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**Assessment of the exposure to Allura red colour from the consumption of red juice-based and red soft drinks in Italy**

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Complete List of Authors:	Fallico, Biagio; Università di Catania, GESA Chiappara, Elena; Università di Catania, GESA Elena, Arena; Università di Catania, GESA Gabriele, Ballistreri; Università di Catania, GESA
Methods/Techniques:	Chromatography - HPLC, Exposure - prob modelling, Exposure assessment
Additives/Contaminants:	Colours
Food Types:	Beverages, Fruit juices
Abstract:	<p>This paper reports on a survey and an exposure study, based on a probabilistic approach, concerning red juice-based and red soft drink products in Italy. This study highlighted that the estimations, both of consumption rates and colorant intakes, are related to the hypotheses of scenarios. In fact, the study estimated that, on the average, consumers of red soft drinks consume 53.1 litres per year, ranging from 39.1 litres to 70.7 litres of soft drink products under a scenario, or, 21.3 litres, ranging from 12.7 litres and 35.9 litres under other hypotheses; while 9.5 litres of red juice-based drinks are consumed per year, ranging between 7.0 litres and 12.5 litres, under a scenario, or, on the average, 6.9 litres, ranging from 3.2 litres and 17.7 litres, under the other scenario.</p> <p>The amount of colorant in a red beverage ranges from 10.9 mg/l in a red soft drink up to 55.9 mg/l in a red-juice based product. The risk evaluation process showed that in all cases, the intake of E129 was always lower than the Acceptable Daily Intake value. The exposure assessment showed high average intakes of Allura red in</p>

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	<p>the worst-case scenario, on the average, 6.5 mg/day and 13.9 mg/day, up to 25.0 mg/day and 33.0 mg/day at the 95th percentile, from juice-based and soft drinks respectively. The most realistic scenario estimated a weighted average daily intake of Allura red, on the average about 0.3 mg/day up to 0.5 mg/day at the 95th percentile, and 0.4 mg/day up to 0.6 mg/day at the 95th percentile, from juice-based and soft drinks, respectively. Actually, the highest colorant intake was estimated in a "health" juice-based drink. The intake of E129 significantly increased with a high level of colorant (&gt; 40 mg/l).</p>

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3 1 **Assessment of the exposure to Allura red colour from the consumption of**  
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6 2 **red juice-based and red soft drinks in Italy**  
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23 9 **Abstract**

24  
25 10 This paper reports the results of a survey and an exposure study, based on a probabilistic  
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27 11 approach, concerning red juice-based and red soft drink products in Italy. This study  
28  
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33 14 soft drinks consume 53.1 litres per year, ranging from 39.1 litres to 70.7 litres of soft drink  
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35 15 products under one scenario, or, 21.3 litres, ranging from 12.7 litres and 35.9 litres under  
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37 16 another hypotheses; while 9.5 litres of red juice-based drinks are consumed per year, ranging  
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39 17 between 7.0 litres and 12.5 litres, under one scenario, or, on the average, 6.9 litres, ranging  
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41 18 from 3.2 litres and 17.7 litres, under another scenario. The amount of colourant in a red  
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43 19 beverage ranged from 10.9 mg/l in a red soft drink up to 55.9 mg/l in a red-juice based  
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45 20 product. The risk evaluation process showed that in all cases, the intake of E129 was always  
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47 21 lower than the Acceptable Daily Intake value. The exposure assessment showed high average  
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49 22 intakes of Allura red in the worst-case scenario, on average, 6.5 mg/day and 13.9 mg/day, up  
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51 23 to 25.0 mg/day and 33.0 mg/day at the 95<sup>th</sup> percentile, for juice-based and soft drinks  
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53 24 respectively. The most realistic scenario estimated a weighted average daily intake of Allura  
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55 25 red, on average about 0.3 mg/day up to 0.5 mg/day at the 95<sup>th</sup> percentile, and 0.4 mg/day up to

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3 1 0.6 mg/day for the 95<sup>th</sup> percentile, from juice-based and soft drinks, respectively. Actually, the  
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6 2 highest colorant intake was estimated in a “health” juice-based drink. The intake of E129  
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8 3 significantly increased with a high level of colorant (> 40 mg/l).  
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10 4  
11  
12 5 **Keywords:** Allura red, beverages, risk analysis, EDI, ADI, probabilistic approach, @risk.  
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## 17 **Introduction**

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19 8 Food colourants, both naturally derived and synthetic, are widely used by the food industry.  
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21 9 Allura red (2-hydroxy-1-(2-methoxy, 5-methyl, 4-sulphonatophenylazo)-naphthalene-6-  
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23 10 sulphonate) disodium salt, also known as EU additive 129 (E129) or FD&C Red No. 40  
24  
25 11 (USA), is one of the most widely used synthetic diazo colourants. Directive 94/36/EC on  
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27 12 colours for use in foodstuffs fixes a limit of 100 mg/l for E129 in non-alcoholic flavoured  
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29 13 drinks. Safety aspects have been assessed and reported by the Joint FAO/WHO Expert  
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31 14 Committee on Food Additives (JECFA, 1974, 1980, 1981), as well as by the EU Scientific  
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33 15 Committee for Food (SCF, 1975, 1984, 1989). Both Committees have established an  
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35 16 acceptable daily intake (ADI) of 0-7 mg/kg of body weight/day (mg/kg bw/day). The studies  
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37 17 on which the JECFA and SCF assessments were based showed a very low acute toxicity of  
38  
39 18 Allura red as measured in different species of animals (LD50: 10,000 mg/kg bw for rats and  
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41 19 rabbits and 5000 mg/kg bw for dogs (Weir, 1965a, 1965b, 1967). Recently, Sasaki et al.  
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43 20 (2002) tested 39 food additives and defined a LD50 for Allura red of > 2000 mg/kg. Studies  
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45 21 on sub-chronic and chronic toxicity, as well on carcinogenicity (Serota et al., 1977; Borzelleca  
46  
47 22 et al. 1989, 1991), showed that the incidence of tumours or lesions in control and treated  
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49 23 animals were very similar. Details concerning the safety aspects of Allura Red can be found  
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51 24 in the JECFA (1980, 1981) and WHO reports (2009), respectively.  
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60 25 However, after the publication of the book *Why your Child is Hyperactive?* (Feingold,

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3 1 1975), concerning the role of synthetic colourants on children's behaviour (attention deficit  
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5 2 disorder (ADD) and/or attention deficit hyperactivity disorder (ADHD)), their use has been  
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7 3 widely debated. Vorhees et al. (1983) showed that Allura red in the diet significantly reduced  
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9 4 reproductive success and organ development, and that it modified the behaviour of young  
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11 5 rats, although it was not possible to confirm the Feingold hypothesis. Generally speaking,  
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13 6 there is a strong feeling that a gap in the data exists regarding the assessment of exposure of  
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15 7 infants and children to Allura red. Often, specific toxicity tests are asked to include data on  
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17 8 the relative sensitivity of this sub-population (Reed, 1997). Studies concerning different age  
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19 9 susceptibilities to carcinogenesis (Hattis et al., 2004), as well as studies on paediatric  
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21 10 pharmacokinetics (Ginsberg et al., 2004), have been carried out. Recently, *in vivo* Comet  
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23 11 studies (Tsuda et al., 2001; Sasaki et al., 2002) excluded a general toxicity of Allura red, but  
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25 12 highlighted specific DNA damage in the colon and in the stomach at the very low Allura red  
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27 13 levels of 10 mg/kg and 100 mg/kg, respectively. Moreover, a new study reported that  
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29 14 exposure to two mixtures of four synthetic colours (mixture A: E102, E124, E110, E122;  
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31 15 mixture B: E110, E122, E104, E129) plus a sodium benzoate preservative in the diet resulted  
32  
33 16 in increased hyperactivity in 3-year-old and 8-9-year-old children in the general population  
34  
35 17 (McCann et al., 2007). The colours, and generally the additives, may have not only the above  
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37 18 mentioned effects, but can increase intolerance and allergy in children (Bourrier, 2006). Other  
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39 19 studies have been carried out to assess the daily intake of some food colourants in several  
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41 20 foodstuffs and non-alcoholic beverages. One study designed a screening method to identify  
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43 21 food colourants used in non-alcoholic beverages, which could potentially be consumed at  
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45 22 levels exceeding the ADIs, by using a tiered approach (Tennant 2008). Other studies  
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47 23 concluded that children were exposed to levels of some food colourants, which exceeded the  
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49 24 ADIs (Rao et al., 2004; Husain et al., 2006).

