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SCIENTIFIC OPINION

Scientific Opinion on the re-evaluation of benzoic acid (E 210), sodium benzoate (E 211), potassium benzoate (E 212) and calcium benzoate (E 213) as food additives[1]

EFSA Panel on Food Additives and Nutrient Sources (ANS)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to deliver a scientific opinion re-evaluating benzoic acid (E 210), sodium benzoate (E 211), potassium benzoate (E 212) and calcium benzoate (E 213) when used as food additives. Benzoic acid and its sodium and potassium salts are rapidly absorbed after oral administration. The Panel considered that the absorption, distribution, metabolism and excretion of calcium benzoate will be similar to sodium or potassium salt and, therefore, read-across between the salts was possible. The results of short-term and subchronic studies on benzoic acid and its salts indicate that their toxicity is low. The Panel considered that the use of benzoic acid and its sodium and potassium salts as food additives does not raise a concern with respect to genotoxicity and, based on read-across, also considered that this conclusion is applicable for calcium benzoate. Moreover, the Panel noted that the available data did not indicate any carcinogenic potential. A four-generation reproductive toxicity study with benzoic acid in the diet in rats was considered by the Panel as the pivotal study and a no observed adverse effect level of 500 mg benzoic acid/kg body weight (bw) per day, the highest dose tested, was identified. From the aforementioned studies, the Panel derived an acceptable daily intake (ADI) of 5 mg/kg bw per day (expressed as benzoic acid) using an uncertainty factor of 100. Taking into account food categories for which direct addition of benzoic acid-benzoates is authorised, the group ADI was exceeded in the *brand-loyal scenario* in particular for toddlers and children consuming on a regular basis flavoured drinks. Considering additional exposure due to carry-over, the intake could be increased by up to two to three fold for all high-level consumers compared to the previous scenario with only direct addition to food. This results in exceedance of the group ADI in toddlers and children for the non-brand-loyal scenario. The main food categories contributing to this exceedance were unprocessed fruits and vegetables and flavoured drinks.

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[1] On request from European Commission, Question Nos EFSA-Q-2011-00001, 2011-00002, 2011-00003 and 2011-00004, adopted on 8 March 2016.

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KEY WORDS

food additive, benzoic acid, E 210, CAS No 65-85-0, sodium benzoate, E 211, CAS No 532-31-1, potassium benzoate, E 212, CAS No 582-25-2, calcium benzoate, E 213, CAS No 2090-05-3

SUMMARY

Following a request from the European Commission (EC), the Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to deliver a scientific opinion re-evaluating the safety of benzoic acid (E 210), sodium benzoate (E 211), potassium benzoate (E 212) and calcium benzoate (E 213) when used as food additives.

Benzoic acid, sodium benzoate, potassium benzoate and calcium benzoate (E 210, E 211, E 212 and E 213) are authorised food additives in the European Union (EU) and have previously been evaluated by the EU Scientific Committee on Food (SCF) in 1994 and 2002. The SCF established a group acceptable daily intake (ADI) of 0–5 mg/kg body weight (bw) per day for benzoic acid and its salts, also including benzyl alcohol and related benzyl derivatives used as flavourings. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has evaluated benzoic acid and its salts as food additives on a number of occasions. In 1974, JECFA established a group ADI of 0–5 mg/kg bw for benzoic acid and its salts, expressed as benzoic acid, which was reconfirmed at its most recent evaluation in 1996. JECFA has additionally reviewed benzoic acid as a flavouring substance.

Specific purity criteria have been defined in Commission Regulation (EU) No 231/2012 for benzoic acid and its salts (E 210–213). The Panel noted that the term 'benzoic acid' should be replaced by 'potassium benzoate' or 'calcium benzoate' in the EU specifications for potassium benzoate (E 212) and calcium benzoate (E 213), respectively. In addition, the Panel considered that if metals are used as catalysts in the manufacturing process of benzoic acid as a food additive, the maximum residual level for each metal should be specified in the EU specifications for benzoic acid (E 210). The Panel also considered that the maximum limits for the impurities of toxic elements (lead, mercury and arsenic) in the EC specification for benzoic acid and its salts (E 210–213) should be revised in order to ensure that benzoic acid and its salts (E 210–213) as food additives will not be a significant source of exposure to those toxic elements in food.

The Panel considered that when benzoic acid or its salts and ascorbic acid are used together, considerations should be given to the storage of the soft drinks and the food contact materials to minimise the formation of benzene in beverages.

The available data on absorption, distribution, metabolism and excretion (ADME) in animals and humans indicate that benzoic acid and its sodium and potassium salts are rapidly absorbed, primarily in the proximal part of the gastrointestinal tract, after oral administration. Benzoate is conjugated to glycine to form hippuric acid which is excreted in the urine. No studies appear to have been conducted on calcium benzoate, but the Panel considered that calcium benzoate also dissociates into its constituents calcium and benzoate ions in the small intestine. Consequently, the ADME of this salt will be similar to that of the sodium or potassium salts, despite differences in water solubility. Therefore, the Panel considered read-across between the salts possible.

The results of the available short-term and subchronic studies on benzoic acid and its salts indicated that their toxicity is low, with no marked target organ toxicity, although high intakes of benzoic acid may lead to disturbances in the acid/base balance, and benzoic acid at high doses may interfere with intermediary metabolism

The Panel considered that the use of benzoic acid and its sodium and potassium salts as food additives did not raise a concern with respect to genotoxicity. Based on read-across, the Panel considered that this conclusion is also applicable for calcium benzoate.

The Panel noted that the available carcinogenicity studies on benzoic acid and its salts did not indicate any carcinogenic potential, although they were not conducted in accordance with current test guidelines and had deficiencies both in terms of design and reporting. Overall, given supporting

evidence of lack of carcinogenicity of the related substances benzyl alcohol, benzyl acetate and benzaldehyde as described by JECFA, the Panel considered that the data are sufficient to conclude that benzoic acid and its salts did not raise concern with respect to carcinogenicity.

In a developmental toxicity study in rats with benzoic acid by gavage, a no observed adverse effect level (NOAEL) of 160 mg benzoic acid/kg bw per day was observed for maternal and developmental toxicity The developmental toxicity studies in rats with sodium benzoate in the diet showed a NOAEL of 500 mg/kg bw per day comparable to the NOAEL of the dietary four-generation reproductive toxicity in rats with benzoic acid.

The four-generation reproductive toxicity study with benzoic acid in the diet in rats was considered by the Panel as the pivotal study, as this study was the longest exposure period as compared to the developmental studies. This study showed no effect on growth, fertility, lactation or survival, and provided a NOAEL, for both the parental animals and the offspring, of 500 mg benzoic acid/kg bw per day, the highest dose tested.

The Panel noted that benzoic acid and its salts may enhance hypersensitivity and/or cause skin reactions in sensitive people. Furthermore, anaphylaxis and urticaria have also been observed in sensitive individuals following exposure to benzoic acid and its salts at doses below the ADI. Several studies have shown that subgroups of patients already suffering from atopic dermatitis, pruritus, urticaria or persistent rhinitis may be intolerant even to low doses of benzoate.

The Panel noted the absence of any indication of genotoxicity of benzoic acid and its salts *in vivo*, together with the negative results of limited carcinogenicity studies in rats and mice. The Panel considered that the ADI cannot be derived from a prenatal developmental toxicity study with benzoic acid performed by gavage. The developmental toxicity studies in rats with sodium benzoate in the diet, showed NOAELs of 500 mg/kg bw per day (the highest dose tested) and 1310 mg/kg bw per day, respectively, comparable to or higher than the NOAEL of 500 mg/kg bw per day in the dietary multi-generation reproductive toxicity in rats with benzoic acid. From these reproductive and developmental studies, the Panel derived an ADI of 5 mg/kg bw per day (expressed as benzoic acid) applying an uncertainty factor of 100.

To assess the dietary exposure to benzoic acid-benzoates (E 210–213) from their use as a food additive, the exposure was calculated based on (1) maximum permitted levels (MPLs) set out in the EU legislation (defined as the *regulatory maximum level exposure assessment scenario*) and (2) the reported use levels and analytical data (defined as the *refined exposure assessment scenario*). Dietary exposure through this latter scenario was assessed using two sets of concentration data: reported use levels and analytical data not exceeding the MPLs for food categories for which direct addition of benzoic acid-benzoates is authorised (Annex II to Regulation No 1333/2008); and reported use levels and analytical data not exceeding the MPLs for food categories for which direct addition of benzoic acid-benzoates is authorised and analytical data for food categories which may contain benzoic acid-benzoates due to carry-over and for which data were available.

The exposure estimates in the *regulatory maximum level exposure assessment scenario* exceeded the ADI of 5 mg/kg bw per day for all population groups at the high levels and for toddlers and children also at the mean level.

Considering only food categories for which direct addition of benzoic acid-benzoates to food is authorised, the refined exposure to benzoic acid-benzoates (E 210–213) in toddlers and children, exceeded the ADI of 5 mg/kg bw per day at the high level (95th percentile) in the *refined brand-loyal* exposure estimate, while, for the *non-brand-loyal scenario*, the group ADI was not exceeded in any population group. Considering additional exposure from food categories which may contain benzoic acid-benzoates due to carry-over and for which data were available, in the *refined brand-loyal* exposure scenario, the ADI was exceeded at the high level for all population groups and for infants,

toddlers, children and adolescent at the mean. In the non-*brand-loyal* exposure scenario, the ADI was exceeded only for toddlers and children at the high level; at the mean level, there was no exceedance.

Considering the present toxicological database the Panel identified a NOAEL of 500 mg/kg bw per day and applying an uncertainty factor of 100, the Panel derived a group ADI of 5 mg/kg bw per day, expressed as benzoic acid, for benzoic acid (E 210), sodium benzoate (E 211), potassium benzoate (E 212) and calcium benzoate (E 213).

The Panel concluded that from the use of benzoic acid-benzoates as food additives from direct addition to food, the group ADI was exceeded in the *brand-loyal scenario* for toddlers and children consuming on a regular basis flavoured drinks.

Considering additional exposure from food categories which may contain benzoic acid-benzoates due to carry-over and for which data were available, the Panel concluded that exposure to benzoic acid-benzoates could be increased by up to two to three fold for all high-level consumers compared to the previous scenario for direct addition to food. This results in exceedance of the group ADI in toddlers and children for the *non-brand-loyal scenario*. The main food categories contributing to this exceedance were unprocessed fruits and vegetables and flavoured drinks.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1333/2008[4] of the European Parliament and of the Council on food additives requires that food additives are subject to a safety evaluation by the European Food Safety Authority (EFSA) before they are permitted for use in the European Union. In addition, it is foreseen that food additives must be kept under continuous observation and must be re-evaluated by EFSA.

For this purpose, a programme for the re-evaluation of food additives that were already permitted in the European Union before 20 January 2009 has been set up under Regulation (EU) No 257/2010[5]. This Regulation also foresees that food additives are re-evaluated whenever necessary in the light of changing conditions of use and new scientific information. For efficiency and practical purposes, the re-evaluation should, as far as possible, be conducted by group of food additives according to the main functional class to which they belong.

The order of priorities for the re-evaluation of the currently approved food additives should be set on the basis of the following criteria: the time since the last evaluation of a food additive by the Scientific Committee on Food or by EFSA, the availability of new scientific evidence, the extent of use of a food additive in food and the human exposure to the food additive taking also into account the outcome of the Report from the Commission on Dietary Food Additive Intake in the EU[6] of 2001. The report 'Food additives in Europe 2000',[7] submitted by the Nordic Council of Ministers to the Commission, provides additional information for the prioritisation of additives for re-evaluation. As colours were among the first additives to be evaluated, these food additives should be re-evaluated with the highest priority.

In 2003, the Commission already requested EFSA to start a systematic re-evaluation of authorised food additives. However, as a result of the adoption of Regulation (EU) 257/2010, the 2003 Terms of Reference are replaced by those below.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Commission asks the European Food Safety Authority to re-evaluate the safety of food additives already permitted in the Union before 2009 and to issue scientific opinions on these additives, taking especially into account the priorities, procedure and deadlines that are enshrined in 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.

[4] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, 31.12.2008, p. 16–33.

[5] 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. 19–27.

[6] COM(2001) 542 final.

[7] Food Additives in Europe 2000, Status of safety assessments of food additives presently permitted in the EU, Nordic Council of Ministers, TemaNord 2002, 560.

ASSESSMENT

1. Introduction

The present opinion deals with the re-evaluation of the safety of benzoic acid (E 210), sodium benzoate (E 211), potassium benzoate (E 212) and calcium benzoate (E 213) when used as food additives.

Benzoic acid, sodium benzoate, potassium benzoate and calcium benzoate are authorised as food additives in the EU and were previously evaluated by the EU Scientific Committee on food (SCF) in 1994 and 2002 (SCF, 1994, 2002). The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has evaluated benzoic acid and its salts as food additives on a number of occasions, most recently in 1996 (JECFA, 1996, 1997). JECFA has additionally reviewed benzoic acid as a flavouring substance (JECFA 2001, 2002). Benzoic acid and its salts have also been reviewed by TemaNord (2002).

The Panel was not provided with a newly submitted dossier and based its evaluation on previous evaluations, additional literature that became available since then and the data available following an EFSA public call for scientific data.[8,9,10] To assist in identifying any emerging issue, EFSA has outsourced a contract to deliver an updated literature review on toxicological end-points, dietary exposure and occurrence levels of benzoic acid-benzoates (E 210–213) which covered the period from January 2013 up to the end of 2014.

2. Technical data

2.1. Identity of the substance

2.1.1. Benzoic acid

Benzoic acid (E 210) is an aromatic carboxylic acid, the chemical name according to IUPAC nomenclature rules being benzoic acid. The Chemical Abstracts Service (CAS) Registry number is 65-85-0 and the European Inventory of Existing Commercial chemical Substances (EINECS) number is 200-618-2. The molecular formula for benzoic acid is $C_7H_6O_2$ and the molecular weight is 122.1 g/mol. Its structural formula is given below (Figure 1):

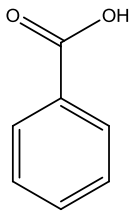

Figure 1: Structural formula of benzoic acid

[8] Call for scientific data on food additives permitted in the EU and belonging to the functional classes of preservatives and antioxidants. Published: 23 November 2009. Available online: http://www.efsa.europa.eu/en/dataclosed/call/ans091123a.htm

[9] Call for approved food additives (sorbates, benzoates and gallates) occurrence data in food and beverages intended for human consumption. Published: 31 May 2012. Available online: http://www.efsa.europa.eu/sites/default/files/consultation/120601.pdf

[10] Call for scientific data on selected food additives permitted in the EU- Extended deadline: 1 September 2014 (batch A), 1 November 2014 (batch B) Available online: http://www.efsa.europa.eu/en/dataclosed/call/140324.htm

The most commonly known synonyms are benzenecarboxylic acid, phenylcarboxylic acid, carboxybenzene and dracylic acid (ChemID Plus, online). Benzoic acid is a white crystalline powder. The melting range is 121.5–123.5˚C (Commission Regulation (EU) No 231/2012[11]). It is slightly soluble in water (2.9 g/l at 20˚C) and freely soluble in ethanol (JECFA, 2006). Benzoic acid is a weak acid with a p*K*a of 4.19 (OECD SIDS, 2001; WHO, 2005) and will be almost completely dissociated at pH 7.

2.1.2. Sodium benzoate

Sodium benzoate (E 211) is the sodium salt of benzoic acid, the chemical name according to IUPAC nomenclature rules being sodium benzoate. The CAS Registry number is 532-32-1 and the EINECS number is 208-534-8. The molecular formula for sodium benzoate is $C_7H_5NaO_2$ and the molecular weight is 144.1 g/mol. Its structural formula is given below (Figure 2):

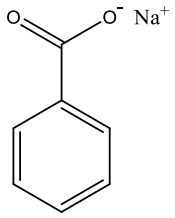

Figure 2: Structural formula of sodium benzoate

The most commonly known synonyms are sodium salt of benzene carboxylic acid, sodium salt of phenyl carboxylic acid and benzoate of soda (ChemID Plus, online). Sodium benzoate is a white, almost odourless, crystalline powder or granule. The compound is freely soluble in water (556 g/l at 20°C) and sparingly soluble in ethanol (OECD SIDS, 2001; Commission Regulation (EU) No 231/2012).

2.1.3. Potassium benzoate

Potassium benzoate (E 212) is the potassium salt of benzoic acid, the chemical name according to IUPAC nomenclature rules being potassium benzoate. The CAS Registry number is 582-25-2 (anhydrous) and the EINECS number is 209-481-3. The molecular formula for anhydrous potassium benzoate is $C_7H_5KO_2$ and the molecular weight is 160.2 g/mol. JECFA specifications refer to both anhydrous and trihydrate forms (JECFA, 2006), while EU specifications refer to the trihydrate only. The structural formula of the anhydrous form is given below (Figure 3):

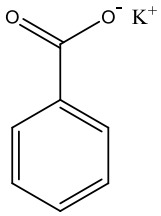

Figure 3: Structural formula of anhydrous potassium benzoate

[11] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council. OJ L 83, 22.3.2012, p. 1–295.

The most commonly known synonyms are potassium salt of benzoic acid, potassium salt of benzenecarboxylic acid and potassium salt of phenylcarboxylic acid (ChemID Plus, online). Potassium benzoate is a white crystalline powder (Commission Regulation (EU) No 231/2012). One gram dissolves in 2 mL of water, in 75 mL ethanol and 50 mL alcohol (90 %) (FCC, 2010-2011).

2.1.4. Calcium benzoate

Calcium benzoate (E 213) is the calcium salt of benzoic acid, the chemical name according to IUPAC nomenclature rules being calcium dibenzoate. The CAS Registry number is 2090-05-3 and the EINECS number is 218-235-4. The molecular formula for calcium benzoate (anhydrous) is $C_{14}H_{10}CaO_4$ and the molecular weight is 282.3 g/mol. EC and JECFA specifications refer to the anhydrous, monohydrate and trihydrate forms. The structural formula of the anhydrous form is given below (Figure 4):

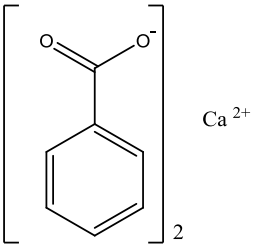

Figure 4: Structural formula of anhydrous calcium benzoate

Synonyms are benzoic acid calcium salt, calcium benzoate and monocalcium benzoate (ChemID Plus, online). Calcium benzoate exists as white or colourless crystals or as a white powder and is sparingly soluble in water (27.2 g/l at 20°C) (Commission Regulation (EU) No 231/2012; JECFA, 2006).

2.2. Specifications

Specifications for benzoic acid and its sodium, potassium and calcium salts have been defined in Commission Regulation (EU) No 231/2012 and by JECFA (2006) (Tables 1–4).

Table 1: Specifications for benzoic acid (E 210) according to Commission Regulation (EU) No 231/2012 and JECFA (2006)

	Commission Regulation (EU) No 231/2012	JECFA (2006)
Definition		
Assay	Not less than 99.5% on anhydrous basis	Not less than 99.5% on dry basis
Description	White crystalline powder	White crystalline solid, usually in the form of scales or needles, having not more than a faint characteristic odour
Identification		
Melting range	121.5–123.5 ^{0}C	121–123 ^{0}C
Sublimation test	Passes test	Place a small amount of the sample in a dry test tube. Wrap the test tube about 4 cm from the bottom with moistened filter paper. Heat the test tube over a low flame. Benzoic acid sublimes and crystals deposit in the colder part of the test tube leaving no residue at the bottom
Test for benzoate	Passes test	Passes test (use 0.1 g of the sample with 0.1 g of calcium carbonate and 5 mL of water)
pH	4 (solution in water)	4 (solution in water)
Solubility	–	Slightly soluble in water, freely soluble in ethanol
Purity		
Loss of drying	Not more than 0.5% (3 h, over sulphuric acid)	Not more than 0.5% (3 h, over sulphuric acid)
Sulphated ash	Not more than 0.05%	Not more than 0.05%
Chlorinated organic compounds	Not more than 0.07% (expressed as chloride corresponding to 0.3% expressed as monochlorobenzoic acid)	Not more than 0.7% (as Cl_2)
Readily oxidisable substances	Add 1.5 mL of sulphuric acid to 100 mL of water, heat to boiling point and add 0.1 N $KMnO_4$ in drops, until the pink colour persists for 30 s. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0.1 N $KMnO_4$ to a pink colour that persists for 15 s. Not more than 0.5 mL should be required	Add 1.5 mL of sulphuric acid to 100 mL of water, heat to boiling point and add 0.1 N $KMnO_4$ in drops, until the pink colour persists for 30 s. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0.1 N $KMnO_4$ to a pink colour that persists for 15 s. Not more than 0.5 mL should be required
Readily carbonisable substances	A cold solution of 0.5 g of benzoic acid in 5 mL of 94.5–95.5% sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0.2 mL of cobalt chloride TSC, 0.3 mL of ferric chloride TSC, 0.1 mL of copper sulphate TSC and 4.4 mL of water	Dissolve 0.5 g of the sample, weighed to the nearest mg, in 5 mL of sulphuric acid TS. The colour produced should not be darker than a light pink ('Matching Fluid Q')
Polycyclic acids	On fractional acidification of a neutralised solution of benzoic acid, the first precipitate must not have a different melting point from that of the benzoic acid	
Arsenic	Not more than 3 mg/kg	–
Lead	Not more than 2 mg/kg	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg	–

Table 2: Specifications for sodium benzoate (E 211) according to Commission Regulation (EU) No 231/2012 and JECFA (2006)

	Commission Regulation (EU) No 231/2012	JECFA (2006)
Definition		
Assay	Not less than 99% of $C_7H_5O_2Na$, after drying at 105 ^{0}C for 4 h	Not less than 99% on dry basis
Description	White, almost odourless, crystalline powder or granules	White, almost odourless, crystalline powder, flakes or granules
Identification		
Solubility	Freely soluble in water, sparingly soluble in ethanol	Freely soluble in water, sparingly soluble in ethanol
Melting range	Melting range of benzoic acid isolated by acidification and not recrystallised (121.5–123.5 ^{0}C) after drying in a sulphuric acid desiccator	–
Test for benzoate	Passes test	Passes test
Test for sodium	Passes test	Passes test
Purity		
Loss of drying	Not more than 1.5% (105 ^{0}C, 4 h)	Not more than 1.5% (105 ^{0}C, 4 h)
Readily oxidisable substances	Add 1.5 mL of sulphuric acid to 100 mL of water, heat to boiling point and add 0.1 N $KMnO_4$ in drops, until the pink colour persists for 30 s. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0.1 N $KMnO_4$ to a pink colour that persists for 15 s. Not more than 0.5 mL should be required	Add 1.5 mL of sulphuric acid to 100 mL of water, heat to boiling point and add 0.1 N $KMnO_4$ in drops, until the pink colour persists for 30 s. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0.1 N $KMnO_4$ to a pink colour that persists for 15 s. Not more than 0.5 mL should be required
Readily carbonisable substances	–	Dissolve 0.5 g of the sample, weighed to the nearest mg, in 5 mL of sulphuric acid TS. The colour produced should not be darker than a light pink ('Matching Fluid Q')
Polycyclic acids	On fractional acidification of a (neutralised) solution of sodium benzoate, the first precipitate must not have a different melting range from that of benzoic acid	
Chlorinated organic compounds	Not more than 0.06% (expressed as chloride corresponding to 0.25% expressed as monochlorobenzoic acid)	Not more than 0.7% (as chlorine)
Acidity and alkalinity	Neutralisation of 1 g of sodium benzoate, in the presence of phenolphthalein, must not require more than 0.25 mL of 0.1 N NaOH or 0.1 N HCl	Dissolve 2 g of the sample, weighed to the nearest mg, in 20 mL of freshly boiled water. Not more than 0.5 mL of either 0.1 N NaOH or 0.1 N HCl should be required for neutralisation, using phenolphthalein TS as indicator
Arsenic	Not more than 3 mg/kg	–
Lead	Not more than 2 mg/kg	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg	–

Table 3: Specifications for potassium benzoate (E 212) according to Commission Regulation (EU) No 231/2012 and JECFA (2006)

	Commission Regulation (EU) No 231/2012	JECFA (2006)
Definition		
Assay	Not less than 99% of $C_7H_5KO_2$, after drying at 105 ^{0}C to constant weight	Not less than 99% on dry basis
Description	White crystalline powder	White crystalline powder
Identification		
Solubility		Freely soluble in water, soluble in ethanol
Melting range	Melting range of benzoic acid isolated by acidification and not recrystallised (121.5–123.5 ^{0}C) after vacuum drying in a sulphuric acid desiccator	-
Test for benzoate	Passes test	Passes test
Test for sodium	Passes test	Passes test
Purity		
Loss of drying	Not more than 26.5% (105 ^{0}C, 4 h)	Not more than 26.5% (105 ^{0}C, 4 h)
Readily oxidisable substances	Add 1.5 mL of sulphuric acid to 100 mL of water, heat to boiling point and add 0.1 N $KMnO_4$ in drops, until the pink colour persists for 30 s. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0.1 N $KMnO_4$ to a pink colour that persists for 15 s. Not more than 0.5 mL should be required	Add 1.5 mL of sulphuric acid to 100 mL of water, heat to boiling point and add 0.1 N $KMnO_4$ in drops, until the pink colour persists for 30 s. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0.1 N $KMnO_4$ to a pink colour that persists for 15 s. Not more than 0.5 mL should be required
Readily carbonisable substances	A cold solution of 0.5 g of benzoic acid in 5 mL of 94.5–95.5% sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0.2 mL of cobalt chloride TSC, 0.3 mL of ferric chloride TSC, 0.1 mL of copper sulphate TSC and 4.4 mL of water	Dissolve 0.5 g of the sample, weighed to the nearest mg, in 5 mL of sulphuric acid TS. The colour produced should not be darker than a light pink ('Matching Fluid Q')
Polycyclic acids	On fractional acidification of a (neutralised) solution of potassium benzoate, the first precipitate must not have a different melting range from that of benzoic acid	
Chlorinated organic compounds	Not more than 0.06% (expressed as chloride corresponding to 0.25% expressed as monochlorobenzoic acid)	Not more than 0.7% (as chlorine)
Acidity and alkalinity	Neutralisation of 1 g of potassium benzoate, in the presence of phenolphthalein, must not require more than 0.25 mL of 0.1 N NaOH or 0.1 N HCl	Dissolve 2 g of the sample, weighed to the nearest mg, in 20 mL of freshly boiled water. Not more than 0.5 mL of either 0.1 N NaOH or 0.1 N HCl should be required for neutralisation, using phenolphthalein TS as indicator
Arsenic	Not more than 3 mg/kg	–
Lead	Not more than 2 mg/kg	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg	–

Table 4: Specifications for calcium benzoate (E 213) according to Commission Regulation (EU) No 231/2012 and JECFA (2006)

	Commission Regulation (EU) No 231/2012	JECFA (2006)
Definition		
Assay	Not less than 99% after drying at 105 ^{0}C	Not less than 99% on dry basis
Description	White or colourless crystals, or white powder	White or colourless crystals, or white powder
Identification		
Solubility		Sparingly soluble in water
Melting range	Melting range of benzoic acid isolated by acidification and not recrystallised (121.5–123.5 ^{0}C) after vacuum drying in a sulphuric acid desiccator	-
Test for benzoate	Passes test	Passes test
Test for sodium	Passes test	Passes test
Purity		
Loss of drying	Not more than 17.5% (105 ^{0}C, to constant weight)	Not more than 17.5% (105 ^{0}C, 4 h)
Water-insoluble matter	Not more than 0.3%	Not more than 0.3%
Readily oxidisable substances	Add 1.5 mL of sulphuric acid to 100 mL of water, heat to boiling point and add 0.1 N $KMnO_4$ in drops, until the pink colour persists for 30 s. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0.1 N $KMnO_4$ to a pink colour that persists for 15 s. Not more than 0.5 mL should be required	Add 1.5 mL of sulphuric acid to 100 mL of water, heat to boiling point and add 0.1 N $KMnO_4$ in drops, until the pink colour persists for 30 s. Dissolve 1 g of the sample, weighed to the nearest mg, in the heated solution, and titrate with 0.1 N $KMnO_4$ to a pink colour that persists for 15 s. Not more than 0.5 mL should be required
Readily carbonisable substances	A cold solution of 0.5 g of benzoic acid in 5 mL of 94.5–95.5% sulphuric acid must not show a stronger colouring than that of a reference liquid containing 0.2 mL of cobalt chloride TSC, 0.3 mL of ferric chloride TSC, 0.1 mL of copper sulphate TSC and 4.4 mL of water	Dissolve 0.5 g of the sample, weighed to the nearest mg, in 5 mL of sulphuric acid TS. The colour produced should not be darker than a light pink ('Matching Fluid Q')
Polycyclic acids	On fractional acidification of a (neutralised) solution of calcium benzoate, the first precipitate must not have a different melting range from that of benzoic acid	
Chlorinated organic compounds	Not more than 0.06 % (expressed as chloride corresponding to 0.25 % expressed as monochlorobenzoic acid)	Not more than 0.7% (as Cl_2)
Acidity and alkalinity	Neutralisation of 1 g of calcium benzoate, in the presence of phenolphthalein, must not require more than 0.25 mL of 0.1 N NaOH or 0.1 N HCl	Dissolve 2 g of the sample, weighed to the nearest mg, in 20 mL of freshly boiled water. Not more than 0.5 mL of either 0.1 N NaOH or 0.1 N HCl should be required for neutralisation, using phenolphthalein TS as indicator
Fluoride	Not more than 10 mg/kg	Not more than 10 mg/kg
Arsenic	Not more than 3 mg/kg	–
Lead	Not more than 2 mg/kg	Not more than 2 mg/kg
Mercury	Not more than 1 mg/kg	–

The Panel noted that in the EU specifications for potassium benzoate (E 212) and calcium benzoate (E 213), 'Readily carbonisable substances' are described as 'a solution of 0.5 g of benzoic acid'; however, the term 'benzoic acid' should be replaced by 'potassium benzoate' or 'calcium benzoate', respectively.

From the general information on the manufacturing process (see Section 2.3), several by-products might be formed (benzaldehyde, benzyl alcohol, benzyl benzoate, benzyl formate, benzyl acetate, biphenyl, methyl biphenyls and phthalic acid) next to residual toluene used as raw material. The Panel considered that a maximum limit for toluene and any by-products produced during the manufacturing process of benzoic acid as a food additive should be included in the EU specifications. In addition, the Panel noted that some catalysts (e.g. cobalt naphthenate) can be used in the manufacturing process. Therefore, the Panel also considered that if metals are used as catalysts in the manufacturing process of benzoic acid as a food additive, the maximum residual level for each metal should be specified in the EU specifications.

The Panel noted that according to the EU specifications for benzoic acid and its salts, impurities of the toxic elements lead, mercury and arsenic are accepted up to a concentration of 2, 1 and 3 mg/kg, respectively. Contamination at those levels would have a significant impact on the exposure to these metals, for which the exposure already are close to the health-based guidance values established by EFSA (EFSA CONTAM Panel 2009, 2010, 2012).

