (13)	13–54 (11)	6.3–37 (14)	13–39 (6)
09.2	Processed fish and fishery products including molluscs and crustaceans	–	–	6.5 (1)	5.4–7.9 (4)	7.6–17 (3)
12.2	Herbs, spices, seasonings	7.2–9.7 (2)	5.3–5.5 (2)	11 (1)	18 (1)	5.4–22 (2)
12.5	Soups and broths	6.5 (1)	5.7–17 (3)	16 (1)	6.6–20 (2)	8.3–18 (2)
12.6	Sauces	7.0–11 (4)	6.8–28 (10)	5.1–33 (9)	5.0–32 (13)	5.7–29 (6)
14.1.4	Flavoured drinks	13–35 (4)	8.6–48 (15)	9.6–60 (12)	8.2–64 (15)	6.2–52 (5)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	–	–	–	7.8–16 (4)	5.5–15 (4)
15.1	Potato-, cereal-, flour- or starch-based snacks	5.5–7.3 (2)	5.3 (1)	5.7–15 (3)	–	–
16	Desserts excluding products covered in categories 1, 3 and 4	14–15 (2)	5.6–12 (5)	5.1–8.1 (2)	6.1 (1)	8.0 (1)
17	Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children	–	–	–	–	5.2 (1)

(a): The total number of surveys may be greater than the total number of countries as listed in Table 3, as some countries submitted more than one survey for a specific age range.

**Table 6:** Main food categories contributing to exposure to Brilliant Black BN (E 151) using the brand-loyal refined exposure scenario (> 5 % to the total mean exposure) and number of surveys in which each food category is a contributor

FCS category No	Foods	Minimum and maximum percentage contribution of food categories to total dietary exposure across dietary surveys (number of surveys) <sup>(a)</sup>				
		Toddlers	Children	Adolescents	Adults	The elderly
01.4	Flavoured fermented milk products including heat-treated products	5.2–52 (5)	5.8–15 (3)	–	12 (1)	11 (1)
05.2	Other confectionery including breath-freshening microsweets	–	24 (1)	–	5.1–18 (2)	9.6 (1)
07.2	Fine bakery wares	13–93 (7)	6.4–95 (15)	38–92 (11)	12–85 (14)	33–92 (6)
12.5	Soups and broths	5.3 (1)	7.7 (1)	7.7 (1)	9.9 (1)	11 (1)
14.1.4	Flavoured drinks	5.3–46 (5)	6.7–83 (11)	5.3–89 (11)	9.5–73 (14)	9.1–41 (4)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	–	–	–	5.1–28 (4)	24–47 (2)
16	Desserts excluding products covered in categories 1, 3 and 4	7.9–35 (3)	5.4–25 (6)	6.3 (1)	7.1 (1)	8.5–9.1 (2)
17	Food supplements	–	–	–	–	11 (1)

(a): The total number of surveys may be greater than the total number of countries as listed in Table 3, as some countries submitted more than one survey for a specific age range.

**Table 7:** Main food categories contributing to exposure to Brilliant Black BN (E 151) using the non-brand-loyal exposure scenario (> 5 % to the total mean exposure) and number of surveys in which each food category is a contributor

FCS category No	Foods	Minimum and maximum percentage contribution of food categories to total dietary exposure across dietary surveys (number of surveys) <sup>(a)</sup>				
		Toddlers	Children	Adolescents	Adults	The elderly
01.4	Flavoured fermented milk products including heat-treated products	6.8–85 (7)	7.4–52 (13)	5.7–18 (9)	5.2–33 (12)	5.5–25 (6)
03	Edible ices	14 (1)	5.5–13 (8)	5.8–9.4 (2)	5.3–6.7 (2)	6.0 (1)
05.2	Other confectionery including breath-freshening microsweets	–	6.9–7.1 (2)	7.1 (1)	5.4 (1)	–
07.2	Fine bakery wares	12–68 (6)	5.8–63 (15)	5.7–60 (12)	7.8–46 (14)	11–54 (6)
09.2	Processed fish and fishery products including molluscs and crustaceans	–	5.5–9.1 (3)	5.6–18 (11)	9.0–10 (2)	11 (1)
9.3	Fish roe	–	5.2–20 (2)	6.6–9.3 (2)	10–12 (2)	5.3–12 (2)
12.2	Herbs, spices, seasonings	–	–	–	6.0 (1)	7.2 (1)
12.5	Soups and broths	6.5–26 (3)	6.0–47 (7)	6.8–47 (5)	6.1–49 (7)	6.4–50 (3)
12.6	Sauces	–	5.2–10 (3)	5.3–12 (5)	5.2–12 (7)	5.1–8.2 (3)