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60 25 European Parliament and Council Directives 94/35/EC, 94/36/EC and 95/2/EC require

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3 1 each Member State to monitor the consumption and usage of food additives (Report EU,  
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5 2 2001). The European Food Safety Authority (EFSA), specifically the Panel on Food  
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7 3 Additives, Flavourings, Processing Aids and Food Contact materials, following a request  
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9 4 from the European Commission, was asked to assess the results of the McCann study and it  
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11 5 was concluded that this study provided limited evidence that the two different mixtures tested  
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13 6 had a small and statistically significant effect on activity and attention in the selected children,  
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15 7 and that the clinical significance of the observed effects remains unclear. Therefore, the panel  
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17 8 concluded that the results of the McCann study cannot be used as the basis for altering the  
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19 9 ADIs of the respective food colourants or sodium benzoate (EFSA, 2008, 2009).  
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25 10 Recently, in order to harmonise the use of food additives in foods in the community,  
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27 11 the European Parliament and the Council of the European Union adopted Regulation (EC)  
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29 12 No. 128/2008 of 22th December 2008 on food additives. This regulation defines 'colours' as  
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31 13 substances that add or restore colour in a food, and include natural constituents of foods and  
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33 14 natural sources which are normally not consumed as foods as such and not normally used as  
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35 15 characteristic ingredients of food. Preparations obtained from foods and other edible natural  
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37 16 source materials obtained by physical and/or chemical extraction resulting in a selective  
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39 17 extraction of the pigments relative to the nutritive or aromatic constituents are colours within  
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41 18 the meaning of the Regulation'.  
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46 19 Despite this scientific advice, since July 2010, Annex V of Regulation (EC) No.  
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48 20 1333/2008 provides a list of food colours (E 110, E 104, E 122, E 129, E 102, E 124) which  
49  
50 21 must be included on food labels with the following information: 'may have an adverse effect  
51  
52 22 on activity and attention in children'.  
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55 23 Over the last few years, after a period where 100% juices seemed to be very popular  
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57 24 and widespread, the market showed a slowdown in sales of these products and a significant  
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59 25 increase in sales of fruit juice-based drinks (Rossi, 2006; Muraca, 2007). These beverages  
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3 1 allowed both a product innovation and, overall, a significant reduction of fruit and, as a  
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5 2 consequence, a reduction in costs (Rossi, 2006). The beverages sector is one of the most  
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7 3 important food areas where Allura red is widely used, mainly in fruit-based drinks and soft  
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9 4 drinks based on red fruit juices. The success of these beverages comes from the increasing  
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11 5 consumer demand for foods containing anthocyanins due to their health properties (Mazza,  
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13 6 2007; Bitsch et al., 2004; Galvano et al., 2004; Bonina et al., 2005). Many foods are important  
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15 7 sources of anthocyanins (Wu et al., 2006), but in Italy these are immediately associated with  
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17 8 red (blood) oranges (Maccarone et al., 1983, 1985). The chemical composition (Fallico et al.,  
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19 9 1996; Arena et al., 1998; Maccarone et al., 1998; Rapisarda et al., 1998; Arena et al., 2006),  
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21 10 the influence of processing (Arena et al., 2000; Arena et al., 2001a; Arena et al., 2001b), the  
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23 11 recovery of valuable products (Di Mauro et al., 2000; Di Mauro et al., 2002) and the safety  
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25 12 aspects (Fallico et al., 2009) of red oranges have been thoroughly investigated.

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27 13 Risk assessment is based on a deterministic approach, when the calculated risk is  
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29 14 based on a point estimate, or on a probabilistic approach, where both the variability and  
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31 15 uncertainty of input variables are taken into consideration by using probability distributions to  
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33 16 represent the input variables instead of point estimates (Vose, 2000; Spanjersberg et al.,  
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35 17 2007). The probabilistic approach was used by Slob and Pieters (1998) to estimate acceptable  
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37 18 human exposure limits (RfD, ADI, TDI) by using distributions of extrapolation factors instead  
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39 19 of single uncertainty factors, which are more conservative. Besides this, Slob (2006)  
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41 20 published a study on probabilistic dietary exposure assessments, taking into account the  
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43 21 variability in both amount and frequency of consumption. The probabilistic model was also  
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45 22 used (Spanjersberg et al., 2007) for allergen risk assessment, resulting in a more exhaustive  
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47 23 risk assessment than traditional deterministic risk assessments.

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49 24 This paper reports the results of a research project, which investigated the  
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51 25 characteristics of red beverages, both juice-based and soft drinks, in Italy. In particular, the



1 intake and exposure of the Italian population to Allura red from these beverages was  
2 estimated. This assessment was carried out using different modelling intakes.

### 3 **Materials and methods**

#### 4 *Sampling and chemical analysis*

#### 5 *HPLC analyses of colourants*

6 Sample (10 ml) was appropriately diluted with water and filtered through a 0.45µm (Albet).  
7 HPLC analyses were conducted on a Shimadzu ClassVP LC-10ADvp equipped with a SPD-  
8 M10Avp diode array detector. The column was a C18 Omnispher (Varian) (150 mm × 4.6  
9 mm, 5µm) and the chromatographic conditions were in agreement with those of Miniotti et al.  
10 (2007). Each colourant was identified by comparing the retention time, splitting the peak of  
11 colours detected in the sample with the colour standard, and comparing the UV-vis spectra of  
12 the colour standards with those of the samples. The amount of each colour was determined  
13 using an external calibration curve, measuring the signal at 504 nm for E129, 485 nm for  
14 E110 and 516 nm for E122. The purity of the colours was evaluated according to Miniotti et  
15 al. (2007) and Dir CE 2008/128: they were 88.1% for E129, 88.7% for E110 and 86.9% for  
16 E122. Details (uncertainty, limits of detection and precision) of the HPLC method are  
17 reported in Fallico et al. (2010).

#### 18 *Estimation of the consumption of red beverages*

19 For the first two scenarios the consumers characteristics (age, weight), the food categories and  
20 the daily consumption rates of juice-based and soft drinks were those reported in INRAN-  
21 SCAI 2005-06 survey (Leclercq et al. 2009). For all others the estimates of yearly and daily  
22 consumption, as well as the number of consumers, of total red beverages, red fruit juice-based  
23 and red soft drinks, were made using yearly sales data of the 27 selected shops. Personal

1 communication with the managers of the shopping chain was essential in order to obtain both  
2 sets of data.