2.3. Manufacturing process

According to Maki and Takeda (2000), benzoic acid is produced, worldwide, by liquid-phase oxidation of toluene with molecular oxygen. Originally the oxidation reaction was carried out at 140 °C and ca. 0.2 MPa with a cobalt naphthenate catalyst (0.1%). Other oil-soluble cobalt salts were also used as catalysts. The purity of toluene is critical because sulphur compounds, nitrogen compounds, phenols and olefins inhibit the oxidation reaction. The oxidation reaction is a free-radical chain process. Peroxides are reaction intermediates. In a typical modern process, the oxidation is conducted at 165 °C and 0.9 MPa. The pressure of the liquid discharged from the reactor is reduced to atmospheric, and unreacted toluene is recovered. Benzoic acid is purified by rectification. The bottom residue is extracted to recover the cobalt catalyst. In the oxidation reaction, several by-products are formed: benzaldehyde, benzyl alcohol and benzyl benzoate. Other esters, including benzyl formate and benzyl acetate, are also present. Biphenyl and methyl biphenyls are formed in smaller amounts. Small amounts of phthalic acid can also be present. For food and pharmaceutical uses, benzoic acid is upgraded by further processing. Sublimation, recrystallisation and neutralisation processes have been proposed. To remove phthalic acid, whose presence is not allowed for food uses, treatment with amines and rinsing is required.

According to industry (Doc. provided to EFSA n. 2), 'production of benzoic acid is by liquid-phase oxidation of toluene in the presence of a cobalt catalyst. Air is the source of oxygen in this free radical reaction. Reaction by-products include benzaldehyde, acetic acid, formic acid and benzyl alcohol. Crude benzoic acid is recovered by distillation' and 'for sodium benzoate production sodium hydroxide (caustic soda) is added to benzoic acid'.

Sodium benzoate is produced by the neutralisation of benzoic acid with sodium hydroxide (Maki and Takedi, 2000; Doc. provided to EFSA n. 2). Potassium benzoate is obtained in high yield by reacting an aromatic hydrocarbon solution of benzoic acid, such as that which is obtained from the toluene oxidation process, with potassium hydroxide preferably in concentrated aqueous solution, thereby precipitating solid potassium benzoate (Hills, 1975). No information was available regarding the manufacture of calcium benzoate; the ANS Panel assumed that it is manufactured similarly, by reaction of benzoic acid with calcium hydroxide, or other calcium salt. The Panel noted that if limestone is the source of calcium carbonate which is used in the production of calcium benzoate,

then calcium benzoate could be contaminated with aluminium. In its opinion on the re-evaluation of calcium carbonate (E 170) as a food additive (EFSA ANS Panel, 2011), the ANS Panel noted that limestone may contain aluminium at concentrations up to 190 mg/kg. Therefore, specifications for the maximum level of aluminium in calcium benzoate may be required.

2.4. Methods of analysis in food

The Panel noted that a vast number of methods have been described for the determination of benzoic acid and benzoate salts in foods. From the available literature it is evident that the decision on the appropriate method of analysis that should be used may depend primarily on the matrix in which the benzoic acid and benzoate salts are present, although there are some analytical methods which appear to apply to all matrices. High-performance liquid chromatography (HPLC) (Mandrou et al. 1998; Pylypiw and Grether 2000, Tfouni and Toledo 2002; Techakriengkrai and Surakarnkul 2007; Mota et al. 2003), ion chromatography (Xie et al. 1999) and capillary electrophoresis (CE) (Han et al. 2008; Wei et al. 2011) techniques were frequently applied for the analysis of preservatives including benzoic acid and benzoate salts in foodstuffs. Gas chromatographic (GC) methods have also been used where sample pre-treatment involving liquid–liquid extraction, anion-exchange clean-up and precipitation of proteins was often needed (De Luca et al. 1995; González et al. 1999; Dong and Wang 2006).

Kokya et al. (2012) have developed a dispersive liquid–liquid micro-extraction (DLLME) method based on the dispersion of tiny droplets of the extraction liquid within aqueous solution which is followed by GC analysis.

The Panel decided to refer to these publications for more details on the method of analysis of benzoic acid and its salts in a specific food item.

More specifically, the simultaneous determination of sorbic and benzoic acids in tomato sauce and ketchup using HPLC was performed by Nour et al. (2009).

A validated HPLC method for the measurement of benzoic acid in soft drinks has been described by Ene and Diacu (2009).

A novel reversed-phase HPLC method for simultaneous determination of potassium sorbate and sodium benzoate in soft drinks was described by Can et al. (2011) and in beverage, vinegar and fruit jam by CE after online pre-concentration by dynamic pH junction by Zhang et al. (2011).

The determination of benzoic acid residue from fruit juice by gas chromatography with mass spectrometry detection technique was described by Sen et al. (2011).

The analysis of nine food additives, including benzoic acid, in red wine by ion-suppression reversed-phase HPLC using trifluoroacetic acid and ammonium acetate as ion-suppressors was described by Zhao et al. (2012). The simultaneous determination of 11 preservatives in foods, including benzoic acid in various foodstuffs by using ultrasound-assisted emulsification micro-extraction followed by gas chromatography-mass spectrometry (GC-MS), was described by Yang et al. (2012).

The evaluation of analytical performance parameters and uncertainty budget of the HPLC method with UV diode array detection on a reverse phase column for traceable determination of benzoic acid in soft drinks was described by Jurcovan et al. (2012).

The quantification for benzoic acid in processed foods using quantitative proton nuclear magnetic resonance spectroscopy was described by Ohtsuki et al. (2012).

The determination of benzoic acid in milk by solid-phase extraction and ion chromatography with conductivity detection was described by Wang et al. (2013).

The determination of five organic acid preservatives, including benzoic acid, in fruits and beverages diluted with a phosphate buffer solution followed by liquid chromatography analysis was described by Lin et al. (2013).

HPLC and liquid chromatography-mass spectrometry/mass spectrometry (LC-MS/MS) methods were developed and validated for the quantitative analysis of sodium benzoate and potassium sorbate in tomato ketchup and orange juice by Gören et al. (2015) and the outcome of a proficiency testing of a number of accredited laboratories was presented.

2.5. Reaction and fate in food

Benzoic acid and its salts are primarily used as food additives (preservatives) in acidified foodstuffs and beverages such as fruit juice, soft drinks and carbonated drinks. Information on the stability of the salts of the benzoic acid in food is very limited, but the benzoate anion is chemically stable, and degradation in food or reactions with food components are not anticipated, with the exception of the reaction with ascorbic acid under certain conditions described below.

2.5.1. Formation of benzene from benzoic acid in the presence of ascorbic acid

Small amounts of benzene can be formed from benzoic acid in the presence of ascorbic acid and transition metal ions like copper(II) and iron(III) (Chang and Ku 1993; Gardner and Lawrence 1993; McNeal et al., 1993). The chemical reaction is catalysed by metal ions, which are present at low concentrations in drinking water. The studies performed by Chang and Ku (1993), Gardner and Lawrence (1993) and McNeal et al. (1993) were summarised by the German Federal Institute for Risk Assessment (BfR, 2005).

In 2006, the European Commission and Member States had become aware of the potential formation of benzene under certain conditions in soft drinks from the reaction of benzoic acid and other ingredients. The issue was considered in the meetings of the Standing Committee of the Food Chain and Animal Health in July and December 2007 (EC, 2007a, b). 'The Committee noted that the reformulation work by the industry appeared to be working given the limited number of samples in which levels of benzene were above 10 µg/L. However it was considered that further monitoring would be useful although no further formal action was considered necessary by the Commission at this time'.

The Norwegian Scientific Committee for Food Safety reported results of analysis of benzene content in 16 soft drinks containing both sodium benzoate and ascorbic acid; 13 samples contained non-detectable levels of benzene and three samples contained benzene at levels between 0.7 and 4.7 mg/L (VKM, 2007).

In Germany, the concentrations of benzene measured in non-alcoholic beverages were below the EU drinking water limit of 1 µg/L while higher concentrations were found in previous years (Steinbrenner et al., 2010).

Therefore, the Panel considered that combining ascorbic acid with benzoic acid in soft drinks could lead to the formation of benzene from benzoic acid. The Panel noted that benzene is a genotoxic carcinogen classified by the International Agency for Research on Cancer as *carcinogenic to humans* (Group 1) (IARC, 2012), that the World Health Organization (WHO) has derived a guideline value

for benzene in drinking water of 10 µg/L (WHO, 2011), that according to the Council Directive 98/83/EC[12] the maximum level of benzene in drinking water is 1 µg/L in the European Union and that the German Federal Institute for Risk Assessment considered that the concentration of benzene in beverages should be as low as reasonably achievable (BfR 2013).

2.6. Case of need and proposed uses

Maximum levels of benzoic acid-benzoates (E 210–213) have been defined in Annex II and Annex III to Regulation (EC) No 1333/2008 on food additives, as amended. These levels are defined by the Panel as maximum permitted levels (MPLs) in this document.

Currently, benzoic acid-benzoates (E 210–213) are authorised as food additives in the EU with MPLs ranging from 150 to 6,000 mg/kg in foods. The Panel noted that benzoic acid-benzoates (E 210–213) are authorised in combination with sorbic acid-sorbates (E 200, 202, 203) and *p*-hydroxybenzoates (PHB; E 214, 215, 218, 219) (Regulation (EC) No 1333/2008).

Table 5 summarises foods that are permitted to contain benzoic acid-benzoates (E 210–213) and the corresponding MPLs as defined in Annex II to Regulation (EC) No 1333/2008.

Table 5: MPLs of benzoic acid-benzoates (E 210–213) in foods according to Annex II to Regulation (EC) No 1333/2008

FCS category number	FCS food category	E -number	MPL (mg/L or mg/kg as appropriate)	Restrictions/exception
01.4	Flavoured fermented milk products including heat-treated products	E 200–213	300[(a),(b)]	Only non-heat treated dairy-based desserts
04.2.2	Fruit and vegetables in vinegar, oil or brine	E 200–213	2,000[(a),(b)]	Only vegetables (excluding olives)
04.2.2	Fruit and vegetables in vinegar, oil or brine	E 210–213	500[(a),(b)]	Only olives and olive-based preparations
04.2.4.1	Fruit and vegetable preparations excluding compote	E 210–213	500[(a),(b)]	Only seaweed preparations, olives and olive-based preparations
04.2.4.1	Fruit and vegetable preparations excluding compote	E 210–213	2,000[(a),(b)]	Only cooked red beet
04.2.5.1	Extra jam and extra jelly as defined by Directive 2001/113/EEC	E 210–213	500[(a),(b)]	Only low-sugar and similar low-calorie or sugar-free products, *mermeladas*
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EEC	E 210–213	500[(a),(b)]	Only low-sugar and similar low-calorie or sugar-free products; *mermeladas*
04.2.5.3	Other similar fruit or vegetable spreads	E 200–213	1,500[(a),(b)]	Only *marmelada*
04.2.5.3	Other similar fruit or vegetable spreads	E 210–213	500[(a),(b)]	Other fruit-based spreads, *mermeladas*
04.2.5.3	Other similar fruit or vegetable spreads	E 210–213	1,000[(a),(b)]	Only *dulce de membrillo*

FCS category number	FCS food category	E -number	MPL (mg/L or mg/kg as appropriate)	Restrictions/exception
05.2	Other confectionery including breath refreshening microsweets	E 200–219	1,500[(a),(b),(c)]	Except candied, crystallised or glacé fruit and vegetables
05.2	Other confectionery including breath refreshening microsweets	E 200–213	1,000[(a),(b)]	Only candied, crystallised or glacé fruit and vegetables
05.3	Chewing gum	E 200–213	1,500[(a),(b)]	
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	E 200–219	1,500[(a),(b),(c)]	
08.3.1	Non-heat-treated processed meat	E 200–219	*Quantum satis* [(a),(b)]	Only surface treatment of dried meat products
08.3.2	Heat-treated processed meat	E 210–213	500[(a),(b)]	Only aspic
09.2	Processed fish and fishery products including molluscs and crustaceans	E 200–213	200[(a),(b)]	Only salted, dried fish
09.2	Processed fish and fishery products including molluscs and crustaceans	E 200–213	2,000[(a),(b)]	Only semi-preserved fish and fisheries products including crustaceans, molluscs, surimi and fish/crustacean paste; cooked crustaceans and molluscs
09.2	Processed fish and fishery products including molluscs and crustaceans	E 200–213	6000	Only cooked *Crangon crangon* and *Crangon vulgaris*
09.2	Processed fish and fishery products including molluscs and crustaceans	E 210–213	1,000[(a),(b)]	Only cooked Crustaceans and molluscs
09.2	Processed fish and fishery products including molluscs and crustaceans	E 210–213	1,500[(a),(b)]	Only cooked shrimps in brine
09.3	Fish roe	E 200–213	2,000[(a),(b)]	Only semi-preserved fish products including fish roe products
10.2	Processed eggs and egg products	E 200–213	5,000[(a),(b)]	Only liquid egg (white, yolk or whole egg)
11.4.1	Table-top sweeteners in liquid form	E 200–219	500[(a),(b)]	Only if the water content higher than 75 %
12.2.2	Seasonings and condiments	E 200–213	1,000[(a),(b)]	
12.4	Mustard	E 200–213	1,000[(a),(b)]	
12.5	Soups and broths	E 200–213	500[(a),(b)]	Only liquid soups and broths (excluding canned)
12.6	Sauces	E 210–213	1,000[(a),(b)]	Only emulsified sauces with a fat content of less than 60%
12.6	Sauces	E 200–213	1,000[(a),(b)]	Only emulsified sauces with a fat content of 60% or more; non-emulsified sauces
12.6	Sauces	E 210–213	500[(a),(b)]	Only emulsified sauces with a fat content of 60% or more
12.7	Salads and savoury-based sandwich spreads	E 200–213	1,500[(a),(b)]	

FCS category number	FCS food category	E -number	MPL (mg/L or mg/kg as appropriate)	Restrictions/exception
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	E 200–213	1,500[(a),(b)]	
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)	E 200–213	1,500[(a),(b)]	
14.1.2	Fruit juices as defined by Council Directive 2001/112/EC and vegetable juices	E 200–213	2,000[(a),(b)]	Only grape juice, unfermented, for sacramental use
14.1.2	Fruit juices as defined by Council Directive 2001/112/EC and vegetable juices	E 210–213	200[(a),(b)]	Only *Sød….saft* and *sødet….saft*
14.1.3	Fruit nectars as defined by Council Directive 2001/112/EC and vegetable nectars and similar products	E 210–213	150[(a),(b)]	Only traditional Swedish and Finnish fruit syrups
14.1.4	Flavoured drinks	E 210–213	150[(a),(b)]	Excluding dairy-based drinks
14.1.5.2	Other	E 200–213	600[(a),(b)]	Only liquid tea concentrates and liquid fruit and herbal infusion concentrates
14.2.1	Beer and malt beverages	E 210–213	200[(a),(b)]	Only alcohol-free beer; beer in kegs containing more than 0.5% added fermentable sugar and/or fruit juices or concentrates
14.2.2	Wine and other products defined by Regulation (EC) No 1234/2007, and alcohol-free counterparts	E 210–213	200[(a),(b)]	Only alcohol-free
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15% of alcohol	E 210–213	200[(a),(b)]	Only alcoholic drinks with less than 15% of alcohol
16	Desserts excluding products covered in category 1, 3 and 4	E 200–213	300[(a),(b)]	Only non-heat-treated dairy-based desserts
16	Desserts excluding products covered in category 1, 3 and 4	E 210–213	500[(a),(b)]	Only *frugtgrød* and *Rote Grütze*
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms	E 200–213	1,000[(a),(b)]	Only when supplied in dried form and containing preparations of vitamin A and of combinations of vitamins A and D
17.2	Food supplements supplied in a liquid form	E 200–213	2,000[(a),(b)]	

FCS, Food Categorisation System (food nomenclature) presented in Annex II to Regulation (EC) No 1333/2008;
E 210–213: benzoic acid-benzoates; E 200–213: sorbic acid-sorbates; benzoic acid-benzoates; E 200–219: sorbic acid-sorbates; benzoic acid-benzoates; PHB.
(a): The additives may be added individually or in combination.
(b): The maximum level is applicable to the sum and the levels are expressed as the free acid.
(c): E 214–219: PHB, maximum 300 mg/kg.

According to Annex II, Part B, benzoic acid may be present in certain fermented products resulting from the fermentation process following good manufacturing practice.

In addition, benzoic acid, sodium benzoate and potassium benzoate (E 210–211–212) are permitted to be used as food additives other than carriers in food additives according to Annex III to Regulation (EC) No 1333/2008 (Part 2). Thus, these three food additives may be used at concentrations up to 1,500 mg/kg in food additives (colour preparations) individually or in combination (with sorbic acid-sorbates) in the preparation resulting in a maximum of 15 mg/kg in the final product expressed as the free acid. Added to that, benzoic acid (E 210) and sodium benzoate (E 211) are also permitted to be used as food additives including carriers in food enzymes according to Annex III to Regulation (EC) No 1333/2008 (Part 3). They may be used in enzyme preparations up to 5,000 mg/kg individually or in combination (expressed as the free acid) resulting in a maximum of 1.7 mg/kg in the final food, except for beverages, where a maximum level of 0.85 mg/L is authorised. The maximum level in enzyme preparation is 12,000 mg/kg in rennet, and thus maximum levels are 5 mg/kg in cheese where rennet has been used and 2.5 mg/L in whey-based beverages where rennet has been used. Finally, according to Annex III, Part 4, to Regulation (EC) No 1333/2008, benzoic acid-benzoates (E 210–213) are authorised as food additives including carriers in food flavourings in all food flavourings up to 1,500 mg/kg (singly or in combination, expressed as free acid).

The Panel is aware that additional usages from the existing authorisation of benzoic acid-benzoates (E 210–213) in applications for colour preparations, enzyme preparations and flavourings may add substantially to the overall exposure to benzoic acid-benzoates. The Panel noted that, from a methodological point of view, it was not feasible to differentiate between all contributions (i.e. uses as food additives and in enzyme/colour preparations and flavouring) in the overall exposure to benzoic acid-benzoates. Therefore, the Panel considered that the use of analytical data in the refined exposure assessment would be the most appropriate approach to capture all uses and to address the overall safety assessment of benzoic acid-benzoates (E 210–213).

2.7. Reported use levels or data on analytical levels of benzoic acid-benzoates (E 210–213) in food

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 might be 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 *quantum satis* (*QS*).

In the framework of Regulation (EC) No 1333/2008 on food additives and of Commission Regulation (EU) No 257/2010[13] regarding the re-evaluation of approved food additives, EFSA issued a public call[14,15] for occurrence data on benzoic acid-benzoates (E 210–213). In response to this public call, Member States submitted analytical data on benzoic acid to EFSA. In addition, information on the use levels of benzoic acid-benzoates (E 210–213) in foods was made available to EFSA by industry.

[13] 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.

[14] Call for scientific data on food additives permitted in the EU and belonging to the functional classes of preservatives and antioxidants. Published: 23 November 2009. Available online: http://www.efsa.europa.eu/en/dataclosed/call/ans091123a.htm

[15] Call for approved food additives (sorbates, benzoates and gallates) occurrence data in food and beverages intended for human consumption. Published: 31 May 2012. Available online: http://www.efsa.europa.eu/sites/default/files/consultation/120601.pdf

2.7.1. Summarised data on reported use levels in foods provided by industry

Information on the actual use levels of benzoic acid-benzoates (E 210–213) in foods was made available to EFSA by FoodDrinkEurope (FDE), the Union of European Soft Drinks Associations (UNESDA) and Mars Chocolate UK. EFSA was provided with data on use levels for 9 out of the 45 food categories in which benzoic acid-benzoates (E 210–213) are authorised.

Appendix A provides data on the use levels in foods as reported by industry.

2.7.1.1. Summarised data extracted from the Mintel GNPD

Mintel's Global New Products Database (GNPD) is an online database which monitors product introductions in consumer packaged goods markets worldwide. It contains information of over 2 million food and beverage products with more than 800,000 of those in the European food market. Mintel started covering European Union's food markets in 1996, having 20 out of its 28 member countries presented in the GNPD.[16]

The Panel noted that, according to the Mintel GNDP database,[17] more than 10,000 products labelled to contain benzoic acid-benzoates (E 210–213) were put on the European market between 1996 and 2015. The usage of benzoic acid-benzoates highly increased in this time period, especially from 2013. The main food categories to which benzoic acid-benzoates are added are carbonated soft drinks, table sauces and fish products.

2.7.2. Summarised data on concentration levels in food submitted by Member States

In total, 39,303 analytical results were reported to EFSA by 12 countries: Slovakia (n = 15,899), Germany (n = 12,722), Denmark (n = 3,209), Austria (n = 2,644), Hungary (n = 1,472), Cyprus (n = 1,679), the Czech Republic (n = 614), Ireland (n = 637), Spain (n = 327), Portugal (n=49), Bulgaria (n = 41) and Luxembourg (n = 10). All analytical results referred to benzoic acid. Foods were sampled between 2000 and 2015 and the majority of them (97%) were analysed in the year of collection. Analytical results of benzoic acid were not quantified (less than the limit of quantification (LOQ)) in 16,943 samples and not detected (less than the limit of detection (LOD)) in 8,398 samples. In total, 13,956 samples were numerical values (quantified). Six results were qualitative (binary results) and gave only indication of presence or absence of benzoic acid. These six samples were therefore removed from the final database. Only 86 of all these samples came from a non-accredited laboratory. The Panel noted that complete information on the methods of analysis (e.g. validation) was not made available to EFSA.

The data were mainly on flavoured drinks (Food Categorisation System (FCS) 14.1.4), fine bakery wares (FCS 07.2) and salads and savoury-based sandwich spreads (FCS 12.7).

In order to include only recent data from the 10-year period, analytical results sampled before 2004 (n = 1603) were excluded from further analyses.

In total, 16,382 samples were classified either at upper level 1 of the FCS (therefore, it was not possible to classify them according to the FCS food categories properly) or in a subgroup other than those authorised and were, therefore, also excluded. This related to the following food categories: dairy products and analogues (FCS 01); fats and oils, and fat emulsions (FCS 02); edible ices (FCS 03); fruit and vegetables (FCS 04); cereals and cereal products (FCS 06); bakery wares (FCS 07);

[16] Missing Bulgaria, Cyprus, Estonia, Latvia, Lithuania, Luxembourg, Malta and Slovenia.
[17] Mintel Global New Products Database (http://www.mintel.com/global-new-products-database) [Accessed: 18 December 2015].

meat (FCS 08); fish and fishery products (FCS 09); sugars, syrups, honey and table-top sweeteners (FCS 11); salts, spices, soups, sauces, salads and protein products (FCS 12); foods intended for particular nutritional uses (FCS 13); non-alcoholic beverages (FCS 14.1); and alcoholic beverages (FCS 14.2).

Data (n = 328) above the MPL set for authorised uses of benzoic acid-benzoates (E 210–213) as food additives were reported mainly in the following food categories: flavoured drinks (FCS 14.1.4) (n = 232) and sauces (FCS 12.6) (n = 35). The Panel considered exposure resulting only from authorised uses with occurrence levels not exceeding the MPLs because results over MPL are part of risk management measures, e.g. non-compliance purpose. For this reason, such analytical results over the MPLs were not considered in the exposure assessment.

Overall, 20,984 out of the 39,303 total analytical results reported for benzoic acid in foods were considered by the Panel for the exposure estimates after discarding the following: the data sampled before 2004 (n = 1,603), the qualitative results (n = 6), the provided analytical results on foods in which the direct addition of benzoic acid-benzoates (E 210–213) is not authorised according to Annex II to Regulation (EC) No 1333/2008 (n= 16,382) and the samples exceeding the MPL (n = 328).

Appendix B shows the analytical results of benzoic acid in foods as reported by Member States (whole set of analytical data reported (Appendix B1) and dataset excluding results above the MPLs (Appendix B2)).

2.8. Information on existing authorisations and evaluations

Benzoic acid (E 210), sodium benzoate (E 211), potassium benzoate (E 212) and calcium benzoate (E 213) are authorised as food additives in the EU in accordance with Annex II and Annex III to Regulation (EC) No 1333/2008 on food additives. Specific purity criteria have been defined in Commission Regulation (EU) No 231/2012.

Benzoic acid, sodium benzoate, potassium benzoate and calcium benzoate (E 210, E 211, E 212 and E 213) have been previously evaluated by the SCF in 1994 and 2002 (SCF, 1994, 2002). JECFA evaluated benzoic acid and its salts as food additives at its sixth, ninth, seventeenth, twenty-seventh and forty-sixth meetings (JECFA, 1962, 1966, 1974a, 1974b, 1983, 1996, 1997). JECFA have additionally reviewed benzoic acid as a flavouring substance (JECFA, 2001, 2002). Benzoic acid and its salts have also been reviewed by TemaNord (2002).

In its 1994 opinion on benzoic acid and its salts, the SCF (1994) set a temporary acceptable daily intake (ADI) of 5 mg/kg body weight (bw) based on an overall no observed adverse effect level (NOAEL) of 500 mg/kg bw per day from long-term and multi-generation studies. Further studies on developmental toxicity and genotoxicity were requested. In 2002, the SCF evaluated additional *in vivo* genotoxicity, reproductive and developmental toxicity studies with benzoic acid, benzyl alcohol, benzyl acetate or sodium benzoate (SCF, 2002). A NOAEL of 500 mg benzyl acetate/kg bw per day was identified by the SCF in a developmental toxicity study in rats, based on effects on fetal weight and this NOAEL was considered by the SCF to be consistent with the NOAELs seen in the reproduction and developmental toxicity studies with the other benzyl derivatives. The SCF (2002) established a group ADI of 5 mg/kg bw per day expressed as benzoic acid for benzoic acid and its salts including benzyl alcohol and related benzyl derivatives used as flavourings.

In 1974, JECFA established a group ADI of 0–5 mg/kg bw for benzoic acid and its salts, expressed as benzoic acid (JECFA, 1974a, b). This ADI was based on the results of a multi-generation study in rats in which a dose level of 1% in the diet, equivalent to 500 mg/kg bw per day, had no effect on growth, fertility, lactation or lifespan (JECFA, 1974b). In 1993, at its 41st meeting, as part of its evaluation of

benzyl acetate as a flavouring agent, JECFA noted the absence of reproduction/teratology studies for the substances in the general group of benzyl derivatives and recommended that benzoic acid, the benzoates, benzyl alcohol, benzaldehyde and benzyl acetate should be re-evaluated to determine whether these or other studies were required (JECFA, 1993). After receipt of new information, a comprehensive review was carried out at its 46th meeting (JECFA, 1996, 1997). JECFA concluded that the data reviewed on the compounds in this group were *sufficient to demonstrate lack of carcinogenic, developmental and reproductive potential* and the group ADI of 0–5 mg/kg bw was maintained (JECFA, 1997), based on the same multi-generation study in rats used in 1974, supported by the results of other reproductive and developmental toxicity studies.

JECFA has evaluated the dietary exposure to benzoates and concluded that *the 95th percentile exposures for the consumers-only group exceeded the upper bound of the ADI in some cases: up to 10.9 mg/kg bw per day for toddlers and young children and up to 7.0 mg/kg bw per day for other children, including adolescents. Additionally, the Committee noted that in some countries, the overall dietary exposure to benzoates for toddlers, young children and adolescents also exceeds the upper bound of the ADI at the high percentiles. Reduction of those exposures exceeding the upper bound of the ADI would require consideration of dietary patterns for both beverage and non-beverage foods containing benzoates and typical/allowed benzoate use levels in those countries* (JECFA, 2015).

In 2008, the EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials (AFC) assessed the results of McCann et al. (2007) study that has concluded that exposure to two mixtures of four synthetic colours plus sodium benzoate, as a preservative, in the diet resulted in increased hyperactivity in 3-year-old and 8- to 9-year-old children in the general population. The AFC Panel concluded that the study *provides limited evidence that the two different mixtures of synthetic colours and sodium benzoate tested had a small and statistically significant effect on activity and attention in some children selected from the general population, although the effects were not observed for all children in all age groups and were not consistent for the two mixtures. The findings may thus be relevant for specific individuals within the population, showing sensitivity to food additives in general or to food colours in particular* (EFSA, 2008).

Benzoic acid (FL-No. 08.021) is included in the Union list of flavourings (Commission Implementing Regulation (EU) No 872/2012[18]). JECFA reviewed benzoic acid as a flavouring substance at its 59th meeting, as one of a group of benzyl derivatives, at which the group ADI of 0–5 mg/kg bw for benzoic acid and related compounds was reconfirmed (JECFA 2001, 2002). EFSA has evaluated benzoic acid as a supporting substance in its opinion on benzyl alcohols, benzaldehydes, a related acetal, benzoic acids and related esters from chemical group 23 and 30 (EFSA CEF Panel, 2011, 2012), in which it was concluded on the basis of the default maximised survey-derived daily intake (MSDI) approach that these substances would not give rise to safety concerns at the estimated levels of intake arising from their use as flavouring substances.

Benzoic acid as a biocide was evaluated by Germany (BAuA, 2011; Assessment report, 2013a, 2013b) and is permitted for this use according to Commission Implementing Regulation (EU) 1035/2013.[19]

Benzoic acid and sodium benzoate have also been evaluated by the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP, 2002) and the Scientific

[18] Commission implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting a list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC. OJ L 267, 2.10.2012, p. 1–161

[19] Commission implementing Regulation (EC) No 1035/2013 of 24 October 2013 approving benzoic acid as an existing active substance for use in biocidal products for products – types 2 and 4. OJ L 283, 25.10.2003, p. 31–34.

Committee on Consumer Products (SCCP, 2005). Additionally, benzoic acid has been reviewed as a pesticide-active substance (EC, 2003).

Benzoic acid and sodium benzoate are included in the European Union Register[20] of feed additives (Regulation (EC) No 1831/2003[21]). Benzoic acid is authorised as technological feed additive (acidity regulator) for pigs for fattening (10,000 mg/kg), as zootechnical additive for weaned piglets (5,000 mg/kg) and pigs for fattening (10,000 mg/kg) and as a chemically defined flavouring (125 mg/kg) (EFSA FEEDAP Panel, 2016).

2.9. Exposure assessment

2.9.1. Food consumption data used for exposure assessment

2.9.1.1. 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 (cf. Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a)). New consumption surveys recently[22] added in the Comprehensive database were also taken into account in this assessment.[23]

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' underreporting and/or misreporting of the consumption amounts. Nevertheless, the EFSA Comprehensive Database represents the best available source of food consumption data across Europe at present.

Food consumption data from the following population groups: infants, toddlers, children, adolescents, adults and the elderly were used for the exposure assessment. For the present assessment, food consumption data were available from 33 different dietary surveys carried out in 19 European countries (Table 6).

[20] Available online: http://ec.europa.eu/food/food/animalnutrition/feedadditives/comm_register_feed_additives_1831-03.pdf
[21] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29–43.
[22] Available online: http://www.efsa.europa.eu/en/press/news/150428.htm
[23] Available online: http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm

Table 6: Population groups considered for the exposure estimates of benzoic acid-benzoates (E 210–213)

Population	Age range	Countries with food consumption surveys covering more than 1 day
Infants	From 4 up to and including 11 months of age	Bulgaria, Denmark, Finland, Germany, Italy, UK
Toddlers	From 12 months up to and including 35 months of age	Belgium, Bulgaria, Denmark, Finland, Germany, Italy, the Netherlands, Spain, UK
Children[(a)]	From 36 months up to and including 9 years of age	Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, Netherlands, Spain, Sweden, UK
Adolescents	From 10 years up to and including 17 years of age	Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Italy, Latvia, Spain, Sweden, UK
Adults	From 18 years up to and including 64 years of age	Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Romania, Spain, Sweden, UK
The elderly[(a)]	From 65 years of age and older	Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Romania, Sweden, UK

(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 to Regulation (EC) No 1333/2008, part D, to perform exposure calculations.

