SCIENTIFIC OPINION

Scientific Opinion on the re-evaluation of sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) as food additives[1]

EFSA Panel on Food Additives and Nutrient Sources added to Food (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 sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) when used as food additives. Sorbic acid is absorbed and mainly excreted as expired carbon dioxide. The Panel noted that there was no evidence of genotoxic activity for sorbic acid or potassium sorbate. Sub-acute, sub-chronic and chronic toxicity studies did not show any adverse effects at concentrations up to 9 200 mg/kg body weight (bw)/day in rats. Given the lack of genotoxicity data on calcium sorbate and the available positive genotoxicity data on sodium sorbate, the Panel concluded that calcium sorbate should be excluded from the group ADI. The Panel concluded that the present dataset on reproductive and developmental toxicity gives a reason to revise the group ADI of 25 mg/kg bw/day set by the Scientific Committee on Food in 1996. The Panel considered that the no observed adverse effect level of 300 mg sorbic acid/kg bw/day from the two-generation reproductive toxicity study in rats can be used to allocate a temporary group ADI for sorbic acid and its potassium salt. By applying an uncertainty factor of 100, the Panel established a new temporary group ADI expressed as 3 mg sorbic acid/kg bw/day for sorbic acid and its potassium salt. The Panel noted that the most realistic approach using reported use levels and analytical data in the non-brand-loyal scenario did not exceed the temporary group ADI in any population group at the mean or in adolescents, adults and the elderly at the high level, except in the toddler and children population groups in one country.

KEY WORDS

sorbic acid, E 200, calcium sorbate, E 202, potassium sorbate, E 203, food additives

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SUMMARY

Following a request from the European Commission, the Panel on Food Additives and Nutrient Sources added to Food (ANS) of the European Food Safety Authority (EFSA) was asked to re-evaluate sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) when used as food additives.

Sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) are authorised as food additives in accordance with Annex II and Annex III of Regulation (EC) No 1333/2008 and were previously evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 1974 and by the Scientific Committee on Food (SCF) in 1996.

JECFA evaluated sorbic acid and its salts in 1961, 1965 and, most recently, in 1973. A group Acceptable Daily Intake (ADI) of 25 mg/kg body weight (bw)/day expressed as sorbic acid was allocated, covering sorbic acid, sodium sorbate, potassium sorbate and calcium sorbate (JECFA, 1974). This ADI was based on a no observed adverse effect level (NOAEL) of 5 % in the diet of rats in a long-term study, equivalent to 2 500 mg/kg bw/day.

Based on studies originally evaluated by JECFA (1974), as well as more recent studies, the SCF endorsed the group ADI of 25 mg/kg bw/day for sorbic acid, potassium sorbate and calcium sorbate allocated by JECFA. The SCF noted that there were no toxicological studies on calcium sorbate, but nevertheless included this substance in the group ADI (SCF, 1996).

The Panel considered that data available on the absorption, distribution, metabolism and excretion of sorbic acid show that sorbic acid is absorbed and mainly excreted as expired carbon dioxide. As no data on bioavailability were available on potassium sorbate and calcium sorbate, the Panel considered that, owing to the ionisation properties of sorbic acid ($pK_a = 4.76$), the unionised forms of these sorbates are absorbed by a diffusion process in the stomach. Potassium and calcium sorbate might dissociate into their constituents—potassium, calcium and sorbate ions—in the small intestine. Accordingly, sorbate from potassium or calcium sorbate should be bioavailable and absorbed in the same manner as from sorbic acid. The calcium and potassium ions are expected to enter normal homeostatic processes and are not expected to have an impact on the toxicity of the salts. Thus, the properties of the cations are not discussed further in the opinion.

Short-term and sub-chronic toxicity studies performed in rats and mice did not show any adverse effects at the concentrations tested (up to 9 200 mg/kg bw/day in rats).

Sorbic acid and potassium sorbate were investigated in *in vitro* and *in vivo* genotoxicity assays. Overall, the Panel considered that the database was sufficiently robust and that there was no evidence of genotoxic activity for sorbic acid or potassium sorbate. The Panel noted that no data on genotoxicity were available for calcium sorbate. The Panel considered that read-across from sorbic acid and potassium sorbate data on genotoxicity to calcium sorbate would be theoretically possible. However, given the available positive genotoxicity data on sodium sorbate (as reported by the SCF (1996)), the Panel considered that genotoxicity data on calcium sorbate are needed.

The Panel also noted that potential reaction products that may result from the interaction of sorbic acid with nitrites and with ascorbic acid in the presence of iron salts were demonstrated to be mutagenic *in vitro* and that there are certain food categories for which the use of these food additives (sorbic acid with ascorbic acid in the presence of iron salts or sorbic acid with nitrites) is permitted in parallel. However, these reaction products have been shown to be formed under optimal experimental conditions in an aqueous environment only and may not be formed to any major extent in food matrices.

The Panel also noted that the major reaction products resulting from the interaction of sorbic acid with different amines (e.g. methylamine, ethylamine, propylamine, butylamine and benzylamine) were not mutagenic in the bacterial reverse mutation assay.

Five long-term/carcinogenicity toxicity studies performed before 1976 were available, but more recent studies have not been identified in the literature. The Panel revisited all the relevant original reports and publications, except the Lang et al. (1967) study used to allocate the ADI by JECFA (1974), which was not available.

A two-generation reproductive toxicity study was performed in CD/Crl:CD rats in accordance with the Organisation for Economic Co-operation and Development (OECD) Guideline 416 and Good Laboratory Practice (GLP). Sorbic acid was administered by gavage at a dose of 0, 300, 1 000 or 3 000 mg/kg bw/day. Several adverse effects were described in pups, such as a decrease in mean litter body weight, milestones of physical development in F_1 pups, a delay in functional development in F_1 pups and a decrease in anogenital distance in male F_2 pups in the mid- and high-dose groups. Considering the aforementioned observations, the Panel concluded that, by gavage, the NOAEL for developmental toxicity is 300 mg/kg bw/day. Furthermore, the Panel noted that, by gavage, the NOAEL for parental toxicity is 1 000 mg/kg bw/day based on effects on body weights of the parental male animals.

In a developmental toxicity study performed in rabbits in accordance with OECD Guideline 414 and GLP at doses of 0 (control), 300, 1 000 or 3 000 mg sorbic acid/kg bw/day by gavage from day 6 to 29 of gestation, maternal and fetal toxicity were observed in the mid- and high-dose groups. The Panel considered that the maternal NOAEL was 300 mg sorbic acid/kg bw/day and the NOAEL for the fetuses was also 300 mg sorbic acid/kg bw/day.

Given the lack of genotoxicity data on calcium sorbate and the available positive genotoxicity data on sodium sorbate, the Panel concluded that calcium sorbate should be excluded from the group ADI.

The Panel concluded that the present dataset on reproductive and developmental toxicity gives a reason to revise the group ADI of 25 mg/kg bw/day set by the SCF in 1996. The Panel considered that the NOAEL of 300 mg sorbic acid/kg bw/day from the two-generation reproductive toxicity study in rats can be used to allocate a temporary group ADI for sorbic acid and its potassium salt. By applying an uncertainty factor of 100, the Panel established a new temporary group ADI expressed as 3 mg sorbic acid/kg bw/day for sorbic acid (E 200) and potassium sorbate (E 202).

Exposure assessments to sorbic acid – sorbates (E 200, 202, 203) were carried out by the ANS Panel based on (1) maximum permitted levels (MPLs) set out in the European Union (EU) legislation (defined as the *regulatory maximum level exposure assessment scenario*) and (2) usage or analytical data (defined as the *refined exposure assessment scenario*).

Using the *regulatory maximum level exposure assessment scenario*, the Panel noted that this exposure estimate of sorbic acid – sorbates (E 200, 202, 203) exceeded the temporary group ADI of 3 mg/kg bw/day for all population groups at the mean and high levels. The main contributing food categories to the total mean exposure estimates for children, adolescents and adults in this scenario were bread and rolls, fine bakery wares and flavoured drinks. For the elderly, the main contributing food categories were bread and rolls and fine bakery wares, while, for toddlers, the main contributing food categories were bread and rolls, fine bakery wares and processed cheese.

From the *refined estimated exposure scenario* using only reported use levels, the Panel noted that the refined brand-loyal and non-brand-loyal exposure estimates exceeded the temporary group ADI of 3 mg/kg bw/day for all population groups at the mean and high levels. The main contributing food categories for all groups were bread and rolls and fine bakery wares.

From the *refined estimated exposure scenario* using reported use levels and analytical data, the Panel noted that, for the refined brand-loyal exposure estimate, all population groups exceeded the temporary group ADI of 3 mg/kg bw/day at the mean and high levels (95th percentile), whilst, for the *non-brand-loyal scenario*, the temporary group ADI was exceeded in only toddler and children population groups in one country. The main contributing food categories for all groups were bread and rolls and fine bakery wares in the *brand-loyal scenario* and bread and rolls, fine bakery wares, flavoured drinks and sauces in the *non-brand-loyal scenario*.

The Panel noted that the most realistic approach using reported use levels and analytical data in the *non-brand-loyal scenario* did not exceed the temporary group ADI in any population group at the mean or in adolescents, adults and the elderly at the high level, except in the toddler and children population groups in one country. The Panel noted that, in these estimates, the main food contributors were bread and rolls, fine bakery wares and flavoured drinks.

The Panel also recommended that:

- genotoxicity studies on calcium sorbate need to be performed in order to consider including calcium sorbate in the group ADI;
- an extended one-generation reproductive toxicity study in rats including the second generation by diet needs to be performed in order to reconsider the temporary group ADI;
- if divalent transition metals are used as catalysts in the manufacturing process of sorbic acid, maximum residual levels of divalent transition metals should be included in the EC specifications for sorbic acid (E 200);
- the maximum limits for the impurities of toxic elements (lead, mercury and arsenic) in the EC specification for sorbic acid and its salts (E 200, 202, 203) should be revised in order to ascertain that sorbic acid – sorbates (E 200, 202, 203) as food additives will not be a significant source of exposure to those toxic elements in food;
- future research be performed on the occurrence of breakdown and reaction products of possible toxicological concern under realistic conditions of food processing and storage—especially when sorbic acid, potassium sorbate or calcium sorbate is used in parallel with ascorbic acid in the presence of iron salts or with nitrites.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1333/2008 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 the Regulation (EU) No 257/2010[4]. This Regulation also foresees that food additives are re-evaluated whenever necessary in 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 (SCF) 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[5] of 2001. The report "Food additives in Europe 2000[6]" 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 a highest priority.

In 2003, the Commission already requested EFSA to start a systematic re-evaluation of authorised food additives. However, as a result of adoption of Regulation (EU) 257/2010 the 2003 Terms of References 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, procedures and deadlines that are enshrined in the Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with the Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.

[4] OJ L 80, 26.3.2010, p. 19.
[5] COM(2001) 542 final.
[6] 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 sorbic acid (E 200), potassium sorbate (E 202) and calcium sorbate (E 203) when used as food additives.

Sorbic acid and sorbates (E 200, 202, 203) are authorised as food additives in the European Union (EU) in accordance with Annex II to Regulation (EC) No 1333/2008[7] and have previously been evaluated by the Joint FAO/WHO expert Committee on Food Additives (JECFA) in 1974 and by the Scientific Committee on Food (SCF) in 1996.

The Panel on Food Additives and Nutrient Sources added to Food (ANS) was not provided with a newly submitted dossier and based its evaluation on previous evaluations, additional literature that has become available since then and the data available following a European Food Safety Authority (EFSA) public call for scientific data.[8,9]

2. Technical data

2.1. Identity of the substances

2.1.1. Sorbic acid

Sorbic acid (E 200) has the chemical name (*2E,4E*)-hexa-2,4-dienoic acid. The molecular formula is $C_6H_8O_2$ and the molecular weight is 112.12 g/mol. The Chemical Abstracts Service (CAS) registry number is 110-44-1 and the European Inventory of Existing Commercial chemical Substances (EINECS) number is 203-768-7.

Synonyms include *trans,trans*-2,4-hexadienoic acid, 2,4-hexadienoic acid (*E,E*), (*E,E*)-1,3-pentadiene-1-carboxylic acid (SciFinder® software).