### 3 *Risk assessment*

4 The estimated daily intake (EDI) of Allura red was made by following the methods described  
5 in Petersen and Barraja (1996) and Douglass and Tennant (1997). A tired approach was used to  
6 estimate the exposure with different scenarios. Details of each scenario are reported in table 1.  
7 First, a MPL (Maximum Permitted Level) (EFSA, 2009) than a SPM (Single Point Method)  
8 (Petersen and Barraja, 1996), were hypothesised. After, as to our knowledge no specific data,  
9 both for consumption and for colorant levels, in Italian red fruit based beverages were  
10 available, more refined scenarios were attempt. This part of the study was carried out with the  
11 collaboration of the Roberto Abate spa company, which owns a chain of more than 40 shops,  
12 each having from 200 to 6000 m<sup>2</sup> of selling area. It represents about the 10% of food retailers  
13 in the metropolitan area of Catania (Italy) (~1.0-1.5 million people). One year selling data  
14 from 27 shops, including all of the largest ones, were used for this study. Moreover, from  
15 these shops, all of the red fruit juice-based and red soft drinks were sampled in triplicate,  
16 excluding 100% juices. A total of seventeen different brands were collected. For these  
17 scenarios (3A, 3B and 4) a probabilistic approach was used. The distribution of the colour  
18 concentration (mg/kg) in non-alcoholic beverages was multiplied with the distribution of  
19 beverages. In order to carry out a safety evaluation of colourant E129 exposure, a risk  
20 assessment model with a probabilistic approach from @Risk software ver.5.5 was used  
21 (Palisade Inc., Newfield, NY, USA). In this kind of analysis the single values are replaced  
22 from distributions of probability; a value selected at random from the food consumption  
23 distribution curve was multiplied by a value drawn at random from the colour concentration  
24 distribution curve; this process was repeated thousands of times until the pre-planned number

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3 1 of repetitions was reached.  
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## 6 2 *Simulations*

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10 3 Simulations were run in order to obtain estimations of the following parameters: the number  
11 4 of customers (total, red beverages, red soft drinks and red juice-based drinks (Table 4); the  
12 5 distribution of red beverage consumption for consumers only (Table 5); yearly and daily  
13 6 intakes (mg) of E129 for each beverage (Tables 6-8). The conditions of each simulation were  
14 7 as follows: number of iterations: 10,000; sampling type: Latin hypercube. For each simulation  
15 8 output the probability distribution between the 5<sup>th</sup> and 95<sup>th</sup> percentiles, the mean, the standard  
16 9 deviation and the uncertainty parameters were recorded. Moreover the best fitting  
17 10 distribution, according to the K-S value, was extrapolated.  
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## 30 11 **Results and discussion**

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34 12 The estimation of daily intake of a substance from a food source needs data concerning the  
35 13 amount of food eaten and the level at which the compound is present in that food. Many  
36 14 methods can be used to obtain these data; the most common refer to the literature and specific  
37 15 surveys of food intake (Douglass and Tennant, 1997). Data concerning the consumption of  
38 16 juices, nectars and soft drinks in Italy in 2009 indicates a consumption of 66 litres per year per  
39 17 capita for carbonated, still and sports/energy drinks and of 15 litres per year per capita for  
40 18 pure juices, nectars and juice-based drinks (Bevitalia, 2010 a,b). However, to the best of our  
41 19 knowledge, specific data concerning the red beverages sector do not exist.  
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53 20 The sales data of the selected 27 shops over a one-year period, covering a total area  
54 21 with 1-1.5 million people, are reported in Table 2. In one year 5,100,630 receipts were given  
55 22 out and 49,856 red beverages were sold with a total of 62,682.8 litres. In particular, the red  
56 23 juice-based drinks accounted for 32,640.8 litres and the red soft drinks for 30,042 litres.  
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3 1 Furthermore, from the collected data it was possible to establish that red juice-based drinks  
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5 2 represented about 5.7% of all juice-based drinks, while red soft drinks represented 1.5% of all  
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7 3 soft drinks sold during this period.  
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10 4 Table 3 shows the results concerning the presence of colourants, the percentages of  
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12 5 colourants and the amounts in litres of the 17 studied beverages. Almost 48% of the red  
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14 6 beverages was made up by the red soft drinks, with one alone representing the 35.2% of the  
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16 7 market. Concerning the 15 red juice-based drinks, they ranged from a minimum of 0.17% to a  
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18 8 maximum of 11.96% of the market. Most of these were referred to as red orange juice (Fallico  
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20 9 et al., 2010), and, concerning their colour, in 7 this was due to the addition of anthocyanin  
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22 10 extracts, but in 8 it was due to the presence of Allura red. The colour of the two red soft  
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24 11 drinks was due to colourants: one contained a mixture of E122 and E110 and the other was  
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26 12 coloured with E129. The amount of colourants ranged from 10.86 mg/l in the first soft drink  
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28 13 (the sum of E122 and E110) to 55.91 mg/l in a juice-based drink (no. 14). It is interesting to  
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30 14 note that all but the soft drinks, which are usually perceived negatively, were very similar to  
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32 15 fruit juices. The contribution of actual fruit juices in these drinks to their colour is very small  
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34 16 or even sometimes negligible (Fallico et al., 2010). Instead, they have significant amounts of  
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36 17 colourants added, which are often quite higher than the amounts in soft drinks. The levels of  
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38 18 added colourants were very high in beverage nos. 5, 11 and 14, with 42.83, 48.51 and 55.91  
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40 19 mg/l of E129, respectively. The first one claimed to have red orange juice properties whilst  
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42 20 the other two claimed to have strong antioxidant activity and berries. It is important to note  
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44 21 that consumption of the colourant depended on both its concentration in the beverages and on  
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46 22 beverage consumption rates. For instance, sample no. 17 represented the 35.2% of the market,  
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48 23 but it contributed 50.6% of Allura red consumption. Beverage nos. 11 and 14 each  
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50 24 represented each less than 3% of the market, but contributed to the 5.8% and 7.5% of Allura  
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52 25 red consumption, respectively.  
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3 1 The average level of colourant in the red juice-based drinks was 29.6 mg/l and the  
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5 2 levels were lognormally distributed, while in the two soft drinks the average value was 20.5  
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7 3 mg/l and the levels were normally distributed (Table 3).  
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10 4 In order to build a more realistic scenario to assess the daily intake of Red Allura from  
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12 5 red beverages, estimation of the number of consumers and a survey of these beverages was a  
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14 6 primary goal of this research. Literature data and the number of receipts were used to estimate  
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16 7 the total number of customers of the shopping centres. In turn, estimation for red drink  
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18 8 products consumers in one year was attempt.  
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22 9 Studies aimed to understand buyers' habits in Italy (Audipress, 2008; TNS, 2010)  
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24 10 highlighted that the majority of consumers, about the 75%, prefer shopping chain.  
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26 11 Considering these as our population, their percentages as well as the frequency of purchases  
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28 12 are reported in Table 4. First, the total number of customers was divided in four categories,  
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30 13 considering the frequency of purchases. Then, considering that the number of receipts for  
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32 14 each category, is given by the number of customers multiplying the number of purchases, the  
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34 15 inverse formula ( $n. \text{ of receipts} / n. \text{ of purchases}$ ) was used to estimate the number of customers  
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36 16 for each category. The number of receipts for each category was the result of a binomial  
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38 17 distribution of the total number of receipts and the related percentage. The total number of  
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40 18 customers was given by adding the customers of all categories. The resulting number was  
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42 19 137370 as average, with a minimum value of 123648 and maximum of 153921 total  
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44 20 customers. The best-fit distribution is a  $\beta$ -General one (Table 4).  
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50 21 From this, taking into account the tendency of customers to buy red beverages, the  
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52 22 incidence of red products on the category and the number of consumers per buyer, were  
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54 23 estimated the number of consumers for red beverages for the two scenarios 3A and 3B,  
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56 24 respectively (Table 4). The two scenarios differ each other for the number of consumers per  
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58 25 buyer (or item). In fact, the scenario 3A hypothesises that each buyer is the consumer of the  
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3 1 item, while the scenario 3B differs between the buyer and the number of consumers. In order  
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5 2 to build scenario 3B during two consecutive days in the largest of the 27 shopping centres, 30  
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7 3 buyers for each category of red beverages, juice based and soft drinks, were asked to say for  
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9 4 who and for how many people they were going to buy the red beverage. Regarding the red  
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11 5 juice based drinks they readily answered “for children” and the most common number of  
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13 6 consumers were one or two, up to three people per item. For this reason was chosen a  
14  
15 7 Triangular distribution (1; 1.37; 3) centred on 1.37 (the average number of children per  
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17 8 female in Italy (ISTAT, 2010)) ranging between one and three. For soft drinks the most  
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19 9 common number of consumers declared per item was 3, ranging between 1 and 4. So, was  
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21 10 chosen a triangular distribution (1; 3; 4).  
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27 11 For scenario 3A the average number of customers buying red soft drinks was  
28  
29 12 estimated to be 585, Log-normal distributed, ranging between 426 and 768 consumers (Table  
30  
31 13 4). While the average number of customers of red juice based drinks was 3571, Log-normal  
32  
33 14 distributed, ranging between 2586 and 4705. For scenario 3B it was estimated 1560 customers  
34  
35 15 for soft drinks,  $\beta$ -general distributed, ranging between 836 and 2360 customers. The estimated  
36  
37 16 number of juice based drinks consumers was 5009, Log-normal distributed, ranging between  
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39 17 3290 and 7210 customers. The sensitivity analysis highlighted that, in scenario 3A, the  
40  
41 18 uncertainty on the estimation of the number of customers was related to the tendency to buy  
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43 19 and to the incidence of the red products; while in scenario 3B it was first related to the  
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45 20 number of consumers per buyer, followed by the two input described above (Table 4).  
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51 21 The yearly (litres) and daily (ml) consumptions of both red soft drinks and red juice-  
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53 22 based drinks were estimated (10000 iterations each) by dividing the litres sold for each  
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55 23 category by the appropriate customer distribution. These results are reported in Table 5. Both  
56  
57 24 consumption distributions were positively skewed, as found for other foods (Zhang et al.,  
58  
59 25 2009). In fact, for both red soft drinks and red juice-based drinks the best fitting distribution  
60