2.9.1.2. Food categories considered for the exposure assessment of benzoic acid-benzoates (E 210–213)

The food categories in which the use of benzoic acid-benzoates (E 210–213) are authorised were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx classification system food codes) at the most detailed level possible (up to FoodEx level 4) (EFSA, 2011b).

Some food categories are not referenced in the EFSA Comprehensive Database and could therefore not be taken into account in the present exposure assessment. This may have resulted in an underestimation of the exposure. The food categories which were not taken into account are described below (in ascending order of the FCS codes):

- 04.2.5.3. Other similar fruit or vegetable spreads, only *dulce de membrillo*, only *marmeladas*
- 05.4. Decorations, coatings and fillings, except fruit-based fillings covered by category 04.2.4
- 08.3.1. Non-heat-treated processed meat, only surface treatment of dried meat products
- 14.1.2. Fruit juices as defined by Council Directive 2001/112/EC and vegetable juices, only grape juice, unfermented, for sacramental use
- 14.1.2. Fruit juices as defined by Council Directive 2001/112/EC and vegetable juices, only *Sød….saft* and *sødet….saft*
- 14.1.3. Fruit nectars as defined by Council Directive 2001/112/EC and vegetable nectars and similar products, only traditional Swedish and Finnish fruit syrups
- 14.1.5.2. Other, only liquid tea concentrates and liquid fruit and herbal infusion concentrates

- 14.2.2. Wine and other products defined by Regulation (EC) No 1234/2007, and alcohol-free counterparts, only alcohol-free
- 16. Desserts excluding products covered in category 1, 3 and 4, only *frugtgrød* and *Rote Grütze*

For the following food categories, the restrictions which apply to the use of benzoic acid-benzoates (E 210–213) could not be taken into account. Therefore, the whole food category was considered for the present exposure estimates. This may have resulted in an overestimation of the exposure:

- 01.4. Flavoured fermented milk products including heat-treated products, only non-heat-treated dairy-based desserts
- 04.2.5.1. Extra jam and extra jelly as defined by Directive 2001/113/EC,[24] only low-sugar and similar low calorie or sugar-free products, *mermeladas*
- 04.2.5.2. Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2001/113/EC, only low-sugar and similar low-calorie or sugar-free products, *mermeladas*
- 09.3. Fish roe, only semi-preserved fish products including fish roe products
- 11.4.1. Table-top sweeteners in liquid form, only if the water content higher than 75%
- 12.6. Sauces, only emulsified sauces with a fat content of less than 60%, or only emulsified sauces with a fat content of 60% or more
- 17.1. Food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms, only when supplied in dried form and containing preparations of vitamin A and of combinations of vitamins A and D and 17.2. Food supplements supplied in a liquid form

For the FCS 09.2. 'Processed fish and fishery products including molluscs and crustaceans', only salted, dried fish, the fish which are usually salted or dried were taken into account (herring, sprat, anchovy, salmon and trout, cod and whiting).

For the FCS 09.2. 'Processed fish and fishery products including molluscs and crustaceans', two restrictions relate to shrimps: 'only cooked *Crangon crangon* and *Crangon vulgaris*' and 'only cooked shrimps in brine'. As shrimps cannot be differentiated in FoodEx, all shrimps were applied the same concentration level.

Overall, 10 food categories were not taken into account in the exposure assessment because they are not referenced in the EFSA Comprehensive Database. Eight food categories were included in the exposure assessment without considering the restrictions/exceptions as set out in Annex II to Regulation No 1333/2008. For the remaining food categories (n = 25), the refinements considering the restrictions/exceptions as set out in Annex II to Regulation No 1333/2008 were applied. Finally, 35 food categories were included in the present assessment of exposure to benzoic acid-benzoates (E 210–213) (Appendix C).

2.9.2. Exposure to benzoic acid-benzoates (E 210–213) from their use as food additives

The Panel estimated chronic exposure to benzoic acid-benzoates (E 210–213) for the following population groups: infants, toddlers, children, adolescents, adults and the elderly. Dietary exposure to benzoic acid-benzoates (E 210–213) was calculated by multiplying benzoic acid-benzoates (E 210–

[24] Council Directive 2001/113/EC of 20 December 2001 relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption. OJ L 10, 12.1.2002, p. 67–72.

213) concentrations for each food category (Appendix C and H) with their respective consumption amount per kilogram of body weight for each individual in the Comprehensive Database. The exposure per food category was subsequently added to derive an individual total exposure per day. These exposure estimates were averaged over the number of survey days, resulting in an individual average exposure per day for the survey period. Dietary surveys with only 1 day per subject were excluded as they are considered as not adequate to assess repeated exposure.

The dietary exposure was assessed for all individuals per survey and per population group, resulting in distributions of individual exposure per survey and population group (Table 6). Based on these distributions, the mean and 95th percentile of exposure were calculated per survey and per population group. High percentile exposure was only calculated for those population groups where the sample size was sufficiently large (> 60 subjects) to allow calculation of the 95th percentile of exposure (EFSA, 2011a). Therefore, in the present assessment, high levels of exposure for infants from Italy and for toddlers from Belgium, Italy and Spain were not included.

Exposure assessment of food additives under re-evaluation was carried out by the ANS Panel based on (1) MPLs as set down in the EU legislation (defined as the *regulatory maximum level exposure assessment scenario*); and (2) the reported use levels and analytical data (defined as the *refined exposure assessment scenario*). For benzoic acid-benzoates (E 210–213), considering the important number of data received, dietary exposure through this latter scenario was assessed using two sets of concentration data:

1. reported use levels and analytical data considering levels not exceeding the MPLs for food categories for which direct addition of benzoic acid-benzoates is authorised (Annex II to Regulation No 1333/2008) (**dataset 1**)

2. reported use levels and analytical data considering levels not exceeding the MPLs for food categories for which direct addition of benzoic acid-benzoates is authorised and analytical data for food categories which may contain benzoic acid-benzoates due to carry-over and for which data were available (**dataset 2**).

2.9.2.1. Regulatory maximum level exposure assessment scenario

The regulatory maximum level exposure assessment scenario is based on the MPLs as set out in Annex II to Regulation No 1333/2008 and listed in Table 5.

The exposure estimates derived following this scenario should be considered as the most conservative considering only the use of benzoic acid-benzoates (E 210–213) in food categories listed in Annex II to Regulation No 1333/2008, as this scenario assumes that the consumer will be continuously (over a lifetime) exposed to benzoic acid-benzoates (E 210–213) present in the food at the MPLs.

2.9.2.2. Refined exposure assessment scenario

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

Appendices C and H summarise the concentration levels of benzoic acid-benzoates (E 210–213) used in the refined exposure assessment scenario. For the two datasets, the Panel calculated two exposure estimates based on different model populations.

(1) The brand-loyal consumer scenario: It was assumed that a consumer is exposed over a long period of time to the food additive present at the maximum reported use/analytical level, for one food category. This exposure estimate is calculated as follows:

   – By combining food consumption with the maximum reported use level or the maximum of the analytical results, whichever is highest, for the main contributing food category at the individual level

   – By using the mean of the typical reported use levels or the mean of analytical results, whichever is highest, for the remaining food categories

(2) The non-brand-loyal consumer scenario: It was assumed that the population is exposed over a long period of time to the food additive present 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, whichever is highest, for all food categories.

Considering the high heterogeneity of the foods within food category 18 'Processed foods not covered by categories 1–17, excluding foods for infants and young children', the brand-loyal scenario is considered not applicable to this food category; therefore, the mean level was used instead of the maximum level also in the brand-loyal scenario.

In the brand-loyal consumer scenario including food categories which may contain benzoic acid-benzoates due to carry-over and for which data were available (**dataset 2**), the 95th percentile level of a food category was used instead of the maximum value in order to minimise the impact of possible outliers. However, for food categories listed in Annex II to Regulation (EC) No 1333/2008, in case the 95th percentile level was below the MPL, the maximum value below the MPL as reported in dataset 1 was used also in dataset 2.

In the refined exposure assessment scenario, the concentration levels considered by the Panel were extracted from the whole dataset received (i.e. reported use levels and analytical results). To consider left-censored analytical data (i.e. analytical results < LOD or < LOQ), 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, 2010) was used. In the present opinion, analytical data below the LOD or LOQ were assigned half of the LOD or LOQ, respectively (middle-bound). Subsequently, per food category, the mean or median, as appropriate, middle-bound concentration was calculated.

For the reported use levels, the mean typical reported use level for each food category was calculated. If the typical use level was reported as a range, then a normal distribution within the food category was assumed and the mean based on the lower and the upper value of the range was calculated.

2.9.2.3. Exposure to benzoic acid-benzoates (E 210–213)

Table 7 summarises the exposure to benzoic acid-benzoates (E 210–213).

Table 7: Summary of exposure to benzoic acid-benzoates (E 210–213) in six population groups from their use as food additives using the regulatory maximum level exposure assessment scenario and refined exposure assessment scenarios (minimum to maximum across the dietary surveys in mg/kg bw per day)

	Infants (4–11 months)	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
Regulatory maximum level exposure assessment scenario						
Mean	0.2–1.5	0.8–8.4	0.8–6.5	0.5–3.6	0.6–3.4	0.4–2.8
High level	0.8–5.5	3.3–13.8	3.6–14.7	1.8–8.7	1.7–7.8	1.2–7.0
Refined estimated exposure scenario considering concentration levels not exceeding the MPLs for food categories listed under Annex II to Regulation No 1333/2008 (dataset 1)						
Brand-loyal scenario						
Mean	0.07–0.8	0.6–3.2	0.7–2.6	0.4–1.9	0.4–2.0	0.2–1.6
High level	0.4–3.2	1.9–7.0	2.7–7.1	1.5–5.3	1.2–5.1	0.6–4.3
Non-brand-loyal scenario						
Mean	0.02–0.3	0.1–1.6	0.3–1.5	0.2–1.1	0.1–0.6	0.04–0.4
High level	0.05–1.7	0.2–4.7	1.1–3.8	0.7–2.6	0.5–1.9	0.2–1.0
Refined estimated exposure scenario considering in addition to dataset 1, analytical data for food categories which may contain benzoic acid-benzoates due to carry-over and for which data were available (dataset 2)						
Brand-loyal scenario						
Mean	5.4–7.2	7.3–10.6	4.6–9.8	2.5–5.2	2.9–4.6	3.0–4.7
High level	10.3–15.9	12.3–19.6	8.0–17.6	4.9–11.0	5.3–8.5	5.4–7.8
Non-brand-loyal scenario						
Mean	1.3–2.1	2.2–3.5	1.5–3.1	0.8–1.9	1.0–1.6	0.8–1.5
High level	2.3–4.1	3.4–6.9	3.1–5.6	1.7–3.7	1.7–3.0	1.3–2.6

From the *regulatory maximum level exposure assessment scenario*, mean exposure to benzoic acid-benzoates (E 210–213) from their use as food additives ranged from 0.2 mg/kg bw per day in infants to 8.4 mg/kg bw per day in toddlers. The high level (95th percentile) of exposure to benzoic acid-benzoates (E 210–213) ranged from 0.8 mg/kg bw per day in infants to 14.7 mg/kg bw per day in children.

From the *refined estimated exposure scenario* considering concentration levels not exceeding the MPLs for food categories listed under Annex II to Regulation No 1333/2008, in the *brand-loyal scenario*, mean exposure to benzoic acid-benzoates (E 210–213) from their use as food additives ranged from 0.07 mg/kg bw per day in infants to 3.2 mg/kg bw per day in toddlers. The high exposure to benzoic acid-benzoates (E 210–213) ranged from 0.4 mg/kg bw per day in infants to 7.1 mg/kg bw per day in children. In the *non-brand-loyal scenario*, mean exposure to benzoic acid-benzoates (E 210–213) from their use as food additives ranged from 0.02 mg/kg bw per day in infants to 1.6 mg/kg bw per day in toddlers. The high exposure to benzoic acid-benzoates (E 210–213) ranged from 0.05 mg/kg bw per day in infants to 4.7 mg/kg bw per day in toddlers.

From the *refined estimated exposure scenario* considering concentration levels not exceeding the MPLs for food categories for which direct addition of benzoic acid-benzoates is authorised and analytical data for food categories which may contain benzoic acid-benzoates due to carry-over and for which data were available, in the *brand-loyal scenario*, mean exposure to benzoic acid-benzoates (E 210–213) ranged from 2.5 mg/kg bw per day in adolescents to 10.6 mg/kg bw per day in toddlers. The high exposure to benzoic acid-benzoates (E 210–213) ranged from 4.9 mg/kg bw per day for adolescents to 19.6 mg/kg bw per day in toddlers. In the *non-brand-loyal scenario*, mean exposure to

benzoic acid-benzoates (E 210–213) ranged from 0.8 mg/kg bw per day for adolescents and the elderly to 3.5 mg/kg bw per day in toddlers. The high exposure to benzoic acid-benzoates (E 210–213) ranged from 1.3 mg/kg bw per day for the elderly to 6.9 mg/kg bw per day in toddlers.

The inclusion of analytical results above the MPLs for the food categories listed under Annex II to Regulation No 1333/2008 did not change the results of the scenario using dataset 2. Appendix L shows the anticipated exposure to benzoic acid- benzoates using this last scenario.

2.9.3. Main food categories contributing to exposure to benzoic acid-benzoates (E 210–213)

From the *regulatory maximum level exposure assessment scenario*, the main contributing food categories to the total mean exposure estimates for infants and toddlers were flavoured fermented milk products. For children and adolescents, the main contributing food categories were confectionary, flavoured drinks and processed fish and fishery products; while, for adults and the elderly, the main contributing food categories were processed fruit and vegetables and sauces.

The main contributing food categories from the *refined estimated exposure scenario* considering concentration levels not exceeding the MPLs for food categories listed under Annex II to Regulation No 1333/2008, in the *brand-loyal scenario* were flavoured fermented milk products and sauces for infants, flavoured fermented milk products, processed fish and fishery products and flavoured drinks; for children, adolescents, adults and the elderly, they were flavoured drinks, sauces and processed fish and fishery products. In the *non-brand-loyal scenario*, the main contributing food categories were flavoured drinks and sauces for all population groups.

The main contributing food categories from the *refined estimated exposure scenario* considering concentration levels not exceeding the MPLs for food categories for which direct addition of benzoic acid-benzoates is allowed and analytical data for food categories which may contain benzoic acid-benzoates due to carry-over and for which data were available, the *brand-loyal scenario*, were unprocessed fruits and vegetables for all population groups. When considering the *non-brand-loyal scenario*, the main contributing food categories were also processed fruits and vegetables and processed foods for infants; for toddlers, they were unprocessed fruits and vegetables, flavoured drinks and processed foods; for children and adolescents, the main contributing food categories were flavoured drinks and unprocessed fruits and vegetables and for adults and the elderly, the main contributing food categories were unprocessed fruits and vegetables and coffee, tea, herbal and fruit infusions, chicory.

The main food categories contributing to the combined exposure to benzoic acid-benzoates (E 210–213) are presented in Appendices E, F, G, J and K.

2.9.4. Uncertainty analysis

Uncertainties in the exposure assessment of benzoic acid-benzoates (E 210–213) have been discussed above. According to the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2006), the sources of uncertainty summarised in Table 8 have been considered.

Table 8: Qualitative evaluation of influence of uncertainties on the dietary exposure estimate

Sources of uncertainty	Direction[(a)]
Consumption data: different methodologies/representativeness/underreporting/misreporting/no portion size standard	+/–
Use of data from food consumption surveys of a few days to estimate long-term (chronic) exposure for high percentiles (95th percentile)	+
Correspondence of reported use levels and analytical data to the food items in the EFSA Comprehensive Food Consumption Database: uncertainties as to which types of food the levels refer to	+/–
Food categories selected for the exposure assessment: exclusion of food categories owing to missing FoodEx linkage (n = 10/45 food categories)	–
Food categories selected for the exposure assessment: inclusion of food categories without considering the restriction/exception (n = 8/45 food categories)	+
Concentration data: levels considered applicable for all items within the entire food category, exposure calculations based on the maximum or mean levels (reported use from industry or analytical data from Member States)	+/–
Regulatory maximum level exposure assessment scenario:	
- food categories which may contain benzoic acid-benzoates due to carry-over not considered	–
- food categories authorised at MPL according to Annex II to Regulation (EC) No 1333/2008	+
Refined exposure scenarios dataset 1:	
- food categories which may contain benzoic acid-benzoates due to carry-over not considered	–
- concentration data: levels considered applicable for all items within the entire food category, exposure calculations based on the maximum reported use levels/p95 of analytical data or mean levels	+/–
- analytical levels above the MPLs were excluded	–
Refined exposure scenarios dataset 2:	
- food categories which may contain benzoic acid-benzoates due to carry-over considered	+/–
- concentration data: levels considered applicable for all items within the entire food category, exposure calculations based on the maximum reported use levels/p95 of analytical data or mean levels	+/–
- analytical levels above the MPLs were excluded	–
Uncertainty in possible national differences in use levels of food categories, concentration data not fully representative of foods on the EU market	+/–

MPL: maximum permitted level.

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

Overall, the Panel considered that the uncertainties identified would generally lead to an overestimate of the real exposure to benzoic acid-benzoates as food additives in European countries for the *regulatory maximum level exposure scenario* as it is considered that benzoates are used in food categories listed in annex II to Regulation No°1333/2008 at the MPL.

For the refined estimated exposure scenario considering concentration levels not exceeding the MPLs for food categories listed under Annex II to Regulation No 1333/2008 (dataset 1), uncertainties would lead to an underestimation of exposure to benzoic acid-benzoates if it is considered the food additive may be present in foods according to Annex III to Regulation No°1333/2008.

3. Biological and toxicological data

3.1. Absorption, distribution, metabolism and excretion (ADME)

The Panel considered that due to its ionisation properties (p*K*a = 4.19), the non-ionised form of benzoic acid will be absorbed by a diffusion process in the acid environment of the stomach. The Panel also considered that sodium benzoate, potassium benzoate and calcium benzoate will dissociate into their constituent sodium, potassium or calcium and benzoate ions in the small intestine. In the case of calcium benzoate, while this salt is of lower solubility than sodium or potassium benzoate, the Panel considered that its solubility would be sufficient to allow dissolution and dissociation to benzoate and calcium ions in the gastrointestinal tract.

3.1.1. *In vitro* studies

The *ex vivo* intestinal absorption of benzoic acid was studied in perfused rat small intestine preparations (Cong et al., 2001). A rapid and uneven absorption was observed among the segmental regions, absorption being highest in the jejunum and slightly lower in the ileum. The absorption pattern paralleled the distribution of the monocarboxylic acid transporter (Mct1), suggesting that this transporter may play a role in the absorption of benzoic acid.

3.1.2. *In vivo* studies

Animal data

As summarised by JECFA (1997, 2001, 2002), SCF (1994), SCCP (2005) and EFSA CEF Panel (2011, 2012), after oral intake, benzoates are rapidly and fully absorbed from the gastrointestinal tract, metabolised primarily in the liver, and excreted in the urine as glycine conjugates of benzoic acid derivatives, mainly as hippuric acid (*N*-benzoyl glycine) but also potentially as benzoic acid, benzoyl glucuronide, 3-hydroxy-3-phenylpropionic acid and ornithic acid. After administration of high doses (> 1000 mg/kg bw), formation of the glycine conjugate is limited by the availability of glycine in the species under study. When glycine is depleted, free benzoic acid may sequester acetyl coenzyme A or be excreted unchanged or as the glucuronic acid conjugate. The Panel noted that there is an inter-species difference in relation to the ability to metabolise benzoic acid in that cats have a limited capacity for glucuronidation, resulting in a greater susceptibility of this species to benzoate toxicity compared to other species (WHO, 2005).

When rats were fed 1.5 % sodium benzoate in the diet, they excreted between 94% and 95% as hippuric acid in the urine. As the benzoate in the diet was increased to 3.75%, between 72% and 73% was excreted as hippuric acid in the urine. Addition of glycine (as a percentage of the diet, between 0.39 and 1.56) to a diet containing 3% sodium benzoate increased the percentage excreted as hippuric acid from between 71% and 73% to 86% and 99%. The only other derivative found in significant amounts in the urine was presumed by the authors to be benzoyl glucuronide (Griffith, 1929).

JECFA 1997 stated that *benzoic acid and hippuric acid are generated as a result of phenylalanine and tyrosine metabolism*, likely based on data reported by Bernhard et al (1955). They reported that when guinea pigs, rabbits and humans were given oral doses of deuterio-DL-phenylalanine (guinea pigs 300–520 mg/kg bw per day, rabbits 50–400 mg/kg bw per day, humans 14–28 mg/kg bw per day) for 6–12 days, 0.03–0.15%, 0.2–2.82% and 0.04–0.14%, respectively, of the label were found in the urine as benzoate. From the results the authors concluded that phenylalanine is a source of benzoate formation. However, the authors also discussed the possibility that intestinal bacteria may have formed benzoate. Current textbook knowledge does not indicate that DL-phenylalanine is metabolised to benzoate. Given that experimental analytical details are poorly reported, the Panel considered the

results of Bernhard et al. (1955) not reliable for this risk assessment and considered that there is no evidence that benzoic acid is generated endogenously from phenylalanine or tyrosine.

In studies on the distribution and elimination of 1-^{14}C-labelled sodium benzoate administered intraperitoneally to rats (50 mg/animal), there was no evidence of bioaccumulation of benzoate (Lang and Lang, 1956). Almost complete excretion occurred in the urine within 1–2 days; less than 1% of radiolabel appeared in the faeces. The authors discussed the possibility that in this study the total detectable radioactivity in the organs was present in the form of the unchanged benzoic acid. The Panel considered that it was more likely that the tissues contain benzoic acid conjugates than the acid itself.

Ring-labelled ^{14}C-benzoic acid was given orally at doses in the range of 1–400 mg/kg bw to various species including primates, pigs, rabbits, rodents, cats, dogs, hedgehogs, bats, birds and reptiles. Hippuric acid was the primary urinary metabolite in most species with 95–100% of ^{14}C-benzoic acid excreted as hippuric acid within 24 h by rodents, rabbits and the capuchin monkey. In rhesus monkey, ^{14}C-benzoic acid at a dose of 20 mg/kg bw was excreted entirely as hippuric acid (Bridges et al., 1970).

Following oral administration of 305 mg ^{14}C-benzoic acid/kg bw to rats, 91–94% of the radioactivity was recovered in the urine of rats after 72 h, whereas only 1–6% was present in the faeces. In addition to benzoic acid (0.4–12.8%), the following metabolites were identified: hippuric acid (70.2–84.2%), benzoyl glucuronide (0.7–1.8%) and 3-hydroxy-3-phenylpropionic acid (0.1–0.2%) (Nutley, 1990).

Human data

In humans, benzoic acid is rapidly absorbed and its metabolites are completely excreted in the urine (Schachter, 1957; Schanker et al., 1958; Barnes, 1959 as referred to by JECFA, 1996). A single healthy male volunteer given 6, 9, 13.9, 34.7, and 69.3 mmol sodium benzoate (864, 1296, 2002, 4996 mg benzoate/day) showed complete elimination in the urine as hippurate and benzoyl glucuronide within 10–14 h (Schachter, 1957).

A dose of l mg ^{14}C-benzoic acid/kg bw was excreted in the urine (99.4–99.7% of total dose) entirely as hippuric acid in two males (Bridges et al., 1970).

As reported by EFSA CEF Panel (2012), male volunteers were given oral doses of 2,000 or 5,000 mg sodium benzoate with or without sequential administration of glycine (Amsel and Levy, 1969). Benzoate was excreted in the urine mainly as hippuric acid and no free benzoic acid was detected in the urine for at least 8 h following the administration of sodium benzoate. Minor amounts of benzoyl glucuronide were detected in the urine at both doses. Sequential administration of glycine with benzoate increased the rate of hippuric acid excretion, indicating that at high dose levels, conjugation with glycine is the rate-limiting step in the formation of hippuric acid.

In order to investigate the types and quantities of beverages that increase urinary hippuric acid excretion, 137 healthy students were recruited and divided into quintiles based on their consumption of non-alcoholic beverages containing benzoic acid. HPLC was used to determine benzoic acid intake from beverages and urinary hippuric acid before, 1.5 and 3 h after consumption of various beverages. The range of benzoic acid in 13 beverages was 0–1.02 mg/mL and the benzoic acid intakes from the beverages for groups 1–5, respectively, were: 0.4 ± 0.5 mg; 23.4 ± 9.8 mg; 55.2 ± 2.3 mg; 76.3 ± 4.0 mg; and 116.5 ± 16.5 mg. Urinary hippuric acid geometric mean concentrations before consuming beverages in the five groups, respectively, were 0.276, 0.270, 0.207, 0.262 and 0.316 g/L; 1.5 hours after beverage consumption, they were 0.210, 0.603, 1.026, 1.066 and 1.688 g/L, and significantly increased ($p < 0.001$) after adjustment for urinary hippuric acid before ingestion. Three hours after beverage consumption, urinary hippuric acid geometric mean concentrations in the five groups, respectively, were 0.160, 0.232, 0.306, 0.287 and 0.337 g/L ($p < 0.001$). The authors concluded that

intakes of more than 100 mg benzoic acid from consumption of beverages containing the preservative at a single occasion may increase urinary hippuric acid significantly (Chang et al., 2000 as referred to by EFSA CEF Panel, 2012).

After administration of oral doses of 40, 80 and 160 mg/kg bw of sodium benzoate to humans, the mean plasma area under the curve (AUC) of benzoic acid increased disproportionately to the dose, 3.7 and 12.0 times greater respectively, for the higher dosages than for the lowest dose indicating saturation of the metabolic pathway, while the mean AUC for hippuric acid was proportional to dose (Kubota et al., 1988; Kubota and Ishizaki, 1991, as reported by EFSA CEF Panel, 2012). Peak plasma concentrations of benzoic acid increased with increasing dose, while peak hippuric acid concentrations did not change. According to the authors, the data suggest that the conjugation with glycine to form hippuric acid is a saturable process in humans.

Overall, the Panel considered that the available ADME data in animals and humans indicate that benzoic acid and its sodium and potassium salts are rapidly absorbed, primarily in the proximal part of the gastrointestinal tract, after oral administration. Benzoate is conjugated to glycine to form hippuric acid which is excreted in the urine. No studies have been conducted on calcium benzoate, but the Panel considered that calcium benzoate will dissociate into its constituents calcium and benzoate ions in the small intestine and that the ADME of this salt will be similar to that of the sodium or potassium benzoate. Therefore, the Panel considered read-across between the salts possible.

3.2. Toxicological data

The Panel noted the conclusions of the SCF (2002) and JECFA (1997), that there is evidence of a common and rapid route of metabolism of the salts of benzoic acid and the three benzyl derivatives benzyl alcohol, benzyl acetate and benzaldehyde to benzoic acid and subsequently to hippuric acid. It is therefore reasonable to assume that studies on any of these substances provide valid information for the assessment of the toxicity of benzoic acid and its salts (JECFA, 1997; SCF, 2002). The Panel agreed with this conclusion.

3.2.1. Acute oral toxicity

In its 1996 evaluation, JECFA (1997) presented the results of acute oral toxicity studies in rats, rabbits and dogs, showing LD_{50} values for benzoic acid or sodium benzoate ranging from 2,000 to 2,700 mg/kg bw. At its 57th meeting JECFA reviewed two further acute oral toxicity studies on benzoic acid in mice, one providing a LD_{50} value of 1,200 mg/kg bw, and the other a value of 2,000 mg/kg bw (JECFA, 2001).

An acute study with benzoic acid by gavage in male and female mice was available to the Panel. This unpublished study (Bio-Research Laboratories, 1979 [Doc. provided to EFSA n. 1]) showed a LD_{50} of 2,250 (1,875–2,700) mg benzoic acid/kg bw.

An acute study by gavage with benzoic acid in albino rats was available to the Panel. This unpublished study (International Research and Development Corporation, 1974 [Doc. provided to EFSA n. 10]) showed a LD_{50} for males of 2,742 mg benzoic acid/kg bw and for females of 2,565 mg benzoic acid/kg bw.

In conclusion, the acute oral toxicity of benzoic acid is low with LD_{50} values in the range of 1,200–2,742 mg/kg bw.

3.2.2. Short-term and subchronic toxicity

3.2.2.1. Mice

In a 3-month study, two groups of 50 male and 50 female cross-bred white mice (no available information on strain) were given benzoic acid by oral gavage at a dose of 80 mg/kg bw per day (Shtenberg and Ignat'ev, 1970). Body weight gain was reduced in the mice receiving 80 mg benzoic acid/kg bw per day compared with controls, although food consumption was similar in the two groups. The highest mortality rate was observed in mice given a combination of benzoic acid and sodium bisulphite (30% survival after 2.5 months compared with 60% in controls); however, mortality was slightly lower in animals given benzoic acid compared with controls. A 5-day period of food restriction at 2.5 months induced 85% mortality as compared to a 56% mortality in the control group. The Panel noted that the mortality in the control group of this study is very high; hence, the results of the study are of limited value.

Sodium benzoate was administered in the diet to four groups of five male and four or five female B6C3F1 (Crj.B6C3F1) mice over a 10-day period in a study primarily designed to investigate the effect of benzoate anion on the liver (Fujitani, 1993). The animals were 5 weeks old at the start of the study. Mice were fed 0, 2.08, 2.50 or 3.0% (equivalent[25] to 0, 3,120, 3,750 and 4,500 mg sodium benzoate/kg bw per day). Investigations included clinical signs of toxicity, body weights, organ weights (selected organs only), blood chemistry and histopathological examination of liver and kidney. One out of five males and two out of five females receiving 4,500 mg/kg bw per day sodium benzoate developed convulsions and the two female mice died on days 5 or 9 respectively of the study. No effect was seen on body weight of mice, but absolute and relative liver weights of male and female mice receiving 4,500 mg/kg bw per day were significantly higher than those of the control group, while relative kidney weight of female mice receiving 4,500 mg/kg bw per day was also increased. Serum cholesterol and phospholipid levels were increased in male mice receiving 4,500 mg/kg bw per day, while serum cholinesterase was increased in male mice receiving 3,750 or 4,500 mg/kg bw per day. Hypertrophy of hepatocytes accompanied by eosinophilic cytoplasm and occasionally single cell necrosis and vacuolation of hepatocytes were seen in liver from all male mice receiving 4,500 mg/kg. A similar effect in females was not mentioned. No treatment-related histopathological effects were apparent in the kidney. The authors concluded that the results observed in male mice suggested a hepatotoxic effect of sodium benzoate and stated that it might be possible that long-term exposure may induce severe damage in the liver. The Panel considered that the results found may also point to an increase in e.g. peroxisome proliferation, which is generally not considered as an adverse effect relevant for humans.