FCS category No	Foods	Minimum and maximum percentage contribution of food categories to total dietary exposure across dietary surveys (number of surveys) <sup>(a)</sup>				
		Toddlers	Children	Adolescents	Adults	The elderly
14.1.4	Flavoured drinks	7.8–23 (4)	5.5–41 (15)	5.7–54 (12)	11–62 (14)	5.3–47 (4)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts	–	–	5.6 (1)	6.7–40 (13)	5.6–53 (6)
15.1	Potato-, cereal-, flour- or starch-based snacks	5.9 (1)	–	6.3–11 (2)	–	–
16	Desserts excluding products covered in categories 1, 3 and 4	9.9–34 (3)	6.9–27 (8)	6.1–21 (5)	5.7–16 (4)	5.8–23 (3)

(a): The total number of surveys may be greater than the total number of countries as listed in Table 3, as some countries submitted more than one survey for a specific age range.

### 3.3. Discussion

EFSA has performed an exposure assessment of Brilliant Black BN (E 151) taking into consideration its MPLs laid down in Annex II of Regulation (EC) No 1333/2008, as well as newly submitted information on its reported use provided by industry and analytical data reported by the Member States.

To date, EFSA has used the maximum occurrence value (maximum reported usage/analytical level) available for each authorised food category. However, given the extensive range of analytical data that has been made available through the most recent calls, it was considered that this should also be used in additional scenarios of the exposure assessment approach intended to provide more realistic exposure estimates agreed by the Panel at its 52<sup>nd</sup> plenary meeting<sup>16</sup>, which is to be followed for the exposure assessment procedure as part of the safety assessment of food additives under re-evaluation. Therefore, EFSA calculated the refined exposure scenarios based on different assumptions: a brand-loyal consumer scenario, where it was assumed that the population experiences long-term exposure to the food additive at the maximum reported usage/analytical levels for one food category and at the mean reported usage/analytical levels for the remaining food categories; and a non-brand-loyal consumer scenario, where it was assumed that the population experiences long-term exposure to the food additive at the mean reported usage/analytical levels in all foods.

Overall, the regulatory maximum level exposure assessment scenario is considered to be very conservative, as it assumes that all authorised processed foods and beverages contain Brilliant Black BN (E 151) at the MPLs. On the other hand, the refined exposure assessment approach is considered to be a more realistic scenario, as it is based on the range of usage/analytical data provided by industry and Member States. This scenario assumes that the processed foods and beverages contain Brilliant Black BN (E 151) at the mean concentration level for all products (non-brand-loyal consumer scenario) except for one product, where it assumes that it contains Brilliant Black BN (E 151) at the maximum concentration level (brand-loyal consumer scenario). For this exposure assessment scenario, food categories with no or inadequate reported use/analytical levels were not considered in the exposure assessment.

The results of the present exposure assessment for Brilliant Black BN (E 151) following the MPL scenario are of the same order of magnitude as those estimated in the 2010 opinion (EFSA ANS Panel, 2010) at the mean levels, whereas the 95<sup>th</sup> percentile exposure levels are lower, particularly in adults. The differences in the outcomes between the current and previous exposure estimates for Brilliant Black BN (E 151) are a result of the availability of more detailed consumption data covering a range

<sup>16</sup> <http://www.efsa.europa.eu/en/events/event/140701a-m.pdf>

of European countries. New consumption data and the refinements in the selection of food items within the FoodEx nomenclature may contribute to the decreased 95<sup>th</sup> percentile exposure. Indeed, some of the child consumption surveys currently included in the EFSA Comprehensive Database were also used in the opinion of the ANS Panel on Brilliant Black BN (E 151) in 2010, but the food categories used in the previous assessment were broader with respect to those available in FoodEx. In the current assessment, individual food consumption data were used to estimate dietary exposure, whereas, in the 2010 ANS opinion, only summary statistics were available. Moreover, for adults, only UK consumption data were available, retrieved from various reports (Tennant, 2006, 2007).

For the refined scenario of the current exposure assessment, new usage/analytical levels reported recently to EFSA covering a range of food categories were used, whereas fewer reported usage/analytical levels were available in the previous assessment. The exposure estimates based on usage/analytical levels are considerably lower at the mean and high exposure levels, for both children and adults, in the current assessment. However, an accurate comparison with the previous assessment is not possible owing to the different approaches taken. In the 2010 assessment, the exposure calculation used maximum usage/analytical levels and MPLs to replace the missing usage/analytical levels for the majority of food categories, whereas, in the current assessment, besides maximum usage/analytical levels, mean typical usage/analytical levels were also used and the food categories for which no usage/analytical value was available were not included in the assessment.