1 was a lognormal one. Data suggest that, in scenario 3A, on average, a consumer drinks 53.1  
2 litres of a red soft beverage per year. However, none of the values between 39.1 and 70.7  
3 litres per year can be excluded (Table 5). This would mean a daily consumption of 145.4 ml  
4 of red soft drinks, ranging between 107.1 and 193.8 ml. These data fully agree with literature,  
5 both with the industrial and food consumption surveys. In fact, of the 65 litres of yearly  
6 consumption per capita, 79% (51.4 litres) must be ascribed to carbonated drinks (Bevitalia,  
7 2010a), while the Italian food consumption survey reports a mean value of 130.9 ml up to 330  
8 ml (95<sup>th</sup> percentile) as daily consumption (Leclercq et al., 2009). Thus, the approach used here  
9 to estimate the number of consumers of red beverages seemed to be appropriate. Moreover,  
10 the consumption of red soft drinks only concerned a small fraction of the population;  
11 however, this was at the same level as all of the other soft drinks. It seems that the  
12 consumption of red soft drinks was not added to that of the other soft drinks, but rather it was  
13 treated as an alternative to them. The yearly estimated consumption of red juice-based drinks,  
14 for the same scenario, was 9.5 l (25.6 ml/day), ranging between a minimum of 7.0 l (19.0  
15 ml/day) and a maximum of 12.5 l (34.3 ml/day). The values reported here are similar to those  
16 in Bevitalia (2010 b) (12.5 litres/year (34.6 ml/day)) for the category of nectars and juice  
17 drinks; they are lower than those, reported as fruit and vegetable juices, found in the Italian  
18 food consumption survey (64.4 ml up to 250 ml at the 95<sup>th</sup> percentile, Leclercq et al. 2009).  
19 Lower values were estimated for scenario 3B (Table 5). In fact, the yearly estimated  
20 consumption of red soft drinks ranged between 12.7 and 35.9 litres, with a most probable  
21 value of 21.3 litres. It means a daily consumption of 58.3 ml ranging between 34.8 and 98.4  
22 ml/day. As concerns the estimation of consumption of red juice based products in scenario 3B  
23 the results are the following: 6.9 litres/year (18.9 ml/day) ranging between 12.4 and 27.2  
24 litres/year. The sensitivity analysis, analogously to the number of consumers estimation, have  
25 shown that in scenario 3A the main uncertainty factors are the tendency to buy and the



1 incidence of the red beverages on the category, while in scenario 3B these factors are  
2 overcome by the number of consumers/buyer.

3 Combining the daily beverages consumption value with the concentration of the  
4 colourant (Scenarios 1 and 2) or the distributions of E129 concentrations with those of  
5 beverage consumption (Scenarios 3-4), the per capita estimation of yearly and daily intakes of  
6 E129 were obtained (Tables 6-8). In the worst case (Scenario 1), considering a consumption  
7 per capita of 64.4 and 130.9 ml/d on the average, 250 and 330 ml/d at the 95th percentile, for  
8 juice based and soft drinks (Leclercq et al., 2009), the average colorant intake was 6.5 mg/day  
9 and 13.0 mg/day for juice-based and soft drinks, respectively. The daily intakes, for  
10 consumers, at the 95<sup>th</sup> percentile were 25.0 and 33 mg/day for juice-based drinks and soft  
11 drinks, respectively (Table 6). The second Scenario took in account the same consumption  
12 rates of Scenario 1, but instead of the Maximum Permitted Level of the colorant (100 mg/l),  
13 were used the average values found in these beverages (Table 3). Under these hypotheses the  
14 intake of colorant was 1.9 and 2.7 mg/day from juice based and soft drinks, respectively. At  
15 the 95<sup>th</sup> percentile the intake was 7.4 and 6.8 mg/day, respectively (Table 6).

16 These intakes, both for Scenario 1 and 2, according to categories of consumers  
17 reported in Leclercq et al., (2009) (children (3-9.9 years), teenagers (10-17.9 years) and adults  
18 (18-64.9 years)), were converted in  $\mu\text{g kgbw}^{-1}\text{day}^{-1}$  (Table 6). These data, analogously to  
19 literature (Tennant 2008, EFSA 2009, EXPOCHI 2010), highlighted that the most exposed  
20 were children because of their high consume/body weight ratio. In fact, for Scenario 1, the  
21 mean exposure values for red juice based and red soft drinks were 247.5 and 498.1  $\mu\text{g kgbw}^{-1}$   
22  $\text{day}^{-1}$ , respectively. At the 95<sup>th</sup> percentile the childrens' exposure was 957.9 and 1264.4  $\mu\text{g}$   
23  $\text{kgbw}^{-1}\text{day}^{-1}$ , respectively. The above data represent the 3.5% and the 7.1% on the mean, up to  
24 13.7% and 18.1% at the 95<sup>th</sup> percentile of the A.D.I. value, for juice based and soft drinks,  
25 respectively. Moreover, comparing the above data to those reported in the EXPOCHI (2010)



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3 1 study (M.P.L. scenario) concerning the total exposure to E129 of Italian Children, 773.7 and  
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5 2 6635.4  $\mu\text{g kgbw}^{-1}\text{day}^{-1}$  as mean value and at the 95<sup>th</sup> percentile, respectively. They represent,  
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8 3 on the average the 32% up to the 64.4% of total intake for juice-based and soft drinks,  
9  
10 4 respectively. Lower values, 14.4% and 19.1% at the 95<sup>th</sup> percentile.