3.2.2.2. Rats

Sodium benzoate was administered in the diet to four groups of six male and six female Fisher (F344/Ducrj) rats over a 10-day period in a study primarily designed to investigate the effect of benzoate anion on the liver (Fujitani, 1993). The animals were 5 weeks old at the start of the study. Rats were fed levels of 0, 1.81, 2.09 or 2.40% sodium benzoate in the diet, equivalent[25] to 1,810, 2,090 and 2,400 mg/kg bw per day, respectively. Investigations included clinical signs of toxicity, body weights, organ weights (selected organs only), blood chemistry and histopathological examination of liver and kidney. One male receiving 2,400 mg/kg bw per day sodium benzoate died on day 8 of the study; no other deaths or clinical signs were observed. Mean body weight of both male and female rats receiving 2,400 mg/kg bw per day only was significantly decreased ($p < 0.05$) compared to controls. Relative liver weights of male rats receiving 2,090 or 2,400 mg/kg bw per day and of female rats receiving 2,400 mg/kg bw per day were significantly higher than controls, and

[25] Calculated by the Panel according to EFSA Scientific Committee (2012).

relative kidney weight of male and female rats receiving 2,400 mg/kg bw per day was also significantly higher than controls. No treatment-related histopathological effects were apparent in the kidney. Serum albumin, total protein and albumin:globulin ratios were significantly increased compared with controls in male rats receiving 2,090 or 2,400 mg/kg bw per day and serum albumin was increased in female rats receiving 2,400 mg/kg bw per day. Serum cholesterol was decreased in male rats receiving 2,400 mg/kg bw per day and in all treated females. Gamma-glutamyl transpeptidase was increased in males receiving 2,400 mg/kg bw per day. There were no other dose-related effects on blood chemistry in treated animals. Livers from male rats receiving 2,400 mg/kg bw per day showed periportal eosinophilic foci accompanied by enlargement of hepatocytes with glassy cytoplasm. The authors concluded that the results observed in male rats suggested a hepatotoxic effect of sodium benzoate and stated that it might be possible that long-term exposure may induce severe damage in the liver.

In a short-term study focusing on haematological parameters, sodium benzoate was administered orally every 48 h for 14 days to four groups of nine male Wistar albino rats at dose levels of 0, 30, 60 and 120 mg/kg bw (assumed by the Panel to be by gavage but not specifically stated) (Ibekwe et al., 2007). The authors reported a significant ($p < 0.05$) and dose-dependent decrease in haemoglobin at all levels of sodium benzoate (30, 60 and 120 mg/kg bw) administration; however, the data to support this were not provided due to an error in the publication resulting in an omission of the table containing haematological results. The authors reported that white blood cell count was also decreased in animals receiving 60 and 120 mg/kg bw (data not provided), although no significant effect was observed for the lowest dose level of 30 mg/kg bw. Plasma levels of sodium, potassium, chloride, bicarbonate ions and total protein were also measured. No treatment-related effects on plasma protein concentration were noted, but plasma levels of sodium and potassium were reported to increase over the period of the study in animals receiving 60 and 120 mg/kg bw/every 2 days. No changes were seen in levels of plasma chloride or bicarbonate ions.

Twenty-eight young rats (62–70 g at start of study, sex and strain not specified) were given a diet containing 5% sodium benzoate (equivalent[25] to 6,000 mg/kg bw per day) for 3 weeks (Kieckebusch and Lang, 1960). Nineteen animals died within 2 weeks and the remainder died in the third week. Food consumption was significantly reduced, and most animals developed severe diarrhoea. The changes seen at autopsy were haemorrhage in the gut and nasal blood crust. Five adult rats on a similar diet died within 5 weeks with severe weight loss.

Three groups of adult male Sprague-Dawley rats were given sodium benzoate at a dietary level of 0 (10 animals) or 5% sodium benzoate (equivalent[25] to 6,000 mg/kg bw per day) (15 animals) or 5% sodium benzoate plus 1% glycine (15 animals) for 3 weeks (Kowalewski, 1960). Supplementary glycine corrected the potassium and phospholipid deficiencies. The body weights of animals fed sodium benzoate were reduced, but less so when 1% glycine was added. The total cholesterol content of the liver was unaffected by treatment with benzoate, but the level of liver phospholipids was significantly reduced. The potassium concentration of skeletal muscle was also low in rats on the 5% sodium benzoate diet.

Groups of five male and five female Sherman rats were fed sodium benzoate for 30 days at levels of 16–1,090 mg/kg bw per day (Smyth and Carpenter, 1948). There were no effects on body weight, appetite, or mortality and no histological changes in organs.

Groups of three male and three female Sherman rats were fed diets containing 0, 2 or 5% sodium benzoate (equivalent[25] to 2,000 and 6,000 mg/kg bw per day in rats weighing 40–50 g at the start of the study) for 28 days (Fanelli and Halliday, 1963). All animals at the 5,000 mg/kg bw per day group died during the first 2 weeks after showing hyperexcitability, urinary incontinence and convulsions. Male rats at the 2,000 mg/kg bw per day group showed a significant decrease in body weight, and the food intake of male and female animals at this dose was decreased in comparison with controls.

Groups of 4–19 male rats (strain not specified), 4–5 weeks old and weighing 45–60 g, were fed diets containing sodium benzoate at a level of 0, 1.5, 2.0, 2.5, 3, 3.25 or 3.75% (equivalent[25] to 0, 1,800, 2,400, 3,000, 3,600, 3,900 and 4,500 mg/kg bw per day) for 40 days (Griffith, 1929). Sodium benzoate in the diet at levels greater than 3,600 mg/kg bw per day resulted in a less than 50% survival rate and surviving animals failed to grow normally. Addition of glycine reduced the toxic effects. Animals died after showing incoordination, tremor or convulsions and severe eye inflammation. Groups of 10–15 young male rats were fed restricted diets containing 0, 1.5, 2.0, 2.5 or 3% sodium benzoate (equivalent[25] to 0, 1,800, 2,400, 3,000 and 3600 mg/kg bw per day). Animals in the 3,600 mg/kg bw per day group showed a reduction in body weight gain compared to the control, and the proportion of deaths was greater than in the non-restricted diet group fed the same concentration of sodium benzoate. Supplementary glycine addition again alleviated the reduction in body weight gain.

Groups of 10 male and 10 female Fischer 344 rats, 4–5 weeks old and weighing 110–150 g, were fed diets containing sodium benzoate at levels of 0, 0.5, 1, 2, 4 or 8% (equivalent[25] to 600, 1,200, 2,400, 4,800 and 9,600 mg/kg bw per day) for 6 weeks (Sodemoto and Enomoto, 1980). All rats in the 9,600 mg/kg bw per day group and 19 rats in the 4,800 mg/kg bw per day group died within 4 weeks; one male in the 2,400 mg/kg bw per day group, two males in the 1,200 mg/kg bw per day group and three males in the 600 mg/kg bw per day group also died, but all females at these dose levels survived for 6 weeks. Significant reductions in body weight gain were seen only in animals in the 4,800 and 9,600 mg/kg bw per day groups. No morphological change was seen at necropsy, except for atrophy of the spleen and lymph nodes in rats in the 4,800 and 9,600 mg/kg bw per day groups.

Groups of four to five male and four to five female young Sherman rats were fed diets containing 1, 2, 4 or 8% sodium benzoate (equivalent[25] to 900, 1,800, 3,600 and 7,200 mg/kg bw per day) for 90 days (Deuel et al., 1954). Four rats in the 7,200 mg/kg bw per day group died within an average of 13 days. The body weight gain of the four survivors was two-thirds that of controls with an identical food intake. Kidney and liver weights were significantly higher than those of the control group in the 7,200 mg/kg bw per day group.

Conclusion on short-term and subchronic toxicity of benzoic acid and its salts

The results of the available short-term and subchronic studies on benzoic acid and sodium benzoate indicated that the toxicity of benzoic acid and its salts is low with no marked target organ toxicity. The Panel noted however that the majority of available studies were conducted many years ago, and were not in accordance with current test guidelines.

3.2.3. Genotoxicity

3.2.3.1. Previous evaluations

JECFA at its 46th meeting (JECFA, 1997) evaluated the genotoxicity of benzoic acid in different *in vitro* and *in vivo* genotoxicity tests and concluded that benzoic acid was not mutagenic in the Ames test, either with or without metabolic activation but showed weak clastogenic activity *in vitro* which was not reproduced *in vivo*.

JECFA's conclusion regarding the clastogenicity of benzoic acid was based on the results from two *in vitro* chromosome aberration studies in Chinese hamster fibroblasts (Ishidate et al., 1984) and in root tips of *Vicia faba* (Njagi and Gopalan, 1982) which showed weak cytogenetic effects. However, the Panel noted that the assay on root tips of *V. faba* does not belong to the assays recommended for regulatory purposes and that the study by Ishidate et al. (1984) was of limited value because in the evaluation of clastogenic effects only results for total aberrations were reported, which included gaps not normally considered for the evaluation of clastogenicity. In addition, the study was poorly reported. The SCF in its 2002 evaluation (SCF, 2002) of benzoic acid and its salts noted that all the

relevant studies *in vivo* were negative at somatic or germ cell levels and concluded that *it is very unlikely that benzoic acid would interact with chromosomes in vivo* and recommended *The observations of clastogenic activity of benzoic acid in vitro indicate that it should be tested for clastogenic activity in vivo in peripheral lymphocytes or bone marrow in animals and that blood or bone marrow levels respectively of benzoic acid should be measured in such a study.*

TemaNord (2002) has evaluated the genotoxicity of benzoic acid, sodium benzoate, potassium benzoate and calcium benzoate, and concluded that benzoic acid/sodium benzoate was without mutagenic effect in *in vitro* mutagenicity tests. However, *with respect to sodium benzoate – but not benzoic acid – positive or ambiguous results were obtained in some of the in vitro chromosomal aberration tests and tests for effects on DNA. Negative results were seen in two in vivo chromosomal aberration tests with sodium benzoate.*

SCCP (2005), in reviewing the mutagenicity and genotoxicity of benzoic acid and sodium benzoate, evaluated the same studies considered by JECFA and SCF and concluded that *On the basis of provided data, the SCCP is of the opinion that benzoic acid and sodium benzoate are safe for use for preservative and non-preservative purposes in cosmetic rinse-off products.*

In the framework of classification, labelling and packaging of substances and mixtures according to Regulation (EC) No 1272/2008, benzoic acid was evaluated by the German Federal Institute for Occupational Safety and Health (BAuA, 2011). The BAuA considered that *while the reverse mutation assays and sister chromatid exchange assays (except one equivocal result) with benzoic acid, sodium benzoate and the metabolite hippuric acid were negative, weak genotoxic effects or equivocal results were observed in most of the chromosome aberration assays in mammalian cell lines with benzoic acid and sodium benzoate.* The BAuA further considered that *All the in vivo genotoxicity tests were negative at somatic or germ cell level.* Accordingly, BAuA concluded that *On this basis and the negative results obtained in two carcinogenicity studies in rats and mice for sodium benzoate, notwithstanding some limitations, it is very unlikely that benzoic acid would interfere with chromosomes in vivo. In the absence of a genotoxic potential in in vivo studies and negative results in carcinogenicity studies, no classification and labelling regarding mutagenicity is required.*

The EFSA CEF Panel has re-evaluated a number of benzyl derivatives in Flavouring Group Evaluation 20 (FGE.20Rev4) (EFSA CEF Panel, 2012), with a particular focus on genotoxicity. Benzoic acid was a supporting substance in this evaluation. The CEF Panel concluded that *While some of the in vitro studies indicated equivocal weak positive or positive results, considering the weight of evidence from candidate and supporting substances and the in vivo studies, the Panel concluded there was no safety concern with respect to genotoxicity of the substances in the present flavouring group.*

3.2.3.2. Genotoxicity studies not reported in previous evaluations

In vitro genotoxicity studies

In a study by the EG&G Mason Research Institute (1979 [Doc. provided to EFSA n. 3]) benzoic acid (purity 99.5%) was tested for its mutagenicity in the Ames test with *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 using the plate incorporation method both in the absence and presence of rat liver S9 metabolic activation up to 1,000 µg/plate. The highest concentration was based on a toxicity test with strain TA100 in which the background bacterial lawn was slightly reduced at 976.6 µg/plate and markedly reduced at 3,125 and 10,000 µg/plate. No increases in the frequency of revertant colonies were observed with benzoic acid under any experimental condition.

Benzoic acid, sodium benzoate and potassium benzoate were investigated for their potential to cause chromosomal aberrations, sister chromatid exchanges (SCEs) and micronuclei formation in cultured human peripheral lymphocytes (Yilmaz et al., 2009; Zengin et al., 2011). The potential of sodium benzoate and potassium benzoate to induce DNA damage was also investigated in the alkaline Comet assay. Test concentrations were 50, 100, 200 and 500 μg/mL for benzoic acid, 6.25, 12.5, 25, 50 and 100 μg/mL for sodium benzoate and 62.5, 125, 250, 500 and 1,000 μg/mL for potassium benzoate. Cells were exposed for 24 or 48 h for the chromosomal aberration and SCE assays, for 48 h in the micronucleus assay and for 1 h for comet assay. The mitotic index was reduced in a dose-related manner in all treatment groups compared to the negative controls, but it was not lower than 50% of control in any of the cultures, even at the highest dose for each benzoate, indicating that cytotoxicity was not a major factor in the induction of chromosome aberrations. None of the substances affected the replication index of the lymphocyte cultures. Chromosome aberrations were significantly increased compared to controls in cultures treated with benzoic acid and its sodium and potassium salts at all test concentrations. The frequencies of SCEs were similarly increased in a dose-related manner by all three benzoates, benzoic acid showing a slightly weaker response than either sodium or potassium benzoate. Micronuclei formation was significantly increased in a dose-related manner following treatment of the lymphocyte cultures with 200 or 500 μg/mL benzoic acid, or with 25, 50 and 100 μg/mL sodium benzoate, or with 125, 250, 500 and 1,000 μg/mL potassium benzoate. In the comet assay, a positive response was seen in the presence of sodium benzoate but not potassium benzoate. The authors concluded that benzoic acid, sodium benzoate and potassium benzoate are clastogenic, mutagenic and cytotoxic to human lymphocytes *in vitro* (Yilmaz et al., 2009; Zengin et al., 2011). The Panel noted that treatment and sampling times used in the chromosomal aberration and SCE assays from both studies deviate from relevant OECD TG Guideline 473. Furthermore, the different concentrations used for sodium and potassium benzoate (the concentration of potassium benzoate was 10 times higher than the concentration of sodium benzoate) appear to be inexplicable as the difference between the two compounds is only in the cation which is not expected to elicit any genotoxicity *per se* and no justification was reported for the application of these different concentrations. Overall, the Panel considered these studies as not adequate for risk assessment.

Demir et al. (2010) investigated the effects of benzoic acid, benzyl alcohol, benzyl acetate and benzaldehyde in an *in vitro* comet assay. Lymphocytes from two human volunteers were exposed to concentrations of 0, 0.05, 0.1, 0.3, 1 or 5 mM benzoic acid or 0, 1, 5, 10, 25 or 50 mM benzyl alcohol, benzyl acetate and benzaldehyde. Control cultures were exposed to distilled water alone, while ethylmethanesulphonate (EMS, 5 mM) was used as a positive control. Tail moment and % tail DNA were used as tail parameters in analysing the results of the study. Benzoic acid at a concentration of 5 mM produced a significant increase in both tail moment (4.28 $\pm$ 1.11) and % tail DNA (13.08 $\pm$ 2.03), with no effect being seen at lower concentrations of benzoic acid compared with control. Positive results were also seen with benzyl alcohol at concentrations of 25 and 50 mM, with benzyl acetate at 50 mM and with benzaldehyde at 10, 25 and 50 mM. EMS induced both tail moment (16.59 $\pm$ 2.71) and % tail DNA (28.73 $\pm$ 3.87). The authors concluded that these benzyl compounds showed evidence of genotoxicity at high test concentrations in the *in vitro* comet assay. However, the Panel noted that statistically significant increases observed for benzoic acid were modest and similar to the values observed for the negative controls used for the other substances assessed in this study. Statistical significance was only achieved due to the low value obtained in the concurrent control. The outcome obtained is therefore of no biological relevance. The Panel further noted major shortcomings which include the following:

i) The use of distilled water as negative solvent control is not recommended due to significant modification of the osmolality of culture medium;
ii) Cells employed in the study appear to be human lymphocytes, only mentioned in the abstract. No indication whether whole blood cells or purified lymphocytes and relevant procedures followed was reported;

iii) No indication about treatment and sampling times of the cells, two key points in this study, was provided;
iv) Cytotoxicity was not assessed;
v) Concentrations used, in most cases, exceeded the limit dose of 10 mM to be used in *in vitro* studies.

Overall the study is considered not adequate for risk assessment.

In the study by Yilmaz et al. (2014), benzoic acid was assessed for its potential to induce DNA breakage in the alkaline comet assay in purified human lymphocytes (one male and one female healthy subject). Concentrations used were 50, 100, 200 and 500 µg/mL and cells were treated for 1 h at 37°C. Cell viability was evaluated by the incorporation of trypan blue dye in cells. Two slides were prepared for each concentration of benzoic acid and 200 selected cells (100 cells from each of the two replicate slides) were analysed per treatment using the image analysis system (Comet Assay IV, Perceptive Instruments Ltd., UK). The tail length and tail intensity (%) parameters were used to estimate the extent of DNA breakage. The results obtained indicated moderate, no dose-related increases in both tail length and tail intensity (%) compared to the relevant solvent control culture, which achieved statistical significance at all concentrations employed. However, the Panel noted some limitations in the study, which include the absence of historical negative control values, the lack of dose-response over a 10-fold dose range and only 200 cells analysed per test point compared to 300 normally scored. Furthermore, the Panel noted that in a previous study (Zengin et al., 2011), the same authors reported negative results for potassium benzoate in the comet assay even at higher concentrations.

The Panel noted that the genotoxicity of benzoic acid and its salts was investigated *in vitro* in some further studies: in a mutation assay in superoxide dismutase-deficient *S. cerevisiae* (Piper, 1999); in a mutation assay with *Escherichia coli* cells (with no further details given) (Salih, 2006); in an SCE assay in human lymphocytes (Mpountoukas et al. 2008). However, these studies do not belong to the assays recommended for regulatory purposes.

In vivo genotoxicity studies

SCCNFP (2002) and BAuA (2011) evaluated the tests performed by Litton Bionetics (1974 [Doc. provided to EFSA n. 11]) in which sodium benzoate was assessed for its genotoxicity in the host-mediated assay in mice, in the rat bone marrow chromosomal aberration assay and in the dominant lethal assay in rats. In all assays performed, the treatment regime used consisted of three dose levels of 50, 500 and 5,000 mg sodium benzoate/kg bw, administered acutely by oral gavage, as single dose or subacute using the same dosages as those in the acute study, each day for five consecutive days, 24 h apart.

1. In the host-mediated assay, 10 ICR random-bred male mice/group were dosed as indicated above and the indicator organisms used were *S. typhimurium* TA1530 and G46 for mutagenicity and *Saccharomyces cerevisiae* strain D3 for mitotic recombination. The results obtained indicated that, except for a marked increase in mutation frequencies observed in *S. typhimurium* TA1530 in the acute study at the intermediate dose level of 500 mg/kg bw, which was not reproduced at the higher dose level in the absence of any toxicity, no increases in mutant and recombinant frequencies in both *S. typhimurium* TA1530 and G46 and *S. cerevisiae* strain D3 respectively, at both dosing regimens were observed. The authors considered that overall the results were negative. The Panel agreed with this conclusion and noted that the host-mediated assay has not received further validation and it is presently considered to be obsolete.

2. In the rat bone marrow cell chromosomal aberration assay, five male Sprague-Dawley rats for each treatment group were sacrificed at 6, 24 and 48 h from the administration of test compound in the acute treatment, while in the subacute treatment (for 5 days), sampling was

only performed at 6 h from the last administration. Bone marrow cells were used to prepare cytogenetic slides following administration of colcemid at 4 mg/kg by intraperitoneal injection to accumulate cells in metaphase before sacrifice of animals. Fifty metaphase spreads per animal were scored for chromosomal aberration analyses. The mitotic indices were also evaluated by scoring a total of 1,000 cells (mitotic and interphase cells) per animal to assess cytotoxicity. The result obtained showed no relevant increases in chromosomal aberration at any dose level and sampling time employed. No reduction of mitotic indices in the test substance treatment groups was observed indicating no signs of bone marrow toxicity despite the very high dose levels employed. The Panel noted that according to the current version of the OECD guideline TG475 (OECD, 2014), at least 200 metaphases should be analysed for each animal for structural chromosomal aberrations. However, scoring of 50 metaphases per animals was consistent with the recommendations at the time when the study was performed. The Panel further noted that there was no evidence that bone marrow cells were exposed to test substance as no mitotic index reduction was observed at any test point. However, the Panel also considered that the highest dose level applied (5,000 mg/kg bw) significantly exceeded the maximum dose level (2,000 mg/kg bw) recommended by the relevant OECD Guideline TG475.

In the dominant lethal assay, 10 male Sprague-Dawley rats per group following treatments as indicated above, were sequentially mated with two females per week for seven or eight consecutive weeks in the subacute or acute treatment, respectively. Fertility index, total implants (live fetuses plus early and late fetal deaths), total dead (early and late fetal deaths), dead implants per total implants and preimplantation loss (calculated as the difference between the total corpora lutea and total implant counts) were evaluated and the results obtained were considered by the authors to be of no concern with respect to genotoxicity. The Panel agreed with this conclusion.

In the study by Kawachi et al. (1980), a negative result in terms of induction of chromosomal aberrations was observed in the rat bone marrow chromosomal aberration assay. However, the reliability of the study could not be evaluated as details on methods and results were not reported.

In the study by Sasaki et al. (2002), groups of male CD-1 mice were administered once by gavage at a single dose of 1,000 mg/kg bw with benzoic acid or sodium benzoate. Isolated nuclei from glandular stomach, colon, liver, kidney, urinary bladder, lung, brain and bone marrow were analysed 3 and 24 h after treatment. No DNA migration was observed in nuclei from any of the tissues analysed. Necropsy and histopathological examination revealed no treatment-related effect in any tissue/organ analysed.

In the study by Demir et al. (2008), the genotoxicity of benzoic acid, benzyl alcohol, benzyl acetate and benzaldehyde was investigated in the wing somatic mutation and recombination test in *Drosophila melanogaster* and the authors concluded that benzoic acid, benzyl alcohol, benzyl acetate and benzaldehyde are genotoxic. The Panel noted that the test systems employed have not received any validation and are presently considered to be obsolete and that they do not belong to the assays recommended for regulatory purposes. Therefore, the results of these studies were not further considered in the assessment.

Overall conclusion on genotoxicity of benzoic acid and its salts

Overall, the Panel considered that positive or equivocal results reported for clastogenicity *in vitro* of benzoic acid and its salts sodium and potassium benzoates (Ishidate et al., 1984; Yilmaz et al. 2009; Zengin et al. 2011) have not been reproduced in well performed and relevant *in vivo* studies using the alkaline comet assay (Sasaki et al., 2002), the rodent bone marrow chromosome aberration assay and the dominant lethal assay in rats (Litton Bionetics, 1974). Therefore, the Panel considered that the use of benzoic acid and its sodium and potassium salts as food additives does not raise a concern with respect to genotoxicity. Based on read-across, the Panel considered that this conclusion is also applicable for calcium benzoate.

3.2.4. Chronic toxicity and carcinogenicity

The results of long-term studies of toxicity and carcinogenicity with benzoic acid and sodium benzoate and related substances were reviewed by JECFA at its 46th meeting (JECFA, 1996, 1997). The Panel noted that no haematological and clinical chemistry parameters were determined in these studies.

3.2.4.1 Mice

Sodium benzoate (purity, 99%) was administered as a 2% solution in drinking water to 50 male and 50 female 5-week-old Swiss mice for their lifetime (Toth, 1984). The daily intakes of sodium benzoate were estimated to be 6,200 mg/kg bw per day for males and 5,960 mg/kg bw per day for females, on the basis of daily water consumption of 6.2 and 5.9 mL, respectively. Groups of 100 males and 100 females were used as untreated controls. Body weights were measured weekly, and gross pathological changes were recorded. The animals were either allowed to die or were sacrificed when moribund. Complete necropsies were performed on all animals, and the liver, spleen, kidneys, bladder, thyroid, heart, pancreas, testes, ovaries, brain, nasal turbinates, at least four lobes of the lungs and organs with gross pathological changes were examined histologically. Treatment had no effect on survival or the incidence of tumours in the limited numbers of tissues investigated, and the NOAEL for this study was therefore 5,960 mg sodium benzoate/kg bw per day. The Panel noted the limited number of investigations carried out in this non-guideline study and also the deficiencies in the reporting of the results, including uncertainty about whether histopathological end-points other than neoplasms were investigated. Therefore, the Panel considered that this study was not adequate for the risk assessment.

3.2.4.2 Rats

Groups of 50 male and 52 female Fischer 344 rats, 4–5 weeks old, received diets containing 0%, 1% or 2% sodium benzoate (equivalent[26] to 0, 500 and 1,000 mg/kg bw per day) for up to 24 months (Sodemoto and Enomoto, 1980). Controls, consisting of 25 male and 43 female rats, received basal diet. Survival was very poor in all groups, due to intercurrent sialodacryoadenitis and mycoplasma infections. All surviving animals were sacrificed between 18 and 25 months and various tissues were examined histopathologically. No adverse clinical signs directly attributable to treatment were observed, and only negligible differences in average body weight and mortality rate were seen between the treated and control groups. Although a variety of tumours occurred among treated and control rats of each sex, they were of similar type and incidence. The Panel noted that this study had a number of limitations, including poor survival due to the disease status of the animals.

No further data on the carcinogenicity of benzoic acid or its salts were found.

The Panel noted that the available carcinogenicity studies on benzoic acid and its salts did not indicate any carcinogenic potential, although they were not conducted in accordance with current test guidelines and had deficiencies both in terms of design and reporting.

3.2.5. Reproductive and developmental toxicity

3.2.5.1. Reproductive toxicity

In a multi-generation reproductive toxicity study on benzoic acid, which also included limited investigations into the chronic toxicity of benzoic acid, three groups of 20 male and 20 female white

[26] Calculated by the Panel according to EFSA Scientific Committee (2012).

rats were pair fed for 8 weeks on a standard rat diet, prepared as a feed mix with either 0, 0.5 or 1% benzoic acid (Kieckebusch and Lang, 1960). The authors did not provide information regarding the strain of the rat used, only stating that they were sourced from Bayer, Elberfeld (Germany). The rats were fed *ad libitum* over four generations resulting in an approximate intake of benzoic acid of 0, 250 or 500 mg/kg bw per day. Two generations were fed for their whole lifespan, the third and fourth generations were autopsied after 16 weeks. No treatment-related effects were observed on growth, fertility, lactation throughout all four generations and lifespan (for the first two generations). On the contrary, *ad libitum* ingestion of the 0.5% benzoic acid feed mix resulted in a significantly longer lifespan in the first and second generation of the rats, based on statistical analysis of the two generations combined. In the third generation, autopsied at 16 weeks, no treatment-related effects were reported on organ weights and histopathological findings in organs. The assessment of reproductive parameters was considered to be valid by the Panel, and provided a NOAEL, for both the parental animals and the offspring over four generations, of 500 mg benzoic acid/kg bw per day, the highest dose tested.

3.2.5.2. Developmental toxicity

Mice

Pregnant CD-1 mice (20–12 per group) were treated by gavage once daily from gestation day (GD) 6 to 15 with doses of 0, 1.75, 8, 38 or 175 mg sodium benzoate/kg bw per day in water (FDRL, 1972 (Doc. provided to EFSA n. 9)). Body weights were recorded at regular intervals during gestation and all animals were observed daily for appearance and behaviour. Two females of the control group died before GD 17. All dams were subjected to caesarean section, and the numbers of implantation sites, resorption sites, live and dead fetuses, and body weights of live pups were recorded. All fetuses were examined grossly for external abnormalities (one-third detailed visceral examination and two-third stained and examined for skeletal defects). At necropsy on GD 17 doses up to 175 mg sodium benzoate/kg bw ‘per day, no dose-related effects were observed on maternal toxicity. There was no evidence of developmental toxicity in animals receiving sodium benzoate compared to controls neither on implantation nor on maternal and fetal survival. The numbers of live or dead fetuses, resorptions, average implant sites and fetal weights did not differ among the groups. The sex ratio of fetuses was not affected by the treatment. The number of abnormalities seen in either soft tissues or skeletons at fetal pathological examination of the sodium benzoate-treated groups did not differ from the number occurring in vehicle-treated dams of the control group.

Rats

Pregnant Wistar rats (23–24 per group) were treated by gavage once daily from GD 6 to 15 with doses of 0, 1.75, 8, 38 or 175 mg sodium benzoate/kg bw per day in water (FDRL, 1972 (Doc. provided to EFSA n. 9)). Body weights were recorded at regular intervals during gestation and all animals were observed daily for appearance and behaviour. All dams were subjected to caesarean section, and the numbers of implantation sites, resorption sites, live and dead fetuses, and body weights of live pups were recorded. All fetuses were examined grossly for external abnormalities (one-third detailed visceral examination and two-third stained and examined for skeletal defects). At necropsy on GD 20, no dose-related effects were observed on maternal toxicity. There was no evidence of developmental toxicity in animals receiving sodium benzoate compared to controls neither on implantation nor on maternal and fetal survival. The numbers of live or dead fetuses, resorptions, average implant sites and fetal weights did not differ among the groups. The sex ratio of fetuses was not affected by the treatment. The number of abnormalities seen in either soft tissues or skeletons at fetal pathological examination of the sodium benzoate- treated groups did not differ from the number occurring in vehicle-treated dams of the control group.

A developmental toxicity study in which groups of 27–30 pregnant Wistar rats were fed diets containing 0, 1, 2, 4, or 8% sodium benzoate on days 1–20 of gestation, equal to 0, 700, 1,310, 1,875 or 965 mg/kg bw per day based on total food intake over the period (Onodera et al., 1978). All but five animals in each group were sacrificed on day 20 of gestation, and the numbers of viable fetuses, dead fetuses, early and late resorptions, and fetal, placental and ovarian weights were measured; abnormalities of maternal organs and fetal appearance were also recorded. About 75% of the fetuses from treated animals were stained with alizarin red S for skeletal examination, and the remainder were fixed with Bouin's solution and examined for visceral anomalies by Wilson's method. The remaining five dams in each group were allowed to deliver naturally, and the number of offspring, survival, body weight, and abnormalities were recorded. Three weeks after birth, all surviving pups were weaned and examined for gross abnormalities, and one-half of the pups and all of the dams were necropsied. The remaining pups were necropsied at 8 weeks of age, body weight and food intake being measured weekly until necropsy.