The structural formula is shown in Figure 1.

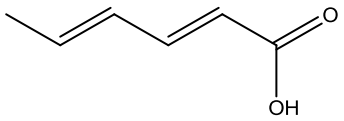

Figure 1: Structural formula of sorbic acid

Sorbic acid is a white free-flowing powder or takes the form of colourless needles. It is slightly soluble in water and soluble in ethanol. The melting point is between 133 and 135 °C (Commission Regulation (EU) No 231/2012[10]). The pK_a is 4.76.

[7] 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.

[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: 1 June 2012. Available online: http://www.efsa.europa.eu/en/dataclosed/call/120601.htm

[10] 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.

2.1.2. Potassium sorbate

Potassium sorbate (E 202) has the chemical name potassium (*2E,4E*)-hexa-2,4-dienoate. The molecular formula is $C_6H_7O_2K$ and the molecular weight is 150.22 g/mol. The CAS registry number is 24634-61-5 and the EINECS number is 246-376-1.

Synonyms include 2,4-hexadienoic acid potassium salt, (*E,E*); and sorbic acid, potassium salt (SciFinder software).

The structural formula is shown in Figure 2.

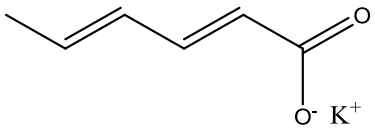

Figure 2: Structural formula of potassium sorbate

Potassium sorbate is a white crystalline powder. Potassium sorbate is freely soluble in water and soluble in ethanol (JECFA, 2006; Commission Regulation (EU) No 231/2012).

2.1.3. Calcium sorbate

Calcium sorbate (E 203) has the chemical name calcium (*2E,4E*)-dihexa-2,4-dienoate. The molecular formula is $C_{12}H_{14}O_4Ca$ and the molecular weight is 262.32 g/mol. The CAS registry number is 7492-55-9 and the EINECS number is 231-321-6.

Synonyms include 2,4-hexadienoic acid calcium salt, (*E,E*); and sorbic acid, calcium salt (SciFinder software).

The structural formula is shown in Figure 3.

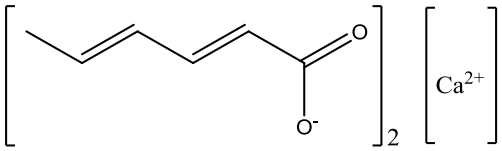

Figure 3: Structural formula of calcium sorbate

Calcium sorbate is a fine white crystalline powder. It is soluble in water and practically insoluble in ethanol (JECFA, 2006; Commission Regulation (EU) No 231/2012).

2.1.4. Mechanism of antimicrobial action of sorbic acid and sorbates

The exact mechanisms of antimicrobial activity (inhibition of cell growth and multiplication, germination and outgrowth of spore-forming bacteria) are not well defined (Freese et al., 1973; Freese and Levin, 1978, as referred to by Stopforth et al., 2005; Sofos, 1989), but several mechanisms of the inhibition of metabolic activity of certain microbia by sorbates have been proposed (Stopforth et al., 2005).

Sorbates inhibit microbial growth by inducing alterations in the morphology, integrity and function of cell membranes and by inhibiting transport functions and metabolic activity (Sofos, 1989). Sorbates are known to inhibit the *in vitro* activity of many enzymes, especially sulphydryl-containing enzymes (Kouassi and Shelef, 1995a, b, as referred to by Stopforth et al., 2005).

With respect to the inhibition of transport functions, sorbates may interfere with substrate and electron transport mechanisms, probably through the incorporation of sorbic acid into the cell membrane,

where it may cause steric disorganisation of active membrane transport proteins (Sofos 1989, 1992, the latter as referred to by Stopforth et al., 2005). Another mechanism proposed for the inhibitory action of sorbic acid in cell growth is the excessive consumption of cellular energy that occurs as a consequence of the cell eliciting a stress response while attempting to maintain pH homeostasis (Bracey et al., 1998). Death of microorganisms exposed to high concentrations of sorbate has been attributed to the generation of holes in the cell membrane (Freese and Levin, 1978).

Numerous studies have also documented the effectiveness of sorbates in moulds, and it is well known that one of the major applications of sorbates is the inhibition of moulds in cheese (Chichester and Tanner, 1972, as referred to by Stopforth et al., 2005).

Sorbates were found to inhibit many bacterial strains: *Enterobacter*, *Bacillus*, *Campylobacter*, etc. Inhibition of bacteria appears to cause an extension of the lag phase, with a lesser influence on rate and extent of growth. Under certain conditions, some microbial strains are resistant to sorbates or even metabolise the compound (Sofos, 1989).

Sorbates were also found to inhibit the formation of mycotoxins by various moulds in culture media and in foods (Bullerman, 1983, 1984, 1985, as referred to by Stopforth et al., 2005). However, sub-inhibitory levels of sorbate may stimulate the production of mycotoxins (Bullerman and Olivigni, 1974, as referred to by Stopforth et al., 2005).

Overall, however, sorbate is considered as a more effective inhibitor of yeasts and moulds than of bacteria. The mechanism of inhibition or of delay of growth by sorbates is dependent on the microbial types, species, strains, substrate properties and environmental factors (Skirdal and Eklund, 1993, as referred to by Stopforth et al., 2005; Sofos, 1989).

2.2. Specifications

Specifications have been defined in Commission Regulation (EU) No 231/2012 and by JECFA (JECFA, 2006) (Tables 1–3).

Table 1: Specifications for sorbic acid (E 200) according to Commission Regulation (EU) No 231/2012 and JECFA (2006)

	Commission Regulation (EU) No 231/2012	**JECFA (2006)**
DEFINITION		
CAS number	Not listed	110-44-1
EINECS	203-768-7	Not listed
Chemical formula	$C_6H_8O_2$	$C_6H_8O_2$
Molecular weight (g/mol)	112.12	112.12
Assay	Content ≥ 99 % on the anhydrous basis	≥ 99.0 % calculated on the anhydrous basis
Description	Colourless needles or white free-flowing powder, having a slight characteristic odour and showing no change in colour after heating for 90 minutes at 105 °C	Colourless needles or white free-flowing powder, having a slight characteristic odour
IDENTIFICATION		
Melting range	Between 133 and 135 °C after vacuum drying for four hours in a sulphuric acid desiccator	Between 132 and 135 °C (the melting apparatus should be preheated to 125 °C before introducing the sample)
Solubility	Slightly soluble in water, soluble in ethanol	Slightly soluble in water, soluble in ethanol
Spectrometry	A propan-2-ol solution (1 in 4 000 000) shows absorbance maximum at 254 ± 2 nm	A 1 in 400 000 solution in isopropanol solution shows absorbance maximum at 254 ± 2 nm

	Commission Regulation (EU) No 231/2012	JECFA (2006)
Positive test for double bonds	Passes test	Shake about 0.02 g of the sample with 1 ml bromine TS; the colour disappears
PURITY		
Water content	≤ 0.5 % (Karl Fischer method)	≤ 0.5 % (Karl Fischer method)
Sulphated ash	≤ 0.2 %	≤ 0.2 %
Aldehydes	≤ 0.1 % (as formaldehyde)	≤ 0.1 % (as formaldehyde)
Arsenic	≤ 3 mg/kg	–
Lead	≤ 2 mg/kg	≤ 2 mg/kg
Mercury	≤ 1 mg/kg	–

Table 2: Specifications for potassium sorbate (E 202) according to Commission Regulation (EU) No 231/2012 and JECFA (2006)

	Commission Regulation (EU) No 231/2012	JECFA (2006)
DEFINITION		
CAS number	Not listed	24634-61-5
EINECS	246-376-1	Not listed
Chemical formula	$C_6H_7O_2K$	$C_6H_7KO_2$
Molecular weight (g/mol)	150.22	150.22
Assay	Content ≥ 99 % on the dried basis	≥ 98 % and ≤ 102 % at the dried basis
Description	White crystalline powder showing no change in colour after heating for 90 minutes at 105 °C	White or yellowish-white crystals or crystalline powder or granules
IDENTIFICATION		
Melting range (of sorbic acid derived from the sample)	Melting range of sorbic acid isolated by acidification and not recrystallised is 133 to 135 °C after vacuum drying in a sulphuric acid desiccator	132–135 °C Acidify a solution of the sample with dilute hydrochloric acid TS. Collect the precipitated sorbic acid on a filter paper, wash free of chloride with water and dry under vacuum over sulphuric acid
Solubility	Not listed	Freely soluble in water, soluble in ethanol
Positive tests	Positive tests for potassium and for double bonds	Test for unsaturation
PURITY		
Loss on drying	≤ 1 % (105 °C, three hours)	≤ 1 % (105 °C, three hours)
Acidity or alkalinity	≤ 1 % (as sorbic acid or K_2CO_3)	≤ 1 % (as sorbic acid or potassium carbonate)
Aldehydes	≤ 0.1 % (calculated as formaldehyde)	≤ 0.1 % (as formaldehyde)
Arsenic	≤ 3 mg/kg	–
Lead	≤ 2 mg/kg	≤ 2 mg/kg
Mercury	≤ 1 mg/kg	–

Table 3: Specifications for calcium sorbate (E 203) according to Commission Regulation (EU) No 231/2012 and JECFA (2006)

	Commission Regulation (EU) No 231/2012	JECFA (2006)
DEFINITION		
CAS number	Not listed	7492-55-9
EINECS	231-321-6	Not listed
Chemical formula	$C_{12}H_{14}O_4Ca$	$C_{12}H_{14}O_4Ca$

	Commission Regulation (EU) No 231/2012	JECFA (2006)
Molecular weight (g/mol)	262.32	262.32
Assay	Content ≥ 98 % on the dried basis	≥ 98 % and ≤ 102 % after drying
Description	Fine white crystalline powder not showing any change in colour after heating at 105 °C for 90 minutes	Fine white crystalline powder not showing any change in colour after heating at 105 °C for 90 minutes
IDENTIFICATION		
Melting range (of sorbic acid derived from the sample)	Melting range of sorbic acid isolated by acidification and not recrystallised is 133 to 135 °C after vacuum drying in a sulphuric acid desiccator	132–135 °C Acidify a solution of the sample with dilute hydrochloric acid TS. Collect the precipitated sorbic acid on a filter paper, wash free of chloride with water and dry under vacuum over sulphuric acid
Solubility	Not listed	Soluble in water, practically insoluble in ethanol
Positive tests	Test for calcium and for double bonds	Test for calcium and unsaturation
PURITY		
Loss on drying	≤ 2 %, determined by vacuum drying for four hours in a sulphuric acid desiccator	≤ 3 % (over sulphuric acid in vacuum, four hours)
Aldehydes	≤ 0.1 % (as formaldehyde)	≤ 0.1 % (as formaldehyde)
Fluoride	≤ 10 mg/kg	≤ 10 mg/kg
Arsenic	≤ 3 mg/kg	–
Lead	≤ 2 mg/kg	≤ 2 mg/kg
Mercury	≤ 1 mg/kg	–

Concerning the substances used in the manufacturing process only, the limit for aldehydes of ≤ 0.1 % (as formaldehyde) is specified.

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

2.3. Manufacturing process

Sorbic acid, in the form of its lactone, occurs naturally in some fruits, notably rowan berries, from which the substance was first isolated and identified (hence the name of the substance, which is derived from the Latin name of the rowan tree, *Sorbus aucuparia* L.). Commercial sorbic acid is manufactured by chemical synthesis (Sofos, 1989).

The most widely used manufacturing method of sorbic acid is currently the ketene–crotonaldehyde condensation method. Ketene (ethenone, $H_2C=C=O$, CAS registry number 463-51-4) and crotonaldehyde (2-butenal, CH_3–CH=CH–CHO, CAS registry number 123-73-9 (*trans* form) or 4170-30-3 (racemic)) react in the presence of salts of divalent transition metals as catalysts to form a polymeric ester of 3-hydroxy-4-hexenoic acid, with a molecular mass around or above 2 000 g/mol. This polyester can be cleaved to give sorbic acid in good yield by a thermal process in the presence of metal complexes (Sofos, 1989; Lipinski, 2009). Lipinski (2009) did not give further information on the catalysts used, but, according to the Van Nostrand's Scientific Encyclopedia (Van Nostrand's Scientific Encyclopedia, 2007), catalysts are composed of metals (zinc, cadmium, nickel, copper, manganese and cobalt), metal oxides or carboxylate salts of bivalent transition metals (zinc isovalerate). According to the information received from industry, this manufacturing process was employed for the production of the material used in toxicological studies and, therefore, for safety assessments of sorbates by the SCF and JECFA (Lipinski, 2009).