5 Using the average levels of the colorant (Scenario 2) took to a much lower intake  
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15 6 (Table 6). In fact, under this scenario the daily intake per kilogram of body weight for Italian  
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17 7 children was 73.2 and 102.3  $\mu\text{g}$  for juice-based and soft drinks, respectively. It could achieve  
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19 8 283.5 and 260.5  $\mu\text{g}$  at the 95<sup>th</sup> percentile. Representing the 1.0 and 4.1% of the A.D.I. at mean  
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21 9 and the 95<sup>th</sup> percentile for juice-based drinks and 1.5 and 3.7% for soft drinks, respectively.  
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24 10 The comparison with results of the “analytical scenario” reported in EXPOCHI (2010) study  
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26 11 (524.3 and 1257.5  $\mu\text{g kgbw}^{-1}\text{day}^{-1}$  as mean value and at 95<sup>th</sup> percentile, respectively)  
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28 12 highlights that the consumption of these beverages provides the 14.0% of colorant total daily  
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30 13 intake (up to the 22.5%) from juice-based drinks or the 19.5% (up to 20.7%) for soft drinks.  
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34 14 The above scenarios took in account results of surveys not specific for red beverages  
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36 15 and, scenario 1, using the maximum permitted level of the colorant. Moreover, these did not  
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38 16 consider properly the amount of knowledge contained in the Input parameters in terms of  
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40 17 uncertainty and the associated probability. Here follow the results of the E129 daily intake,  
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42 18 using a probabilistic approach, in always more realistic scenarios (3A, 3B and 4) aimed to  
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44 19 manage the uncertainty and variability about the number of consumers as well as the colorant  
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46 20 level in the beverages.  
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50 21 Under the hypotheses of scenarios 3A and 3B, using the distributions of: colorant  
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52 22 levels, the year beverages intake and the appropriate number of consumers, dividing for 365,  
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54 23 was possible to get an estimation of the Red Allura daily intake (Table 6). Under scenario 3A  
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56 24 it was 0.8 mg/d, ranging between 0.2 and 1.7 mg/day for juice-based drinks. The intake of  
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58 25 E129 from red soft drinks was estimated to be 3.0 mg/day, ranging between 0.4 and 5.9  
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1 mg/day. The best fitting distribution for the daily intake was, in both cases, a lognormal one. Under scenario 3B the daily intake from juice-based drinks was 0.6 mg (range 0.2 – 1.3 mg/day); it was 1.2 mg/day from red soft drinks, ranging between 0.1 and 2.6 mg/day.

The above data suggest that the intake ( $\mu\text{g}$ ) per children' kilogram of body weight (Table 6) is 35.5  $\mu\text{g}$ , ranging between 9.3 and 87.4  $\mu\text{g kgbw}^{-1}\text{d}^{-1}$ , from juice-based drinks under Scenario 3A and 29  $\mu\text{g}$ , ranging between 6.6 and 67.7  $\mu\text{g kgbw}^{-1}\text{d}^{-1}$ , under Scenario 3B, respectively. Representing, under the two scenarios, the 0.5% (0.1-1.3%) and the 0.4% (0.1-1.0%) of the A.D.I. value, respectively.

The daily intake of E129 from red soft drinks was 3.0 mg, ranging between 0.4 and 5.9 mg/day, under Scenario 3A, and 1.2 mg, ranging between 0.1 and 2.6 mg/day, under Scenario 3B (Table 6). These mean 130.5  $\mu\text{g kgbw}^{-1}\text{d}^{-1}$  (38.3-310.7  $\mu\text{g kgbw}^{-1}\text{d}^{-1}$ ) under Scenario 3A and 54.0  $\mu\text{g kgbw}^{-1}\text{d}^{-1}$  (12.9-137.8  $\mu\text{g kgbw}^{-1}\text{d}^{-1}$ ) under Scenario 3B. Representing the 1.9% (0.6-4.4%) and the 0.8% (0.2-2.0%) of the A.D.I. value, respectively.

The sensitivity analysis highlighted that most of the uncertainty in the estimation of E129 daily intake in both scenarios was due to the variability of E129 level in red beverages, followed by the tendency to buy and the market incidence for scenario 3A and the number of consumers per buyer, the tendency to buy and the market incidence in scenario 3B, respectively. The number of consumers per buyer becomes very meaningful in the estimation of daily intake from soft drinks under scenario 3B (Table 6).

Although the intakes shown above can be considered as realistic since they were based on both the true E129 concentration distribution and on red beverages consumption, they do not provide information about brand loyalty behaviour. Moreover, this approach did not take into account the contribution of each beverage to the E129 intake. For these reasons, an estimation of E129 intake was made for each beverage and a weighted average were taken (Scenario 4). Similar to other foods (Leclercq et al., 2003; Zhang et al., 2009), the market

1 incidence, calculated using the percentage of litres (Table 3), and the number of consumers  
2 found in scenario 3B, was used to estimate the per capita consumption of each beverage. The  
3 E129 intake values were obtained for each beverage by dividing the mg/year of colourant  
4 (Table 3) by the consumer distribution (Table 4), from which, in turn, the estimated daily  
5 intake was obtained (Table 7).

6 A new average intake (Table 8), both for red juice-based and red soft drinks, was  
7 estimated using the following equation:  $EDI = \sum(EDI_i * L_i/L_T)$ . Where  $EDI_i$  is the estimated  
8 daily intake for a single beverage,  $L_i$  is the litres of the beverage and  $L_T$  are the total litres for  
9 each category of juice-based and soft drinks. For the juice-based drinks (Table 7): three  
10 beverages (11, 14 and 15) showed a daily intake higher or equal to 1 mg/day. For beverage  
11 14, under the brand loyalty scenario, the intake of E129 achieved very high levels: 2.6 mg/day  
12 (3.6 mg/day at the 95<sup>th</sup> percentile). All other juice-based drinks containing E129 (1, 2, 4, 5,  
13 10) showed a daily intake equal or lower than 0.7 mg/day. As mentioned above, beverage no.  
14 5 claims to have red orange juice properties, whereas the other two, 11 and 14, claim to have  
15 very high antioxidant levels and healthy properties of berries. The EDI values for the two soft  
16 drinks (Table 7) were 0.2 and 0.5 mg/day with the highest values of 0.3 and 0.8 mg/day,  
17 respectively. The weighted average daily intake for Allura red showed (Table 8) a lognormal  
18 distribution centred on 0.3 mg/day for red juice-based drinks and 0.4 mg/day for red soft  
19 drinks. The highest values (95% percentile) were 0.5 and 0.6 mg/day, respectively. These data  
20 suggest a children intake of  $14.7 \mu\text{g kg bw}^{-1}\text{d}^{-1}$  ( $6.9\text{-}28.2 \mu\text{g kg bw}^{-1}\text{d}^{-1}$ ) from juice-based  
21 drinks and  $19.8 \mu\text{g kg bw}^{-1}\text{d}^{-1}$  ( $9.1\text{-}37.6 \mu\text{g kg bw}^{-1}\text{d}^{-1}$ ) from soft drinks, respectively.  
22 Representing the 0.2% (0.1-0.4%) of the A.D.I. value for juice-based drinks and the 0.3%  
23 (0.1-0.5%) of the A.D.I. value for soft drinks, respectively. Under this scenario the  
24 uncertainty was due exclusively to the number of consumers.

25 The above data show that the estimation of the E129 daily intake changes significantly

1 with the hypotheses under each scenario. There is a deep difference between the first scenario  
2 and all others. In fact, under scenario 1, the daily intake at the 95<sup>th</sup> percentile of the colourant  
3 from red soft drinks can achieve the 64% of the A.D.I. value for children. The more the  
4 scenario becomes realistic the lower is the anticipated intake of E129, at least from red  
5 beverages. In fact the anticipated daily intake from these beverages is always far from the  
6 A.D.I. value.

7 The more refined becomes the scenario the lower is difference of the colourant intake  
8 from juice-based and soft drinks, respectively: the colourant level in the beverages is the most  
9 important factor affecting its daily intake. The loyalty to a single red beverage, if it has high  
10 E129 levels, can significantly increase the daily intake of the colourant.