Maternal body weight and body weight gain were comparable in the controls and in animals receiving 1 and 2% sodium benzoate in the diet; animals at the 4% level did not gain weight and those at 8% lost weight (statistical comparisons not presented). Feed intake was also comparable in the controls and animals at 1% and 2% dietary levels but was markedly reduced in those at 4% and 8%. Two dams at 4% and three at 8% died after convulsions and depressed motor activity. Animals receiving 1% or 2% sodium benzoate showed no differences compared with controls in the average number of implants per female, the numbers of dead, resorbed or viable fetuses, or the average weight of viable fetuses on day 20 of gestation; in the groups at 4% and 8%, the number of dead or resorbed fetuses was significantly increased, and the average body weight of viable fetuses was significantly lower than that of controls. Significant abnormalities and pathological findings were seen only in the fetuses at 4% and 8%; these included mild systemic oedema, anophthalmia, microphthalmia, hydrocephalus, pyelectasis, hydroplasia and cerebral hypoplasia. Delayed ossification, lumbar or cervical ribs, and varied sternebrae were reported in animals in both the control and treated groups. The percentage of animals with these findings was comparable to that in controls among animals at 1% and 2% (each about 37%) but was increased in the groups at 4% (96.5%) and 8% (100%). Additional anomalies seen in the treated groups included a higher incidence of wavy ribs and abnormal vertebrae in the rats at 4%, but not at 8%.

Among pups that were delivered naturally, no differences in the delivery rate, number of perinatal deaths, lactation rate or survival up to week 8 were reported at the 1% and 2% dietary levels, but the groups at 4% and 8% were reported to have delivery rates reduced by 50% and 8.2%, respectively, with complete loss of litters after parturition. The surviving pups in the control group and at 1% and 2% showed no significant differences in birth weight, weight at week 3 or week 8, incidence of abnormalities at week 3 or 8, or organ weights at week 8. The authors suggested that the effects on the dams and fetuses at the 4% and 8% dietary levels were due to reduced maternal feed intake in these groups, leading to malnutrition, as the actual compound intake of the animals at 8% was lower than that of the group at 2%, in which no adverse effects were seen. The authors concluded that the NOAEL was 1,310 mg sodium benzoate/kg bw per day (Onodera et al., 1978). The Panel agreed with the authors.

Groups of 10 pregnant female Wistar rats were administered sodium benzoate at levels of 0%, 0.1%, 0.5% or 1% in the diet (equivalent[27] to 0, 50, 250 or 500 mg/kg bw per day) over the whole gestation period, throughout lactation and to pups after weaning up to day 45 of age (Crane and Lachance, 1985). Parameters monitored included body weight change and food consumption; spontaneous locomotor activity (at day 6, 9, 12, 15, 18, 21 of age and thereafter continuously up to termination); brain levels of serotonin, dopamine and norepinephrine (at day 9, 15, 21 of age and at termination), and brain weight. No adverse effect was reported on any of these parameters and the authors

[27] Calculated by the Panel according to EFSA Scientific Committee (2012).

concluded that the NOAEL was 500 mg sodium benzoate/kg bw per day, the highest dose tested. The Panel agreed with the authors; however, the Panel noted that this study did not comply with the OECD Guideline 414 (OECD, 2001).

Groups of 25 pregnant rats were given benzoic acid (purity 96.7%) by gavage from GD 7–16 dose levels of 0, 30, 160, or 450 mg benzoic acid/kg of body weight in a 0.5% aqueous suspension of methyl cellulose (EPA, 1992 (Doc. provided to EFSA n. 5)). Overt maternal toxicity occurred at 450 mg/kg as indicated by death in four rats, significant depression in body weight gain and feed consumption during the dosing period, an increased incidence of ruffled fur and increased relative liver weight on post-mortem examination. Haemorrhages of the gastric mucosa were observed in three of the four rats that died. A transient but significant decrease in body weight gain also occurred in dams in the 160 mg/kg group during the first 4 days of dosing. The number of pregnant females at caesarean section was 16, 14, 18 and 19 for the control, low-, mid- and high-dose, respectively.

No compound-related effects on reproductive parameters were demonstrated. Fetal weight was significantly decreased in the 160 and 450 mg/kg groups. The Panel noted that the effect on fetal weight in the mid-dose group was related to the higher number of fetuses per litter in this group when compared with the control group; calculated mean litter weight of the mid-dose group was 10% higher than in the control group. Significant increases in malformations, fetal developmental variations and variations due to retarded development were observed in the group administered 450 mg benzoic acid/kg bw per day.

The authors considered 30 mg benzoic acid/kg bw per day as the no observed effect level (NOEL) for the dams based on the effect on body weight gain at 160 mg/kg bw per day. The NOEL for the fetuses was also 30 mg/kg bw per day based on the decreased fetal weight at the mid-dose. The Panel considered the transitory effect on maternal body weight gain in the mid-dose group not relevant for identification of the NOAEL. Owing to a higher number of fetuses in the low-dose group compared to the control group, the decreased mean fetal weight in combination with the increased mean litter weight was not considered to be a developmental toxic effect by the Panel. The only fetal alterations demonstrated to be dose related and significantly increased above the control incidence occurred in the 450 mg/kg group in the presence of overt toxicity and maternal death. Therefore, the Panel considered that 160 mg benzoic acid/kg bw per day was the NOAEL for maternal and developmental toxicity in this study.

Hamsters

Pregnant Golden hamsters (21–22 animals per group) were treated by gavage once daily from GD 6 to 10 with doses of 0, 3, 14, 65 or 300 mg sodium benzoate/kg bw per day in water (FDRL, 1972 (Doc. provided to EFSA n. 9)). Body weights were recorded at regular intervals during gestation and all animals were observed daily for appearance and behaviour. All dams were subjected to caesarean section, and the numbers of implantation sites, resorption sites, live and dead fetuses, and body weights of live pups were recorded. All fetuses were examined grossly for external abnormalities (one-third detailed visceral examination and two-third stained and examined for skeletal defects). One female of the low-dose group died or aborted before GD 14. At necropsy on GD 14, doses up to 300 mg sodium benzoate/kg bw per day induced no maternal toxicity. There was no evidence of developmental toxicity in animals receiving sodium benzoate compared to controls neither on implantation nor on maternal and fetal survival. The numbers of live or dead fetuses, resorptions, average implant sites and fetal weights did not differ among the groups. The sex ratio of fetuses was not affected by the treatment. The number of abnormalities seen in either soft tissues or skeletons at fetal pathological examination of the sodium benzoate treated groups did not differ from the number occurring in vehicle-treated dams of the control group.

Rabbits

Artificially inseminated Dutch-belted rabbits (10–12 animals per group) were treated by gavage once daily from GD 6 to 18 with doses of 0, 2.5, 12, 54 or 250 mg sodium benzoate/kg bw per day in water (FDRL, 1972 (Doc. provided to EFSA n. 9)). Body weights were recorded at regular intervals during gestation and all animals were observed daily for appearance and behaviour. All dams were subjected to caesarean section, and the numbers of implantation sites, resorption sites, live and dead fetuses, and body weights of live pups were recorded. All fetuses were examined grossly for external abnormalities and visceral and skeletal abnormalities. One, 4, 0, 2 and 2 does of the 0, 2.5, 12, 54 and 250 mg sodium benzoate/kg bw per day groups died or aborted before GD 29. Therefore, there were only 9, 10, 8, 5, or 8 litters at necropsy on GD 29. At necropsy on GD 29 doses up to 250 mg sodium benzoate/kg bw per day, no dose-related effects were observed on maternal toxicity. There was no evidence of developmental toxicity in animals receiving sodium benzoate compared to controls neither on implantation nor on maternal and fetal survival. The numbers of live or dead fetuses, resorptions, average implant sites and fetal weights did not differ among the groups. The sex ratio of fetuses was not affected by the treatment. The number of abnormalities seen in either soft tissues or skeletons at fetal pathological examination of the sodium benzoate-treated groups did not differ from the number occurring in vehicle-treated dams of the control group. The Panel noted that the number of pregnant does at caesarean section was very low in all groups, especially in the low-dose group.

Overall, in two developmental studies in rats with sodium benzoate in the diet the NOAEL was 500 mg sodium benzoate/kg bw per day (the highest dose tested) (Crane and Lachance, 1985) and 1,310 mg sodium benzoate/kg bw per day (Onodera et al., 1978). Onodera et al. (1978) also studied the effects of higher concentrations in the diet – doses equal to 1,875 mg sodium benzoate/kg bw per day induced severe maternal toxicity and were associated with embryotoxic and fetotoxic effects and fetal malformations.

In studies in mice, rats, hamsters and rabbits with sodium benzoate administered by gavage (FDRL, 1972 (Doc. provided to EFSA n. 9)), no developmental effects were observed up to doses of 175, 174, 300 and 250 mg sodium benzoate/kg bw per day, the highest doses tested respectively in each species.

In another developmental toxicity study in rats with benzoic acid by gavage, a NOAEL of 160 mg benzoic acid/kg bw per day was observed for maternal and developmental toxicity (EPA, 1992 (Doc. provided to EFSA n. 5)).

The four-generation reproductive toxicity study (Kieckebusch and Lang, 1960) with benzoic acid in the diet in rats was considered by the Panel as the pivotal study, as this study was the longest exposure period as compared to the developmental studies. This study showed no effect on growth, fertility, lactation or survival, and provided a NOAEL, for both the parental animals and the offspring, of 500 mg benzoic acid/kg bw per day, the highest dose tested.

3.2.6. Allergenicity, hypersensitivity and intolerance

3.2.6.1. Animal studies

Several studies including guinea pig maximisation and Buehler tests (Gad et al. 1986) and a local lymph node assay in mice (Gerberick et al., 1992) did not reveal any sensitising potential for benzoic acid.

3.2.6.2. Human data

An anaphylactic reaction was described in a 19-year-old woman in response to ingestion of sodium benzoate in foodstuffs. Adherence to a benzoate-free diet prevented recurrence of the symptoms. An

oral challenge with 20 mg sodium benzoate induced localised itching on the arms and generalised itching (Michils et al., 1991).

In nine patients with atopic dermatitis and positive reactions after oral provocation tests, increased leukotriene production was observed in four of nine patients administered benzoate (Worm et al., 2001). Furthermore, in the presence of benzoate, the mean value of leukotriene production in basophils from the same patients was approximately 10 times higher than in basophils from patients having negative reactions after an oral provocation test.

In a double-blind placebo-controlled study (Pacor et al., 2004), 226 patients (76 males and 150 females) aged 12–60 years (mean age 40.2 ± 16.3 years) were maintained for 1 month on an additive-free diet regimen, followed by an open challenge (food additive-rich diet for 2 weeks). Twenty of the 226 subjects (8.8%) challenged with sodium benzoate induced objective (sneezing and rhinorrhoea) and subjective symptoms (nasal blockage and nasal itching) of rhinitis. The authors concluded that the observation that non-atopic persistent rhinitis may be caused by the repeated ingestion of small doses of a non-tolerated substance suggests that some patients with 'chronic vasomotor rhinitis' may be intolerant to a particular food additive. According to the authors, sodium benzoate can be considered a trigger or an aggravating factor, rather than an aetiological factor.

The incidence of oral intolerance to sodium benzoate was studied among subjects who experienced repeated episodes of acute urticaria/angio-oedema after ingestion of a meal or a product containing sodium benzoate (Nettis et al. 2004). Of the 47 subjects enrolled in the study, five showed at least one positive reaction to an immunoglobulin E (IgE) test for food allergens. Only one subject had a reaction after the ingestion of 75 mg of sodium benzoate without an adverse reaction to placebo. The authors concluded that this study showed that the percentage of episodes of acute urticaria/angio-oedema reactions induced by sodium benzoate is very low.

A 75-year-old woman with a 6-year history of diffuse, severe pruritus, started an elimination diet (free of food additives) and after 1 week, pruritus had totally disappeared (Asero, 2006). Reintroduction of oral sodium benzoate (100 mg) resulted in relapse of diffuse pruritus within 24 h after intake. This finding was confirmed by a second series of two double-blind, placebo-controlled challenges including sodium benzoate and placebo.

3.2.6.3. *In vitro* immunotoxicity

The effect of sodium benzoate on the production of various cytokines by human peripheral blood mononuclear cells was investigated (Maier et al., 2010). Sodium benzoate was able to suppress the Th1 response in a dose-dependent manner, thus suggesting an anti-inflammatory effect. The Panel noted that this apparent beneficial effect might be counterbalanced by an associated possible diminished immune response to pathogens and tumours due to the decreased Th1 type response. In addition, the resulting shift towards Th2 immunity may favour the development of allergic diseases. The Panel also noted that the concentrations used were in the millimolar range and therefore, their relevance to the *in vivo* situation is questionable. These data, although supporting a mechanistic hypothesis for a potential immunomodulatory capacity of sodium benzoate, were considered by the Panel to be of limited relevance for its safety assessment.

Overall, the Panel noted that several studies reported that subgroups of patients already suffering from atopic dermatitis, pruritus, urticaria or persistent rhinitis can react to low doses of benzoate, even below the ADI. The Panel noted that these data, although available for a limited population of individuals following oral exposure, indicated that benzoic acid and its salts used as food additives could trigger the symptoms of asthma and eczema in people who already have these conditions.

3.2.7. Other studies

3.2.7.1. Animals

Noorafshan et al. (2014) dosed Sprague-Dawley rats (10 per group; body weight 180–230 g) by gavage with 0 or 200 mg sodium benzoate /kg bw per day for 4 weeks. At the end of the fourth week, anxiety and motor function were tested in an elevated plus maze and a rotarod test. The sodium benzoate-treated animals spent less time in the open arms and had fewer entrances to the open arms in comparison with the control group. In addition, the performance of the treated animals in the rotarod was impaired. In this studies no other parameters such as clinical signs, body weight, food intake or necropsy data were described.

3.2.7.2. Humans

Lok et al. (2013) tested the effect of 45 mg/person per day of sodium benzoate on the behaviour of one hundred and thirty 8- to 9-year-old schoolchildren and found no significant associations between sodium benzoate in Chinese children's behaviour. The study was a randomised, double-blind, placebo control study in Hong Kong.

Lennerz et al. (2015) studied the acute effects of sodium benzoate on glucose homeostasis and metabolic profiles in humans in a randomised, controlled, cross-over study in 14 overweight subjects. They did not find a statistically significant effect following an oral glucose challenge (75 g glucose solution), in the presence or absence of sodium benzoate (1% benzoate). Glucose, insulin, glucagon as well as temporal mass spectrometry-based metabolic profiles were measured. The Panel noted that this oral glucose tolerance test was performed in overweight subjects (body mass index (BMI) 25–30 kg/m^2) who have a high prevalence of pathological response in this test (Shalitin et al., 2005). Therefore, as the study was done in this sensitive subpopulation, the results demonstrate the absence of an endocrine effect at a benzoate dose of 5.65 mg/kg (4.7–7.5 mg/kg) on the glucose homeostasis and metabolic profile in humans.

4. Discussion

The Panel was not provided with a newly submitted dossier and based its evaluation on previous evaluations, additional literature that became available since then and the data available following an EFSA public call for scientific data. The Panel noted that not all original studies on which previous evaluations were based were available for re-evaluation by the Panel.

Benzoic acid, sodium benzoate, potassium benzoate and calcium benzoate (E 210, E 211, E 212 and E 213) are authorised food additives in the EU and have previously been evaluated by the SCF in 1994 and 2002. The SCF established a group ADI of 0–5 mg/kg bw for benzoic acid and its salts including benzyl alcohol and related benzyl derivatives used as flavourings (SCF, 2002). JECFA has evaluated benzoic acid and its salts as food additives on a number of occasions, most recently in 1996 (JECFA, 1996, 1997). JECFA has additionally reviewed benzoic acid as a flavouring substance (JECFA, 2001, 2002). In 1974, JECFA established a group ADI of 0–5 mg/kg bw for benzoic acid and its salts, expressed as benzoic acid, which was reconfirmed at its most recent evaluation in 1996. In both cases, the ADI was derived from a NOAEL of 500 mg/kg bw per day identified from a multi-generation study in rats (Kieckebusch and Lang, 1960), in which a dose level of 1% in the diet, equivalent to 500 mg/kg bw per day, had no effect on growth, fertility, lactation or lifespan (JECFA, 1974b).

Specific purity criteria have been defined in Commission Regulation (EU) No 231/2012 for benzoic acid and its salts (E 210–213). The Panel noted that the term 'benzoic acid' should be replaced by 'potassium benzoate' or 'calcium benzoate' in the EU specifications for potassium benzoate (E 212) and calcium benzoate (E 213), respectively. In addition, the Panel considered that if metals are used

as catalysts in the manufacturing process of benzoic acid as a food additive, the maximum residual level for each metal should be specified in the EU specifications for benzoic acid (E 210). The Panel also considered that the maximum limits for the impurities of toxic elements (lead, mercury and arsenic) in the EC specification for benzoic acid and its salts (E 210–213) should be revised in order to ensure that benzoic acid and its salts (E 210–213) as food additives will not be a significant source of exposure to those toxic elements in food.

The Panel noted that the formation of benzene in beverages containing benzoic acid or its salts as preservatives is linked to certain formulations, such as ascorbic acid in the presence of metallic ions and also to conditions of storage. Therefore, the Panel considered that when benzoic acid or its salts and ascorbic acid are used together, consideration should be given to the storage of soft drinks and food contact materials to minimise the formation of benzene in beverages.

Benzoic acid is absorbed by a diffusion process in the gastrointestinal tract. Sodium benzoate and potassium benzoate dissociate into their constituent sodium, potassium and benzoate ions in the small intestine. The available ADME data in animals and humans indicate that benzoic acid and its sodium and potassium salts are rapidly absorbed, primarily in the proximal part of the GI, after oral administration. Benzoate is conjugated to glycine to form hippuric acid, which is excreted in the urine. No studies appear to have been conducted on calcium benzoate, but the Panel considered that calcium benzoate also dissociates into its constituents calcium and benzoate ions in the small intestine. Consequently, the ADME of this salt will be similar to that of the sodium or potassium salts, despite differences in water solubility. Therefore, the Panel considered possible read-across between the salts.

The results of the available short-term and subchronic studies on benzoic acid and sodium benzoate indicated that their toxicity is low with no marked target organ toxicity, although high intakes of benzoic acid may lead to disturbances in the acid–base balance, and benzoic acid at high doses may interfere with intermediary metabolism. The Panel noted that most of the available studies were not conducted in accordance with the current test guidelines. The Panel considered that none of these studies were appropriate for identification of a NOAEL for short-term and subchronic toxicity of benzoic acid and its salts.

The Panel considered that positive or equivocal results reported for clastogenicity *in vitro* of benzoic acid and its salts sodium, potassium and calcium benzoates (Ishidate et al., 1984; Yilmaz et al. 2009; Zengin et al. 2011) have not been reproduced in well performed and relevant *in vivo* studies using the alkaline comet assay (Sasaki et al., 2002), the rodent bone marrow chromosome aberration assay and the dominant lethal assay in rats (Litton Bionetics 1974 (Doc. provided to EFSA n. 11)). Therefore, the Panel considered that the use of benzoic acid and its sodium and potassium salts as food additives did not raise a concern with respect to genotoxicity. Based on read-across, the Panel considered that this conclusion is also applicable for calcium benzoate.

The Panel noted that the available carcinogenicity studies on benzoic acid and its salts did not indicate any carcinogenic potential, although they were not conducted in accordance with current test guidelines and had deficiencies both in terms of design and reporting. Overall, given supporting evidence of lack of carcinogenicity of the related substances benzyl alcohol, benzyl acetate and benzaldehyde as described by JECFA (1996, 2001, 2002), the Panel considered that the data are sufficient to conclude that benzoic acid and its salts did not raise concern with respect to carcinogenicity.

In two developmental toxicity studies in rats with sodium benzoate in the diet, the NOAEL was 500 mg sodium benzoate/kg bw per day (the highest dose tested) (Crane and Lachance, 1985) and 1,310 mg sodium benzoate/kg bw per day (Onodera et al., 1978). Onodera et al (1978) studied also the effects of higher concentrations in the diet. Doses equal to 1,875 mg sodium benzoate/kg bw per day induced severe maternal toxicity and were associated with embryotoxic and fetotoxic effects and fetal

malformations. In studies in mice, rats, hamsters and rabbits with sodium benzoate administered by gavage (FDRL, 1972 (Doc. provided to EFSA n. 9)), no developmental effects were observed up to doses of 175, 174, 300 and 250 mg sodium benzoate/kg bw per day, the highest doses tested respectively in each species. In another developmental toxicity study in rats with benzoic acid by gavage, a NOAEL of 160 mg benzoic acid/kg bw per day was observed for maternal and developmental toxicity (EPA, 1992 (Doc. provided to EFSA n. 5)). In relation to developmental toxicity, the SCF noted that hippuric acid, the glycine conjugate of benzoic acid, was the main urinary metabolite and there was evidence in both humans and rodents that large, bolus doses can cause glycine depletion (SCF, 1994). The SCF concluded that: *The data available give adequate reassurance that the use of benzoic acid and its salts as food preservatives is temporarily acceptable. However, the role of glycine in the rate limiting step for hippuric acid formation from benzoic acid suggests that there may be a narrow margin between the metabolic demand for glycine and the rate at which glycine is formed or made available in the body. Glycine is not generally regarded as an essential amino acid but it has been suggested that in rapidly growing organisms glycine may be a conditionally essential amino acid and that this fine balance might be disturbed by benzoic acid. An adequate teratogenicity study using a dietary route of administration is therefore desirable*. The Panel agreed with this conclusion of the SCF.

The four-generation reproductive toxicity study (Kieckebusch and Lang, 1960) with benzoic acid in the diet in rats was considered by the Panel as the pivotal study, as this study was the longest exposure period as compared to the developmental studies. This study showed no effect on growth, fertility, lactation or survival, and provided a NOAEL, for both the parental animals and the offspring, of 500 mg benzoic acid/kg bw per day, the highest dose tested.

The Panel noted that benzoic acid and its salts may enhance hypersensitivity and/or cause skin reactions. Furthermore, anaphylaxis and urticaria have also been observed in sensitive individuals following exposure to benzoic acid and its salts at doses below the ADI. Several studies have shown that subgroups of patients already suffering from atopic dermatitis, pruritus, urticaria or persistent rhinitis may be intolerant even to low doses of benzoate.

The Panel noted that intolerance reactions to benzoic acid and its salts have been reported in the literature, manifesting as gastrointestinal disturbances, skin reactions (urticaria, pruritus, etc.), bronchial hyper reactivity or asthmatic attacks, effects on the central nervous system or even anaphylaxis. The Panel also noted that benzoate-sensitive individuals may show reactions below the ADI.

The Panel noted the absence of any indication of genotoxicity of benzoic acid and its salts *in vivo*, together with the negative results of limited carcinogenicity studies in rats and mice. The Panel considered that the ADI cannot be derived from a prenatal developmental toxicity study with benzoic acid performed by gavage (EPA, 1992 (Doc. provided to EFSA n. 5)). The developmental toxicity studies in rats (Crane and Lachance, 1985 and Onedera et al., 1978) with sodium benzoate in the diet showed NOAELs of 500 (the highest dose tested) and 1,310 mg/kg bw per day, respectively, comparable to or higher than the NOAEL of 500 mg/kg bw per day in the dietary multi-generation reproductive toxicity in rats with benzoic acid (Kieckebusch and Lang, 1960). From these reproductive and developmental studies, the Panel derived an ADI of 5 mg/kg bw per day (expressed as benzoic acid) using an uncertainty factor of 100.

To assess the dietary exposure to benzoic acid-benzoates (E 210–213) from their use as a food additive, the exposure was calculated based on (1) MPLs set out in the EU legislation (defined as the *regulatory maximum level exposure assessment scenario*) and (2) the reported use levels and analytical data (defined as the *refined exposure assessment scenario*). Dietary exposure through this latter scenario was assessed using two sets of concentration data: reported use levels and analytical data considering levels not exceeding the MPLs for food categories for which direct addition of benzoic acid-benzoates is authorised (Annex II to Regulation No 1333/2008) (dataset 1); in addition

to dataset 1, analytical data for food categories which may contain benzoic acid-benzoates due to carry-over and for which data were available (dataset 2).

Based on the available datasets, the Panel calculated two refined exposure estimates based on different assumptions: a *brand-loyal consumer scenario*, where it is assumed that the population is exposed over a long period of time to the food additive present at the maximum reported use/analytical levels for one food category and to a mean reported use/analytical level for the remaining food categories; and a *non-brand-loyal scenario*, where it is assumed that the population is exposed over a long period of time to the food additive present at the mean reported use/analytical levels in all relevant food categories.

The exposure estimates in the *regulatory maximum level exposure assessment scenario* exceeded the ADI of 5 mg/kg bw per day for all population groups at the high level (95th percentile) and for toddlers and children also at the mean level (Table 7). The main contributing food categories to the total mean exposure estimates for infants and toddlers in this scenario were flavoured fermented milk products. For children and adolescents, the main contributing food categories were confectionary and flavoured drinks; while, for adults and the elderly, the main contributing food categories were processed fruit and vegetables and sauces. The Panel noted that the estimated long-term exposures based on this scenario are very likely conservative, as this scenario assumes that all foods and beverages listed under Annex II to Regulation No 1333/2008 contain benzoic acid-benzoates (E 210–213) as food additives at the MPL.

From the *refined estimated exposure scenario* considering only food categories for which direct addition of benzoic acid-benzoates to food is authorised, in the *brand-loyal scenario*, mean exposure to benzoic acid-benzoates (E 210–213) ranged from 0.07 mg/kg bw per day in infants to 3.2 mg/kg bw per day in toddlers. The high exposure to benzoic acid-benzoates (E 210–213) ranged from 0.4 mg/kg bw per day in infants to 7.1 mg/kg bw per day in children. In the *non-brand-loyal scenario*, mean exposure to benzoic acid-benzoates (E 210–213) ranged from 0.02 mg/kg bw per day in infants to 1.6 mg/kg bw per day in toddlers. The high exposure to benzoic acid-benzoates (E 210–213) ranged from 0.05 mg/kg bw per day in infants to 4.7 mg/kg bw per day in toddlers. The main contributing food categories for all population groups were flavoured drinks and sauces in both scenarios.

From the *refined estimated exposure scenario* considering additional exposure from food categories which may contain benzoic acid-benzoates due to carry-over and for which data were available, in the *brand-loyal scenario*, mean exposure to benzoic acid-benzoates (E 210–213) ranged from 2.5 mg/kg bw per day for adolescents to 10.6 mg/kg bw per day for toddlers. The high exposure to benzoic acid-benzoates (E 210–213) ranged from 4.9 mg/kg bw per day for adolescents to 19.6 mg/kg bw per day in toddlers. The main contributing food categories were unprocessed fruits and vegetables for all population groups. In the *non-brand-loyal scenario*, mean exposure to benzoic acid-benzoates (E 210–213) ranged from 0.8 mg/kg bw per day for adolescents to 3.5 mg/kg bw per day for toddlers. The high exposure to benzoic acid-benzoates (E 210–213) ranged from 1.3 mg/kg bw per day in the elderly to 6.9 mg/kg bw per day in toddlers. The main contributing food categories were processed fruits and vegetables and processed foods for infants; for toddlers, they were unprocessed fruits and vegetables, flavoured drinks and processed foods; for children and adolescents, the main contributing food categories were flavoured drinks and unprocessed fruits and vegetables and for adults and the elderly, the main contributing food categories were unprocessed fruits and vegetables and coffee, tea, herbal and fruit infusions, chicory.

Therefore, considering only food categories for which direct addition of benzoic acid-benzoates to food is authorised, the exposure to benzoic acid-benzoates (E 210–213), in toddlers, children, adolescents and adults exceeded the ADI of 5 mg/kg bw per day at the high level (95th percentile) in the *refined brand-loyal* exposure estimate, while, for the *non-brand-loyal scenario*, the group ADI was not exceeded in any population groups (Table 7). Considering additional exposure from food categories which may contain benzoic acid-benzoates due to carry-over and for which data were

available, in the *refined brand-loyal* exposure scenario, the ADI was exceeded at the high level for all population groups and for infants, toddlers, children and adolescent at the mean. In the *non-brand-loyal* exposure scenario, the ADI was exceeded only for toddlers and children at the high level; at the mean level there was no exceedance.

The Panel considered that the refined exposure assessment approach resulted in more realistic long-term exposure estimates compared to the *regulatory maximum level exposure assessment scenario*. This approach is based on the extensive range of analytical data available and assumes that people, in the long term, are exposed to foods and beverages that contain the food additive at a mean concentration level for all products (*non-brand-loyal scenario*) or that one product contains the food additive at the maximum concentration level (*brand-loyal scenario*) and the remaining products contain the additive at a mean concentration level. For benzoic acid-benzoates (E 210–213), reported use/analytical levels were available. However, not all available data could be included in the assessment owing to specific restrictions/exceptions regarding products not referenced in the FoodEx classification. This may have resulted in an underestimation of exposure to benzoic acid and benzoates. On the other hand, several food categories for which usage/analytical data were available were included without considering specific restrictions/exceptions, which may have overestimated the exposure to benzoic acid and benzoates.

The Panel noted that from all contributing sources, exposure from non-alcoholic beverages provided a realistic situation of possible exceedance of the ADI in those population groups due to the fact of the existence of consumer being brand-loyal to non-alcoholic beverage and of the consistency mean value observed from the large number of data that have been submitted (around 7000) from industries or from Member States with a mean of 100 mg/L from reported typical use level vs a mean of 80 mg/L from analytical mean measurement.

The Panel also noted that the exposure assessment considering *brand-loyal* exposure using dataset 1 was concordant with the recent JECFA re-evaluation on the dietary exposure to benzoates where exceedance of the ADI of 5 mg/kg bw per day was only observed at the 95th percentile exposures for the consumers-only group of non-alcoholic beverages for toddlers, children and adolescents (JECFA, 2015).

CONCLUSIONS

Considering the present database, the Panel identified a NOAEL of 500 mg/kg bw per day and applying an uncertainty factor of 100, the Panel derived a group ADI of 5 mg/kg bw per day, expressed as benzoic acid, for benzoic acid (E 210), sodium benzoate (E 211), potassium benzoate (E 212) and calcium benzoate (E 213).

The Panel concluded that from the use of benzoic acid-benzoates as food additives from direct addition to food, the group ADI was exceeded in the *brand-loyal scenario* for toddlers and children consuming on a regular basis flavoured drinks.

Considering additional exposure from food categories which may contain benzoic acid-benzoates due to carry-over and for which data were available, the Panel concluded that exposure to benzoic acid-benzoates could be increased by up to two to three fold for all high-level consumers compared to the previous scenario for direct addition to food. This is resulting in exceedance of the group ADI in toddlers and children for the *non-brand-loyal* scenario. The main food categories contributing to this exceedance were unprocessed fruits and vegetables and flavoured drinks.

RECOMMENDATIONS

The Panel recommended that:

- the maximum limits for the impurities of toxic elements (lead, mercury and arsenic) in the EC specification for benzoic acid and its salts (E 210–213) should be revised in order to ensure that benzoic acid and its salts (E 210–213) as food additives will not be a significant source of exposure to those toxic elements in food.

- When benzoic acid or its salts and ascorbic acid are used together, consideration should be given to the storage of soft drinks and food contact materials to minimise the formation of benzene in beverages as low as reasonably achievable.