Alternatively, the cleavage of the polymeric ester can be achieved by treatment with acids (as is done commercially) or bases, but this does not seem to have practical importance. Both acidic and basic cleavage may result in different by-products from the thermal cleavage of the polyester (Klug, 2006; Lipinski, 2009).

The Panel noted that transition metals can be used as catalysts in the manufacturing process and that maximum residual levels should be included in the EC specifications.

Production of the potassium salt can be from finished sorbic acid or from a stream in the sorbic acid production route before the final drying step (Nostrand, 2006).

Other production processes described in the literature either have been abandoned or are used in only laboratory syntheses and apparently have not gained industrial importance (Nostrand, 2006; Lipinski, 2009).

2.4. Methods of analysis in food

Following a public call for data, industry submitted information on the use of a high-performance liquid chromatography (HPLC) method for the analysis of organic acids (formic acid, acetic acid, sorbic acid and propionic acid) in animal feed (Kemira, 2010).

Sorbates can be measured in the form of an anion or an acid. The most commonly used analytical method for the quantitative determination of sorbates in food is reversed-phase HPLC equipped with an ultraviolet (UV) detector or a UV/diode array detector (DAD) with or without the use of an internal standard, i.e. methyl-3-hydroxybenzoic acid (Leth et al., 2010), where injection occurs directly before or after dilution. The use of a DAD provides the most reliable analytical results, as sufficient quantification and identification of the substance is feasible (Pylypiw and Grether, 2000). Sorbates can also be measured via chromatography gas (GC) analysis, resulting in reliable results if combined with mass spectrometry (MS) (De Luca et al., 1995).

2.5. Reaction and fate in food

The stability of sorbic acid in food is influenced by a number of factors including pH, temperature, food composition, water activity, presence of other additives, metal ions and packaging (Arya, 1980; Vidyasagar and Arya, 1983, 1984; Arya and Thakur, 1988; Sofos, 1989; Ferrand et al., 2000a; Yarramraju et al., 2007). In aqueous model food systems, sorbic acid is relatively unstable and degrades by first-order kinetics (Thakur et al., 1994). In preparations of preserved peaches, after three months of storage at 30 °C, losses may amount to up to 35 % (Gerschenson et al., 1986a, b). In foods of intermediate moisture, sorbic acid showed losses of less than 25 % after 40 days' storage at 35 °C (Torres et al., 1989; Thakur et al., 1994).

Sorbic acid is reactive through its carboxyl group and yields salts and esters. The conjugated double bonds are important for nucleophilic addition reactions in sorbates (Ferrand et al., 2000a, b). Thus, oxidising agents attack sorbates at the conjugated double bonds, which results in the formation of peroxides followed by their degradation and polymerisation. The main degradation products are carbonyl compounds including crotonaldehyde, malondialdehyde, acrolein, formic acid, malonic acid, fumaraldehydic acid, 2-methyl-5-acetyl furan and others (Thakur et al., 1994).

It has been shown that sorbate can react with amines in the food to form various adducts, while high temperatures favour auto-oxidation reactions that produce carbonyl compounds, which can lead to browning of the food (Ferrand et al., 2000a, b). The combination of potassium sorbate, ascorbic acid and ferrous salts can be used in foods, but the high reactivity of potassium sorbate and the oxidative potential of ascorbic acid in the presence of iron salts (such as ferric citrate, ferrous gluconate, ferric pyrophosphate and ferrous sulphate) could lead to the formation of toxic compounds (Kitano et al., 2002). Sorbic acid can be present with nitrite (natural or incorporated as a food additive) in some foods such as meat products. Sorbic acid may react with nitrite to produce compounds containing *C*-

nitro, *C*-nitroso and *N*-nitro groups, yielding potentially mutagenic products such as 1,4-dinitro-2 methylpyrrole and ethylnitrolic acid (Namiki et al., 1980, 1981). Further studies on the reactivity of these products and their stability to a range of pH values identified the formation of the acetonitrile oxide, a compound with alkylating capabilities (Pérez-Prior et al., 2008, 2009).

The Panel considered that there is limited information about the occurrence of breakdown and reaction products of possible toxicological concern under realistic conditions of food processing and storage. This could be especially relevant when sorbic acid, potassium sorbate or calcium sorbate are used in parallel with ascorbic acid in the presence of iron salts or with nitrites. Future research is recommended in this respect.

2.6. Case of need and proposed uses

Maximum permitted levels (MPLs) of sorbic acid – sorbates (E 200, 202, 203) have been defined in Annex II to Regulation (EC) No 1333/2008 on food additives.

Currently, sorbic acid – sorbates (E 200, 202, 203) are authorised as food additives in the EU with MPLs ranging from 20 to 6 000 mg/kg in foods. The Panel noted that sorbic acid – sorbates are authorised to be used in combination with benzoic acid – benzoates (E 210–213) and *p*-hydroxybenzoates (PHB; E 214, 215, 218, 219) (Regulation (EC) No 1333/2008).

Table 4 summarises foods that are permitted to contain sorbic acid – sorbates (E 200, 202, 203) and the corresponding MPLs as set by Annex II to Regulation (EC) No 1333/2008.

Table 4: MPLs of sorbic acid – sorbates (E 200, 202, 203) in foods according to Annex II of Regulation (EC) No 1333/2008

FCS category number	Foods	E number/group	Restrictions/exceptions	Maximum level [(a)] (mg/l or mg/kg as appropriate)
01.3	Unflavoured fermented milk products, heat-treated after fermentation	SA	Only curdled milk	1 000 [(a),(b)]
01.4	Flavoured fermented milk products including heat-treated products	SA + BA	Only non-heat-treated dairy-based desserts	300 [(a),(b)]
01.7.1	Unripened cheese excluding products falling in category 16	SA		1 000 [(a),(b)]
01.7.2	Ripened cheese	SA	Only cheese, prepacked, sliced and cut; layered cheese and cheese with added foods	1 000 [(a),(b)]
01.7.2	Ripened cheese	SA	Only ripened products, surface treatment	*QS*
01.7.4	Whey cheese	SA	Only cheese, prepacked, sliced; layered cheese and cheese and cheese with added foods	1 000 [(a),(b)]
01.7.5	Processed cheese	SA		2 000 [(a),(b)]

FCS category number	Foods	E number/group	Restrictions/exceptions	Maximum level [a] (mg/l or mg/kg as appropriate)
01.7.6	Cheese products (excluding products falling in category 16)	SA	Only unripened products; ripened products, prepacked, sliced; layered ripened products and ripened products with added foods	1 000 [a],[b]
01.7.6	Cheese products (excluding products falling in category 16)	SA	Only ripened products surface treatment	*QS*
01.8	Dairy analogues, including beverage whiteners	SA	Only cheese analogues (surface treatment only)	*QS* [a],[b]
01.8	Dairy analogues, including beverage whiteners	SA	Only analogues of cheese based on protein	2 000 [a],[b]
02.2.2	Other fat and oil emulsions including spreads as defined by Regulation (EC) No 1234/2007 and liquid emulsions	SA	Only fat emulsions (excluding butter) with a fat content of 60 % or more	1 000 [a],[b]
02.2.2	Other fat and oil emulsions including spreads as defined by Regulation (EC) No 1234/2007 and liquid emulsions	SA	Only fat emulsions with a fat content less than 60 %	2 000 [a],[b]
04.1.1	Entire fresh fruit and vegetables	SA	Only surface treatment of unpeeled fresh citrus fruit	20
04.2.1	Dried fruit and vegetables	SA	Only dried fruit	1 000 [a],[b]
04.2.2	Fruit and vegetables in vinegar, oil or brine	SA + BA	Only vegetables (excluding olives)	2 000 [a],[b]
04.2.2	Fruit and vegetables in vinegar, oil or brine	SA	Only olives and olive-based preparations	1 000 [a],[b]
04.2.2	Fruit and vegetables in vinegar, oil or brine	SA + BA	Only olives and olive-based preparations	1 000 [a],[b]
04.2.4.1	Fruit and vegetable preparations excluding compote	SA	Only fruit and vegetable preparations including seaweed-based preparations, fruit-based sauces, aspic, excluding purée, mousse, compote, salads and similar products, canned or bottled	1 000 [a],[b]
04.2.4.1	Fruit and vegetable preparations excluding compote	SA + BA	Only olive-based preparations	1 000 [a],[b]

FCS category number	Foods	E number/group	Restrictions/exceptions	Maximum level [(a)] (mg/l or mg/kg as appropriate)
04.2.5.1	Extra jam and extra jelly as defined by Directive 2001/113/EEC	SA + BA	Only low-sugar and similar low calorie or sugar-free products, *mermeladas*	1 000 [(a),(b)]
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2001/113/EEC	SA + BA	Only low-sugar and similar low calorie or sugar-free products, spreads, *mermeladas*	1 000 [(a),(b)]
04.2.5.3	Other similar fruit or vegetable spreads	SA + BA	Other fruit-based spreads, *mermeladas*	1 000 [(a),(b)]
04.2.5.3	Other similar fruit or vegetable spreads	SA + BA	Only *marmelada*	1 500 [(a),(b)]
04.2.6	Processed potato products	SA	Only potato dough and pre-fried potato slices	2 000 [(a),(b)]
05.2	Other confectionery including breath-freshening microsweets	SA + BA + PHB	Except candied, crystallised or glacé fruit and vegetables	1 500 [(a),(b),(c)]
05.2	Other confectionery including breath-freshening microsweets	SA + BA	Only candied, crystallised or glacé fruit and vegetables	1 000 [(a),(b)]
05.3	Chewing gum	SA + BA		1 500 [(a),(b)]
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	SA	Only toppings (syrups for pancakes, flavoured syrups for milkshakes and ice cream; similar products)	1 000 [(a),(b)]
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	SA + BA + PHB		1 500 [(a),(b),(c)]
06.4.4	Potato gnocchi	SA		1 000 [(b)]
06.4.5	Fillings of stuffed pasta (ravioli and similar)	SA		1 000 [(a),(b)]
06.6	Batters	SA		2 000 [(a),(b)]
06.7	Pre-cooked or processed cereals	SA	Only polenta	200 [(a),(b)]
06.7	Pre-cooked or processed cereals	SA	Only *semmelknödelteig*	2 000 [(a),(b)]
07.1	Bread and rolls	SA	Only prepacked sliced bread and rye-bread, partially baked, prepacked bakery wares intended for retail sale and energy-reduced bread intended for retail sale	2 000 [(a),(b)]
07.2	Fine bakery wares	SA	Only with a water activity of more than 0.65	2 000 [(a),(b)]
08.3.1	Non-heat-treated processed meat	SA + BA + PHB	Only surface treatment of dried meat products	*QS* [(a),(b)]