11 All of the beverages, with colourant concentrations below 30 mg/l, did not show any  
12 potential risk. Considering the findings reported in risk evaluation processes (EFSA, 2009),  
13 these data clearly suggest that the main risk from the colourants in beverages may be from the  
14 overall levels used. Although the risk assessment process did not call for a modification of the  
15 allowed amounts of E129, the obligation of art. 24 of REG 1333/08 to include the additional  
16 information "*may have an adverse effect on activity and attention of children*", can have, in  
17 practice, the same effect as a ban on these products. A significant reduction in the amount of  
18 E129 allowed in non-alcoholic beverages would help to protect young consumers. Moreover,  
19 the data above highlight that if a risk does exist, it often comes from beverages claiming to  
20 have healthy properties on their labels. Major restrictions from this point of view would be  
21 very useful.

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Table 1 – Description of Input used for the models.

	<b>Method</b>	<b>Input</b>	<b>References</b>
1 2 3 4	1 Maximum Permitted Level (M.P.L.).	<ul style="list-style-type: none"> <li>Consumption of fruit juices, ml/day: <b>130.9; 330</b> (mean; 95th).</li> <li>Consumption of Soft drinks, ml/day: <b>64.4; 250</b> (mean; 95th).</li> <li>Maximum Concentration allowed of E129 in beverages: <b>100 mg/l</b>.</li> </ul>	<ul style="list-style-type: none"> <li>The Italian National Food Consumption Survey 2005-06 (Leclercq et al., 2009).</li> <li>Annex II, REG. EC 1333/08 (L 354/16).</li> </ul>
5 6 7 8	2 Single Point Method (S.P.M.)	<ul style="list-style-type: none"> <li>Consumption of fruit juices, ml/day: <b>130.9; 330</b> (mean; 95th).</li> <li>Mean concentration of E129 in juice based drinks: Table 3.</li> <li>Consumption of Soft drinks ml/day: <b>64.4; 250</b> (mean; 95th).</li> <li>Mean concentration of E129 in soft drinks: Table 3.</li> </ul>	<ul style="list-style-type: none"> <li>The Italian National Food Consumption Survey 2005-06 (Leclercq et al., 2009).</li> </ul>
9 10 11 12 13 14 15 16 17 18 19	3A Probabilistic	<p><b>Red juice based drinks</b></p> <ul style="list-style-type: none"> <li>Consumption of beverages in the selected shops (liter/year) : <b>Table 2</b></li> <li>Distribution of tendency to drink: <b>Uniform (0.35; 0.56)</b>.</li> <li>Distribution of number of buyers: <math>\Sigma</math>(<b>Binomial</b>, (number of receipt; <math>P_i</math>)/Purchases per year).</li> <li>Distribution of market share in the selected shops: <b>Normal (Table 2)</b>.</li> <li>Number of consumers/buyer: <b>1</b>.</li> </ul> <p><b>Soft Drinks</b></p> <ul style="list-style-type: none"> <li>Consumption of Red Soft drinks in the selected shops (liter/year): <b>Table 2</b></li> <li>Distribution of tendency to drink: <b>Uniform (0.218; 0.35)</b>.</li> <li>Distribution of number of buyers: <math>\Sigma</math>(<b>Binomial</b>, (number of receipt; <math>P_i</math>)/Purchases per year).</li> <li>Distribution of market share in the selected shops: <b>Normal Table 2</b>.</li> <li>Number of consumers/buyer: <b>1</b>.</li> </ul>	<ul style="list-style-type: none"> <li>Audipress, 2008.</li> <li>Bevitalia, 2010 a,b.</li> <li>Giovenali, 2008.</li> <li>The Italian National Food Consumption Survey 2005-06 (Leclercq et al., 2009).</li> <li>Arcella and Leclercq 2005.</li> </ul>
20 21 22 23 24 25 26 27 28 29 30	3B Probabilistic	<p><b>Red juice based drinks</b></p> <ul style="list-style-type: none"> <li>Consumption of beverages in the selected shops (liter/year): <b>Table 2</b></li> <li>Distribution of tendency to drink: <b>Uniform (0.35; 0.56)</b>.</li> <li>Distribution of number of buyers: <math>\Sigma</math>(<b>Binomial</b>, (number of receipt; <math>P_i</math>)/Purchases per year).</li> <li>Distribution of market share in the selected shops: <b>Table 2</b>.</li> <li>Distribution of number of consumers: <b>Triang (1, 1.21, 2)</b>.</li> </ul> <p><b>Soft Drinks</b></p> <ul style="list-style-type: none"> <li>Consumption of Soft drinks in the selected shops (liter/year): <b>Table 2</b></li> <li>Distribution of tendency to drink: <b>Uniform (0.218; 0.35)</b>.</li> <li>Distribution of number of buyers: <math>\Sigma</math>(<b>Binomial</b>, (number of receipt; <math>P_i</math>)/Purchases per year).</li> <li>Distribution of market share in the selected shops: <b>Table 2</b></li> <li>Distribution of number of consumers: <b>Triang (1, 3, 4)</b>.</li> </ul>	<ul style="list-style-type: none"> <li>Audipress, 2008.</li> <li>Bevitalia, 2010 a,b.</li> <li>Giovenali, 2008.</li> <li>ISTAT, 2010.</li> <li>The Italian National Food Consumption Survey 2005-06 (Leclercq et al., 2009).</li> <li>Arcella and Leclercq 2005.</li> </ul>
31 32 33 34 35 36	4 Probabilistic	<p><b>Red juice based drinks</b></p> <ul style="list-style-type: none"> <li>Consumption of each red fruit based beverages (liters/year).</li> <li>Distribution of number of consumers: <b>Scenario 3B</b>.</li> </ul> <p><b>Soft Drinks</b></p> <ul style="list-style-type: none"> <li>Consumption of each soft drink in the selected shops (liters/year).</li> <li>Distribution of number of consumers: <b>Scenario 3B</b>.</li> </ul>	<ul style="list-style-type: none"> <li>Leclercq et al., 2003.</li> </ul>

Table 2 – Data from the shopping centers.

No. Of shopping centers	27
No. Of receipts	5100630
No. Of items per year (red beverages)	49856
Litres per year (red beverages)	62682.8
Litres per year (red juice based)	32640.8
Litres per year (red soft drinks)	30042
Incidence of red soft drink	1.5%
Incidence of red juice based drinks	5.7%

Table 3 – Market incidence and colorant data of each beverage.

Beverage no.	Drinks	Litres per year			Colourants				
		Litres	% on Total	% on Category	Colourant	mg/l (st. dev.)	mg/year (st. dev.)	% on Total	% on Category
1		4774	7.62	14.63	E 129	29.30 (0.52)	139878.2 (2482.4)	10.6	25.00
2		1043	1.66	3.20	E 129	23.76 (1.06)	24781.7 (1105.5)	1.9	4.00
3		2536	4.05	7.77	No Colourants				
4		7497	11.96	22.97	E 129	16.71 (0.36)	125274.9 (2699.0)	9.5	22.00
5		862	1.38	2.64	E 129	42.83 (1.79)	36919.5 (1543.1)	2.8	7.00
6		4966	7.92	15.21	No Colourants				
7		729.75	1.16	2.24	No Colourants				
8	<b>Juice based</b>	594	0.95	1.82	No Colourants				
9		786.75	1.26	2.41	No Colourants				
10		1647.75	2.63	5.05	E 129	16.03 (0.22)	26413.4 (362.5)	2.0	5.00
11		1586.25	2.53	4.86	E 129	48.51 (2.44)	76949.0 (3870.4)	5.8	14.00
12		109.5	0.17	0.34	No Colourants				
13		1803	2.88	5.52	No Colourants				
14		1759.8	2.81	5.39	E 129	55.91 (0.44)	98390.4 (774.4)	7.5	17.00
15		1946	3.10	5.96	E 129	17.93 (1.58)	34891.8 (3074.8)	2.6	6.00
<b>LogNormal (29.6; 18.1)</b>									
16	<b>Soft</b>	7977	12.73	27.00	E122 + E110	10.86 (1.80)	86630.2 (4360)	6.6	11.00
17		22065	35.20	73.00	E 129	30.22 (1.49)	666804.3 (32876)	50.6	89.00
<b>Normal (20.5; 10.9)</b>									

Table 4 – Estimated number of red beverages per year.