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APPENDICES

A. Summary of reported use levels (mg/kg) of benzoic acid-benzoates (E 210–213) provided by industry

FCS Category N°	FCS Food Category	MPL	Restrictions / exceptions	Typical mean (range)	Max	Information provided by	Comments
05.2	Other confectionery including breath refreshening microsweets	1500 / 1000	except candied, crystallised or glacé fruit and vegetables / only candied, crystallised or glacé fruit and vegetables	60 (0-120)	120	FDE (2013)	confectionary (excluding chocolate)
				0	0	FDE (2013)	pralines (reported as not used)
				0	0	FDE (2013)	Bars (reported as not used)
				0	0	FDE (2013)	Dragées (reported as not used)
05.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4	1500		0	0	FDE (2013)	fillings for chocolates (reported as not used)
				0.002	0.002	Mars (2010)	chocolates
12.6	Sauces	1000	non emulsified sauces	132 (0-263)	850*	FDE (2013)	non-emulsified sauces *850 mg/kg in 1 products from few EU countries, not used in the exposure assessment
				0	0	FDE (2013)	ketchup (reported as not used)
		500	only emulsified sauces with a fat content of 60 % or more	0	0	FDE (2013)	sauces for barbecue (reported as not used)
				0	0	FDE (2013)	sauces for pasta (reported as not used)
12.7	Salads and savoury based sandwich spreads	1500		1000	1500	FDE (2013)	prepared salads (reported as 65% of products do not contain these FA)
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	1500		125 (100-150)	150	FDE (2013)	dietetic foods intended for special medical purposes
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)	1500		125 (100-150)	150	FDE (2013)	dietetic formulae for weight control: in the product in powder as sold, needs to be diluted

FCS Category N°	FCS Food Category	MPL	Restrictions / exceptions	Typical mean (range)	Max	Information provided by	Comments
14.1.4	Flavoured drinks	150	excluding dairy-based drinks	98 (50-145)	150	FDE (2013)	non-alcoholic flavoured drinks
				98 (50-145)	150	FDE (2013)	carbonates
				100 (50-150)	150	UNESDA (2010)	carbonates
				98 (50-145)	145	FDE (2013)	lemon flavoured carbonates (for non-lemon flavoured: reported as very low use)
				100 (60-140)	150	UNESDA (2010)	still drinks
				125 (110-140)	150	FDE (2013)	still drinks; level reported as representative which does not imply that all or the majority of the products use this food additive
				0	0	UNESDA (2010)	iced coffee (reported as not used)
				100 (60-140)	150	UNESDA (2010)	iced tea
				113 (85-140)	150	FDE (2013)	iced tea
				103 (60-145)	150	UNESDA (2010)	squashes/syrups (concentrates)
				0	0	UNESDA (2010)	fruit powder (reported as not used)
				130 (120-140)	150	FDE (2013)	energy drinks
				113 (85-140)	150	UNESDA (2010)	energy drinks
				70 (0-140)	150	FDE (2013)	sports drinks; reported as occasional use in sports drinks
				138 (130-145)	150	UNESDA (2010)	sports drinks

FCS Category N°	FCS Food Category	MPL	Restrictions / exceptions	Typical mean (range)	Max	Information provided by	Comments
14.2.1	Beer and malt beverages	200	only alcohol free beer; beer in kegs containing more than 0.5 % added fermentable sugar and/or fruit juices or concentrates	125 (100-150)	200	FDE (2013)	alcohol-free beer in keg
16	Desserts excluding products covered in category 1, 3 and 4	300	only non-heat-treated dairy-based desserts	50	50	FDE (2013)	non-heat treated dairy base desserts (limited representation for the Swedish market)

FCS, Food Categorisation System; FDE, FoodDrinkEurope; MPL, maximum permitted level; *QS*, *quantum satis*; UNESDA, Union of European Soft Drinks Associations.

B. Summary of analytical results (mg/kg) of benzoic acid provided by Member States

B1. All data received

									LOD		LOQ		Middle-bound				
FCS Category number	**Food category**	**MPL**	**restrictions**	**N**	**No LC**	**% LC**	**No > MPL**	**% > MPL**	**Min**	**Max**	**Min**	**Max**	**Min**	**Median**	**Mean**	**P95**	**Max**
01.1	Unflavoured pasteurised and sterilised (including UHT) milk			16	9	56.3			0.2	3.8	0.5	12.5	0.5	2.2	11.3	52.0	52.0
01.2	Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non-heat-treated after fermentation			88	76	86.4			0.0	4.0	0.0	12.5	0.3	1.9	3.2	14.0	20.5
01.3	Unflavoured fermented milk products, heat-treated after fermentation			484	115	23.8			0.0	3.0	0.0	50.0	0.0	9.8	9.9	21.1	73.0
01.4	Flavoured fermented milk products including heat treated products	300	only non-heat treated dairy based desserts	1118	539	48.2	0	0.0	0.0	20.0	0.0	50.0	0.0	2.4	5.2	16.0	116.7
01.5	Dehydrated milk as defined by Directive 2001/114/EC			2	2	100.0			0.3	0.4	1.0	1.0	0.5	0.5	0.5	0.5	0.5
01.6	Cream and cream powder			12	5	41.7			0.0	3.4	0.0	10.1	0.3	5.8	26.9	253.0	253.0
01.6.3	Cream and cream powder			253	184	72.7			0.0	11.3	0.0	33.9	0.0	0.3	2.7	13.5	38.2
01.7	Cheese and cheese products			157	132	84.1			1.0	6.7	5.0	20.0	0.6	1.9	13.6	22.0	1224.4
01.7.1	Unripened cheese excluding products falling in category 16			131	24	18.3			0.0	37.8	0.0	113.3	0.3	8.0	74.1	532.1	1029.0
01.7.2	Ripened cheese			239	107	44.8			0.0	10.0	0.0	50.0	0.0	5.0	12.5	25.0	982.0
01.7.3	Edible cheese rind			13	5	38.5			0.2	0.4	0.5	1.0	0.3	5.0	4.4	9.2	9.2
01.7.4	Whey cheese			168	89	53.0			0.0	37.8	0.0	113.3	0.0	0.5	11.4	35.7	369.3
01.7.5	Processed cheese			858	368	42.9			0.0	20.0	0.0	50.0	0.0	4.8	9.1	23.5	786.6

									LOD		LOQ		Middle-bound				
FCS Category number	**Food category**	**MPL**	**restrictions**	**N**	**No LC**	**% LC**	**No > MPL**	**% > MPL**	**Min**	**Max**	**Min**	**Max**	**Min**	**Median**	**Mean**	**P95**	**Max**
01.7.6	Cheese products (excluding products falling in category 16)			8	1	12.5			0.2	0.3	0.6	1.0	0.3	7.3	8.9	22.6	22.6
01.8	Dairy analogues, including beverage whiteners			10	7	70.0			0.0	14.0	0.0	45.0	0.0	4.6	4.1	9.1	9.1
02.1	Fats and oils essentially free from water (excluding anhydrous milk fat)			381	380	99.7			0.0	125.0	0.0	125.0	0.0	0.3	1.5	0.5	66.5
02.2	Fat and oil emulsions mainly of type water-in-oil			24	22	91.7			0.2	11.3	0.5	54.0	0.3	1.9	58.2	317.0	1016.0
02.2.1	Butter and concentrated butter and butter oil and anhydrous milk fat			26	20	76.9			0.0	0.4	0.0	1.0	0.3	0.3	3.1	13.6	16.9
02.2.2	Other fat and oil emulsions including spreads as defined by Regulation (EC) No 1234/2007 and liquid emulsions			189	189	100.0			0.0	20.0	0.0	50.0	0.0	1.9	2.7	10.0	10.0
03	Edible ices			314	244	77.7			0.0	7.6	0.0	75.0	0.0	2.5	12.8	26.0	800.0
04.1	Unprocessed fruit and vegetables			11	9	81.8			1.0	3.0	5.0	50.0	0.5	2.5	12.1	50.0	50.0
04.1.1	Entire fresh fruit and vegetables			92	81	88.0			0.0	10.0	0.0	20.0	0.3	2.5	70.0	766.0	1010.0
04.1.2	Peeled, cut and shredded fruit and vegetables			24	18	75.0			0.0	11.3	0.0	33.9	0.0	0.3	83.7	394.5	548.0
04.1.3	Frozen fruit and vegetables			106	96	90.6			0.0	37.8	0.0	113.3	0.0	0.3	41.7	344.3	872.0
04.2	Processed fruit and vegetables			105	74	70.5			0.3	20.0	0.6	50.0	0.2	7.5	192.5	1271.5	1802.5
04.2.1	Dried fruit and vegetables			1086	982	90.4			0.0	20.0	0.0	60.0	0.0	0.5	9.7	50.0	1425.0
04.2.2	Fruit and vegetables in vinegar, oil, or brine	2000	only vegetables (excluding olives)	1003	624	62.2	3	0.3	0.0	37.8	0.0	113.5	0.0	7.5	267.4	1174.0	2270.0
04.2.2	Fruit and vegetables in vinegar, oil, or brine			27	20	74.1			0.3	56.5	1.0	169.5	0.5	5.0	260.0	1450.0	1640.0

									LOD		LOQ		Middle-bound				
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04.2.2	Fruit and vegetables in vinegar, oil, or brine	500	only olives and olive-based preparations	114	88	77.2	7	6.1	1.0	20.0	3.0	50.0	0.5	7.5	97.4	544.0	1339.0
04.2.3	Canned or bottled fruit and vegetables			1283	893	69.6			0.0	37.8	0.0	115.0	0.0	0.9	241.8	1298.9	3652.4
04.2.4	Fruit and vegetable preparations, excluding products covered by 5.4			87	85	97.7			2.0	20.0	2.0	50.0	1.0	10.0	17.9	10.0	818.0
04.2.4.1	Fruit and vegetable preparations excluding compote			122	111	91.0			0.3	20.0	0.6	50.0	0.2	2.5	21.0	10.0	817.0
04.2.4.1	Fruit and vegetable preparations excluding compote	2000	only cooked red beet	4	3	75.0	0	0.0	0.3	3.3	0.6	15.0	0.3	6.3	193.6	761.7	761.7
04.2.4.1	Fruit and vegetable preparations excluding compote	500	only seaweed preparations, olives and olive-based preparations	13	0	0.0	8	61.5					300.0	540.0	513.8	690.0	690.0
04.2.4.2	Compote, excluding products covered by category 16			402	381	94.8			0.0	20.0	0.0	50.0	0.0	0.3	8.6	10.0	943.0
04.2.5	Jam, jellies and marmalades and similar products			769	598	77.8			0.0	20.0	0.0	75.0	0.0	5.0	50.4	349.0	1139.0
04.2.5.1	Extra jam and extra jelly as defined by Directive 2001/113/EEC	500	only low-sugar and similar low calorie or sugar-free products , *mermeladas*	262	257	98.1	0	0.0	0.2	20.0	0.5	50.0	0.3	10.0	7.9	10.0	83.3
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EEC	500	only low-sugar and similar low calorie or sugar-free products; *mermeladas*	593	510	86.0	12	2.0	0.3	50.0	1.0	60.0	0.3	2.5	38.7	250.0	1260.0

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04.2.5.3	Other similar fruit or vegetable spreads	500	other fruit-based spreads, *mermeladas*	468	423	90.4	1	0.2	0.2	50.0	0.5	75.0	0.3	10.0	23.1	92.0	649.0
04.2.5.3	Other similar fruit or vegetable spreads	1000	only *dulce de membrillo*	0			0										
04.2.5.3	Other similar fruit or vegetable spreads	1500	only *marmelada*	6	0	0.0	0	0.0	6.7	6.7	20.0	20.0	338.3	589.4	554.0	824.0	824.0
04.2.5.4	Nut butters and nut spreads			7	7	100.0			1.7	1.7	5.0	5.0	2.5	2.5	2.5	2.5	2.5
04.2.6	Processed potato products			93	92	98.9			0.2	20.0	0.5	50.0	0.3	7.5	7.1	10.0	18.5
05.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC			54	46	85.2			0.0	37.8	0.0	113.5	0.0	0.5	3.3	18.9	22.9
05.2	Other confectionery including breath refreshening microsweets	1500	except candied, crystallised or glacé fruit and vegetables	340	301	88.5	0	0.0	0.0	20.0	0.0	50.0	0.0	2.5	46.0	346.8	1027.0
05.2	Other confectionery including breath refreshening microsweets	1000	only candied, crystallised or glacé fruit and vegetables	164	151	92.1	0	0.0	0.0	10.0	0.0	30.0	0.0	1.9	18.5	110.0	418.0
05.3	Chewing gum	1500		5	4	80.0	0	0.0	0.2	20.0	0.5	50.0	0.5	10.0	89.9	419.0	419.0
05.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4	1500		73	67	91.8	0	0.0	1.7	3.8	5.0	15.0	1.9	1.9	47.0	411.0	780.2
06	Cereals and cereal products			3	3	100.0			3.8	3.8	12.5	12.5	1.9	1.9	1.9	1.9	1.9
06.1	Whole, broken, or flaked grain			6	6	100.0			0.2	10.0	0.6	20.0	0.3	5.0	4.2	7.5	7.5
06.2	Flours and other milled products and starches			2	1	50.0			1.7	1.7	5.0	5.0	2.5	6.8	6.8	11.1	11.1
06.2.1	Flours			18	17	94.4			0.0	6.0	0.0	18.0	0.0	1.8	2.2	9.0	9.0
06.2.2	Starches			1	1	100.0			0.2	0.2	0.6	0.6	0.3	0.3	0.3	0.3	0.3
06.3	Breakfast cereals			67	57	85.1			0.0	22.6	0.0	67.8	0.0	2.5	3.5	15.8	33.9
06.4	Pasta			34	33	97.1			0.0	20.0	0.0	20.0	0.0	7.5	10.8	10.0	180.0

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06.4.1	Fresh pasta			3	3	100.0			0.5	5.0	1.5	15.0	0.3	2.5	1.8	2.5	2.5
06.4.2	Dry pasta			3	3	100.0			0.2	0.3	0.5	1.0	0.3	0.3	0.3	0.5	0.5
06.4.4	Potato gnocchi			9	9	100.0			0.0	20.0	0.0	20.0	0.0	5.0	6.1	10.0	10.0
06.6	Batters			3	3	100.0			1.0	10.0	3.0	30.0	0.5	0.5	2.0	5.0	5.0
06.7	Pre-cooked or processed cereals			1	1	100.0					15.0	15.0	7.5	7.5	7.5	7.5	7.5
07.1	Bread and rolls			1501	1475	98.3			0.2	20.0	0.5	30.0	0.3	5.0	5.4	10.0	265.9
07.1.1	Bread prepared solely with the following ingredients: wheat flour, water, yeast or leaven, salt			299	298	99.7			0.0	3.8	0.0	12.5	0.0	0.3	0.5	1.9	17.0
07.1.2	Pain courant français; Friss búzakenyér, fehér és félbarna kenyerek			1	1	100.0			3.3	3.3	10.0	10.0	5.0	5.0	5.0	5.0	5.0
07.2	Fine bakery wares			2937	2526	86.0			0.0	37.8	0.0	113.5	0.0	2.5	18.3	48.0	1900.0
08.1	Unprocessed meat			11	10	90.9			0.2	1.7	0.5	5.0	0.3	2.5	9.8	92.0	92.0
08.2	Meat preparations			6	4	66.7			0.2	1.7	0.5	5.0	0.3	2.5	138.8	423.0	423.0
08.3	Meat products			163	141	86.5			0.0	37.8	0.0	113.3	0.0	0.3	465.4	478.8	68772.6[(a)]
08.3.1	Non heat treated processed meat		only surface treatment of dried meat products	114	110	96.5			1.3	3.3	1.3	20.0	0.6	6.3	7.9	10.0	147.5
08.3.2	Heat treated processed meat	500	only aspic	85	64	75.3	3	3.5	0.0	37.8	0.0	113.3	0.0	2.5	47.5	198.7	842.1
08.3.3	Casing and Coatings and decorations for meat			1	1	100.0			1.7	1.7	5.0	5.0	2.5	2.5	2.5	2.5	2.5
08.3.4	Traditionally cured meat products with specific provisions concerning nitrites and nitrates			3	3	100.0			1.7	1.7	5.0	5.0	2.5	2.5	2.5	2.5	2.5

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08.3.4.1	Traditional immersion cured products (meat products cured by immersion in a curing solution containing nitrites and/or nitrates, salt and other components)			1	0	0.0							181.0	181.0	181.0	181.0	181.0
08.3.4.2	Traditional dry-cured products (dry curing process involves dry application of curing mixture containing nitrites and/or nitrates, salt and other components to the surface of the meat followed by a period of stabilisation/maturation).			3	3	100.0			0.5	1.0	1.5	3.0	0.3	0.3	0.3	0.5	0.5
08.3.4.3	Other traditionally cured products (immersion and dry cured processes used in combination or where nitrite and/or nitrate is included in a compound product or where the curing solution is injected into the product prior to cooking)			3	3	100.0			0.3	0.3	1.0	1.0	0.5	0.5	0.5	0.5	0.5
09.1.1	Unprocessed fish			42	26	61.9			0.2	10.0	0.5	75.0	0.3	2.2	289.5	1600.0	2029.8
09.1.2	Unprocessed molluscs and crustaceans			47	45	95.7			1.7	3.8	5.0	12.5	1.9	2.5	5.7	5.0	101.1
09.2	Processed fish and fishery products including molluscs and crustaceans			611	322	52.7			0.0	10.0	0.0	30.0	0.0	10.0	353.6	1592.0	2427.0
09.2	Processed fish and fishery products including molluscs and crustaceans	200	only salted, dried fish	39	39	100.0	0	0.0			20.0	20.0	10.0	10.0	10.0	10.0	10.0

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09.2	Processed fish and fishery products including molluscs and crustaceans	2000	only semi-preserved fish and fisheries products including crustaceans, molluscs, surimi and fish / crustacean paste; cooked crustaceans and molluscs	326	135	41.4	2	0.6	1.3	3.3	1.3	15.0	0.6	195.0	410.9	1400.0	3200.0
09.2	Processed fish and fishery products including molluscs and crustaceans	6000	only cooked *Crangon crangon* and *Crangon vulgaris*	92	40	43.5	0	0.0	0.2	1.7	0.5	20.0	2.5	337.2	454.6	1200.0	3800.0
09.2	Processed fish and fishery products including molluscs and crustaceans	1000	only cooked crustaceans and molluscs	41	27	65.9	0	0.0	0.2	50.0	0.5	150.0	0.5	10.0	155.6	834.0	881.4
09.2	Processed fish and fishery products including molluscs and crustaceans	1500	only cooked shrimps in brine	0			0										
09.3	Fish roe	2000	only semi-preserved fish products including fish roe products	68	22	32.4	0	0.0	0.0	1.7	0.0	5.0	0.3	663.3	644.2	1686.0	1994.6
09.3	Fish roe			16	9	56.3			1.0	6.7	1.0	20.0	0.5	10.0	463.4	1529.7	1529.7
10.1	Unprocessed eggs			5	3	60.0			1.7	1.7	5.0	5.0	2.5	2.5	295.7	986.0	986.0
10.2	Processed eggs and egg products			16	6	37.5			0.5	37.8	1.5	113.3	0.3	263.0	441.9	4000.0	4000.0
10.2	Processed eggs and egg products	5000	only liquid egg (white, yolk or whole egg)	47	41	87.2	0	0.0	6.7	6.7	20.0	20.0	10.0	10.0	461.6	3855.0	3890.0

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11.1	Sugars and syrups as defined by Directive 2001/111/EC			6	6	100.0			0.3	37.8	1.0	113.4	0.5	7.5	8.2	18.9	18.9
11.2	Other sugars and syrups			219	69	31.5			0.0	37.8	0.0	113.4	0.0	59.0	101.4	675.6	1664.4
11.3	Honey as defined in Directive 2001/110/EC			2	0	0.0			0.2	0.2	0.5	0.5	63.0	85.0	85.0	107.0	107.0
11.4	Table-top sweeteners			2	2	100.0			0.3	0.9	1.0	1.0	0.4	0.5	0.5	0.5	0.5
11.4.1	Table-top sweeteners in liquid form			2	2	100.0			1.0	1.0	3.0	20.0	0.5	5.3	5.3	10.0	10.0
11.4.1	Table-top sweeteners in liquid form	500	only if the water content higher than 75 %	0			0										
12.1.1	Salt			1	1	100.0			0.2	0.2	0.5	0.5	0.3	0.3	0.3	0.3	0.3
12.1.2	Salt substitutes			36	32	88.9			0.0	0.4	0.0	1.0	0.0	0.3	78.5	776.9	988.9
12.2	Herbs, spices, seasonings			30	23	76.7			1.7	2.0	5.0	75.0	2.5	2.5	119.3	850.0	850.0
12.2.1	Herbs and spices			38	34	89.5			0.0	14.0	0.0	45.0	0.1	7.5	78.7	761.8	1156.0
12.2.2	Seasonings and condiments	1000		282	228	80.9	1	0.4	0.0	36.0	0.0	50.0	0.3	7.5	94.1	556.9	3227.0
12.3	Vinegars			67	62	92.5			0.0	10.0	0.0	50.0	0.0	0.3	2.0	7.5	51.2
12.4	Mustard	1000		500	380	76.0	2	0.4	0.0	36.0	0.0	50.0	0.0	1.5	106.6	797.0	1034.0
12.5	Soups and broths			321	307	95.6			0.0	10.0	0.0	30.0	0.0	0.3	5.2	5.0	704.3
12.5	Soups and broths	500	only liquid soups and broths (excluding canned)	47	46	97.9	0	0.0	0.0	20.0	0.2	50.0	0.1	7.5	7.8	10.0	58.0
12.5	Soups and broths			44	43	97.7			0.0	2.2	0.0	6.7	0.0	0.4	0.4	0.5	3.4
12.6	Sauces			839	554	66.0			0.0	36.0	0.0	75.0	0.0	7.5	109.7	670.0	1513.5
12.6	Sauces	1000	only emulsified sauces with a fat content of less than 60 %	887	448	50.5	18	2.0	0.0	37.8	0.0	113.5	0.0	10.0	287.2	896.0	1535.5
12.6	Sauces	500	only emulsified sauces with a fat content of 60 % or more	178	141	79.2	17	9.6	0.5	36.0	1.5	50.0	0.3	2.5	108.8	820.0	990.0

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12.6	Sauces	1000	non emulsified sauces	0			0										
12.7	Salads and savoury based sandwich spreads	1500		3314	1128	34.0	17	0.5	0.0	1345.0	0.0	1345.0	0.0	131.5	255.1	839.7	3675.9
12.9	Protein products, excluding products covered in category 1.8			6	4	66.7			0.2	6.7	0.5	20.0	0.3	4.0	817.6	4800.0	4800.0
13	Foods intended for particular nutritional uses as defined by Directive 2009/39/EC			10	9	90.0			2.0	14.0	2.0	45.0	1.0	5.0	13.6	99.1	99.1
13.1.1	Infant formulae as defined by Commission Directive 2006/141/EC			3	2	66.7			1.5	3.4	4.5	10.1	1.7	2.3	3.5	6.7	6.7
13.1.2	Follow-on formulae as defined by Directive 2006/141/EC			51	47	92.2			0.2	23.9	0.5	71.7	0.3	3.0	5.3	35.9	35.9
13.1.3	Processed cereal-based foods and baby foods for infants and young children as defined by Commission Directive 2006/125/EC			7	7	100.0			0.5	10.0	1.5	30.0	0.3	0.3	1.5	5.0	5.0
13.1.4	Other foods for young children			2	2	100.0			0.5	1.0	1.5	3.0	0.3	0.4	0.4	0.5	0.5
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	1500		216	139	64.4	0	0.0	0.2	100.0	0.4	100.0	0.1	5.0	23.0	112.0	502.0
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)	1500		6	6	100.0	0	0.0	0.6	7.5	3.6	22.4	0.3	1.3	3.7	11.2	11.2

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13.4	Foods suitable for people intolerant to gluten as defined by Commission Regulation (EC) No 41/2009			3	3	100.0			5.0	5.0	15.0	15.0	2.5	7.5	5.8	7.5	7.5
14.1	Non-alcoholic beverages			25	12	48.0			1.7	11.3	5.0	33.9	2.5	35.9	48.4	132.0	192.8
14.1.1	Water, including natural mineral water as defined in Directive 2009/54/EC and spring water and all other bottled or packed waters			138	9	6.5			0.0	1.7	0.0	10.0	0.0	117.5	105.8	153.3	250.0
14.1.2	Fruit juices as defined by Directive 2001/112/EC and vegetable juices			1479	968	65.4			0.0	166.7	0.0	500.0	0.0	2.5	22.9	113.3	1909.2
14.1.2	Fruit juices as defined by Council Directive 2001/112/EC and vegetable juices	2000	only grape juice, unfermented, for sacramental use	0			0										
14.1.2	Fruit juices as defined by Council Directive 2001/112/EC and vegetable juices	200	only *Sød….saft* and *sødet….sa*ft	0			0										
14.1.3	Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products			308	182	59.1			0.0	10.0	0.0	24.0	0.0	2.0	29.8	119.8	905.0
14.1.3	Fruit nectars as defined by Council Directive 2001/112/EC and vegetable nectars and similar products	150	only traditional Swedish and Finnish fruit syrups	0			0										
14.1.4	Flavoured drinks			10	7	70.0			1.7	11.3	5.0	33.9	2.5	5.0	23.0	92.8	92.8
14.1.4	Flavoured drinks	150	excluding dairy-based drinks	6835	2941	43.0	232	3.4	0.0	37.8	0.0	165.0	0.0	7.5	57.1	143.2	1290.0

									LOD		LOQ		Middle-bound				
FCS Category number	**Food category**	**MPL**	**restrictions**	**N**	**No LC**	**% LC**	**No > MPL**	**% > MPL**	**Min**	**Max**	**Min**	**Max**	**Min**	**Median**	**Mean**	**P95**	**Max**
14.1.5	Coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products			21	14	66.7			0.0	10.0	0.0	30.0	0.0	3.6	39.6	148.0	208.0
14.1.5.1	Coffee, coffee extracts			8	8	100.0			0.0	3.8	0.0	12.5	0.0	0.5	0.8	1.9	1.9
14.1.5.2	Other	600	only liquid tea concentrates and liquid fruit and herbal infusion concentrates	26	20	76.9	1	3.8	0.2	6.7	0.6	20.0	0.1	10.0	70.8	257.0	845.0
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts			9	3	33.3			3.8	3.8	12.5	12.5	1.9	143.0	109.7	198.0	198.0
14.2.1	Beer and malt beverages			226	158	69.9			0.0	5.0	0.0	15.0	0.0	0.3	2.4	7.5	76.0
14.2.1	Beer and malt beverages	200	only alcohol free beer; beer in kegs containing more than 0.5 % added fermentable sugar and/or fruit juices or concentrates	65	54	83.1	0	0.0	0.2	1.7	1.0	10.0	0.1	2.5	4.9	22.0	60.0
14.2.2	Wine and other products defined by Regulation (EC) No 1234/2007, and alcohol free counterparts			679	674	99.3			0.0	10.0	0.0	20.0	0.0	5.0	5.2	5.0	881.6
14.2.2	Wine and other products defined by Regulation (EC) No 1234/2007, and alcohol-free counterparts	200	only alcohol-free	0			0										
14.2.3	Cider and perry			1092	1038	95.1			0.0	10.0	0.0	30.0	0.0	0.3	2.1	7.5	121.0

									LOD		LOQ		Middle-bound				
FCS Category number	**Food category**	**MPL**	**restrictions**	**N**	**No LC**	**% LC**	**No > MPL**	**% > MPL**	**Min**	**Max**	**Min**	**Max**	**Min**	**Median**	**Mean**	**P95**	**Max**
14.2.4	Fruit wine and made wine			12	11	91.7			0.0	6.7	0.0	20.0	0.3	10.0	16.9	117.1	117.1
14.2.4	Fruit wine and made wine			1	1	100.0			3.3	3.3	10.0	10.0	5.0	5.0	5.0	5.0	5.0
14.2.5	Mead			4	4	100.0			6.7	11.3	5.0	20.0	2.5	6.3	6.3	10.0	10.0
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 and Mistrà			62	28	45.2			0.0	0.3	0.0	15.0	0.0	101.3	67.5	157.0	192.2
14.2.7	Aromatised wine-based products as defined by Regulation (EEC) No 1601/91			22	5	22.7			1.7	1.7	5.0	5.0	2.5	160.0	123.3	200.0	200.0
14.2.7.1	Aromatised wines			16	16	100.0			0.0	0.3	0.0	1.0	0.0	0.3	0.3	0.5	0.5
14.2.7.2	Aromatised wine-based drinks except bitter soda, sangria, claria, zurra			4	4	100.0			0.0	10.0	0.0	15.0	0.0	2.6	2.6	5.0	5.0
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol	200	only alcoholic drinks with less than 15 % of alcohol	139	63	45.3	1	0.7	0.0	16.7	0.0	50.0	0.0	104.0	76.9	188.0	401.7
15.1	Potato-, cereal-, flour- or starch-based snacks			166	165	99.4			0.0	20.0	0.0	50.0	0.0	2.5	5.7	10.0	207.8
15.2	Processed nuts			4	4	100.0			0.3	1.7	1.0	20.0	0.5	1.5	3.4	10.0	10.0

									LOD		LOQ		Middle-bound				
FCS Category number	**Food category**	**MPL**	**restrictions**	**N**	**No LC**	**% LC**	**No > MPL**	**% > MPL**	**Min**	**Max**	**Min**	**Max**	**Min**	**Median**	**Mean**	**P95**	**Max**
16	Desserts excluding products covered in category 1, 3 and 4	300	only non-heat-treated dairy-based desserts	366	330	90.2	2	0.5	1.7	20.0	2.0	50.0	0.8	7.5	12.4	15.0	580.0
16	Desserts excluding products covered in category 1, 3 and 4	500	only *frugtgrød* and *Rote Grütze*	0			0										
17	Food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council excluding food supplements for infants and young children			236	178	75.4			0.1	100.0	0.3	113.5	0.1	6.2	88.0	678.6	1197.8
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms	1000	only when supplied in dried form and containing preparations of vitamin A and of combinations of vitamin A and D	3	3	100.0	0	0.0	3.3	3.4	9.9	10.1	5.0	5.1	5.0	5.1	5.1
17.2	Food supplements supplied in a liquid form	2000		20	6	30.0	1	5.0	0.5	10.0	1.5	30.0	0.3	716.4	794.2	2040.5	2126.0
18	Processed foods not covered by categories 1 to 17, excluding foods for infants and young children			167	148	88.6			0.0	10.0	0.0	30.0	0.0	2.5	12.4	21.4	723.2

LC, left-censored data; % LC, percentage of left-censored data; FCS, Food Categorisation System; LOD, limit of detection; LOQ, limit of quantification; Max, maximum; MB, middle bound; Min, minimum; MPL, maximum permitted level; N, number of analytical results; P95, 95th percentile.