For the adult population, the main contributing food categories under the MPL scenario were fine bakery wares and flavoured drinks. Soft drinks were also the most important contributors in the previous assessment (EFSA ANS Panel, 2010). In children, besides fine bakery wares and flavoured drinks, flavoured fermented milk products were also an important contributor when estimating dietary exposure based on MPLs, which is in line with a previous assessment in 2010. A similar pattern was observed for the main contributors when exposure estimates were based on refined scenarios. In addition, for these scenarios, alcoholic beverages were also estimated to be important contributors to the total exposure to Brilliant Black BN (E 151) in adult population groups.

The occurrence data received do not cover all food categories in which Brilliant Black BN (E 151) is authorised. Food categories for which no or inadequate reported use/analytical levels were available were not considered in the exposure assessment. Therefore, it should be noted that, if Brilliant Black BN (E 151) is nevertheless used in those food categories not considered in the exposure estimate, the calculated refined exposure assessment might result in underestimation. It was observed that, for two food categories (processed fish and fishery products and food supplements), quantified analytical levels of Brilliant Black BN (E 151) were measured; nevertheless, no use for these food categories was reported. The FoodEx food classification system and the Comprehensive Database provide very detailed information on food items. However, it was not always possible to find an appropriate link between the food categories used in the Comprehensive Database and those listed in the food additive legislation, in particular with respect to the restrictions/exceptions. In cases of very particular restrictions/exceptions, for example ‘only *mostarda di frutta*’, it was assumed that the food was rarely consumed and was therefore considered to be a minor contributor to the total mean exposure to Brilliant Black BN (E 151). As the FoodEx classification system does not contain such detailed foodstuffs, the value would not be assigned to the entire food category; therefore, it could not be included in the calculation. This approach might have led to an underestimation. In other cases, when more than one MPL within the same food category applied, the highest MPL/usage level/analytical result was assigned to the whole category, because it was not possible to have specific restrictions/exceptions corresponding to different MPLs. This approach may overestimate exposure.

Toddlers and children were the population groups in which the highest exposure levels were observed for all three scenarios considered. This may be explained by a higher amount of food consumed in relation to their body weight. Considering the scenario using MPLs, the estimated 95<sup>th</sup> percentile of total dietary exposure to Brilliant Black BN (E 151) is above the ADI of 5 mg/kg bw/day for toddlers (in one dietary survey) and for children (in three dietary surveys). It is possible that Brilliant Black BN (E 151) is not currently used in some food categories in which it is authorised, e.g. for flavoured milk

products, where no usage data and no quantified values were observed from the data received from industry and Member States. This view is also supported by a very limited number of quantified analytical values measured across a wide range of food categories and reported to EFSA. If this is the case, the exposure estimates calculated using the above-mentioned scenario are likely to be overestimated for those food categories. Considering the refined brand-loyal and non-brand-loyal scenarios based on maximum and mean reported usage/analytical levels, mean and high-level dietary exposure estimates are below the ADI of 5 mg/kg bw/day for all population groups.

Overall, fine bakery wares and flavoured milk products were estimated to be very important contributors to the total exposure to Brilliant Black BN (E 151) for all three scenarios. It should be noted that any restriction/exception for these food categories is set by Regulation (EC) No 1333/2008; therefore, the whole category was considered for the exposure assessment. The FoodEx classification system includes plenty of products within food categories, but it was assumed to be unlikely that Brilliant Black BN (E 151) is used in all those types of products and particularly for fine bakery wares. This is confirmed by the huge set of analytical data ( $n = \sim 900$ ) where no quantified values were measured; therefore, the exposure is likely to be overestimated for those food categories, particularly in the brand-loyal consumer scenario, where the highest reported level is used. This observation raised for discussion the issue of if any food restriction information (as ‘niche product’) is needed to refine food classifications to be taken into account in exposure calculations for the fine bakery wares food category, rather than using the whole food category, which probably overestimates the exposure results.

### 3.4. Uncertainty analysis

According to the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2006), the sources of uncertainty in Table 8 have been considered. These have already been discussed in the sections above and are summarised in Table 8.

**Table 8:** Qualitative evaluation of the influence of uncertainties

Sources of uncertainty	Direction <sup>(a)</sup>
Consumption data: different methodologies/representativeness/under-reporting/misreporting/no portion size standard	+/-
Use of food consumption surveys of a few days to estimate long-term (chronic) exposure	+
Correspondence of reported use levels to the food items in the EFSA Comprehensive Food Consumption Database: uncertainties on the precise types of food the levels refer to	+/-
Use of MPLs in exposure assessment	+
Brand-loyal exposure model: exposure calculations based on the maximum reported use/maximum analytical levels	+
Non-brand-loyal exposure model: exposure calculations based on the mean reported use/mean analytical levels	+/-
Concentration data: no or inadequate information on use/occurrence available	-
Uncertainty in possible national differences in use levels of food categories; dataset not fully representative of foods on the EU market	+/-

(a): + = uncertainty with the potential to cause overestimation of exposure; - = uncertainty with the potential to cause underestimation of exposure.