Total customers of the shopping centres	Input	Frequency of purchases	%	Purchases per year	Number of customers	
		Never	25	-		
		1 per month	13.1	12	Binomial (5100630; 0.131)/12	
		2-3 per month	23.6	Uniform (24; 36)	Binomial (5100630; 0.236)/Uniform (24; 36)	
		4-8 per month	52.8	Uniform (48; 96)	Binomial (5100630; 0.528)/Uniform (48; 96)	
		> 21 per month (daily)	10.5	252	Binomial (5100630; 0.105)/252	
Output	<b>Total customers</b> Mean: 137370; st.dev.:9212; min (5%): 123648; Max (95%): 153921 β-General (1.99; 3.2; 119333; 166273); K-S: 0.01					
Scenario 3A	Input	Total Customers	β-General (1.99; 3.2; 119333; 166273)			
			<b>Red Soft</b>		<b>Red Juice based</b>	
		Tendency to buy	Uniform (0.218; 0.35)		Uniform (0.35; 0.562)	
		Incidence on category	Normal (0.015; 0.0015)		Normal (0.057; 0.0057)	
	Number of consumers per buyer	1		1		
Output	<b>Number of consumers</b> (Uncertainty (rank and regr.))	<b>Mean: 585; st. dev.: 106; min (5%): 426; Max (95%): 768</b> <b>LogNormal (585; 106); K-S: 0.0173</b> (1. tendency to buy: 0.74; 2. Incidence %: 0.55).		<b>Mean: 3571; st. dev.: 654; min (5%): 2586; Max (95%): 4705</b> <b>LogNormal (3571; 654); K-S: 0.013</b> (1. tendency to buy: 0.74; 2. Incidence %: 0.55).		
Scenario 3B	Input	Total Customers	β-General (1.99; 3.2; 119333; 166273)			
			<b>Red Soft</b>		<b>Red Juice based</b>	
		Tendency to buy	Uniform (0.218; 0.35)		Uniform (0.35; 0.562)	
		Incidence on category	Normal (0.015; 0.0015)		Normal (0.057; 0.0057)	
	Number of consumers per buyer	Triang (1; 3; 4)		Triang (1; 1.21; 2)		
Output	<b>Number of consumers</b> (Uncertainty (rank and regr.))	<b>Mean: 1560; st. dev.: 465; min (5%): 836; Max (95%): 2360</b> <b>β-General (4.9; 9.4; 252; 4080); K-S: 0.0074</b> (1. N. of consumers: 0.78; 2. tendency to buy: 0.45; 3. Incidence %: 0.34).		<b>Mean: 5009; st. dev.: 1194; min (5%): 3290; Max (95%): 7210</b> <b>LogNormal (5009; 1194); K-S: 0.0075</b> (1. N. of consumers: 0.64; 2. tendency to buy: 0.57; 3. Incidence %: 0.42).		

Table 5 – Estimation of yearly and daily consumption of red beverages.

		<b>Red soft drinks</b>	<b>Uncertainty (rank and regr.)</b>	<b>Red juice based</b>	<b>Uncertainty (rank and regr.)</b>
<b>Scenario 3A</b>		<b>Yearly (litres)</b>		<b>Yearly (litres)</b>	
	Mean (St. dev.):	<b>53.1 (9.8)</b>		<b>9.5 (1.8)</b>	
	Min (5%):	39.1		7.0	
	Max (95%):	70.7		12.5	
	Best fit:	LogNormal (53.1; 9.8); K-S: 0.0154	1) tendency to buy: -0.73	LogNormal (9.5; 1.8); K-S: 0.0185	1) tendency to buy: -0.73
		<b>Daily (milliliters)</b>	2) Incidence %: - 0.55	<b>Daily (milliliters)</b>	2) Incidence %: - 0.55
	Mean (St. dev.):	<b>145.4 (27)</b>		<b>25.6 (4.8)</b>	
	Min (5%):	107.1		19.0	
	Max (95%):	193.8		34.3	
Best fit:	LogNormal (145.4; 27); K-S: 0.0154		LogNormal (25.6; 4.8); K-S: 0.0185		
<b>Scenario 3B</b>		<b>Yearly (litres)</b>		<b>Yearly (litres)</b>	
	Mean (St. dev.):	<b>21.3 (7.4)</b>		<b>6.9 (1.6)</b>	
	Min (5%):	12.7		3.2	
	Max (95%):	35.9	1) n. of consumers: -0.79	17.7	1) n. of consumers: -0.61
	Best fit:	LogNormal (21.3; 7.4); K-S: 0.0082	2) tendency to buy: -0.38	LogNormal (6.9; 1.6); K-S: 0.0071	2) tendency to buy: -0.58
		<b>Daily (milliliters)</b>	3) Incidence %: - 0.30	<b>Daily (milliliters)</b>	3) Incidence %: - 0.43
	Mean (St. dev.):	<b>58.3 (20.4)</b>		<b>18.9 (4.5)</b>	
	Min (5%):	34.8		12.4	
	Max (95%):	98.4		27.2	
Best fit:	LogNormal (58.3; 20.4); K-S: 0.0082		LogNormal (18.9; 4.5); K-S: 0.0071		



Table 6 – Estimation of E129 Daily Intake from red beverages.

<i>Intake (mg/d)</i>		<i>Intake (µg/d/kg bw)</i>			<i>Uncertainty (rank and regr.)</i>
<b>Scenario 1</b>		<b>3-9.9 years</b>	<b>10-17.9 years</b>	<b>18-64.9 years</b>	
Red juice based	Intake <sub>av.</sub> = 0.0644 * 100 = 6.4	247.5	122.8	92.7	
	Intake <sub>95th</sub> = 0.250 * 100 = 25.0	957.9	475.3	358.7	
Red soft	Intake <sub>av.</sub> = 0.131 * 100 = 13.1	498.1	247.1	186.5	
	Intake <sub>95th</sub> = 0.330 * 100 = 33.0	1264.4	627.4	473.5	
<b>Scenario 2</b>					
Red juice based	Intake <sub>av.</sub> = 0.0644 * 29.6 = 1.9	73.2	36.3	27.4	
	Intake <sub>95th</sub> = 0.250 * 29.6 = 7.4	283.5	140.7	106.2	
Red soft	Intake <sub>av.</sub> = 0.131 * 20.5 = 2.7	102.3	50.8	38.3	
	Intake <sub>95th</sub> = 0.330 * 20.5 = 6.8	260.5	129.3	97.6	
<b>Scenario 3A</b>					
Red juice based	<i>Intake (mg/d) = (LogNormal (29.6; 18.1)*LogNormal (9.5, 1.8)/(LogNormal (3571; 654))/365</i>				
	Intake <sub>av.</sub> = 0.8 (0.5)	35.5 (64.7)	16.3 (12.3)	12.0 (8.0)	1) mg/l of E129: 0.94
	Intake <sub>5th</sub> = 0.2	9.3	4.8	3.7	2) tendency to buy: -0.213
Red soft	<i>Intake (mg/d) = (LogNormal (20.5; 10.8)*LogNormal (53.1, 9.8)/LogNormal (585; 106))/365</i>				
	Intake <sub>av.</sub> = 3.0 (1.7)	130.5 (304.4)	61.2 (42.4)	44.9 (28.2)	1) mg/l of E129: 0.935
	Intake <sub>5th</sub> = 0.4	38.3	19.7	15.0	2) tendency to buy: -0.24
	Intake <sub>95th</sub> = 5.9	310.7	135.1	97.7	3) incidence %: -0.181
<b>Scenario 3B</b>					
Red juice based	<i>Intake (mg/d) = (LogNormal (29.6; 18.1)*LogNormal (6.9, 1.6)/LogNormal (5009; 1194))/365</i>				
	Intake <sub>av.</sub> = 0.6 (0.4)	29.1 (262.3)	12.2 (9.5)	9.0 (6.5)	1) mg/l of E129: 0.91
	Intake <sub>5th</sub> = 0.2	6.6	3.4	2.5	2) n. of consumers: -0.215
	Intake <sub>95th</sub> = 1.3	67.7	29.0	21.1	3) tendency to buy: -0.202
Red soft	<i>Intake (mg/d) = (LogNormal (20.5; 10.8)*LogNormal (21.3, 7.4)/LogNormal (1560; 465))/365</i>				
	Intake <sub>av.</sub> = 1.2 (0.8)	54.0 (100.8)	24.5 (20.6)	17.9 (12.7)	1) mg/l of E129: 0.81
	Intake <sub>5th</sub> = 0.1	12.9	6.7	5.1	2) n. of consumers: -0.417
	Intake <sub>95th</sub> = 2.6	137.8	58.1	41.8	3) tendency to buy: -0.202
					4) Incidence %: - 0.161