FCS category number	Foods	E number/group	Restrictions/exceptions	Maximum level [(a)] (mg/l or mg/kg as appropriate)
08.3.2	Heat-treated processed meat	SA + PHB	Only pâté	1 000 [(a),(b)]
08.3.2	Heat-treated processed meat	SA	Only aspic	1 000 [(a),(b)]
08.3.2	Heat-treated processed meat	SA + BA + PHB	Only surface treatment of dried meat products	*QS* [(a),(b)]
08.3.3	Casings and coatings and decorations for meat	SA	Only collagen-based casings with water activity greater than 0.6	*QS*
08.3.3	Casings and coatings and decorations for meat	SA+ PHB	Only jelly coatings of meat products (cooked, cured or dried)	1000 [(a),(b)]
09.2	Processed fish and fishery products including molluscs and crustaceans	SA	Aspic	1 000 [(a),(b)]
09.2	Processed fish and fishery products including molluscs and crustaceans	SA + BA	Only salted, dried fish	200 [(a),(b)]
09.2	Processed fish and fishery products including molluscs and crustaceans	SA + BA	Only semi-preserved fish and fisheries products including crustaceans, molluscs, surimi and fish/crustacean paste; cooked crustaceans and molluscs	2 000 [(a),(b)]
09.2	Processed fish and fishery products including molluscs and crustaceans	SA + BA	Only cooked *Crangon crangon* and *Crangon vulgaris*	6 000
09.3	Fish roe	SA + BA	Only semi-preserved fish products including fish roe products	2 000 [(a),(b)]
10.2	Processed eggs and egg products	SA	Only dehydrated and concentrated frozen and deep frozen egg products	1 000 [(a),(b)]
10.2	Processed eggs and egg products	SA + BA	Only liquid egg (white, yolk or whole egg)	5 000 [(a),(b)]
11.4.1	Table-top sweeteners in liquid form	SA + BA + PHB	Only if the water content higher than 75 %	500 [(a),(b)]
12.2.2	Seasonings and condiments	SA + BA		1 000 [(a),(b)]
12.4	Mustard	SA + BA		1 000 [(a),(b)]
12.5	Soups and broths	SA + BA	Only liquid soups and broths (excluding canned)	500 [(a),(b)]
12.6	Sauces	SA	Only emulsified sauces with a fat content of less than 60 %	2 000 [(a),(b)]
12.6	Sauces	SA	Only emulsified sauces with a fat content of 60 % or more	1 000 [(a),(b)]

FCS category number	Foods	E number/group	Restrictions/exceptions	Maximum level [(a)] (mg/l or mg/kg as appropriate)
12.6	Sauces	SA + BA	Only emulsified sauces with a fat content of 60 % or more; non-emulsified sauces	1 000 [(a),(b)]
12.6	Sauces	SA + BA	Only emulsified sauces with a fat content of less than 60 %	2 000 [(a),(b)]
12.7	Salads and savoury-based sandwich spreads	SA + BA		1 500 [(a),(b)]
12.9	Protein products, excluding products covered in category 1.8	SA	Only analogues of meat, fish, crustaceans and cephalopods and cheese based on protein	2 000 [(a),(b)]
13.2	Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)	SA + BA		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)	SA + BA		1 500 [(a),(b)]
14.1.2	Fruit juices as defined by Directive 2001/112/EC and vegetable juices	SA	Only sød … saft and sødet … saft	500 [(a),(b)]
14.1.2	Fruit juices as defined by Directive 2001/112/EC and vegetable juices	SA + BA	Only grape juice, unfermented, for sacramental use	2 000 [(a),(b)]
14.1.3	Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products	SA	Only traditional Swedish and Finnish fruit syrups	300 [(a),(b)]
14.1.3	Fruit nectars as defined by Directive 2001/112/EC and vegetable nectars and similar products	SA	Only traditional Swedish fruit syrups, maximum applies if E 210–213, benzoic acid and benzoates, have also been used	250 [(a),(b)]
14.1.4	Flavoured drinks	SA	Excluding dairy-based drinks	300 [(a),(b)]
14.1.4	Flavoured drinks	SA	Maximum applies if E 210–213, benzoic acid and benzoates, have also been used	250 [(a),(b)]

FCS category number	Foods	E number/group	Restrictions/exceptions	Maximum level [(a)] (mg/l or mg/kg as appropriate)
14.1.5.2	Other	SA + BA	Only liquid tea concentrates and liquid fruit and herbal infusion concentrates	600 [(a),(b)]
14.2.1	Beer and malt beverages	SA	Only beer in kegs containing more than 0.5 % added fermentable sugar and/or fruit juices or concentrates	200 [(a),(b)]
14.2.2	Wine and other products defined by Regulation (EEC) No 1234/2007, and alcohol-free counterparts	SA	Only alcohol-free	200 [(a),(b)]
14.2.3	Cider and perry	SA		200 [(a),(b)]
14.2.4	Fruit wine and made wine	SA		200 [(a),(b)]
14.2.5	Mead	SA		200 [(a),(b)]
14.2.7.1	Aromatised wines	SA		200 [(a),(b)]
14.2.7.2	Aromatised wine-based drinks	SA		200 [(a),(b)]
14.2.7.3	Aromatised wine-product cocktails	SA		200 [(a),(b)]
14.2.8	Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol	SA	Only alcoholic drinks with less than 15 % of alcohol and *nalewka na winie owocowym*, *aromatyzowana nalewka na winie owocowym*, *nalewka na winie z soku winogronowego*, *aromatyzowana nalewka na winie z soku winogronowego*, *napój winny owocowy lub miodowy*, *aromatyzowany napój winny owocowy lub miodowy*, *wino owocowe niskoalkoholowe and aromatyzowane wino*	200 [(a),(b)]
15.1	Potato-, cereal-, flour- or starch-based snacks	SA + PHB		1 000 [(a),(b),(c)]
15.2	Processed nuts	SA + PHB	Only coated nuts	1 000 [(a),(b),(c)]
16	Desserts excluding products covered in categories 1, 3 and 4	SA	Only *frugtgrød*, *rote Grütze* and *pasha*	1 000 [(a),(b)]
16	Desserts excluding products covered in categories 1, 3 and 4	SA	Only *ostkaka*	2 000 [(a),(b)]
16	Desserts excluding products covered in categories 1, 3 and 4	SA + BA	Only non-heat-treated dairy-based desserts	300 [(a),(b)]

FCS category number	Foods	E number/group	Restrictions/exceptions	Maximum level [(a)] (mg/l or mg/kg as appropriate)
17.1	Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms	SA + BA	Only when supplied in dried form and containing preparations of vitamin A and of combinations of vitamins A and D	1 000 [(a),(b)]
17.2	Food supplements supplied in a liquid form	SA + BA		2 000 [(a),(b)]

BA, benzoic acid – benzoates (E 210–213); FCS, Food Categorisation System (food nomenclature) presented in Annex II to Regulation (EC) No 1333/2008; PHB, *p*-hydroxybenzoates (ethyl-*p*-hydroxybenzoate, E 214; sodium ethyl-*p*-hydroxybenzoate, E 215; methyl-*p*-hydroxybenzoate, E 218; sodium methyl-*p*-hydroxybenzoate, E 219); *QS*, *quantum satis*; SA, sorbic acid – sorbates (E 200, 202, 203).
(a): The maximum level is applicable to the sum and the levels are expressed as the free acid.
(b): The additives may be added individually or in combination.
(c): E 214–219: *p*-hydroxybenzoates (PHB), maximum 300 mg/kg.

In addition, sorbic acid – sorbates (E 200, 202, 203) are also permitted to be used as food additives other than carriers in food additives and in food enzymes according to Annex III to Regulation (EC) No 1333/2008 (Parts 2 and 3). Sorbic acid – sorbates (E 200, 202, 203) may be used at concentrations up to 1 500 mg/kg in food additives (colour preparations) individually or in combination (with benzoic acid – benzoates) in the preparation resulting in a maximum of 15 mg/kg in the final product expressed as the free acid. Sorbic acid (E 200) and potassium sorbate (E 202) may also be used in enzyme preparations up to 20 000 mg/kg individually or in combination resulting in a maximum of 20 mg/kg in the final food, except for beverages, where a maximum level of 10 mg/l is authorised.

The Panel is aware that additional usages from the existing authorisation of sorbic acid (E 200) and potassium sorbate (E 202) in applications for enzyme preparations may add substantially to the overall exposure to sorbic acid- sorbates. The Panel noted that, from a methodological point of view, it was not feasible to differentiate between both contributions (i.e. uses as food additives and in enzyme preparations) in the overall exposure to sorbic acid- sorbates. Therefore, the Panel considered that the use of analytical data in the refined exposure assessment would be the most appropriate approach to capture both uses and to address the overall safety assessment of sorbic acid – sorbates (E 200, 202, 203).

2.7. Reported use levels or data on analytical levels of sorbic acid 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[11] regarding the re-evaluation of approved food additives, EFSA issued a public call[12] for occurrence data (analytical data) on sorbic acid – sorbates (E 200, 202, 203). In response to this public call, analytical data on sorbic acid were submitted to EFSA by Member States. In addition,

[11] 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.
[12] Call for approved food additives (sorbates, benzoates and gallates) occurrence data in food and beverages intended for human consumption. Published: 1 June 2012. Available online: http://www.efsa.europa.eu/en/dataclosed/call/120601.htm

information on the use levels of sorbic acid – sorbates (E 200, 202, 203) in foods was made available to EFSA by industry.[13]

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

Information on the actual use levels of sorbic acid – sorbates (E 200, 202, 203) in foods was made available to EFSA by industry, including FoodDrinkEurope (FDE), the Union of European Soft Drinks Associations (UNESDA), Cutisin and Mars Chocolate UK.[14] EFSA was provided with data on use levels of sorbic acid – sorbates (E 200, 202, 203) for 25 out of the 59 food categories in which sorbic acid – sorbates (E 200, 202, 203) are authorised.

Appendix A provides data on the use levels of sorbic acid – sorbates (E 200, 202, 203) in foods as reported by industry.

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

Analytical results from Member States were collected through the EFSA call for occurrence data. The Panel noted that complete information on the methods of analysis (e.g. validation) was not made available to EFSA. In total, 34 838 analytical results were reported to EFSA by 10 countries: Slovakia (n = 12 861), Germany (n = 11 328), Denmark (n = 3 080), Austria (n = 2 654), Hungary (n = 1 747), Cyprus (n = 1 684), the Czech Republic (n = 622), Ireland (n = 691), Spain (n = 158) and Bulgaria (n = 13). The data were mainly on flavoured drinks (Food Categorisation System (FCS) 14.1.4), salads and savoury-based sandwich spreads (FCS 12.7) and fine bakery wares (FCS 07.2). All analytical results referred to sorbic acid. Foods were sampled between 2000 and 2012 and the majority of them (96 %) were analysed in the same year of collection. Analytical results of sorbic acid were not quantified (less than the limit of quantification (LOQ)) in 15 609 samples and not detected (less than the limit of detection (LOD)) in 8 300 samples, and 10 929 samples were numerical values (quantified). Only 24 of these samples came from a non-accredited laboratory.

In order to include only recent data from the 10-year period, analytical results sampled before 2004 (n = 916) were excluded from further analyses. A group of analytical data (n = 590) on edible ices (FCS 03), cocoa and chocolate products (FCS 05.1) and processed foods (FCS 18) was included in the further analyses. These food categories are not listed in food categories authorised for use of sorbic acid – sorbates (E 200, 202, 203); however, as explained previously, their use as food additives in enzyme preparations may result in their detection. Therefore, the Panel considered that the use of such analytical data in the refined exposure assessment would be the most appropriate approach to capture both uses and to address the overall exposure to sorbic acid – sorbates (E 200, 202, 203). For this purpose, instead of using the analytical data as reported, a default value of 20 mg/kg as a maximum possible level used in enzyme preparations was assigned to edible ices (FCS 03), cocoa and chocolate products (FCS 05.1) and processed foods (FCS 18).

Other samples (n = 3807) 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 sub-group other than those authorised and were, therefore, also excluded. This relates to the following food categories: dairy products and analogues (FCS 01); fats and oils, and fat emulsions (FCS 02); fruit and vegetables (FCS 04); cereals and cereal products (FCS 06); bakery wares (FCS 07); meat (FCS 08); fish and fishery products (FCS 09); sugars, syrups, honey and table-top sweeteners (FCS 11); salts, spices,

[13] 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

[14] Mars Chocolate UK reported the use of potassium sorbate (E 202) in chocolate (FCS 5.1) and ice cream (FCS 3), which are not food categories authorised according to Annex II to Regulation (EC) No 1333/2008; however, it was clarified that the use of potassium sorbate in these food categories was considered according to Annex III to Regulation (EC) No 1333/2008 (Parts 2 and 3).

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 = 255) above the MPL set for authorised uses of sorbic acid – sorbates (E 200, 202, 203) as food additives were reported in the following food categories: three values in dairy products and analogues; 22 values in fruit and vegetables (FCS 04); two values in other confectionery (FCS 05.2); one value in decorations, coatings and fillings (FCS 05.4); 29 values in bakery wares (FCS 07); one value in meat (FCS 08); one value in fish and fishery products (FCS 09); two values in sugars, syrups, honey and table-top sweeteners (FCS 11); 19 values in salts, spices, soups, sauces, salads and protein products (FCS 12); 77 values in non-alcoholic beverages (FCS 14.1); and 26 values in alcoholic beverages (FCS 14.2). 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 and the maximum level in enzyme preparations were not considered in the exposure assessment.