EFSA considered the impact of the uncertainties in the exposure assessment for Brilliant Black BN and concluded that overall uncertainty could lead to an overestimation of the calculated exposure estimates.

#### 4. Conclusions

The current exposure estimates for Brilliant Black BN (E 151) provide an update of the exposure assessment performed in 2010 (EFSA ANS Panel, 2010).

EFSA concluded that, when using MPLs for calculations, high-level (95<sup>th</sup> percentile) exposure estimates are above the ADI for toddlers and children (in four surveys), whereas mean total population exposure estimates are below the ADI for all age groups. Considering the refined exposure scenarios based on reported usage/analytical levels, and assuming that Brilliant Black BN (E 151) is not used in food categories for which no information was provided, the mean and high-level exposure estimates of Brilliant Black BN (E 151) are below the ADI for all population groups.

In comparison with the previous assessment, the current exposure estimates based on the MPL scenario for both children and adults are of the same order of magnitude at the mean level, whereas high exposure levels (95<sup>th</sup> percentile) are lower, particularly for adults. The current exposure estimates based on refined scenarios (brand-loyal and non-brand-loyal scenarios) are lower at both mean and high exposure levels for children and adults, but the estimates should be compared with caution owing to the different approaches taken. The differences in exposure estimates are mainly the result of the newly available, additional information on reported usage/analytical levels, the updated exposure scenario, the new food consumption data and the refined selection of food items within the FoodEx nomenclature.

EFSA noted that, for the two main contributing food categories for toddlers and children, groups where MPL estimates exceeded the ADI showed a high number of analytical data with no quantified values observed for fine bakery wares or no use levels reported, as well as no detection in analytical data for flavoured milk products. EFSA therefore considered that it is unlikely that in such a case the ADI will be exceeded.

#### DOCUMENTATION PROVIDED TO EFSA

1. FoodDrinkEurope's data collection on some colours (E 100, E 122, E 123, E 129, E 133, E 151, E 155) with 2012 updates. October 2012.
2. FoodDrinkEurope (FDE). Data on use levels of Brilliant Black (E 151). Submitted on 29 November 2013.
3. International Chewing Gum Association (ICGA). Data on use levels of Brilliant Black (E 151). Submitted on 29 November 2013.
4. Private company. Data on use levels of Brilliant Black (E 151). Submitted on 4 July 2014.
5. Analytical data provided by Member States in response to the EFSA call for food additives usage level and/or concentration data in food and beverages intended for human consumption (2013).

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## APPENDICES

### Appendix A. Summary of the reported use levels (mg/kg) of Brilliant Black BN (E 151) provided by industry

FCS category No	Food category as reported by industry	FCS food category	MPL	Restrictions/exceptions	Reported usage levels				Comments
					Number of data	Typical mean or range	Highest maximum level	Information provided by	
3	Edible ices	Edible ices	150		1	300	500	Private company	The level refers to semi-finished product
3	Edible ices	Edible ices	150		2	10	100	FDE, private company	
5.2	Confectionery	Other confectionery including breath-freshening microsweets	300	Except candied fruit and vegetables	2	2–40	91.2	FDE	
5.3	Chewing gum	Chewing gum	300		1	30	50	ICGA	
5.4	Decorations, coatings and fillings	Decorations, coatings and fillings	500	Only decorations, coatings and sauces, except fillings	3	235	500	FDE, private company	
7.2	Fine bakery wares	Fine bakery wares	200		2	101	200	FDE	
9.3	Fish roe	Fish roe	300	Except sturgeons' eggs (caviar)	1	300	300	FDE	
14.1.4	Flavoured drinks	Flavoured drinks	100	Excluding chocolate milk; malt products	4	13.8	25	FDE	
14.2.3	Fruit wines (still or sparkling), cider (except cider bouché) and perry;	Cider and perry	200	Excluding <i>cidre bouché</i>	1	13	n/a	FDE	
14.2.4	aromatised fruit wines, cider and perry	Fruit wine and made wine	200						