Table 7 – Estimation of E129 daily intake from single red beverage.

	<b>% Litres</b>	<b>% Colourants</b>	<b>Consumers</b>	<b>Daily intake (mg)</b>
<b>1</b>				
<i>Min. (5%)</i>			484	0.36
<i>Max. (95%)</i>			1050	0.79
<i>Mean (St. dev.)</i>	<b>14.6</b>	<b>24.8</b>	<b>733 (175)</b>	<b>0.55 (0.13)</b>
<i>Best fit</i>			<b>LogN (484; 175)</b>	<b>LogN (0.55; 0.13)</b>
<b>2</b>				
<i>Min. (5%)</i>			106	0.29
<i>Max. (95%)</i>			229	0.65
<i>Mean (St. dev.)</i>	<b>3.2</b>	<b>4.4</b>	<b>160 (38)</b>	<b>0.45 (0.11)</b>
<i>Best fit</i>			<b>LogN (160; 38)</b>	<b>LogN (0.45; 0.11)</b>
<b>4</b>				
<i>Min. (5%)</i>			759	0.21
<i>Max. (95%)</i>			1649	0.45
<i>Mean (St. dev.)</i>	<b>23.0</b>	<b>22.1</b>	<b>1150 (275)</b>	<b>0.32 (0.08)</b>
<i>Best fit</i>			<b>LogN (1150; 275)</b>	<b>LogN (0.32; 0.08)</b>
<b>5</b>				
<i>Min. (5%)</i>			87	0.53
<i>Max. (95%)</i>			190	1.03
<i>Mean (St. dev.)</i>	<b>2.6</b>	<b>6.6</b>	<b>132 (32)</b>	<b>0.74 (0.20)</b>
<i>Best fit</i>			<b>LogN (132; 32)</b>	<b>LogN (0.74; 0.20)</b>
<b>10</b>				
<i>Min. (5%)</i>			167	0.20
<i>Max. (95%)</i>			362	0.43
<i>Mean (St. dev.)</i>	<b>5.1</b>	<b>4.7</b>	<b>253 (60)</b>	<b>0.30 (0.07)</b>
<i>Best fit</i>			<b>LogN (253; 60)</b>	<b>LogN (0.30; 0.07)</b>
<b>11</b>				
<i>Min. (5%)</i>			161	0.60
<i>Max. (95%)</i>			349	1.32
<i>Mean (St. dev.)</i>	<b>4.9</b>	<b>13.7</b>	<b>243 (58)</b>	<b>0.92 (0.22)</b>
<i>Best fit</i>			<b>LogN (243; 58)</b>	<b>LogN (0.92; 0.22)</b>
<b>14</b>				
<i>Min. (5%)</i>			178	1.85
<i>Max. (95%)</i>			387	3.59
<i>Mean (St. dev.)</i>	<b>5.4</b>	<b>17.5</b>	<b>270 (65)</b>	<b>2.58 (0.55)</b>
<i>Best fit</i>			<b>LogN (270; 65)</b>	<b>LogN (1.55, 0.55; shift 1.02)</b>
<b>15</b>				
<i>Min. (5%)</i>			83	0.70
<i>Max. (95%)</i>			161	1.52
<i>Mean (St. dev.)</i>	<b>6.0</b>	<b>6.2</b>	<b>121 (24)</b>	<b>1.06 (0.25)</b>
<i>Best fit</i>			<b>LogN (121; 24)</b>	<b>LogN (1.06; 0.25)</b>
<b>16</b>				
<i>Min. (5%)</i>			878	0.11
<i>Max. (95%)</i>			1906	0.29
<i>Mean (St. dev.)</i>	<b>26.6</b>	<b>11.5</b>	<b>1330 (318)</b>	<b>0.19 (0.06)</b>
<i>Best fit</i>			<b>LogN (1330; 318)</b>	<b>LogN (0.19; 0.06)</b>
<b>17</b>				
<i>Min. (5%)</i>			2428	0.34
<i>Max. (95%)</i>			5272	0.76
<i>Mean (St. dev.)</i>	<b>73.4</b>	<b>88.5</b>	<b>3679 (879)</b>	<b>0.52 (0.13)</b>
<i>Best fit</i>			<b>LogN (3679; 879)</b>	<b>LogN (0.52; 0.13)</b>

Uncertainty: N. of consumers (regr.> - 0.90)

Table 8 – Weighted estimation of E129 daily intake from red beverages (scenario 4).

<i>Intake (mg/d)</i>	<i>Intake (µg/d/kg bw)</i>			
	<i>3-9.9 years</i>	<i>10-17.9 years</i>	<i>18-64.9 years</i>	
<b><i>Red juices based drinks</i></b>				
<b><i>Mean (St. dev.)</i></b>	<b><i>0.34 (0.09)</i></b>	<b><i>14.7 (34.9)</i></b>	<b><i>6.7 (2.8)</i></b>	<b><i>4.9 (1.7)</i></b>
<b><i>Min. (5%)</i></b>	<i>0.22</i>	<i>6.9</i>	<i>3.7</i>	<i>2.8</i>
<b><i>Max. (95%)</i></b>	<i>0.50</i>	<i>28.2</i>	<i>11.7</i>	<i>8.0</i>
<b><i>Best fit</i></b>	LogNormal (0.34; 0.09) K-S: 0.007			
<b><i>Red soft drinks</i></b>				
<b><i>Mean (St. dev.)</i></b>	<b><i>0.44 (0.11)</i></b>	<b><i>19.8 (53.3)</i></b>	<b><i>9.0 (5.2)</i></b>	<b><i>6.6 (2.3)</i></b>
<b><i>Min. (5%)</i></b>	<i>0.28</i>	<i>9.1</i>	<i>4.8</i>	<i>3.8</i>
<b><i>Max. (95%)</i></b>	<i>0.63</i>	<i>37.6</i>	<i>15.3</i>	<i>10.7</i>
<b><i>Best fit</i></b>	LogNormal (0.44; 0.11); K-S: 0.003			

*Uncertainty: N. of consumers (regr.> - 0.9).*