Overall, 29 270 out of the 34 838 total analytical results reported for sorbic acid in foods were considered by the Panel for the exposure estimates after discarding the following: the data sampled before 2004, the data recognised to have insufficient sensitivity of the analytical method, the provided analytical results on foods in which the direct addition of sorbic acid – sorbates (E 200, 202, 203) is not authorised according to Annex II to Regulation (EC) No 1333/2008, and the samples exceeding the MPL and the maximum level in enzyme preparations.

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

2.8. Information on existing authorisations and evaluations

Sorbic acid and its calcium and potassium salts are authorised[15] as food additives in the EU in accordance with Annex II and III to Regulation (EC) No 1333/2008 on food additives, and specific purity criteria have been defined in Commission Regulation (EU) No 231/2012.

JECFA evaluated sorbic acid and its salts in 1961, 1965 and 1973 (JECFA, 1962, 1966, 1974). A group Acceptable Daily Intake (ADI) of 25 mg/kg body weight (bw)/day was allocated, covering sorbic acid, sodium sorbate, potassium sorbate and calcium sorbate, expressed as sorbic acid (JECFA, 1974).

The SCF endorsed a group ADI of 25 mg/kg bw/day for sorbic acid, potassium sorbate and calcium sorbate (SCF, 1996).

Sorbic acid is a flavouring substance (FL No 08.085) included in the Union list of flavourings (Commission Implementing Regulation (EU) No 872/2012[16]). In 2003, JECFA evaluated sorbic acid for use as a food flavouring substance and concluded that it would not be expected to be of safety concern at its currently estimated levels of intake as a flavouring agent (JECFA, 2004). In 2009, EFSA reviewed the JECFA evaluation of a series of flavouring substances, including sorbic acid, and expressed reservations in endorsing the JECFA evaluation because there were no European production figures for food flavouring purposes (EFSA, 2009).

Sorbic acid and sodium sorbate are included in the European Union Register[17] of feed additives (Regulation (EC) No 1831/2003[18]).The EFSA Scientific Panel on Additives and Products or

[15] The Panel noted that sodium sorbate is not authorised as a food additive (Regulation (EC) No 1333/2008).
[16] 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.
[17] Available online: http://ec.europa.eu/food/food/animalnutrition/feedadditives/comm_register_feed_additives_1831-03.pdf

Substances used in Animal Feed (FEEDAP) evaluated the safety and efficacy of sorbic acid and potassium sorbate when used as technological additives for all animal species and concluded that sorbic acid and potassium sorbate when used at the maximum proposed dose in feed are safe for all animal species (EFSA FEEDAP Panel, 2014).

In the USA, sorbic acid, potassium sorbate, calcium sorbate and sodium sorbate are listed as "generally recognised as safe" (GRAS) when used in accordance with good manufacturing practice (GMP) according to US Code of Federal Regulation, Title 21, Section 182 (Subpart D 3089, 3640, 3225 and 3795, respectively).[19]

In Canada, Australia and New Zealand, sorbic acid, potassium sorbate, calcium sorbate and sodium sorbate are listed as permitted additives.[20] In Japan, sorbic acid and its potassium and calcium salts, but not the sodium salt, are permitted food additives.[21]

Sorbic acid (PM Ref. 87200) is included in the Union list of authorised substances that may be intentionally used in the manufacture of plastic layers in plastic materials and articles (Annex I to Commission Regulation (EU) No 10/2011[22]). Sorbic acid, potassium sorbate and calcium sorbate are permitted as preservatives in cosmetic products (European Commission database – CosIng[23]).

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

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

The Panel estimated chronic exposure for the following population groups: toddlers, children, adolescents, adults and the elderly. Calculations were performed using individual body weights. For the calculation of chronic exposure, intake statistics have been calculated based on individual average consumption over the total survey period, excluding surveys with only one day per subject which are considered as inadequate to assess chronic dietary exposure. High-level exposure was calculated for only those population groups for which the sample size was sufficiently large to allow calculation of the 95th percentile (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.

[18] Regulation (EC) No 1831/2003 of the European Parliament and the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, 29–43.
[19] Available online: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=182
[20] Available online: http://www.foodstandards.gov.au/consumerinformation/additives/
[21] Available online: http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-desin.add-x
[22] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L 12, 15.1.2011, p. 1.
[23] Available online: http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.simple

It should be noted that, in two dietary surveys, namely DIPP_2003_2006 and FINDIET_2007 (both from Finland) (EFSA, 2011a), the consumption of grain-based products including bread and fine bakery products was coded at the level of their ingredients (flour), which resulted in a very low exposure to sorbic acid – sorbates in both populations compared with the other studies. Therefore, both Finnish studies were excluded from the assessment.

Thus, for the present assessment, food consumption data were available from 24 different dietary surveys carried out in 17 European countries, as outlined in Table 5.

Table 5: Population groups considered for the exposure estimates of sorbic acid – sorbates (E 200, 202, 203)

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

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

Consumption records were codified according to the FoodEx classification system (EFSA, 2011b). Nomenclature from the FoodEx classification system has been linked to the FCS as presented in Annex II to Regulation (EC) No 1333/2008, part D, to perform exposure estimates. In practice, FoodEx food codes were matched to the FCS food categories and the exposure was calculated by multiplying MPLs (Table 4) or values reported (Appendix C) for each food category with their consumption amount per kg bw separately for each individual in the database. The exposure per food category was subsequently added to derive an individual total exposure per day. Finally, these exposure estimates were averaged over the number of surveys days, resulting in an individual average exposure per day for the survey period. This was done for all individuals in the survey and per age group, resulting in distributions of individual average exposures per survey and population group (Table 5). Based on these distributions, the mean and 95th percentile exposures were calculated per survey for the total population and per population group.

2.9.1.2. Food categories selected for the exposure assessment of sorbic acid – sorbates (E 200, 202, 203)

The food categories in which the use of sorbic acid – sorbates (E 200, 202, 203) is 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 therefore could not be taken into account in the present estimate. This might result 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):

- 01.3. Unflavoured fermented milk products, only curdled milk

- 01.7.6. Cheese products (excluding products falling in category 16), only flavoured unripened products, only unripened products; ripened products, prepacked, sliced; layered ripened products and ripened products with added foods, or only ripened products surface treatment
- 04.2.5.1. Extra jam and extra jelly as defined by Directive 2001/113/EC[24]
- 05.4. Decorations, coatings and fillings, except fruit-based fillings covered by category 04.2.4, only toppings (syrups for pancakes, flavoured syrups for milkshakes and ice cream; similar products)
- 06.4.4. Potato gnocchi
- 06.6. Batters
- 06.7. Pre-cooked or processed cereals, only *polenta*, or only *semmelknödelteig*
- 08.3.1. Non-heat-treated processed meat, only surface treatment of dried meat products
- 08.3.3. Casings and coatings and decorations for meat, only collagen-based casings with water activity greater than 0.6, or only jelly coatings of meat products (cooked, cured or dried)
- 11.4.1. Table-top sweeteners in liquid form, only if the water content higher than 75 %
- 14.2.4. Fruit wine and made wine
- 14.2.5. Mead
- 14.2.7.2. Aromatised wine-based drinks except bitter soda, sangria, claria, zurra
- 14.2.7.3. Aromatised wine-product cocktails.

For the following food categories, the very specific restrictions which apply to the use of sorbic acid – sorbates (E 200, 202, 203) could not be taken into account. In order to avoid a large overestimation, the whole food category was not considered for the present exposure estimates. This results in an underestimation of the exposure:

- 01.4. Flavoured fermented milk products including heat-treated products, only non-heat-treated dairy-based desserts
- 01.7.2. Ripened cheese, only ripened products surface treatment
- 01.8. Dairy analogues, only analogues of cheese based on protein
- 04.2.4.1. Fruit and vegetable preparations excluding compote, only olive-based preparations
- 04.2.6. Processed potato products, only potato dough, and pre-fried potato slices
- 08.2.2. Heat-treated processed meat, only aspic, or only surface treatment of dried meat products
- 09.2. Processed fish and fishery products including molluscs and crustaceans, only aspic, or only cooked *Crangon crangon* and *Crangon vulgaris*
- 14.1.2. Fruit juices as defined by Directive 2001/112/EC[25] and vegetable juices, only Sød … saft and sødet … saft, or only grape juice, unfermented, for sacramental use
- 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, or only traditional Swedish fruit syrups, maximum applies if E 210–213, benzoic acid—benzoates, have also been used

[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.
[25] Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption. OJ L 10, 12.1.2002, p. 58–66.

- 14.1.5.2. Other, only liquid tea concentrates and liquid fruit and herbal infusion concentrates
- 14.2.1. Beer and malt beverages, only 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,[26] and alcohol-free counterparts, only alcohol-free
- 16. Desserts excluding products covered in categories 1, 3 and 4, only *frugtgrød*, *rote Grütze* and *pasha*, or only *ostkaka*, or only non-heat-treated dairy-based desserts.

For the following food categories, the restrictions which apply to the use of sorbic acid – sorbates (E 200, 202, 203) could not be taken into account, and therefore the whole food category was considered for the exposure estimates. This results in an overestimation of the exposure:

- 01.7.2. Ripened cheese, only cheese, prepacked, sliced and cut; layered cheese and cheese with added foods, or only only ripened products surface treatment
- 01.7.4. Whey cheese, only cheese, prepacked, sliced and cut; layered cheese and cheese with added foods
- 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*
- 09.2. Processed fish and fishery products including molluscs and crustaceans, only salted, dried fish, or only semi-preserved fish and fisheries products including crustaceans, molluscs, surimi and fish/crustacean paste; cooked crustaceans and molluscs
- 09.3. Fish roe, only semi-preserved fish products including fish roe products
- 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
- 15.2. Processed nuts, only coated nuts
- 17.1/17.2. Food supplements, in solid or liquid form.

Overall, 14 food categories were not taken into account in the exposure assessment because they are not referenced in the EFSA Comprehensive Database. In addition, 13 food categories were not taken into account in the exposure assessment owing to specific restrictions/exceptions not referenced in the EFSA Comprehensive Database; however, some of them were included in relation to other restrictions/exceptions. Nine 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, the refinements considering the restrictions/exceptions as set out in Annex II to Regulation No 1333/2008 were applied. Finally, 37 food categories were included in the present assessment of exposure to sorbic acid – sorbates (E 200, 202, 203) (Appendix C).

2.9.2. Exposure to sorbic acid – sorbates (E 200, 202, 203) from their use as food additives

Exposure assessment for food additives under re-evaluation is carried out by the ANS Panel based on (1) MPLs set out in the EU legislation (defined as the *regulatory maximum level exposure assessment scenario*) and (2) the availability of adequate use levels or analytical data (defined as the *refined exposure assessment scenario*).

[26] Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products. OJ L 299, 16.11.2007, p. 1.

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 4.

The exposure estimates derived following this scenario should be considered as the most conservative, as this scenario assumes that the consumer will be continuously (over a lifetime) exposed to sorbic acid – sorbates (E 200, 202, 203) 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 the above data were available to the Panel.

Appendices C and H summarise the concentration levels of sorbic acid – sorbates (E 200, 202, 203) used in the refined exposure assessment scenario. Based on the available dataset, the Panel calculated two 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 levels 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 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 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 for all food categories.

In the refined exposure assessment scenarios, 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 is used.

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.

If both reported use levels and analytical results were available for the same food category, the most reliable value was used. For the majority of food categories (Appendix H), analytical results were considered the most reliable, given the extensive range of data collected through the recent call characterised by good representativeness covering different European countries. It should therefore be noted that, when using the analytical results in the present exposure estimates, the degradation process and loss of sorbic acid – sorbates caused by food processing were considered.

2.9.2.3. Anticipated exposure to sorbic acid and sorbates (E 200, 202, 203)

Table 6 summarises the exposure to sorbic acid and sorbates (E 200, 202, 203).