FCS category No	Food category as reported by industry	FCS food category	MPL	Restrictions/exceptions	Reported usage levels			Comments
					Number of data	Typical mean or range	Highest maximum level	
14.2.6	Spirit drinks as defined in Article 2 of Regulation 110/2008, except: (a) spirit drinks mentioned in Article 5 (1) and defined in Annex II, paragraphs 1 to 14, of that regulation; and (b) fruit spirits, spirits (preceded by the name of the fruit) obtained by maceration and distillation, London gin, sambuca, maraschino, <i>marrasquino</i> or <i>maraskino</i> and <i>mistrà</i> , as defined in Annex II, points 9, 16, 22, 38, 39 and 43, of that regulation. Distilled alcoholic beverages below 15 % volume	Spirits drinks as defined in Regulation (EC) No 110/2008	200	Except: spirit drinks as defined in Article 5(1) and sales denominations listed in Annex II, paragraphs 1–14, of Regulation (EC) No 110/2008 and spirits (preceded by the name of the fruit) obtained by maceration and distillation, <i>geist</i> (with the name of the fruit or the raw material used), London gin, sambuca, maraschino, <i>marrasquino</i> or <i>maraskino</i> and <i>mistrà</i>	1	0–50	185	FDE
16	Desserts	Desserts excluding products covered in categories 1, 3 and 4	150		2	79.3	110	FDE

**Appendix B. Summary of analytical results (middle-bound mg/kg) of Brilliant Black BN (E 151) provided by Members States**

FCS category No	FCS food category	MPL	n	%LC	Range		All data					Positive values					
					LOD	LOQ	Min.	Median	Mean	P95 <sup>(a)</sup>	Max.	n	Min.	Median	Mean	P95 <sup>(a)</sup>	Max.
1.4	Flavoured fermented milk products	150	5	100	8.0–20.0	2.0–60.0	1.0	4.0	5.8	–	10.0	–	–	–	–	–	–
01.6.3	Other creams	150	1	100	0.2	0.5	0.3	0.3	0.3	–	0.3	–	–	–	–	–	–
01.7.1	Unripened cheese	150	3	100	0.2–0.2	0.5–2.0	0.3	1.0	0.8	–	1.0	–	–	–	–	–	–
03	Edible ices	150	133	99	0.0–20.0	0.1–60.0	0.3	5.0	4.1	10.0	10.0	1	–	–	5.0	–	5.0
05.2	Other confectionery, only candied fruit and vegetables	200	12	100	0.5–20.0	2.0–60.0	0.3	10.0	7.0	–	10.0	–	–	–	–	–	–
	Other confectionery, except candied fruit and vegetables	300	612	96	0.0–20.0	0.1–60.0	0.1	2.5	5.7	10.0	123.9	27	0.2	19.0	25.6	–	123.9
05.3	Chewing gum	300	20	100	0.5–20.0	2.0–60.0	0.3	10.0	6.0	–	10.0	–	–	–	–	–	–
07.2	Fine bakery wares	200	874	100	0.2–20.0	0.5–60.0	0.3	10.0	9.2	10.0	10.0	–	–	–	–	–	–
09.2	Processed fish and fishery products, only <i>surimi</i> and similar products and salmon substitutes	500	3	33	0.7–0.7	2.0–2.0	1.0	255.0	180.0	–	284.0	2	255.0	269.5	269.5	–	284.0
09.3	Fish roe	300	7	0	0.0–0.7	0.1–2.0	87.0	164.1	167.9	–	261.0	7	87.0	164.1	167.9	–	261.0
12.2.2	Seasonings and condiments	500	13	100	0.2–20.0	0.5–60.0	0.3	10.0	5.5	–	10.0	–	–	–	–	–	–
12.5	Soups and broths	50	8	100	0.5–20.0	2.4–60.0	0.3	10.0	8.8	–	10.0	–	–	–	–	–	–
12.6	Sauces	500	38	100	0.2–20.0	0.5–60.0	0.3	10.0	6.7	–	10.0	–	–	–	–	–	–
13.2	Dietary foods	50	5	100	20.0–	60.0–60.0	10.0	10.0	10.0	–	10.0	–	–	–	–	–	–