(a) This level of almost 70 mg/kg meat was considered as an outlier and therefore not use in the exposure assessment

B2. Analytical data on food categories listed under Annex II to Regulation No 1333/2008 excluding data above MPLs

				Data < MPL										
						LOD		LOQ		Middle-bound				
FCS category number	**Food category**	**MPL**	**restrictions**	**N**	**No LC**	**Min**	**Max**	**Min**	**Max**	**Min**	**Median**	**Mean**	**p95**	**Max**
01.4	Flavoured fermented milk products including heat treated products	300	only non-heat treated dairy based desserts	1118	539	0.0	20.0	0.0	50.0	0.0	2.4	5.2	16.0	116.7
04.2.2	Fruit and vegetables in vinegar, oil, or brine	2000	only vegetables (excluding olives)	1000	624	0.0	37.8	0.0	113.5	0.0	7.5	261.9	1167.5	1973.0
04.2.2	Fruit and vegetables in vinegar, oil, or brine	500	only olives and olive-based preparations	107	88	1.0	20.0	3.0	50.0	0.5	7.5	44.8	277.0	431.0
04.2.4.1	Fruit and vegetable preparations excluding compote	2000	only cooked red beet	4	3	0.3	3.3	0.6	15.0	0.3	6.3	193.6	761.7	761.7
04.2.4.1	Fruit and vegetable preparations excluding compote	500	only seaweed preparations, olives and olive-based preparations	5	0					300.0	360.0	388.0	490.0	490.0
04.2.5.1	Extra jam and extra jelly as defined by Directive 2001/113/EEC	500	only low-sugar and similar low calorie or sugar-free products , *mermeladas*	262	257	0.2	20.0	0.5	50.0	0.3	10.0	7.9	10.0	83.3
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EEC	500	only low-sugar and similar low calorie or sugar-free products; *mermeladas*	581	510	0.3	50.0	1.0	60.0	0.3	2.5	25.7	203.0	470.0
04.2.5.3	Other similar fruit or vegetable spreads	500	other fruit-based spreads, *mermeladas*	467	423	0.2	50.0	0.5	75.0	0.3	10.0	21.8	79.1	490.0
04.2.5.3	Other similar fruit or vegetable spreads	1000	only *dulce de membrillo*	0										
04.2.5.3	Other similar fruit or vegetable spreads	1500	only *marmelada*	6	0	6.7	6.7	20.0	20.0	338.3	589.4	554.0	824.0	824.0
05.2	Other confectionery including breath refreshening microsweets	1500	except candied, crystallised or glacé fruit and vegetables	340	301	0.0	20.0	0.0	50.0	0.0	2.5	46.0	346.8	1027.0
05.2	Other confectionery including breath refreshening microsweets	1000	only candied, crystallised or glacé fruit and vegetables	164	151	0.0	10.0	0.0	30.0	0.0	1.9	18.5	110.0	418.0
05.3	Chewing gum	1500		5	4	0.2	20.0	0.5	50.0	0.5	10.0	89.9	419.0	419.0

				Data < MPL										
						LOD		LOQ		Middle-bound				
FCS category number	**Food category**	**MPL**	**restrictions**	**N**	**No LC**	**Min**	**Max**	**Min**	**Max**	**Min**	**Median**	**Mean**	**p95**	**Max**
05.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4	1500		73	67	1.7	3.8	5.0	15.0	1.9	1.9	47.0	411.0	780.2
08.3.1	Non heat treated processed meat		only surface treatment of dried meat products											
08.3.2	Heat treated processed meat	500	only aspic	82	64	0.0	37.8	0.0	113.3	0.0	2.5	25.0	198.7	430.0
09.2	Processed fish and fishery products including molluscs and crustaceans	200	only salted, dried fish	39	39			20.0	20.0	10.0	10.0	10.0	10.0	10.0
09.2	Processed fish and fishery products including molluscs and crustaceans	2000	only semi-preserved fish and fisheries products including crustaceans, molluscs, surimi and fish / crustacean paste; cooked crustaceans and molluscs	324	135	1.3	3.3	1.3	15.0	0.6	180.0	395.9	1341.4	1900.0
09.2	Processed fish and fishery products including molluscs and crustaceans	6000	only cooked *Crangon crangon* and *Crangon vulgaris*	92	40	0.2	1.7	0.5	20.0	2.5	337.2	454.6	1200.0	3800.0
09.2	Processed fish and fishery products including molluscs and crustaceans	1000	only cooked crustaceans and molluscs	41	27	0.2	50.0	0.5	150.0	0.5	10.0	155.6	834.0	881.4
09.2	Processed fish and fishery products including molluscs and crustaceans	1500	only cooked shrimps in brine	0										
09.3	Fish roe	2000	only semi-preserved fish products including fish roe products	68	22	0.0	1.7	0.0	5.0	0.3	663.3	644.2	1686.0	1994.6
10.2	Processed eggs and egg products	5000	only liquid egg (white, yolk or whole egg)	47	41	6.7	6.7	20.0	20.0	10.0	10.0	461.6	3855.0	3890.0
11.4.1	Table-top sweeteners in liquid form	500	only if the water content higher than 75 %	0										
12.2.2	Seasonings and condiments	1000		281	228	0.0	36.0	0.0	50.0	0.3	7.5	83.0	548.1	865.6
12.4	Mustard	1000		498	380	0.0	36.0	0.0	50.0	0.0	1.5	102.9	790.5	996.9

				Data < MPL										
						LOD		LOQ		Middle-bound				
FCS category number	**Food category**	**MPL**	**restrictions**	**N**	**No LC**	**Min**	**Max**	**Min**	**Max**	**Min**	**Median**	**Mean**	**p95**	**Max**
12.5	Soups and broths	500	only liquid soups and broths (excluding canned)	47	46	0.0	20.0	0.2	50.0	0.1	7.5	7.8	10.0	58.0
12.6	Sauces	1000	only emulsified sauces with a fat content of less than 60 %	869	448	0.0	36.0	0.0	101.0	0.0	10.0	266.3	869.4	1000.0
12.6	Sauces	500	only emulsified sauces with a fat content of 60 % or more	161	141	0.5	36.0	1.5	50.0	0.3	2.5	40.5	307.8	500.0
12.6	Sauces	1000	non emulsified sauces	0										
12.7	Salads and savoury based sandwich spreads	1500		3297	1128	0.0	1345.0	0.0	1345.0	0.0	129.1	246.4	822.5	1486.0
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	1500		216	139	0.2	100.0	0.4	100.0	0.1	5.0	23.0	112.0	502.0
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)	1500		6	6	0.6	7.5	3.6	22.4	0.3	1.3	3.7	11.2	11.2
14.1.2	Fruit juices as defined by Council Directive 2001/112/EC and vegetable juices	2000	only grape juice, unfermented, for sacramental use	0										
14.1.2	Fruit juices as defined by Council Directive 2001/112/EC and vegetable juices	200	only *Sød….saft* and *sødet….saft*	0										
14.1.3	Fruit nectars as defined by Council Directive 2001/112/EC and vegetable nectars and similar products	150	only traditional Swedish and Finnish fruit syrups	0										

				Data < MPL										
						LOD		LOQ		Middle-bound				
FCS category number	**Food category**	**MPL**	**restrictions**	**N**	**No LC**	**Min**	**Max**	**Min**	**Max**	**Min**	**Median**	**Mean**	**p95**	**Max**
14.1.4	Flavoured drinks	150	excluding dairy-based drinks	6603	2941	0.0	37.8	0.0	165.0	0.0	7.5	46.2	135.1	150.0
14.1.5.2	Other	600	only liquid tea concentrates and liquid fruit and herbal infusion concentrates	25	20	0.2	6.7	0.6	20.0	0.1	10.0	39.9	201.0	257.0
14.2.1	Beer and malt beverages	200	only alcohol free beer; beer in kegs containing more than 0.5 % added fermentable sugar and/or fruit juices or concentrates	65	54	0.2	1.7	1.0	10.0	0.1	2.5	4.9	22.0	60.0
14.2.2	Wine and other products defined by Regulation (EC) No 1234/2007, and alcohol-free counterparts	200	only alcohol-free	0										
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol	200	only alcoholic drinks with less than 15 % of alcohol	138	63	0.0	16.7	0.0	50.0	0.0	103.5	74.5	182.9	196.0
16	Desserts excluding products covered in category 1, 3 and 4	300	only non-heat-treated dairy-based desserts	364	330	1.7	20.0	2.0	50.0	0.8	7.5	9.5	13.0	199.0
16	Desserts excluding products covered in category 1, 3 and 4	500	only *frugtgrød* and *Rote Grütze*	0										
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms	1000	only when supplied in dried form and containing preparations of vitamin A and of combinations of vitamin A and D	3	3	3.3	3.4	9.9	10.1	5.0	5.1	5.0	5.1	5.1
17.2	Food supplements supplied in a liquid form	2000		19	6	0.5	10.0	1.5	30.0	0.3	705.0	724.1	1955.0	1955.0

LC, left-censored data; % LC, percentage of left-censored data; FCS, Food Categorisation System; LOD, limit of detection; LOQ, limit of quantification; Max, maximum; MB, middle bound; Min, minimum; MPL, maximum permitted level; N, number of analytical results; P95, 95th percentile.

C. Concentration levels of benzoic acid-benzoates (E 210–213) used in the MPL scenario and refined exposure scenario using dataset 1[(a)] (mg/kg)

FCS Category number	FCS Food category	restrictions/exception	MPL	Concentration levels used in the refined exposure assessment scenario (only reported use levels)		Comments
				Mean	Maximum	
01.4	Flavoured fermented milk products including heat treated products	only non-heat treated dairy based desserts	300	5	117	Analytical data
04.2.2	Fruit and vegetables in vinegar, oil, or brine	only vegetables (excluding olives)	2000	262	1973	Analytical data
04.2.2	Fruit and vegetables in vinegar, oil, or brine	only olives and olive-based preparations	500	45	431	Analytical data
04.2.4.1	Fruit and vegetable preparations excluding compote	only seaweed preparations, olives and olive-based preparations	500	388	490	Analytical data
04.2.4.1	Fruit and vegetable preparations excluding compote	only cooked red beet	2000	194	762	Analytical data
04.2.5.1	Extra jam and extra jelly as defined by Directive 2001/113/EEC	only low-sugar and similar low calorie or sugar-free products , m*ermeladas*	500	20	470	Analytical data
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EEC	only low-sugar and similar low calorie or sugar-free products; *mermeladas*	500			
04.2.5.3	Other similar fruit or vegetable spreads	other fruit-based spreads, m*ermeladas*	500			
04.2.5.3	Other similar fruit or vegetable spreads	only *marmelada*	1500	-	-	Not taken into account (no FoodEx code)
04.2.5.3	Other similar fruit or vegetable spreads	only *dulce de membrillo*	1000	-	-	Not taken into account (no FoodEx code)
05.2	Other confectionery including breath refreshening microsweets	except candied, crystallised or glacé fruit and vegetables	1500	46	1027	Analytical data
05.2	Other confectionery including breath refreshening microsweets	only candied, crystallised or glacé fruit and vegetables	1000	19	418	Analytical data
05.3	Chewing gum		1500	90	419	Analytical data
05.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4		1500	-	-	Not taken into account (no FoodEx code)

FCS Category number	FCS Food category	restrictions/exception	MPL	Concentration levels used in the refined exposure assessment scenario (only reported use levels)		Comments
				Mean	Maximum	
08.3.1	Non heat treated processed meat	only surface treatment of dried meat products	*QS*	-	-	Not taken into account (no FoodEx code)
08.3.2	Heat treated processed meat	only aspic	500	25	430	Analytical data
09.2	Processed fish and fishery products including molluscs and crustaceans	only salted, dried fish	200	10	10	Analytical data
09.2	Processed fish and fishery products including molluscs and crustaceans	only semi-preserved fish and fisheries products including crustaceans, molluscs, surimi and fish / crustacean paste; cooked crustaceans and molluscs	2000	396	1900	Analytical data
09.2	Processed fish and fishery products including molluscs and crustaceans	only cooked *Crangon crangon* and *Crangon vulgaris*	6000	455	3800	Analytical data
09.2	Processed fish and fishery products including molluscs and crustaceans	only cooked Crustaceans and molluscs	1000	156	881	Analytical data
09.2	Processed fish and fishery products including molluscs and crustaceans	only cooked shrimps in brine	1500	-	-	Analytical data
09.3	Fish roe	only semi-preserved fish products including fish roe products	2000	663	1995	Analytical data
10.2	Processed eggs and egg products	only liquid egg (white, yolk or whole egg)	5000	462	3855	Analytical data
11.4.1	Table-top sweeteners in liquid form	only if the water content higher than 75 %	500	3	10	Analytical data
12.2.2	Seasonings and condiments		1000	83	866	Analytical data
12.4	Mustard		1000	103	997	Analytical data
12.5	Soups and broths	only liquid soups and broths (excluding canned)	500	8	58	Analytical data
12.6	Sauces	only emulsified sauces with a fat content of less than 60 %	1000	266	1000	Analytical data
12.6	Sauces	only emulsified sauces with a fat content of 60 % or more; non-emulsified sauces	1000			

FCS Category number	FCS Food category	restrictions/exception	MPL	Concentration levels used in the refined exposure assessment scenario (only reported use levels)		Comments
				Mean	Maximum	
12.6	Sauces	only emulsified sauces with a fat content of 60 % or more	500	41	500	Analytical data
12.7	Salads and savoury based sandwich spreads		1500	246	1486	Analytical data
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)		1500	23	502	Analytical data
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)		1500	4	11	Analytical data
14.1.2	Fruit juices as defined by Council Directive 2001/112/EC and vegetable juices	only grape juice, unfermented, for sacramental use	2000	-	-	Not taken into account (no FoodEx code)
14.1.2	Fruit juices as defined by Council Directive 2001/112/EC and vegetable juices	only *Sød….saft* and *sødet….saft*	200	-	-	Not taken into account (no FoodEx code)
14.1.3	Fruit nectars as defined by Council Directive 2001/112/EC and vegetable nectars and similar products	only traditional Swedish and Finnish fruit syrups	150	-	-	Not taken into account (no FoodEx code)
14.1.4	Flavoured drinks	excluding dairy-based drinks	150	100	150	Reported use levels
14.1.5.2	Other	only liquid tea concentrates and liquid fruit and herbal infusion concentrates	600	-	-	Not taken into account (no reported level/no FoodEx code)
14.2.1	Beer and malt beverages	only alcohol free beer; beer in kegs containing more than 0.5 % added fermentable sugar and/or fruit juices or concentrates	200	125	200	Reported use levels
14.2.2	Wine and other products defined by Regulation (EC) No 1234/2007, and alcohol-free counterparts	only alcohol-free	200	-	-	Not taken into account (no FoodEx code)
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and	only alcoholic drinks with less than 15 % of alcohol	200	75	196	Analytical data

FCS Category number	FCS Food category	restrictions/exception	MPL	Concentration levels used in the refined exposure assessment scenario (only reported use levels)		Comments
				Mean	Maximum	
	spirits with less than 15 % of alcohol					
16	Desserts excluding products covered in category 1, 3 and 4	only non-heat-treated dairy-based desserts	300	10	199	Analytical data
16	Desserts excluding products covered in category 1, 3 and 4	only *frugtgrød* and *Rote Grütze*	500	-	-	Not taken into account (no FoodEx code)
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms	only when supplied in dried form and containing preparations of vitamin A and of combinations of vitamin A and D	1000	626	1955	Analytical data
17.2	Food supplements supplied in a liquid form		2000			

FCS, Food Categorisation System; MPL, maximum permitted level; *QS*, *quantum satis*.

(a) Considering reported use levels and analytical data not exceeding the MPLs for food categories for which direct addition of benzoic acid-benzoates is authorised (Annex II to Regulation No 1333/2008).

D. Summary of total estimated exposure to benzoic acid-benzoates (E 210–213) from their use as food additives per population group and survey for the MPL scenario and refined exposure scenario using dataset 1[(a)]: mean and high level (mg/kg bw per day)

	Number of subjects	MPL scenario		Brand-Loyal scenario		Non-Brand-Loyal scenario	
		Mean	High level	Mean	High level	Mean	High level
Infants							
Bulgaria (NUTRICHILD)	659	0.153	0.833	0.074	0.359	0.021	0.054
Germany (VELS)	159	0.853	3.661	0.571	2.659	0.303	1.683
Denmark (IAT 2006_07)	826	1.148	4.920	0.531	2.121	0.127	0.583
Finland (DIPP_2001_2009)	500	0.278	1.370	0.241	1.203	0.027	0.078
United Kingdom (DNSIYC_2011)	1366	1.495	5.523	0.783	3.164	0.202	0.997
Italy (INRAN_SCAI_2005_06)	12	1.192		0.237		0.042	
Toddlers							
Belgium (Regional_Flanders)	36	8.389		3.180		1.555	
Bulgaria (NUTRICHILD)	428	0.819	3.333	0.617	1.945	0.162	0.909
Germany (VELS)	348	4.420	9.859	2.509	6.985	1.422	4.699
Denmark (IAT 2006_07)	917	2.731	6.590	1.104	2.779	0.396	1.157
Spain (enKid)	17	2.259		0.824		0.097	
Finland (DIPP_2001_2009)	500	1.630	5.673	0.663	2.234	0.075	0.180
United Kingdom (NDNS-RollingProgrammeYears1-3)	185	4.134	8.724	2.154	5.529	0.874	2.155
United Kingdom (DNSIYC_2011)	1314	3.318	9.276	1.795	5.381	0.623	2.002
Italy (INRAN_SCAI_2005_06)	36	1.744		0.851		0.147	
Netherlands (VCP_kids)	322	6.096	13.809	2.419	6.690	0.728	2.520
Children							
Austria (ASNS_Children)	128	2.567	7.739	1.462	5.224	0.555	1.735
Belgium (Regional_Flanders)	625	6.512	14.682	2.448	5.891	1.085	3.221
Bulgaria (NUTRICHILD)	433	0.829	3.611	0.670	2.729	0.271	1.555
Czech Republic (SISP04)	389	3.099	8.678	1.707	5.279	0.672	2.401
Germany (EsKiMo)	835	2.273	6.135	1.288	3.738	0.594	2.071
Germany (VELS)	293	4.425	9.779	2.386	5.710	1.366	3.780
Denmark (DANSDA 2005-08)	298	2.671	5.351	1.260	2.871	0.733	1.803
Spain (enKid)	156	2.629	6.941	1.312	3.865	0.389	1.649
Spain (NUT_INK05)	399	2.580	6.892	1.192	3.419	0.390	1.252
Finland (DIPP_2001_2009)	750	4.067	11.960	1.970	6.954	0.351	1.230
France (INCA2)	482	2.944	6.477	1.557	3.912	0.646	1.723
United Kingdom (NDNS-RollingProgrammeYears1-3)	651	3.615	7.868	2.032	4.861	0.960	2.164
Greece (Regional_Crete)	838	2.173	7.407	1.278	5.625	0.261	1.113
Italy (INRAN_SCAI_2005_06)	193	1.751	9.460	1.254	7.077	0.301	1.427
Latvia (EFSA_TEST)	187	5.444	11.979	2.609	7.092	0.813	2.163
Netherlands (VCP_kids)	957	5.457	12.860	2.096	5.152	0.703	2.102

	Number of subjects	MPL scenario		Brand-Loyal scenario		Non-Brand-Loyal scenario	
		Mean	High level	Mean	High level	Mean	High level
Netherlands (VCPBasis_AVL2007_2010)	447	5.508	11.256	2.554	5.298	1.510	3.392
Sweden (NFA)	1473	5.980	11.804	2.649	5.512	1.381	2.947
Adolescents							
Austria (ASNS_Children)	237	1.694	5.503	1.108	3.833	0.446	1.345
Belgium (Diet_National_2004)	576	2.737	6.485	1.632	4.159	0.925	2.392
Cyprus (Childhealth)	303	0.503	1.784	0.424	1.471	0.270	0.954
Czech Republic (SISP04)	298	2.424	6.935	1.502	4.707	0.671	1.948
Germany (National_Nutrition_Survey_II)	1011	1.993	5.688	1.176	3.547	0.542	1.789
Germany (EsKiMo)	393	1.821	5.060	1.143	3.643	0.587	2.103
Denmark (DANSDA 2005-08)	377	1.519	3.301	0.846	2.090	0.514	1.406
Spain (AESAN_FIAB)	86	0.994	3.153	0.621	2.152	0.179	0.740
Spain (enKid)	209	1.450	3.776	0.866	2.562	0.335	1.166
Spain (NUT_INK05)	651	1.489	3.635	0.828	2.302	0.353	1.128
Finland (NWSSP07_08)	306	2.677	8.604	1.476	5.164	0.318	0.954
France (INCA2)	973	1.457	3.500	0.803	2.083	0.361	1.005
United Kingdom (NDNS-RollingProgrammeYears1-3)	666	2.179	4.367	1.318	2.877	0.746	1.675
Italy (INRAN_SCAI_2005_06)	247	1.163	4.995	0.815	3.200	0.237	0.810
Latvia (EFSA_TEST)	453	3.618	8.715	1.914	5.331	0.584	1.627
Netherlands (VCPBasis_AVL2007_2010)	1142	3.603	7.667	1.839	4.036	1.127	2.614
Sweden (NFA)	1018	3.631	7.839	1.802	3.986	0.891	2.065
Adults							
Austria (ASNS_Adults)	308	2.114	5.402	1.279	3.190	0.355	1.001
Belgium (Diet_National_2004)	1292	2.361	6.252	1.227	3.721	0.598	1.943
Czech Republic (SISP04)	1666	1.116	3.520	0.789	2.647	0.261	0.987
Germany (National_Nutrition_Survey_II)	10419	1.599	4.486	0.864	2.697	0.329	1.237
Denmark (DANSDA 2005-08)	1739	0.934	2.230	0.497	1.472	0.280	0.947
Spain (AESAN)	410	0.746	2.675	0.498	1.836	0.266	1.083
Spain (AESAN_FIAB)	981	0.644	1.843	0.438	1.333	0.156	0.659
Finland (FINDIET2012)	1295	1.594	5.309	0.843	3.048	0.239	0.864
France (INCA2)	2276	1.070	2.603	0.551	1.371	0.224	0.709
United Kingdom (NDNS-RollingProgrammeYears1-3)	1266	1.408	3.391	0.820	2.080	0.394	1.127
Hungary (National_Repr_Surv)	1074	1.113	3.299	0.958	2.980	0.243	0.764
Ireland (NANS_2012)	1274	0.994	2.582	0.666	1.851	0.308	0.950
Italy (INRAN_SCAI_2005_06)	2313	0.695	3.608	0.452	2.433	0.100	0.471
Latvia (EFSA_TEST)	1271	2.779	6.618	1.598	4.980	0.376	1.060

	Number of subjects	MPL scenario		Brand-Loyal scenario		Non-Brand-Loyal scenario	
		Mean	High level	Mean	High level	Mean	High level
Netherlands (VCPBasis_AVL2007_2010)	2057	2.198	5.120	1.073	2.919	0.576	1.718
Romania (Dieta_Pilot_Adults)	1254	0.647	1.750	0.360	1.156	0.161	0.515
Sweden (Riksmaten 2010)	1430	3.374	7.847	2.048	5.148	0.618	1.426
The elderly							
Austria (ASNS_Adults)	92	2.123	4.923	1.231	3.274	0.295	0.834
Belgium (Diet_National_2004)	1215	1.955	4.984	0.630	2.080	0.215	0.747
Germany (National_Nutrition_Survey_II)	2496	1.152	3.221	0.502	1.718	0.146	0.554
Denmark (DANSDA 2005-08)	286	0.579	1.471	0.264	0.640	0.107	0.314
Finland (FINDIET2012)	413	0.852	2.959	0.466	1.642	0.130	0.586
France (INCA2)	348	0.883	2.049	0.433	1.027	0.122	0.320
United Kingdom (NDNS-RollingProgrammeYears1-3)	305	1.265	3.301	0.605	1.605	0.219	0.634
Hungary (National_Repr_Surv)	286	0.870	2.578	0.786	2.476	0.143	0.444
Ireland (NANS_2012)	226	0.653	1.983	0.368	1.323	0.127	0.472
Italy (INRAN_SCAI_2005_06)	518	0.378	1.855	0.237	1.295	0.044	0.241
Netherlands (VCPBasis_AVL2007_2010)	173	1.783	4.370	0.625	1.636	0.245	0.752
Netherlands (VCP-Elderly)	739	1.764	4.638	0.672	1.978	0.228	0.683
Romania (Dieta_Pilot_Adults)	128	0.498	1.191	0.257	0.701	0.109	0.301
Sweden (Riksmaten 2010)	367	2.782	7.019	1.627	4.290	0.427	1.004

(a) Considering reported use levels and analytical data not exceeding the MPLs for food categories for which direct addition of benzoic acid-benzoates is authorised (Annex II to Regulation No 1333/2008).

E. Main food categories contributing to exposure to benzoic acid-benzoates (E 210–213) using MPLs (> 5 % of the total mean exposure) and the number of surveys in which each food category is contributing

FCS Category number	FCS Food category	Infants	Toddlers	Children	Adolescents	Adults	The elderly
		Range of % contribution to the total exposure (Number of surveys)(a)					
01.4	Flavoured fermented milk products including heat-treated products	8.7-49.4 (5)	11.6-68.4 (10)	6.2-36.7 (16)	5.6-18.5 (11)	5.4-15.6 (11)	6.8-18.8 (9)
04.1	Unprocessed fruit and vegetables	30.6 (1)				5.4-7.1 (3)	5.0-13 (8)
04.2	Processed fruit and vegetables	73.2 (1)	13.4-31.7 (2)	5.4-19 (4)	5.5-18.5 (4)	5.3-71.5 (8)	5.7-82.1 (12)
05.2	Other confectionery including breath refreshening microsweets		7.5-27.1 (5)	5.8-52.1 (16)	6.6-60.0 (13)	5.2-33.8 (5)	6.5-17.0 (3)
09.2	Processed fish and fishery products including molluscs and crustaceans	15.5-15.7 (2)	5.5-30.4 (6)	6.3-72.7 (11)	5.6-68.6 (10)	5.4-67.4 (7)	5.6-61.5 (8)
09.3	Fish roe	15.6 (1)	7.6 (1)				
10.2	Processed eggs and egg products					10.7 (1)	15.2 (1)
12.5	Soups and broths	6.4-83.9 (3)	8.2-30.0 (6)	5.6-38.3 (10)	5.2-35.8 (10)	6.6-34.4 (9)	5.8-52.0 (9)
12.6	Sauces	5.4-20.6 (4)	8.7-18.8 (7)	5.4-26.1 (15)	5.2-30.9 (15)	7.3-44.6 (14)	9.8-33.6 (11)
12.7	Salads and savoury based sandwich spreads			6.8-45.4 (4)	8.7-37.2 (3)	6.5-46.1 (5)	5.9-40.4 (3)
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)				5.9 (1)		
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)						6.0 (1)
14.1.4	Flavoured drinks	14.4-45.1 (2)	9.4-38.7 (7)	5.2-44.2 (18)	9.5-78.6 (17)	6.8-40.4 (16)	5.2-22.6 (9)
16	Desserts excluding products covered in categories 1, 3 and 4	6.6-14.7 (3)	7.5-19.2 (5)	5.1-13.2 (7)	5.6-10.2 (2)	5.3-7 (2)	5.5-8.4 (5)
17	Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children	13.1 (1)					6.2-11.0 (2)

FCS, Food Categorisation System.
(a): The total number of surveys may be greater than the total number of countries as listed in Table 5, as some countries submitted more than one survey for a specific population.

F. Main food categories contributing to the exposure to benzoic acid-benzoates (E 210–213) using dataset 1[(a)] for the "brand-loyal refined exposure scenario" (> 5 % of the total mean exposure) and the number of surveys in which each food category is contributing

FCS Category number	FCS Food category	Infants	Toddlers	Children	Adolescents	Adults	The elderly
		Range of % contribution to the total exposure (Number of surveys)[(b)]					
01.4	Flavoured fermented milk products including heat-treated products	5.8-35.5 (5)	5.2-65.1 (8)	6.1-26.2 (7)		5.6 (1)	5.4-7.4 (4)
04.1	Unprocessed fruit and vegetables	24.1 (1)					5.1-7.6 (4)
04.2	Processed fruit and vegetables	78.7 (1)	24.9-40.7 (2)	6.9-20.7 (3)	5.1-22.5 (4)	5.9-79.3 (5)	6.3-88.1 (12)
05.2	Other confectionery including breath refreshening microsweets	5.9 (1)	9.4-21.9 (3)	5.3-70.3 (12)	8.0-72.7 (8)	13.9-39.2 (4)	5.1-19.1 (5)
09.2	Processed fish and fishery products including molluscs and crustaceans	24.6-26.0 (2)	6.3-53.1 (7)	10.8-82.0 (11)	5.9-69.0 (11)	5.2-70.9 (9)	6.0-67.9 (10)
09.3	Fish roe	29.7 (1)	13.7 (1)				
10.2	Processed eggs and egg products			6.3 (1)		11.3 (1)	16.7 (1)
12.5	Soups and broths	49.0 (1)					7.9 (1)
12.6	Sauces	8.7-34.5 (4)	5.8-26.0 (7)	6.4-49.3 (12)	5.4-46.3 (10)	5.2-54.8 (13)	9.3-51.0 (11)
12.7	Salads and savoury based sandwich spreads			7.4-76.2 (4)	9.6-68.4 (3)	6.7-77.7 (5)	10.3-66.9 (3)
14.1.4	Flavoured drinks	7.9-65.8 (3)	18.5-65.8 (7)	7.4-69.5 (18)	14.8-92.5 (17)	5.1-65.5 (17)	6.9-40.3 (11)
16	Desserts excluding products covered in categories 1, 3 and 4	12.7 (1)	5.3-24.4 (3)	6.1-7.8 (2)			5.0-6.3 (2)
17	Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children	7-11.6 (2)				5.2 (1)	7.6-15.1 (2)

FCS, Food Categorisation System.

(a) Considering reported use levels and analytical data not exceeding the MPLs for food categories for which direct addition of benzoic acid-benzoates is authorised (Annex II to Regulation No 1333/2008).

(b) The total number of surveys may be greater than the total number of countries as listed in Table 5, as some countries submitted more than one survey for a specific population.

G. Main food categories contributing to the exposure to benzoic acid-benzoates (E 210–213) using dataset 1[(a)] for the "non-brand-loyal refined exposure scenario" (> 5 % of the total mean exposure) and the number of surveys in which each food category is contributing

FCS Category number	FCS Food category	Infants	Toddlers	Children	Adolescents	Adults	The elderly
		Range of % contribution to the total exposure (Number of surveys) [(b)]					
01.4	Flavoured fermented milk products including heat-treated products	5.5-7.8 (2)	5.4-27.6 (4)				
04.1	Unprocessed fruit and vegetables	21.7 (1)					5.4-7.4 (5)
04.2	Processed fruit and vegetables	30.4 (1)	11.6-19.4 (2)	6.0-6.1 (2)	8.1 (1)	11.6-41.5 (3)	6.5-62.6 (5)
05.2	Other confectionery including breath refreshening microsweets			18.5 (1)	7.4-15.5 (2)	6.8 (1)	
09.2	Processed fish and fishery products including molluscs and crustaceans	22.7-27.5 (2)	7.8-57.7 (5)	5.6-60.5 (11)	5.9-36.1 (7)	5.7-44.3 (6)	6.8-51.2 (8)
09.3	Fish roe	46.7 (1)	17.3 (1)				5.6 (1)
10.2	Processed eggs and egg products					5.4 (1)	9.1 (1)
12.5	Soups and broths	37.1 (1)					7.4 (1)
12.6	Sauces	5.1-40.8 (5)	8.2-55.9 (9)	7.6-44.5 (12)	6.9-33.9 (11)	5.3-36.5 (13)	5.8-45.4 (13)
12.7	Salads and savoury based sandwich spreads			11.3-61.8 (3)	5.8-37.8 (3)	10.4-56.0 (4)	5.6-47.7 (3)
14.1.4	Flavoured drinks	7.5-84.4 (4)	14.8-80.3 (9)	28.6-90.1 (18)	39.3-97.6 (17)	18.6-80.1 (17)	13.6-69.2 (14)
14.2	Alcoholic beverages, including alcohol-free and low-alcohol counterparts					9.3 (1)	6.5-10.3 (3)
16	Desserts excluding products covered in categories 1, 3 and 4		14.2 (1)				
17	Food supplements as defined in Directive 2002/46/EC excluding food supplements for infants and young children	17.8-42.4 (2)	6.1-19.1 (2)	6.8 (1)		6.7 (1)	6.6-17.7 (3)

FCS, Food Categorisation System.