Table 6: Summary of anticipated exposure to sorbic acid – sorbates (E 200, 202, 203) in five 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/day)

	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	7.7–23.7	10.1–19.9	4.7–11.5	5.0–8.9	5.0–7.1
High level	20.7–33.9	20.0–38.7	10.1–25.1	9.9–16.3	9.6–12.8
Refined estimated exposure scenario using only reported use levels					
Brand-loyal scenario					
Mean	6.6–13.7	4.4–15.3	2.8–8.4	3.6–6.0	3.9–4.6
High level	16.0–27.7	11.0–30.8	6.3–19.0	7.2–11.1	7.8–9.2
Non-brand-loyal scenario					
Mean	5.2–10.6	2.5–11.3	2.0–6.3	2.6–4.5	2.8–3.4
High level	11.7–20.4	6.1–23.1	4.7–12.4	5.4–8.4	5.7–6.6
Refined estimated exposure scenario using reported use levels and analytical data [(a)]					
Brand-loyal scenario					
Mean	5.6–11.9	5.4–13.0	2.5–6.8	3.2–4.9	3.7–4.6
High level	15.2–23.4	11.3–26.5	5.6–14.8	5.9–10.0	7.1–8.2
Non-brand-loyal scenario					
Mean	0.7–1.8	0.9–1.7	0.4–1.1	0.3–0.8	0.3–0.6
High level	2.2–3.1	1.8–3.7	0.9–2.4	0.7–1.7	0.6–1.2

(a): This scenario included three food categories for which the direct addition of sorbic acid is not authorised according to Annex II to Regulation (EC) No 1333/2008; however, the use of sorbic acid may result in its presence in these food categories because of carry-over.

2.9.3. Main food categories contributing to exposure to sorbic acid – sorbates (E 200, 202, 203)

The Panel noted that, considering all the authorised uses of sorbic acid and sorbates (E 200, 202, 203) as food additives, both reported use levels and quantified analytical results were reported for the following food categories: processed cheese; fat emulsion; dried fruits; fruit and vegetables in vinegar, oil or brine; olives and olive-based preparations; jam, jellies, marmalades and fruit spreads; other confectionery; bread and rolls; fine bakery wares; fish roe; seasonings and condiments; mustard; sauces; dietary foods for special medical purposes; flavoured drinks; and alcoholic drinks with less than 15 % alcohol. For several food products for which the use of sorbic acid – sorbates (E 200, 202, 203) are authorised (e.g. citrus fruits, chewing gum, potato gnocchi, meat pâté, dehydrated and concentrated frozen eggs, table-top sweeteners in liquid form, protein products, dietary foods for weight control, aromatised wines and processed nuts), no usage levels were reported and reported analytical data also showed only limited sample sizes ($n < 20$). In addition, the Panel further noted that, for some other authorised food categories—such as unripened, ripened and whey cheese and cheese products, processed potato products, potato gnocchi, processed meat, processed fish, processed eggs, table-top sweeteners in liquid form, salads, fruit nectars, beer, wine, fruit wine and made wine, mead, aromatised wines and aromatised wine-based drinks and cocktails, potato-, cereal-, flour- or starch- based snacks, desserts and food supplements—no usages had been reported by industry, while positive analytical results (> LOQ) were obtained from the analytical data.

The main food categories contributing to the combined exposure to sorbic acid –sorbates (E 200, 202, 203) are presented in Appendices E, F, G, J and K.

For the main contributing food categories of bread and rolls (FCS 07.1) and fine bakery wares (FCS 07.2), the analytical data comprised 1 625 and 2 597 samples, respectively. The mean analytical levels (all data, including the left-censored data) were found to be far below the MPL of 2 000 mg/kg (92.2 and 205 mg/kg, respectively), although a significant proportion of the values measured were close to the MPL. The mean typical reported use levels for bread and rolls and fine bakery wares were higher than the mean quantified levels from the set of analytical data: 1 425 versus 1 200 and 1 068 versus 400 mg/kg, respectively. The difference observed in the mean levels is probably due to the food additive not being added systematically in these food categories (occurrence of 9 % in bread and rolls and 52 % in fine bakery wares) and to the fact that using solely analytical data means that the percentage of losses during food processing is included. It is important to mention that, for the present exposure assessment, the sub-categories within the categories "bread and rolls" and "fine bakery wares" in the FoodEx classification system were considered, but the presence of sorbic acid and sorbates in all these sub-categories is unlikely. Therefore, the exposure to sorbic acid and sorbates for bread and rolls and fine bakery wares is probably overestimated.

2.9.4. Uncertainty analysis

Uncertainties in the exposure assessment of sorbic acid – sorbates (E 200, 202, 203) 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 7 have been considered.

Table 7: 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	+
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	+/–
Food categories selected for the exposure assessment: exclusion of food categories owing to missing FoodEx linkage	–
Food categories selected for the exposure assessment: inclusion of food categories without considering the restriction/exception	+
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)	+/–
Uncertainty in possible national differences in use levels of food categories, concentration data not fully representative of foods on the EU market	+/–

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

Overall, the Panel considered that the uncertainties identified would generally lead to an overestimate of the real exposure to sorbic acid – sorbates as food additives in European countries.

3. Biological and toxicological data

The biological properties of sorbic acid and its salts have previously been evaluated by JECFA (1974) and the SCF (1996). The present opinion briefly reports in the major studies evaluated in these reports. Additional information has been identified from the literature and the calls for data.

3.1. Absorption, distribution, metabolism and excretion

No data on bioavailability were available on potassium sorbate or calcium sorbate. However, the Panel considers that, owing to the ionisation properties of sorbic acid ($pK_a = 4.76$), the unionised forms of these sorbates should be absorbed by a diffusion process in the stomach.

Potassium and calcium sorbate should also dissociate into their constituents—potassium, calcium and sorbate ions—in the small intestine. Accordingly, sorbate from potassium or calcium sorbate should be bioavailable and absorbed in the same manner as from sorbic acid.

Fingerhut et al. (1962) investigated the disposition of [1-^{14}C]-sorbic acid in rats receiving oral doses ranging from 61 to 1 213 mg/kg bw. Between 4 and 10 hours post dosing, 85 % of the radioactivity was expired as $^{14}CO_2$, independent of the dose administered, suggesting that sorbic acid was absorbed and bioavailable. Regarding the tissue distribution, 0.7 to 2.5 % of radioactivity was found in the liver, 0.2 to 1.8 % was found in the kidneys, 3 % was found in the skeletal muscles and 6.6 % was found in the other parts of the carcass. Only 2 % and 0.4 % were excreted in the urine and faeces, respectively. According to the authors, the relationship between dose and oxidation rate is linear, with the oxidation half-life reported to be 40–110 minutes.

In a further study, six mice received doses of 40 or 3 000 mg/kg bw of [1-^{14}C]-sorbic acid and were examined for four days (Westöö, 1964). In agreement with the previous study in rats, 77 to 85 % of the radioactivity was released as carbon dioxide, independent of the dose administered. In urine, 2.6 to 5.4 % of the radioactivity was found as muconic acid or sorbic acid. The faecal excretion accounted for only 0.6 to 1 % of the radioactivity given to the mice.

The metabolism of sorbates has been reviewed by Sofos (1989). According to this author, sorbic acid, as the aliphatic carboxylic acid, may be utilised by animal organisms in a manner similar to fatty acids. The metabolic breakdown of sorbates includes activation by coenzyme A, hydration by crotonase to a β-hydroxy acid, dehydration to a β-keto acid and cleavage by β-ketothiolase. The first reaction step (i.e. α–β-dehydrogenation) of β-oxidation does not occur because sorbic acid already has an α–β-double bond.

3.2. Toxicological data

3.2.1. Acute oral toxicity

The oral LD_{50} value for sorbic acid in rats was between 3 660 and 10 500 mg/kg bw (Smyth and Carpenter, 1948, as referred to by JECFA, 1974; Witter et al., 1950; Deuel et al., 1954, as referred to by JECFA, 1974).

The oral LD_{50} value for potassium sorbate in rats is between 4 200 and 6 170 mg/kg bw (Mellon Institute, 1954, as referred to by JECFA, 1974).

3.2.2. Short-term and sub-chronic toxicity

JECFA (1974) briefly described three old studies, one in rats (Mellon Institute, 1954) and two in dogs (Deuel et al., 1954; Mellon Institute, 1954), which were not considered by the Panel as useful for the present evaluation.

3.2.2.1. Rats

A sub-acute toxicity study was performed in rats in accordance with the Organisation for Economic Co-operation and Development (OECD) Guideline 407 (OECD, 2008a) and in compliance with Good Laboratory Practice (GLP) (Ehling, 2003). Groups of Sprague–Dawley rats (five males and five females) were given sorbic acid (99.7 % pure) in the diet at concentrations of 0, 2.5, 5 or 10 %, reported to be equal to 0, 2 300, 4 600 and 9 200 mg/kg bw/day and 0, 2 150, 4 300 and 8 600 mg/kg bw/day, for male and female rats, respectively, for a period of 28 days. The authors concluded that administration of sorbic acid did not cause any effects which could be interpreted as of biological significance and considered the no observed adverse effect level (NOAEL) of this study to be the highest dose tested, equivalent to a daily intake of 9 200 and 8 600 mg/kg bw for male and female rats, respectively.

A sub-chronic toxicity study (90 days) was performed in rats in accordance with OECD Guideline 408 (OECD, 1998) and in compliance with GLP (Ehling, 2004). Groups of Sprague–Dawley rats (20 males and 20 females) were given sorbic acid in the diet at concentrations of 0, 2.5, 5 or 10 %, reported to be equal to 0, 1 700, 3 400 and 6 800 mg/kg bw/day and 0, 1 800, 3 600 and 7 200 mg/kg bw/day for male and female rats, respectively. The authors concluded that administration of sorbic acid at concentrations of 2.5, 5 and 10 % given *ad libitum* in the feed did not cause any effects which could be interpreted as of biological significance and considered the NOAEL of this study to be the highest concentration, with 10 % corresponding to a mean daily intake of 6 800 and 72 00 mg sorbic acid/kg bw/day for males and females, respectively (Ehling, 2004).

3.2.3. Genotoxicity

3.2.3.1. *In vitro* studies

Sorbic acid

In the study by Ishidate et al. (1984), sorbic acid was assessed for its mutagenicity in the Ames test with the *Salmonella typhimurium* tester strains TA1535, TA1537, TA98 and TA100 using the pre-incubation method in both the absence and the presence of rat liver S9 metabolic activation up to a concentration of 10 mg/plate. A total of six concentrations were employed. No increases in the number of revertant colonies were observed at any experimental test point.

In the study by Hasegawa et al. (1984), the potential of sorbic acid to induce chromosomal aberrations, sister chromatid exchanges (SCEs) and gene mutations at the hypoxanthine–guanine phosphoribosyl transferase (HPRT) locus was investigated in a Chinese hamster V79 cell line in the absence of S9 metabolic activation only. V79 cells were treated for three hours with concentrations of 350, 700 or 1 050 µg/ml and following washes they were further incubated for 24 hours. Significant increases for both chromosomal aberrations and SCE compared with the relevant concurrent negative controls were observed at only the highest concentration employed (1 050 µg/ml), a concentration which generates an osmotic pressure of approximately 407 mOsmol/kg, a value for which chromosomal damage might be induced (Galloway et al., 1987; Seeberg et al., 1988). In addition, for chromosomal aberration, the incidence of aberrant cells in the concurrent control was unusually very low and gaps, which are usually excluded from statistical evaluations, were included. For SCE, increases compared with the concurrent control did not exceed 1.2 times. Negative results for the induction of gene mutations were obtained. The Panel noted that the reliability of this study was limited.

In an unpublished study (Müller, 1989a), sorbic acid (purity 99 %) was investigated for induction of unscheduled DNA synthesis (UDS) in the human A549 cell line for its capability to induce DNA excision repair following DNA damage. The test was performed in both the absence and the presence of rat liver S9 metabolic activation. Two separate experiments were performed. In the first experiment, concentrations of 1, 3, 10, 30, 100, 300, 1 000 and 2 000 µg/ml were used, while, in the second experiment, the highest concentration was reduced to 1 000 µg/ml because of increasing cytotoxicity observed in the dose range of 1 000–2 000 µg/ml in both the absence and the presence of S9 metabolic activation. The results obtained indicate no reproducible increases in the incidence of UDS at any of the experimental test points assayed. The study was conducted in compliance with OECD Guideline 482 (OECD, 1986). The data from this report were also published by Jung et al. (1992).