FCS category No	FCS food category	MPL	n	%LC	Range		All data					Positive values						
					LOD	LOQ	Min.	Median	Mean	P95 <sup>(a)</sup>	Max.	n	Min.	Median	Mean	P95 <sup>(a)</sup>	Max.	
	for special medical purposes				20.0													
14.1.4	Flavoured drinks	100	1 158	96	0.0–39.0	0.1–62.0	0.0	0.3	2.9	10.0	36.9	43	0.1	3.0	6.4	–	36.9	
14.2	Alcoholic beverages	200	219	91	0.0–20.0	0.1–60.0	0.0	0.3	2.2	10.0	30.0	19	0.1	1.0	5.3	–	30.0	
14.2.3	Cider and perry	200	73	70	0.2–20.0	0.1–60.0	0.0	0.3	2.5	10.0	17.0	3	0.5	15.1	10.9	–	17.0	
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	200	15	60	0.0–20.0	0.1–60.0	0.0	0.3	2.5	–	15.0	6	0.3	0.6	4.1	–	15.0	
14.2.7.1/	Aromatised wines	200	15	100	0.0–20.0	0.1–60.0	0.0	0.3	3.4	–	10.0	–	–	–	–	–	–	
14.2.7.2/	Aromatised wine-based drinks																	
14.2.7.3	Aromatised wine-product cocktails																	
14.2.8	Other alcoholic drinks	200	10	40	0.0–1.0	0.1–3.0	0.1	0.8	4.9	–	30.0	6	0.1	4.1	7.9	–	30.0	
15.1	Potato-, cereal-, flour- or starch-based snacks	100/200	6	100	0.5–20.0	2.4–60.0	0.3	7.5	5.9	–	10.0	–	–	–	–	–	–	
16	Desserts	150	24	88	0.8–20	2.0–60.0	0.4	10.0	16.1	–	113.6	3	35.0	65.2	71.3	–	113.6	
17	Food supplements	100/300	36	94	0.2–20	0.5–60.0	0.3	10.0	11.5	–	159.1	2	33.0	96.1	96.1	–	159.1	

(a): The 95<sup>th</sup> percentile obtained on occurrence data with fewer than 60 analytical results may not be statistically robust (EFSA, 2011a) and therefore are not reported in the table. n, number of data; %LC, percentage of left-censored data; Min., minimum; P95, 95<sup>th</sup> percentile; Max., maximum.

**Appendix C. Concentration levels of Brilliant Black BN (E 151) used in the refined exposure scenarios (mg/kg or mL/kg)**

FCS category No	FCS food category	MPL	Concentration levels used in the refined exposure assessment		Data source/comments
			Mean	Maximum	
01.4	Flavoured fermented milk products including heat-treated products	150	5.8	10.0	Analytical results
01.6.3	Other creams	150	–	–	Not taken into account (no corresponding FoodEx code)
01.7.1	Unripened cheese excluding products in category 16	150	–	–	Not taken into account (no analytical results or reported use levels)
01.7.3	Edible cheese rind	QS	–	–	Not taken into account (no corresponding FoodEx code)
01.7.6	Cheese products	100	–	–	Not taken into account (no corresponding FoodEx code)
03	Edible ices	150	4.1	10.0	Analytical results
04.2.4.1	Fruit and vegetable preparations excluding compote	200	–	–	Not taken into account (no corresponding FoodEx code)
05.2	Other confectionery including breath-freshening microsweets, except candied fruit and vegetables	200	7.0	10.0	Analytical results
05.2	Other confectionery including breath-freshening microsweets, only candied fruit and vegetables	300	5.7	123.9	
05.3	Chewing gum	300	30	50	Usage levels
05.4	Decorations, coatings and fillings	300/500	–	–	Not taken into account (no corresponding FoodEx code)
06.6	Batters	500	–	–	Not taken into account (no corresponding FoodEx code)
07.2	Fine bakery wares	200	9.2	200	Combination of analytical and usage levels
08.2.3	Casings, coatings and decorations for meat	QS/500	–	–	Not taken into account (no corresponding FoodEx code)
09.2	Processed fish and fishery products, only <i>surimi</i> and similar products and salmon substitutes	500	180.0	284.0	Analytical results
	Processed fish and fishery products, only fish paste and crustacean paste	100	–	–	Not taken into account (no analytical results or reported use levels)
	Processed fish and fishery products, only pre-cooked	250	–	–	Not taken into account (no analytical results)

FCS category No	FCS food category	MPL	Concentration levels used in the refined exposure assessment		Data source/comments
			Mean	Maximum	
	crustaceans				or reported use levels)
	Processed fish and fishery products, only smoked fish	100	–	–	Not taken into account (no analytical results or reported use levels)
09.3	Fish roe	300	167.9	261.0	Analytical results
12.2.2	Seasonings and condiments	500	5.5	10.0	Analytical results
12.4	Mustard	300	–	–	Not taken into account (no analytical results or reported use levels)
12.5	Soup and broths	50	8.8	10.0	Analytical results
12.6	Sauces	500	6.7	10.0	Analytical results
12.9	Protein products, excluding products covered in category 1.8	100	–	–	Not taken into account (no analytical results or reported use levels)
13.2	Dietary foods for special medical purposes	50	10.0	10.0	Analytical results
13.3	Dietary foods for weight-control diets	50	–	–	Not taken into account (no analytical results or reported use levels)
14.1.4	Flavoured drinks	100	2.9	36.9	Analytical results
14.2.3	Cider and perry	200	13.0	17.0	Combination of analytical and usage levels
14.2.6	Spirit drinks as defined in Regulation (EC) No 110/2008	200	50	185	Usage levels
14.2.7.1	Aromatised wines	200	3.4	10.0-	Analytical results
14.2.8	Other alcoholic drinks	200	4.9	30.0	Analytical results
15.1	Potato-, cereal-, flour- or starch-based snacks	100/200	5.9	10.0	Analytical results
15.2	Processed nuts	100	–	–	Not taken into account (no analytical results or reported use levels)
16	Desserts excluding products covered in categories 1, 3 and 4	150	16.1	113.6	Analytical results
17.1/17.2/17.3	Food supplements supplied	100/300	11.5	159.1	Analytical results