(a) Considering reported use levels and analytical data not exceeding the MPLs for food categories for which direct addition of benzoic acid-benzoates is authorised (Annex II to Regulation No 1333/2008).

(b): The total number of surveys may be greater than the total number of countries as listed in Table 5, as some countries submitted more than one survey for a specific population.

H. Concentration levels of benzoic acid-benzoates (E 210–213) used in the refined exposure scenario with dataset 2[(a)] (mg/kg)

FCS Category number	FCS Food category	restrictions/exception	MPL	Concentration levels used in the refined exposure assessment scenario (only reported use levels)		Comments
				Mean	Maximum / p95[(b)]	
01.1	Unflavoured pasteurised and sterilised (including UHT) milk [(c)]		-	11	52	Analytical data
01.2	Unflavoured fermented milk products, including natural unflavoured buttermilk (excluding sterilised buttermilk) non-heat-treated after fermentation [(c)]		-	3	14	Analytical data
01.3	Unflavoured fermented milk products, heat-treated after fermentation [(c)]		-	10	21	Analytical data
01.4	Flavoured fermented milk products including heat treated products	only non-heat treated dairy based desserts	300	5	117	Analytical data
01.5	Dehydrated milk as defined by Directive 2001/114/EC [(c)]		-	0.5	0.5	Analytical data
01.6	Cream and cream powder [(c)]		-	4	15	Analytical data
1.7.1	Unripened cheese excluding products falling in category 16 [(c)]		-	74	532	Analytical data
1.7.2	Ripened cheese [(c)]		-	12.5	25	Analytical data
1.7.4	Whey cheese [(c)]		-	11	36	Analytical data
1.7.5	Processed cheese [(c)]		-	9	23.5	Analytical data
1.8	Dairy analogues, including beverage whiteners [(c)]		-	4	9	Analytical data
2.1	Fats and oils essentially free from water (excluding anhydrous milk fat)[(c)]		-	1.5	1.5	Analytical data
2.2	Fat and oil emulsions mainly of type water-in-oil [(c)]		-	8.3	15	Analytical data
3	Edible ices [(c)]		-	13	26	Analytical data
4.1	Unprocessed fruit and vegetables [(c)]		-	56	470	Analytical data
4.2	Processed fruit and vegetables [(c)]		-	110	839	Analytical data

FCS Category number	FCS Food category	restrictions/exception	MPL	Concentration levels used in the refined exposure assessment scenario (only reported use levels)		Comments
				Mean	Maximum / p95[(b)]	
04.2.1	Dried fruits and vegetables [(c)]			10	50	Analytical data
04.2.2	Fruit and vegetables in vinegar, oil, or brine [(c)]			260	1450	Analytical data
04.2.2	Fruit and vegetables in vinegar, oil, or brine	only vegetables (excluding olives)	2000	262	1973	Analytical data
04.2.2	Fruit and vegetables in vinegar, oil, or brine	only olives and olive-based preparations	500	45	431	Analytical data
04.2.3	Canned or bottled fruits and vegetables [(c)]			242	1299	Analytical data
04.2.4.1	Fruit and vegetable preparations excluding compote	only seaweed preparations, olives and olive-based preparations	500	388	490	Analytical data
04.2.4.1	Fruit and vegetable preparations excluding compote	only cooked red beet	2000	194	762	Analytical data
04.2.4.1	Fruit and vegetable preparations excluding compote [(c)]			10	21	Analytical data
04.2.4.2	Compote [(c)]			9	10	Analytical data
04.2.5.1	Extra jam and extra jelly as defined by Directive 2001/113/EEC	only low-sugar and similar low calorie or sugar-free products , m*ermeladas*	500	20	470	Analytical data
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut puree as defined by Directive 2001/113/EEC	only low-sugar and similar low calorie or sugar-free products; *mermeladas*	500			Analytical data
04.2.5.3	Other similar fruit or vegetable spreads	only *marmelada*	1500			Analytical data
04.2.5.3	Other similar fruit or vegetable spreads	other fruit-based spreads, m*ermeladas*	500			Analytical data
04.2.5.3	Other similar fruit or vegetable spreads	only *dulce de membrillo*	1000	-	-	Not taken into account (no FoodEx code)
04.2.5.4	Nut butter and nut spreads [(c)]			2.5	2.5	Analytical data

FCS Category number	FCS Food category	restrictions/exception	MPL	Concentration levels used in the refined exposure assessment scenario (only reported use levels)		Comments
				Mean	Maximum / p95[(b)]	
04.2.6	Processed potato products [(c)]			7	10	Analytical data
05.1	Cocoa and Chocolate products as covered by Directive 2000/36/EC [(c)]		-	3	19	Analytical data
05.2	Other confectionery including breath refreshening microsweets	except candied, crystallised or glacé fruit and vegetables	1500	46	1027	Analytical data
05.2	Other confectionery including breath refreshening microsweets	only candied, crystallised or glacé fruit and vegetables	1000	19	418	Analytical data
05.3	Chewing gum		1500	90	419	Analytical data
05.4	Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4		1500	-	-	Not taken into account (no FoodEx code)
06.1	Whole, broken, or flaked grain [(c)]		-	4.2	7.5	Analytical data
6.2	Flours and other milled products and starches [(c)]		-	7	11	Analytical data
6.3	Breakfast cereals [(c)]		-	3	16	Analytical data
6.4	Pasta [(c)]		-	10	11	Analytical data
7.1	Bread and rolls [(c)]		-	5	10	Analytical data
7.2	Fine bakery wares [(c)]		-	18	48	Analytical data
8.1	Unprocessed meat [(c)]		-	10	92	Analytical data
8.2	Meat preparations [(c)]		-	35	204	Analytical data
8.3	Meat products [(c)]		-			Analytical data
08.3.1	Non heat treated processed meat	only surface treatment of dried meat products	*QS*	-	-	Not taken into account (no FoodEx code)
08.3.2	Heat treated processed meat	only aspic	500	25	430	Analytical data
09.1	Unprocessed fish and fisheries products [(c)]	Unprocessed fish	-	289.5	1600	Analytical data
09.1	Unprocessed fish and fisheries products [(c)]	Unprocessed molluscs and crustaceans	-	5	6	Analytical data

FCS Category number	FCS Food category	restrictions/exception	MPL	Concentration levels used in the refined exposure assessment scenario (only reported use levels)		Comments
				Mean	Maximum / p95[(b)]	
09.2	Processed fish and fishery products including molluscs and crustaceans	only salted, dried fish	200	10	10	Analytical data
09.2	Processed fish and fishery products including molluscs and crustaceans	only semi-preserved fish and fisheries products including crustaceans, molluscs, surimi and fish / crustacean paste; cooked crustaceans and molluscs	2000	396	1900	Analytical data
09.2	Processed fish and fishery products including molluscs and crustaceans	only cooked *Crangon crangon* and *Crangon vulgaris*	6000	455	3800	Analytical data
09.2	Processed fish and fishery products including molluscs and crustaceans	only cooked Crustaceans and molluscs	1000	156	881	Analytical data
09.2	Processed fish and fishery products including molluscs and crustaceans	only cooked shrimps in brine	1500	-	-	Analytical data
09.2	Processed fish and fishery products including molluscs and crustaceans [(c)]		-	354	1592	Analytical data
09.3	Fish roe	only semi-preserved fish products including fish roe products	2000	663	1995	Analytical data
10.1	Unprocessed eggs [(c)]		-	296	986	Analytical data
10.2	Processed eggs and egg products	only liquid egg (white, yolk or whole egg)	5000	462	3855	Analytical data
11.1	Sugars and syrups as defined by Directive 2001/111/EC [(c)]		-	8	19	Analytical data
11.2	Other sugars and syrups [(c)]		-	101	676	Analytical data
11.3	Honey as defined in Directive 2001/110/EC [(c)]		-	85	107	Analytical data
11.4	Table-top sweeteners[(c)]		-	3	10	Analytical data
11.4.1	Table-top sweeteners in liquid form	only if the water content higher than 75 %	500	3	10	Analytical data
12.1	Salt and salt substitutes[(c)]		-	0.3	0.3	Analytical data

FCS Category number	FCS Food category	restrictions/exception	MPL	Concentration levels used in the refined exposure assessment scenario (only reported use levels)		Comments
				Mean	Maximum / p95[(b)]	
12.2.2	Seasonings and condiments		1000	83	866	Analytical data
12.3	Vinegars[(c)]		-	2	7.5	Analytical data
12.4	Mustard		1000	103	997	Analytical data
12.5	Soups and broths	only liquid soups and broths (excluding canned)	500	8	58	Analytical data
12.6	Sauces	only emulsified sauces with a fat content of less than 60 %	1000	266	1000	Analytical data
12.6	Sauces	only emulsified sauces with a fat content of 60 % or more; non-emulsified sauces	1000			
12.6	Sauces	only emulsified sauces with a fat content of 60 % or more	500	41	500	Analytical data
12.7	Salads and savoury based sandwich spreads		1500	246	1486	Analytical data
12.9	Protein products, excluding products covered in category 1.8 [(c)]		-	818	4800	Analytical data
13.1	Foods for infants and young children [(c)]		-	6	36	Analytical data
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)		1500	23	502	Analytical data
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)		1500	4	11	Analytical data
14.1.2	Fruit juices as defined by Council Directive 2001/112/EC and vegetable juices [(c)]		-	23	113	Analytical data

FCS Category number	FCS Food category	restrictions/exception	MPL	Concentration levels used in the refined exposure assessment scenario (only reported use levels)		Comments
				Mean	Maximum / p95[(b)]	
14.1.2	Fruit juices as defined by Council Directive 2001/112/EC and vegetable juices	only grape juice, unfermented, for sacramental use	2000	-	-	Not taken into account (no FoodEx code)
14.1.2	Fruit juices as defined by Council Directive 2001/112/EC and vegetable juices	only Sød….saft and sødet….saft	200	-	-	Not taken into account (no FoodEx code)
14.1.3	Fruit nectars as defined by Council Directive 2001/112/EC and vegetable nectars and similar products		-	30	120	Analytical data
14.1.3	Fruit nectars as defined by Council Directive 2001/112/EC and vegetable nectars and similar products	only traditional Swedish and Finnish fruit syrups	150	-	-	Not taken into account (no FoodEx code)
14.1.4	Flavoured drinks	excluding dairy-based drinks	150	100	150	Reported use levels
14.1.5.2	Other [(c)]		-	48.7	200	Analytical data
14.1.5.2	Other	only liquid tea concentrates and liquid fruit and herbal infusion concentrates	600	-	-	Not taken into account (no reported level/no FoodEx code)
14.2.1	Beer and malt beverages	only alcohol free beer; beer in kegs containing more than 0.5 % added fermentable sugar and/or fruit juices or concentrates	200	125	200	Reported use levels
14.2.2	Wine and other products defined by Regulation (EC) No 1234/2007, and alcohol-free counterparts	only alcohol-free	200	-	-	Not taken into account (no FoodEx code)
14.2.2	Wine and other products defined by Regulation (EC) No 1234/2007, and alcohol-free counterparts [(c)]		-	5	5	Analytical data
14.2.3	Cider and perry [(c)]		-	2	7.5	Analytical data
14.2.6	Spirits drinks [(c)]		-	66.5	157	Analytical data

FCS Category number	FCS Food category	restrictions/exception	MPL	Concentration levels used in the refined exposure assessment scenario (only reported use levels)		Comments
				Mean	Maximum / p95[(b)]	
14.2.7	Aromatised wine-based products [(c)]		-			Analytical data
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol	only alcoholic drinks with less than 15 % of alcohol	200	75	196	Analytical data
15.1	Potato-, cereal-, flour- or starch-based snacks [(c)]		-	6	10	Analytical data
15.2	Processed nuts [(c)]		-	3	10	Analytical data
16	Desserts excluding products covered in category 1, 3 and 4	only non-heat-treated dairy-based desserts	300	10	199	Analytical data
16	Desserts excluding products covered in category 1, 3 and 4	only *frugtgrød* and *Rote Grütze*	500	-	-	Not taken into account (no FoodEx code)
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms excluding chewable forms	only when supplied in dried form and containing preparations of vitamin A and of combinations of vitamin A and D	1000	626	1955	Analytical data
17.2	Food supplements supplied in a liquid form		2000			
17.3	Food supplements supplied in a syrup-type or chewable form [(c)]		-			
18	Processed foods not covered by categories 1 to 17, excluding foods for infants and young children [(c)]		-	12.4	12.4	Analytical data

FCS, Food Categorisation System; MPL, maximum permitted level; *QS*, *quantum satis*.

(a) Considering reported use levels and analytical data not exceeding the MPLs for food categories for which direct addition of benzoic acid-benzoates is authorised and analytical data for food categories which may contain benzoic acid-benzoates due to carry-over and for which data were available.

(b) the maximum levels were used for the food categories listed under Annex II to Regulation No 1333/2008, after discarding data above the MPL; for the food categories not listed under Annex II to Regulation No 1333/2008, the p95 was used instead of the mean in order to minimise the impact of possible outliers (as explained in section 2.9.2.2 Refined exposure assessment).

(c) Food category for which direct addition of benzoic acid - benzoates is not authorised according to Annex II to Regulation (EC) No 1333/2008; however, the use of benzoic acid - benzoates may result in its presence in these food categories because of carry-over.

I. Summary of total estimated exposure to benzoic acid-benzoates (E 210–213) from their use as food additives per population group and survey for the refined exposure scenario using dataset 2[(a)]: mean and high level (mg/kg bw per day)

	No of subjects	Brand-loyal scenario		Non-brand-loyal scenario	
		Mean	High level	Mean	High level
Infants					
Bulgaria (NUTRICHILD)	659	6.586	14.690	1.903	3.521
Germany (VELS)	159	6.681	14.172	2.106	4.136
Denmark (IAT 2006_07)	826	7.098	14.064	2.051	3.516
Finland (DIPP_2001_2009)	500	5.421	10.308	1.338	2.318
United Kingdom (DNSIYC_2011)	1366	7.241	15.906	2.000	3.854
Italy (INRAN_SCAI_2005_06)	12	6.868		1.676	
Toddlers					
Belgium (Regional_Flanders)	36	8.063		3.341	
Bulgaria (NUTRICHILD)	428	10.627	19.619	2.637	4.467
Germany (VELS)	348	8.409	15.218	3.521	6.881
Denmark (IAT 2006_07)	917	7.593	13.060	2.367	3.676
Spain (enKid)	17	7.803		2.518	
Finland (DIPP_2001_2009)	500	7.328	12.262	2.202	3.411
United Kingdom (NDNS-RollingProgrammeYears1-3)	185	7.930	14.695	2.930	4.723
United Kingdom (DNSIYC_2011)	1314	8.566	16.545	2.795	5.039
Italy (INRAN_SCAI_2005_06)	36	10.046		2.678	
Netherlands (VCP_kids)	322	7.390	12.488	2.647	5.055
Children					
Austria (ASNS_Children)	128	4.608	7.970	1.916	3.248
Belgium (Regional_Flanders)	625	6.714	12.385	2.608	5.116
Bulgaria (NUTRICHILD)	433	9.755	17.580	2.473	4.472
Czech Republic (SISP04)	389	7.684	14.195	2.552	4.562
Germany (EsKiMo)	835	5.762	10.110	2.118	3.728
Germany (VELS)	293	6.988	11.601	3.077	5.595
Denmark (DANSDA 2005-08)	298	6.901	14.030	2.335	4.094
Spain (enKid)	156	5.407	12.256	1.970	4.130
Spain (NUT_INK05)	399	5.206	9.759	1.998	3.463
Finland (DIPP_2001_2009)	750	6.779	12.284	2.224	3.526
France (INCA2)	482	5.307	10.426	2.079	3.758
United Kingdom (NDNS-RollingProgrammeYears1-3)	651	5.942	11.110	2.366	4.143
Greece (Regional_Crete)	838	4.585	9.216	1.514	3.063
Italy (INRAN_SCAI_2005_06)	193	7.134	12.901	2.037	4.123
Latvia (EFSA_TEST)	187	4.912	9.686	1.901	3.926
Netherlands (VCP_kids)	957	5.790	10.846	2.192	3.900
Netherlands (VCPBasis_AVL2007_2010)	447	5.256	9.527	2.613	4.651

	No of subjects	Brand-loyal scenario		Non-brand-loyal scenario	
		Mean	High level	Mean	High level
Sweden (NFA)	1473	5.566	10.758	2.572	4.607
Adolescents					
Austria (ASNS_Children)	237	2.858	5.944	1.212	2.255
Belgium (Diet_National_2004)	576	3.131	6.095	1.536	3.108
Cyprus (Childhealth)	303	2.508	4.909	0.846	1.721
Czech Republic (SISP04)	298	5.200	10.972	1.874	3.664
Germany (National_Nutrition_Survey_II)	1011	2.863	6.168	1.215	2.722
Germany (EsKiMo)	393	4.422	8.860	1.737	3.274
Denmark (DANSDA 2005-08)	377	3.677	7.219	1.392	2.479
Spain (AESAN_FIAB)	86	3.740	7.003	1.092	1.793
Spain (enKid)	209	3.523	6.523	1.326	2.419
Spain (NUT_INK05)	651	3.244	6.337	1.340	2.271
Finland (NWSSP07_08)	306	3.475	7.103	1.223	2.165
France (INCA2)	973	2.704	5.372	1.096	2.021
United Kingdom (NDNS-RollingProgrammeYears1-3)	666	2.989	5.953	1.393	2.511
Italy (INRAN_SCAI_2005_06)	247	4.273	8.466	1.244	2.140
Latvia (EFSA_TEST)	453	3.538	7.278	1.384	2.624
Netherlands (VCPBasis_AVL2007_2010)	1142	3.754	7.022	1.937	3.549
Sweden (NFA)	1018	3.082	6.052	1.533	2.962
Adults					
Austria (ASNS_Adults)	308	3.463	7.167	1.314	2.557
Belgium (Diet_National_2004)	1292	3.290	6.341	1.405	2.766
Czech Republic (SISP04)	1666	2.924	5.322	1.099	2.048
Germany (National_Nutrition_Survey_II)	10419	3.557	6.925	1.352	2.550
Denmark (DANSDA 2005-08)	1739	3.926	6.966	1.500	2.453
Spain (AESAN)	410	3.847	6.907	1.212	2.397
Spain (AESAN_FIAB)	981	4.360	7.594	1.237	2.123
Finland (FINDIET2012)	1295	3.892	7.723	1.436	2.580
France (INCA2)	2276	3.112	6.212	1.174	2.179
United Kingdom (NDNS-RollingProgrammeYears1-3)	1266	3.107	5.938	1.302	2.375
Hungary (National_Repr_Surv)	1074	3.409	6.065	0.991	1.822
Ireland (NANS_2012)	1274	2.875	5.523	1.189	2.211
Italy (INRAN_SCAI_2005_06)	2313	3.706	6.598	0.962	1.706
Latvia (EFSA_TEST)	1271	3.040	6.272	1.106	2.087
Netherlands (VCPBasis_AVL2007_2010)	2057	3.707	6.914	1.640	2.960
Romania (Dieta_Pilot_Adults)	1254	4.551	8.518	1.121	1.996

	No of subjects	Brand-loyal scenario		Non-brand-loyal scenario	
		Mean	High level	Mean	High level
Sweden (Riksmaten 2010)	1430	3.970	7.843	1.593	2.840
The elderly					
Austria (ASNS_Adults)	92	3.019	5.945	1.132	2.124
Belgium (Diet_National_2004)	1215	2.974	5.485	1.068	1.949
Germany (National_Nutrition_Survey_II)	2496	3.507	6.427	1.231	2.179
Denmark (DANSDA 2005-08)	286	3.692	6.938	1.368	2.387
Finland (FINDIET2012)	413	3.342	6.114	1.189	2.144
France (INCA2)	348	3.543	7.012	1.136	2.057
United Kingdom (NDNS-RollingProgrammeYears1-3)	305	3.277	5.385	1.277	2.005
Hungary (National_Repr_Surv)	286	3.350	5.644	0.845	1.341
Ireland (NANS_2012)	226	3.191	5.851	1.177	2.120
Italy (INRAN_SCAI_2005_06)	518	3.908	6.902	0.918	1.540
Netherlands (VCPBasis_AVL2007_2010)	173	3.679	6.259	1.409	2.212
Netherlands (VCP-Elderly)	739	3.707	5.830	1.421	2.266
Romania (Dieta_Pilot_Adults)	128	4.652	7.822	1.139	1.843
Sweden (Riksmaten 2010)	367	3.773	6.859	1.535	2.552

(a) Considering reported use levels and analytical data not exceeding the MPLs for food categories for which direct addition of benzoic acid-benzoates is authorised and analytical data for food categories which may contain benzoic acid-benzoates due to carry-over and for which data were available.

J. Main food categories contributing to the exposure to benzoic acid-benzoates (E 210–213) using dataset 2[(a)] for the "brand-loyal refined exposure scenario" (> 5 % of the total mean exposure) and the number of surveys in which each food category is contributing

FCS Category number	FCS Food category	Infants	Toddlers	Children	Adolescents	Adults	The elderly
		Range of % contribution to the total exposure (Number of surveys)[(b)]					
01.4	Unflavoured pasteurised and sterilised (including UHT) milk	35.9 (1)	5.1-6.0 (3)	5.0 (1)			
01.7.1	Unripened cheese excluding products falling in category 16	7.2 (1)	5.0 (1)				
04.1	Unprocessed fruit and vegetables	43.3-79.2 (6)	43.4-80.8 (10)	27-81.5 (18)	19.5-68.5 (17)	11.8-82.9 (17)	17-83.2 (14)
04.2	Processed fruit and vegetables			13.0-21.2 (2)	12.1 (1)	6.0-9.1 (2)	5.9-6.4 (2)
05.2	Other confectionery including breath refreshening microsweets			12.3 (1)	23.8 (1)	5.7 (1)	
09.1	Unprocessed fish		21.7-25.9 (2)	7.6-26.7 (5)	5.1-25.7 (9)	5.3-13.3 (10)	5.4-13 (7)
09.2	Processed fish and fishery products including molluscs and crustaceans		5.9 (1)	5.6-9.5 (5)	5.3-10.7 (3)	6.1 (1)	
10.1	Unprocessed eggs		11.2 (1)	6.9-11.3 (3)	8.6-10.5 (2)		
10.2	Processed eggs and egg products	11.1 (1)	14.2-20.4 (2)	13.1-15.9 (2)	13.3-20 (2)	6.2-19.5 (6)	5.1-19.9 (7)
11.2	Other sugars and syrups			5.3 (1)	5-5 (1)		
12.6	Sauces			5.1 (1)	5.2-9.3 (5)	5.2-6.1 (2)	
12.7	Salads and savoury based sandwich spreads			5.4-23.1 (3)	13.4-30.3 (2)	13.5-33.6 (3)	13.0-18.8 (2)
12.9	Protein products, excluding products covered in category 1.8			6.1 (1)	5.4 (1)	5.3 (1)	
13.1	Foods for infants and young children	6.7-18.9 (6)					
14.1.2	Fruit juices as defined by Directive 2001/112/EC and vegetable juices		5.3-8.4 (2)	5.9-8.4 (2)	10.2 (1)		
14.1.4	Flavoured drinks		6.3-17.1 (4)	7.3-29.5 (12)	6.4-30.8 (15)	5.6-15.8 (8)	
14.1.5	Coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products	5.0-8.2 (2)	8.3 (1)	5.1-13.3 (5)	5.8-19.4 (6)	6.7-43.4 (13)	12.1-51.2 (11)
18	Processed foods not covered by categories 1 to 17, excluding foods for infants and young children	6.5-8.6 (4)	5-7.6 (2)		5.1 (1)	5.0 (1)	

FCS, Food Categorisation System.

(a) Considering reported use levels and analytical data not exceeding the MPLs for food categories for which direct addition of benzoic acid-benzoates is authorised and analytical data for food categories which may contain benzoic acid-benzoates due to carry-over and for which data were available.

(b): The total number of surveys may be greater than the total number of countries as listed in Table 5, as some countries submitted more than one survey for a specific population.

K. Main food categories contributing to the exposure to benzoic acid-benzoates (E 210–213) using dataset 2[(a)] for the "non-brand-loyal refined exposure scenario" (> 5 % of the total mean exposure) and the number of surveys in which each food category is contributing

FCS Category number	FCS Food category	Infants	Toddlers	Children	Adolescents	Adults	The elderly
		Range of % contribution to the total exposure (Number of surveys)[(b)]					
01.1	Unflavoured pasteurised and sterilised (including UHT) milk	7.6-34.9 (2)	6.2-12.8 (7)	5.6-12.6 (5)	5.1-8.4 (3)		
01.7.1	Unripened cheese excluding products falling in category 16	9.0 (1)	6.6 (1)				
04.1	Unprocessed fruit and vegetables	24.5-39.9 (6)	17.6-39.4 (10)	10.2-39.2 (18)	8.3-31.1 (17)	9.0-41 (17)	12.0-43.2 (14)
04.2	Processed fruit and vegetables	7.0 (1)	5.2 (1)	8.6-13.5 (2)	5.6-7.1 (2)	11.0 (1)	5.7-11.7 (2)
09.1	Unprocessed fish		6.5-24.3 (3)	5.1-17.2 (8)	7.0-15.0 (7)	5.3-20.2 (11)	5.7-13.2 (11)
09.2	Processed fish and fishery products including molluscs and crustaceans		6.0-6.9 (2)	5.4-8.9 (4)	5.8-6.9 (3)		
10.1	Unprocessed eggs	8.0 (1)	6.6-19.8 (4)	5.6-17 (13)	5.4-15.6 (10)	5.6-11.1 (8)	6.0-10.7 (5)
10.2	Processed eggs and egg products	6.2 (1)	6.7-9.8 (2)	6.8 (1)	6.2 (1)	5.7-8.0 (4)	5.4-9.1 (6)
12.6	Sauces		5.0-7.1 (4)	5.1-8.7 (9)	5.5-11 (9)	5.6-9.5 (8)	5.3-6.1 (5)
12.7	Salads and savoury-based sandwich spreads			10.7-14.4 (2)	6.2-16 (2)	8.8-19 (3)	10.8-12.4 (2)
13.1	Foods for infants and young children	10.0-18.6 (6)					
14.1.2	Fruit juices as defined by Directive 2001/112/EC and vegetable juices	5.1 (1)	6.1-11.4 (3)	5.0-11.4 (8)	5.3-9.6 (5)	5.1 (1)	
14.1.4	Flavoured drinks	12.2 (1)	7.2-34 (6)	5.2-47.7 (17)	11.5-47.8 (17)	6.3-30.4 (16)	5.2-8.7 (5)
14.1.5	Coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products	9.8-12.1 (2)	5.6-8.5 (3)	6.0-17.1 (7)	5.1-19.9 (8)	8.4-36.8 (15)	10.4-43.4 (14)
18	Processed foods not covered by categories 1 to 17, excluding foods for infants and young children	16.0-29.8 (5)	6-25.3 (8)	5.7-12.4 (11)	5.1-12.7 (10)	5.2-13.4 (11)	5.1-10.5 (8)

FCS, Food Categorisation System.

(a) Considering reported use levels and analytical data not exceeding the MPLs for food categories for which direct addition of benzoic acid-benzoates is authorised and analytical data for food categories which may contain benzoic acid-benzoates due to carry-over and for which data were available.

(b): The total number of surveys may be greater than the total number of countries as listed in Table 5, as some countries submitted more than one survey for a specific population.

L. Summary of refined estimated exposure to benzoic acid-benzoates (E 210–213) from their use as food additives considering concentration levels above the MPLs for food categories listed in Annex II to Regulation (EC) No 1333/2008 and analytical data for food categories which may contain benzoic acid-benzoates due to carry-over and for which data were available (min-max across the dietary surveys in mg/kg bw per day).

	Infants (4–11 months)	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
Brand-loyal scenario						
Mean	5.4–7.3	7.3–10.7	4.6–9.8	2.5–5.2	2.9–4.6	3.0–4.7
High level	10.3–15.9	12.3–19.6	8.0–17.6	4.9–11.0	5.4–8.5	5.4–7.8
Non-brand-loyal scenario						
Mean	1.3–2.1	2.2–3.5	1.5–3.1	0.8–2.0	1.0–1.7	0.8–1.6
High level	2.3–4.1	3.4–6.9	3.1–5.6	1.7–3.7	1.7–3.0	1.3–2.6

ABBREVIATIONS

ADI	acceptable daily intake
ADME	absorption, distribution, metabolism and excretion
AFC Panel	EFSA Panel on Food Additives, Flavourings, Processing Aids and Food Contact Materials
ANS Panel	EFSA Panel on Food Additives and Nutrient Sources added to Food
AUC	Area under the curve
BAuA	Federal Institute for Occupational Safety and Health
BfR	Bundesinstitut für Risikobewertung [Federal Institute for Risk Assessment]
BMI	body mass index
bw	body weight
CAS	Chemical Abstracts Service
CE	capillary electrophoresis
CEF Panel	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
DLLME	dispersive liquid–liquid micro-extraction
DNA	deoxyribonucleic acid
EC	European Commission
EINECS	European Inventory of Existing Commercial chemical Substances
EMS	ethylmethanesulphonate
EPA	Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FCC	Food Chemical Codex
FCS	Food Categorisation System
FDA	Food and Drug Administration
FDE	FoodDrinkEurope
FDRL	Food and Drug Research Laboratories
FEEDAP Panel	EFSA Panel on Additives and Products or Substances used in Animal Feed
GC	gas chromatography
GD	gestation day
GC-MS	gas chromatography-mass spectrometry
GNPD	Mintel's Global New Products Database
HPLC	high-performance liquid chromatography
IARC	International Agency for Research on Cancer
IgE	immunoglobulin E
JECFA	Joint FAO/WHO Expert Committee on Food Additives

LC-MS/MS	liquid chromatography-mass spectrometry/mass spectrometry
LD_{50}	lethal dose, 50 %, i.e. dose that causes death among 50 % of treated animals
LOD	limit of detection
LOQ	limit of quantification
MPL	maximum permitted level
MS	mass spectrometry
MSDI	maximised survey-derived daily intake
NOAEL	no observed adverse effect level
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
PHB	*p*-hydroxybenzoates
QS	*quantum satis*
SCE	sister chromatid exchange
SCCNFP	Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers
SCCP	Scientific Committee on Consumer Products
SCF	EU Scientific Committee on Food
TemaNord	Nordic Working Group on Food Toxicology and Risk Assessment
UHT	ultra-high temperature processing
UNESDA	Union of European Soft Drinks Associations
VKM	Norwegian Scientific Committee for Food Safety
WHO	World Health Organization