In the study by Schiffmann and Schlatter (1992), sorbic acid was investigated for its genotoxicity in an *in vitro* micronucleus assay in Syrian hamster embryo (SHE) fibroblasts in both the absence and the presence of rat liver with or without S9 metabolic activation. Cells were exposed to individual test compound solutions for five hours at concentrations of 120, 300, 600 or 1 200 µg/ml and, following washes, they were further incubated for 18 hours. Results obtained indicated that sorbic acid did not induce any increase in micronucleated cells (2 000 nuclei per concentration) at any test point evaluated. However, the study deviates from the relevant OECD Guideline 487 (OEDC, 2014), mainly

in relation to treatment regimes (selection of concentrations, treatment times) and the lack of evaluation of cytotoxicity. The Panel noted that the reliability of the results is limited.

Potassium sorbate

In an unpublished study report (Engelbart, 1979), a solution of potassium sorbate was assessed for its mutagenic potential in the Ames test with the *Salmonella typhimurium* tester strains TA98, TA100, TA1535 and TA1537, using the standard plate assays in both the absence and the presence of S9 metabolic activation. Volumes of 2, 10, 50, 100 and 200 µl/plate were used. The results obtained for mutagenicity indicated that the test compound did not increase the number of *his*$^+$ revertants in both the absence and the presence of rat liver S9 metabolic activation. However, the Panel noted that the volumes reported did not permit the concentrations of the test compound employed to be inferred.

In the study by Ishidate et al. (1984), potassium sorbate was assessed for its mutagenicity in the Ames test with the *Salmonella typhimurium* tester strains TA1535, TA1537, TA98 and TA100 using the pre-incubation method in both the absence and the presence of rat liver S9 metabolic activation up to a concentration of 10 mg/plate. A total of six concentrations were employed. No increases in the number of revertant colonies were observed at any experimental test point.

Moreover, no induction of point mutation by potassium sorbate was reported by Fujita and Sasaki (1986) in the Ames test with the *Salmonella typhimurium* tester strains TA97 and TA102 in both the absence and the presence of rat liver S9 metabolic activation at concentrations of 0.1, 0.5, 1.0, 5.0 and 10.0 mg/plate. However, the Panel noted that only a short summary was available.

Similarly, in the study by Münzner et al. (1990), potassium sorbate did not show any increase in *his*$^+$ revertants compared with relevant negative controls in the Ames test using the plate incorporation method with the *Salmonella typhimurium* tester strains TA98 and TA100 in both the absence and the presence of rat liver S9 metabolic activation at concentrations of 0.01, 0.1, 0.5, 1.0 and 2.0 mg/plate.

In the study by Hasegawa et al. (1984), the potential of potassium sorbate to induce chromosomal aberrations, SCE and gene mutations at the HPRT locus was investigated in a Chinese hamster V79 cell line in the absence of S9 metabolic activation only. V79 cells were treated for three hours with concentrations of 5, 10 or 20 mg/ml for chromosomal aberrations and with 5, 10, 15 or 20 mg/ml for SCE and gene mutations. Following washes, they were further incubated for 24 hours. Significant increases were observed only for chromosomal aberrations at the highest concentration employed (20 000 µg/ml) and for SCE at 10 000, 15 000 and 20 000 µg/ml compared with the relevant concurrent negative controls. Negative results were obtained for the induction of gene mutations. The Panel noted overall that the methodology employed by the authors was appropriate for testing the genotoxicity of the compounds. However, all concentrations at which potassium sorbate showed genetic effects far exceed the highest concentration of 5 mg/ml or 10 mM recommended by OECD Guidelines 473 and 476 (OECD, 1997a, b) to be used in *in vitro* assays. For SCE, the positive genotoxicity result claimed by the authors was not considered by the Panel as biologically relevant, as the increase in SCEs was less than two-fold the levels in the negative control.

In a chromosome aberration assay on 242 food additives, potassium sorbate was assayed for its clastogenic properties in a Chinese hamster lung cell line using three concentrations in the absence of S9 metabolic activation (Ishidate et al., 1984). The highest concentration employed (4 mg/ml) was selected from a cytotoxicity test (based on estimation of the 50 % growth inhibition). Increased frequency of chromosomal aberration was observed only at 4 mg/ml corresponding to approximately 26.6 mM, a concentration far exceeding the maximum concentration (10 mM) recommended by OECD Guideline 473 (OECD, 1997a).

In an unpublished report (Cojocel and Knauf, 1989), the DNA-damaging potential of potassium sorbate was evaluated in the *in vitro* alkaline elution assay in the human A549 cell line following three hours' incubation with the test compound in both the absence and the presence of rat liver S9

metabolic activation at concentrations ranging from 0.001 to 1 mg/ml. No induction of DNA breakage was observed. The data from this report were also published by Jung et al. (1992).

In the study by Münzner et al. (1990), potassium sorbate was investigated for possible genotoxic action in the gene mutation HPRT locus and SCE assays in Chinese hamster ovary (CHO) cells at concentrations of 10 000 and 20 000 µg/ml in the absence and presence of S9 metabolic activation. No genetic effects were observed at any test point assayed, despite the very high concentrations employed, which far exceed the maximum concentrations (5 mg/ml or 10 mM) recommended by OECD Guideline 476 (OECD, 1997b).

In the study by Schiffmann and Schlatter (1992), potassium sorbate was investigated for its genotoxicity in an *in vitro* micronucleus assay in SHE fibroblasts in both the absence and the presence of rat S9 metabolic activation. Cells were treated with test compound solutions for five hours at concentrations of 120, 300, 600 or 1 200 µg/ml and, following washes, they were further incubated for 18 hours. Results obtained indicate that potassium sorbate did not induce any increase in micronucleated cells (2 000 nuclei per concentration) at any test point evaluated. However, the study deviates from the relevant OECD Guideline 487 (OECD, 2014), notably in that a short treatment time in the absence of S9 metabolic activation (five hours) was employed and there was an absence of cytotoxic evaluation. The reliability of the study is therefore limited.

Mamur et al. (2010) investigated the genotoxicity of potassium sorbate using the chromosomal aberration, SCE and micronucleus assays and evaluated the induction of DNA breakage by alkaline comet assay in human lymphocytes. For induction of chromosomal aberrations, SCEs and micronuclei, the test compound was added at a concentration of 125, 250, 500 or 1 000 µg/ml for 24 and 48 hours and cultures were sampled 72 hours after lymphocyte stimulation. For the Comet assay, the same concentrations were added to isolated human lymphocytes for one hour. No S9 metabolic activation was used. The results obtained indicate positive effects for the induction of chromosomal aberrations, SCEs and DNA strand breakage in the Comet assay. However, in the same study, contrasting results were obtained in the micronucleus assay, which cannot support positive findings in the chromosomal aberration assay, as it identifies both chromosomal aberrations and non-disjunctional events. In addition, the study bears significant weaknesses in the chromosome aberration assay related to the presence of dicentric chromosomes in the negative control and "chromosome type" aberrations (chromosome breaks) in the potassium sorbate-treated cultures which are not compatible with the clastogenic mechanisms of chemical compounds. In the SCE assay, the reported incidence of third metaphases at both 24- and 48-hour sampling times is unusually very high and, in the comet assay, no evaluation of cytotoxicity has been performed. On these bases, the conclusions reached by the authors do not appear to be supported by the data provided.

3.2.3.2. *In vivo* studies

Sorbic acid

Banerjee and Giri (1986) investigated the induction of chromosomal aberrations in bone marrow cells of mice exposed to sorbic acid (purity 99 %) daily by oral gavage for 30 days at 15 mg/kg bw. Sorbic acid was dissolved in distilled water by heating. No induction of chromosomal aberrations was observed. However, the Panel noted that the study was poorly reported and bears experimental weaknesses, including no criteria for the selection of dose levels, no scoring criteria for chromosomal aberrations based on recommendations in the published literature and no use of a positive control. The Panel noted overall that the methodology employed by the authors was not appropriate for testing the genotoxicity of the compounds.

In the study by Mukherjee et al. (1988), sorbic acid was assessed for its capability to induce SCE and micronuclei in bone marrow cells of mice. For SCE, dose levels of 25, 50, 75 and 100 mg/kg were administered once by intraperitoneal injection. 5-Bromo-2′-deoxyuridine (BrdU), used to detect differential staining of chromatids, was administered subcutaneously as a 50-mg tablet. For the

micronucleus assay, the test compound was administered by intraperitoneal injection once at dose levels of 2.5, 20 and 150 mg/kg bw. Animals were sacrificed 24 and 48 hours after treatment. The authors reported significant increases of SCEs compared with the negative control at the three higher dose levels assayed and, for micronuclei, at the highest dose level used only. It should be noted that, for SCE, reported increases, although significant, were not marked and the maximum range observed (one to eight) is usually found in negative controls of similar studies. Similarly, for micronuclei, significant increases were observed at only the highest dose level employed (150 mg/kg bw) at the 24-hour sampling time, and were not confirmed at the 48-hour sampling time. The observed increase falls within the range usually found for this assay. Furthermore, the study bears a severe weakness related to the limited number of cells scored (20 metaphases per animal per dose level in the assay for SCE and 500 polychromatic erythrocytes in the micronucleus assay). In addition, the evaluation of the results appears to be conducted on the pooled data obtained for each group and not on individual animals, which are the statistical units in the *in vivo* studies.

In an unpublished report (Völkner, 1989), sorbic acid was investigated for its capability to induce SCE in bone marrow cells of mice. Dose levels of 500, 1 500 or 5 000 mg/kg bw were administered once by oral gavage. The highest dose level used was selected in preliminary dose range-finding experiments. BrdU used to detect differential staining of chromatids was administered subcutaneously as a 40-mg tablet. Animals were sacrificed 24 hours after treatment. No induction of SCE was observed. The Panel noted that the study appears to be well conducted and in compliance with internationally recognised protocols for this assay at the time. The data from this report were also published by Jung et al. (1992).

In an unpublished report (Müller, 1989b), sorbic acid (purity greater than 99 %) was investigated for its capability to induce micronuclei in the bone marrow erythrocytes of mice. Dose levels of 500, 1 500 and 5 000 mg/kg bw were administered once by oral gavage. The highest dose level used was selected in preliminary dose range-finding experiments. Animals were sacrificed at 24-, 48- and 72-hour sampling times. No induction of micronuclei was observed. The Panel noted that the study appears to be well conducted and in compliance with internationally recognised protocols for this assay at the time.

Jung et al. (1992) investigated the genotoxicity of sorbic acid in bone marrow SCE assays in mice following a single administration by oral gavage at 500, 1 500 or 5 000 mg/kg bw. BrdU used to detect differential staining of chromatids was administrated subcutaneously with a 50-mg tablet. Animals were sacrificed 24 hours after implantation of the BrdU tablet. No induction of SCE was observed. The Panel noted that the study was performed according to an internationally recognised protocol at the time.

Sasaki et al. (2002) performed an *in vivo* Comet assay in the glandular stomach, colon, liver, kidney, urinary bladder, lung, brain and bone marrow of mice. Sorbic acid was administered once by oral gavage to groups of four ddY mice at a dose level of 2 000 mg/kg bw and animals were sacrificed 3 and 24 hours after the beginning of treatment. The increases in DNA migration reported in some organs were slight but statistically non-significant at both sampling times. The Panel considered that, in this study, sorbic acid showed no evidence of DNA-damaging activity.

Potassium sorbate

Cojocel and Knauf (1989) investigated the genotoxicity of potassium sorbate in liver cells of rats using the *in vivo* alkaline elution assay. The test compound was administered by intraperitoneal injection at 400, 800 or 1 200 mg/kg bw. The animals were sacrificed two hours later and nuclei from liver cells were isolated. DNA single strand breaks were determined after lysis of nuclei on filters. Results obtained clearly indicated absence of induction of DNA breakage. The data from this report were also published by Jung et al. (1992).