**Appendix D. Summary of total estimated exposure of Brilliant Black BN (E 151) from its use as a food additive for the MPL scenario and refined exposure scenarios per population group and survey: mean and high level (mg/kg bw/day)**

	Number of subjects	MPL scenario		Brand-loyal scenario		Non-brand-loyal scenario	
		Mean	High level	Mean	High level	Mean	High level
<b>Toddlers</b>							
Belgium (Regional Flanders)	36	3.88	– <sup>(a)</sup>	0.84	– <sup>(a)</sup>	0.17	– <sup>(a)</sup>
Bulgaria (NUTRICHILD)	428	1.15	2.75	0.65	1.70	0.04	0.11
Finland (DIPP)	497	0.86	3.10	0.08	0.25	0.03	0.11
Germany (DONALD 2006 2008)	261	1.02	2.94	0.27	0.85	0.04	0.11
Italy (INRAN SCAI 2005 06)	36	0.91	– <sup>(a)</sup>	0.34	– <sup>(a)</sup>	0.04	– <sup>(a)</sup>
Spain (enKid)	17	1.46	– <sup>(a)</sup>	0.37	– <sup>(a)</sup>	0.07	– <sup>(a)</sup>
The Netherlands (VCP kids)	322	2.91	6.35	0.73	1.71	0.14	0.30
<b>Children</b>							
Belgium (Regional Flanders)	625	2.92	6.11	0.67	1.36	0.13	0.28
Bulgaria (NUTRICHILD)	433	1.44	3.46	0.74	1.83	0.05	0.12
Czech Republic (SISP04)	389	1.66	3.75	0.55	1.32	0.06	0.14
Denmark (Danish Dietary Survey)	490	1.27	2.53	0.32	0.73	0.04	0.10
Finland (DIPP)	933	1.08	2.73	0.16	0.42	0.03	0.09
Finland (STRIP)	250	1.96	3.53	0.56	1.26	0.07	0.13
France (INCA2)	482	1.52	2.98	0.68	1.39	0.07	0.14
Germany (DONALD 2006 2008)	660	1.70	3.77	0.41	0.97	0.06	0.13
Greece (Regional Crete)	839	1.00	2.14	0.54	1.30	0.05	0.12
Italy (INRAN SCAI 2005 06)	193	0.78	1.79	0.40	1.01	0.03	0.07
Latvia (EFSA TEST)	189	1.23	2.98	0.48	1.21	0.08	0.18
Spain (enKid)	156	1.45	3.48	0.41	1.19	0.06	0.14
Spain (NUT INK05)	399	1.43	3.14	0.40	0.97	0.06	0.14
Sweden (NFA)	1473	2.77	5.30	0.61	1.29	0.10	0.19
The Netherlands (VCP kids)	957	2.70	5.86	0.65	1.53	0.12	0.26
<b>Adolescents</b>							
Belgium (Diet National 2004)	584	1.25	2.89	0.35	0.83	0.05	0.10
Cyprus (Childhealth)	303	0.23	0.65	0.13	0.41	0.01	0.03
Czech Republic (SISP04)	298	1.18	2.93	0.42	1.04	0.04	0.10
Denmark (Danish Dietary Survey)	479	0.91	2.13	0.27	0.68	0.03	0.07
France (INCA2)	973	0.81	1.80	0.36	0.88	0.03	0.08
Germany (National Nutrition Survey II)	1 011	0.88	2.24	0.24	0.79	0.03	0.09
Italy (INRAN SCAI 2005 06)	247	0.56	1.63	0.22	0.64	0.02	0.05
Latvia (EFSA TEST)	470	0.82	1.96	0.30	0.82	0.05	0.12
Spain (AESAN FIAB)	86	0.51	1.27	0.23	0.62	0.02	0.05
Spain (enKid)	209	0.83	1.86	0.27	0.77	0.03	0.07
Spain (NUT INK05)	651	0.90	1.92	0.27	0.66	0.04	0.08
Sweden (NFA)	1 018	1.63	3.33	0.38	0.82	0.05	0.11

	Number of subjects	MPL scenario		Brand-loyal scenario		Non-brand-loyal scenario	
		Mean	High level	Mean	High level	Mean	High level
<b>Adults</b>							
Belgium (Diet National 2004)	1 304	0.93	2.39	0.25	0.68	0.04	0.09
Czech Republic (SISP04)	1 666	0.47	1.27	0.20	0.60	0.02	0.05
Denmark (Danish Dietary Survey)	2 822	0.42	1.19	0.12	0.37	0.02	0.04
Finland (FINDIET 2007)	1 575	0.32	1.11	0.05	0.23	0.01	0.05
France (INCA2)	2 276	0.54	1.22	0.20	0.52	0.02	0.05
Germany (National Nutrition Survey II)	10 419	0.70	1.75	0.21	0.64	0.03	0.08
Hungary (National Repr Surv)	1 074	0.30	0.94	0.09	0.32	0.01	0.03
Ireland (NSIFCS)	958	0.55	1.40	0.15	0.38	0.02	0.07
Italy (INRAN SCAI 2005 06)	2 313	0.28	0.78	0.10	0.32	0.01	0.03
Latvia (EFSA TEST)	1 306	0.47	1.15	0.18	0.54	0.03	0.08
Spain (AESAN)	410	0.47	1.37	0.16	0.49	0.02	0.06
Spain (AESAN FIAB)	981	0.38	1.07	0.16	0.46	0.01	0.04
Sweden (Riksmaten 1997 98)	1 210	0.69	1.64	0.21	0.48	0.03	0.07
The Netherland (DNFCS 2003)	750	1.17	2.52	0.30	0.69	0.05	0.10
United Kingdom (NDNS)	1 724	0.74	1.61	0.17	0.44	0.03	0.07
<b>The elderly</b>							
Belgium (Diet National 2004)	1 230	0.57	1.39	0.18	0.50	0.04	0.09
Denmark (Danish Dietary Survey)	329	0.23	0.58	0.07	0.18	0.01	0.04
Finland (FINDIET 2007)	463	0.14	0.54	0.03	0.11	0.01	0.03
France (INCA2)	348	0.37	0.87	0.15	0.44	0.01	0.03
Germany (National Nutrition Survey II)	2 496	0.50	1.18	0.20	0.60	0.03	0.07
Hungary (National Repr Surv)	286	0.22	0.65	0.08	0.28	0.01	0.03
Italy (INRAN SCAI 2005 06)	518	0.18	0.54	0.08	0.24	0.01	0.02

(a): The 95<sup>th</sup> percentile estimates obtained on dietary surveys/population groups with fewer than 60 observations may not be statistically robust (EFSA, 2011a). Those estimates were not included in this table.

**Appendix E. Main contributors to the total mean dietary exposure to Brilliant Black BN (E 151) for the brand-loyalty scenario. The number of surveys where the food category was ranked as the most important contributor and the total number of surveys are also presented**

<b>FCS category No</b>	<b>FCS food category</b>	<b>Number of surveys where the food category was ranked as the most important contributor</b>	<b>Total number of surveys</b>
<b>Toddlers</b>			
1.4	Flavoured fermented milk products	1	7
7.2	Fine bakery wares	4	7
13.2	Dietary foods for special medical purposes	1	7
16	Desserts	1	7
<b>Children</b>			
7.2	Fine bakery wares	10	15
13.2	Dietary foods for special medical purposes	1	15
14.1.4	Flavoured drinks	4	15
<b>Adolescents</b>			
7.2	Fine bakery wares	8	12
9.2	Processed fish and fishery products	1	12
14.1.4	Flavoured drinks	2	12
17	Food supplements	1	12
<b>Adults</b>			
5.2	Other confectionery	1	15
7.2	Fine bakery wares	9	15
9.2	Processed fish and fishery products	2	15
14.1.4	Flavoured drinks	3	15
17	Food supplements	1	15
<b>The elderly</b>			
5.2	Other confectionery	1	7
7.2	Fine bakery wares	6	7

## ABBREVIATIONS

ADI	Acceptable Daily Intake
ANS Panel	Scientific Panel on Food Additives and Nutrient Sources added to Food
bw	body weight
CIAA	Confederation of the Food and Drink Industries of the EU (now FoodDrinkEurope)
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
EXPOCHI	Individual food consumption data and exposure assessment studies for children
FAO	Food and Agriculture Organization of the United Nations
FCS	Food Categorisation System (food nomenclature) presented in Commission Regulation (EU) No 1129/2011
FDE	FoodDrinkEurope
FSA	UK Food Standard Agency
ICGA	International Chewing Gum Association
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LOD	limit of detection
LOQ	limit of quantification
MPL	Maximum Permitted Level
QS	<i>quantum satis</i>
SCF	Scientific Committee for Food
UK	United Kingdom
UNESDA	Union of European Soft Drinks Associations
WHO	World Health Organization