In the study by Münzner et al. (1990), potassium sorbate was investigated for potential clastogenicity in the bone marrow micronucleus test in mice and Chinese hamsters by either oral gavage or intraperitoneal injection in independent sets of animal groups. In addition, in Chinese hamsters, the bone marrow chromosome aberration and SCE assays were performed by either oral gavage or intraperitoneal injection (at dose levels of 100 or 200 mg/kg bw and using either fresh or stored solutions) in independent sets of animal groups. Clear negative results were observed in the chromosome aberration and SCE assays in Chinese hamsters and in the micronucleus test in mice and Chinese hamsters. The Panel noted that the study was performed according to an internationally recognised protocol at the time and agreed with the conclusions of the authors. However, the Panel noted that the dose levels applied were lower than currently recommended.

Sasaki et al. (2002) performed an *in vivo* Comet assay in the glandular stomach, colon, liver, kidney, urinary bladder, lung, brain and bone marrow of mice. Potassium sorbate was administered once by oral gavage to groups of four ddY mice at a dose level of 2 000 mg/kg bw and animals were sacrificed 3 and 24 hours after the beginning of treatment. The increases in DNA migration reported in some organs were slight but statistically non-significant at both sampling times. The Panel considered that, in this study, potassium sorbate showed no evidence of DNA-damaging activity.

3.2.3.3. Reaction products of sorbic acid and sorbates

Interaction of sorbic acid with amines

The stable major cyclic interaction compound *N*-methyl-6-methyl-3,6-dihydro-2-pyridone generated by reaction of sorbic acid (330 mM) and methylamine (660 mM) in ethanol at temperatures of 20–50 °C for 15 days was investigated for its genotoxicity using the Ames test in both the absence and the presence of S9 metabolic activation at a maximum concentration of 300 μg/plate. *Salmonella typhimurium* tester strains TA98 and TA100 were used, and the 3D DNA damage test with DNA plasmid and genomic DNA from HeLa cells was used following the method developed by Salles and Provot (1998, as referred to by Ferrand et al., 2000b) at a maximum concentration of 1 mg/ml (Ferrand et al., 2000b). Negative results were obtained in both tests. However, the Panel noted that the 3D DNA damage test is not included in the list of assays recommended for regulatory purposes and that the results obtained in the Ames test are of limited value because only *Salmonella typhimurium* tester strains TA98 and TA100 and a very low concentration (300 μg/plate) were used.

The major stable interaction products resulting from incubation of sorbic acid (330 mM) with different amines (330 mM) for 15 days at temperatures of 50 or 80 °C were investigated for their genotoxicity in the Ames and the 3D DNA damage tests with DNA plasmid and genomic DNA from HeLa cells following the method developed by Salles and Provot (1998). The amines used—methylamine, ethylamine, propylamine, butylamine and benzylamine—were selected on the basis of their occurrence in food (Bauza et al., 1995, as referred to by Ferrand et al., 2000c) and the major cyclic products generated were *N*-methyl-6-methyl-3,6-dihydro-2-pyridone, *N*-ethyl-6-methyl-3,6-dihydro-2-pyridone, *N*-propyl-6-methyl-3,6-dihydro-2-pyridone, *N*-buthyl-6-methyl-3,6-dihydro-2-pyridone and *N*-benzyl-6-methyl-3,6-dihydro-2-pyridone, respectively. The Ames test was performed in both the absence and the presence of S9 metabolic activation at a maximum concentration of 5 000 μg/plate using *Salmonella typhimurium* tester strains TA98 and TA100, and the 3D DNA damage test was performed at a maximum concentration of 1 mg/ml. Negative results were observed for all interaction compound' assayed in both tests (Ferrand et al., 2000c). The Panel noted that the 3D DNA damage test is not included in the list of assays recommended for regulatory purposes and that the results obtained in the Ames test are of limited value because only *Salmonella typhimurium* tester strains TA98 and TA100 were used.

However, in a following study by the same authors with the same interaction products and experimental conditions, but with a complete set of *Salmonella typhimurium* tester strains (TA1535, TA1537, TA98, TA100 and TA102), negative results were also obtained (Ferrand et al., 2000d). The

Panel noted that, in this case, the bacterial reverse mutation assay (Ames test) was performed in accordance with the relevant OECD Guideline 471 (OECD, 1997c).

Overall, the major stable interaction products resulting from incubation of sorbic acid (330 mM) and different amines (e.g. methylamine, ethylamine, propylamine, butylamine and benzylamine) at 330 mM for 15 days at temperatures of 50 or 80 °C are not mutagenic in the bacterial reverse mutation assay (Ames test).

Interaction of sorbic acid with nitrites

In the study by Namiki et al. (1980), the interaction products of sorbic acid (10 mM) and sodium nitrite (80 mM) at 60 °C for 30 minutes were ethylnitrolic acid (ENA), mainly produced at pH values of 3.5–5.0; 1,4-dinitro-2-methylpyrrole, produced maximally at pH 3.5; and compounds "B",[27] "F"[28] and other minor products, mainly produced at lower pH values (1.5) and not fully characterised in their chemical structure. Their genotoxicity was investigated in the Rec-assay with *Bacillus subtilis* and in an Ames reversion assay with *Salmonella typhimurium* tester strains TA98 and TA100 in the absence and presence of S9 metabolic activation. The results obtained indicated that 1,4-dinitro-2-methylpyrrole was markedly positive in the Ames test in both TA98 and TA100 *Salmonella typhimurium* tester strains and in the *Bacillus subtilis* Rec-assay, while ENA was positive in the *Bacillus subtilis* Rec-assay and in the Ames test in the TA100 tester strain. Compounds "B" and "F" proved to be negative in both the *Bacillus subtilis* Rec-assay and the Ames test. The authors stated that, although concentrations of nitrite used in the experiments were much higher than the permitted levels in food, the mutagenic interaction products are formed, above the LOD, even at a 1:0.5 molar ratio.

The effect of sodium nitrite (1 mg/kg bw) administered by gavage as a mixture with sorbic acid (7.5 mg/kg bw) for 30 days on the induction of chromosomal aberrations in the bone marrow erythrocytes of Swiss albino mice was investigated (Banerjee and Giri, 1986). Results obtained indicated that sodium nitrite in combination with sorbic acid induced significant increases in chromosomal aberrations in bone marrow cells. The Panel noted that the study is poorly reported, as no indication of the levels of chromosome aberrations in the vehicle and positive control groups to assess reliability of the study is reported and the study bears structural weaknesses, including the absence of any reference criteria for scoring of chromosomal aberrations and statistical analyses performed using data pooled from four sets of experiments performed and not from individual animals, which are the statistical units in the *in vivo* studies.

The *in vivo* induction of SCEs and micronuclei was studied in bone marrow cells of mice treated with sorbic acid, sodium nitrite or a mixture of both compounds (Mukherjee et al., 1988). The Panel noted that this study presents many limitations both in the description of the protocol used and in the data reported. Therefore, the Panel decided not to consider this study for the present assessment.

Interaction of potassium sorbate with ascorbic acid and iron salts

The mutagenicity and DNA-damaging activity of the reaction mixture of potassium sorbate, ascorbic acid and iron (II and III) salts was investigated. The decomposition reaction of potassium sorbate was carried out in an aqueous solution of ascorbic acid in the presence of iron salts (ferric citrate, iron-EDTA, ferrous gluconate, ferric pyrophosphate and ferrous sulphate) for 30 days at room temperature, 40 °C or 50 °C in the presence of air or under a nitrogen atmosphere. At the end of the incubation, about 30 % potassium sorbate was present. The reaction mixtures were assayed with the Ames test in *Salmonella typhimurium* strains TA98 and TA100 in the absence and presence of S9 metabolic activation and with the *Bacillus subtilis* Rec-assay using a recombinationless M45 Rec^- strain and a wild-type H17 Rec^+ strain. There was a positive effect of the reaction mixture in the presence of air in

[27] Compund B contained *C*-nitro and *C*-nitroso groups, but its ultimate structure has not yet been elucidated.
[28] Compund F: 3-(4-methyl-5-oxido-1,2,5-oxadiazol-5-ium-3-yl)prop-2-enoic acid.

the TA100 tester strain in the absence of metabolic activation. As the reaction products obtained under a nitrogen atmosphere did not show any mutagenic or DNA-damaging properties and potassium sorbate, ascorbic acid and iron (II and III) salts were not reactive to DNA when administered separately, the authors concluded that ascorbic acid and iron (II and III) salts oxidise potassium sorbate and that the resulting oxidative products are responsible for mutagenic and DNA-damaging capabilities (Kitano et al., 2002). The Panel noted that this study has several limitations, including the following: (1) not many data are available to characterise the chemico-physical variability of the system and/or consolidate the chemical observations reported and (2) the priority of the work was specifically focused on genotoxicity testing and not on the chemical and physical characterisation of the experimental system under trial, so the chemistry of the system and mutagen formation remain substantially undefined (the suggestion that 4,5-oxohexenoate was a product of the system is reasonable but unproved).

The Panel noted that the combination of potassium sorbate and ascorbic acid in the presence of ferric salts as investigated in this study is relevant for the use of these substances as food additives, as there are two food categories in which they may be used in parallel, i.e. FCS 04.2 (only olives darkened by oxidation) and FCS 17 (food supplements). The use of ferrous gluconate (E 579) and ferrous lactate (E 585) is permitted for olives darkened by oxidation (FCS 04.2.2 and 04.2.3) at a maximum level of 150 mg/kg. Sorbic acid and sorbates are permitted for FCS 04.2.2 at a maximum level of 1 000 mg/kg and ascorbic acid and ascorbates (E 300–302) are permitted for FCS 04.2.3 according to *QS*. Hence, sorbic acid and sorbates, as well as ascorbic acid, may also be used for olives darkened by oxidation. In addition, some iron salts are used as nutritional sources in food supplements which may also contain sorbates and ascorbic acid as food additives.

Conclusion

Overall, the Panel considered the database to be sufficiently robust and that there was no evidence of genotoxic activity for sorbic acid or potassium sorbate.

The Panel also noted that potential reaction products which may result from the interaction of sorbic acid with nitrites (Namiki et al., 1980, 1981) and with ascorbic acid in the presence of iron salts (Kitano et al., 2002) were demonstrated to be mutagenic *in vitro*, and that there are certain food categories for which the use of these food additives (sorbic acid with ascorbic acid in the presence of iron salts or sorbic acid with nitrites) is permitted in parallel. However, these reaction products have been shown to be formed only under optimal experimental conditions in an aqueous environment and may not be formed to any major extent in food matrices.

The Panel also noted that the major reaction products resulting from the interaction of sorbic acid with different amines (e.g. methylamine, ethylamine, propylamine, butylamine and benzylamine) were not mutagenic in the bacterial reverse mutation assay.

The Panel noted that no data on genotoxicity were available for calcium sorbate.

3.2.4. Chronic toxicity and carcinogenicity

3.2.4.1. Mice

ASH/CS1 mice (48 males and 50 females in each group) were given 0, 1, 5 or 10 % sorbic acid in the diet for 80 weeks (Hendy et al., 1976). According to the authors, 1 % of sorbic acid in the diet provided an intake of approximately 1 400 mg/kg bw/day. The diet was kept isocaloric, being a mixture of corn oil and starch (at a ratio of 1:1 by weight). There was no significant relationship between the dose and the total number of deaths at any time. Throughout the experiment, body weights were lower in males fed 10 % sorbic acid (37 g) than in the controls (42 g), the differences being statistically significant, and there was a similar but non-significant difference in females from week 17. The body weights at autopsy of males given 5 % sorbic acid and of both sexes at the highest dose were significantly lower than those of controls.

There were no statistically significant differences between treated female mice and the corresponding controls in the results of the haematological examinations. At the first examination (week 13), the mean haemoglobin concentrations for all treated male groups were lower than those of the controls. There was no indication of a dose–response relationship and this effect was not associated with a decrease in the values for the packed cell volume or erythrocyte count. The lower haemoglobin concentrations found in males after 13 weeks were not dose related, were confined to one sex and one time point, and were not considered by the authors to represent an effect of treatment. At week 26, in the males there were isolated lower values for haemoglobin concentration (5 % group) and erythrocyte count (1 % group). The values at the higher levels were normal. Haematological parameters were not modified in comparison with the controls in all groups of males during the last six months of the study. The weights of several organs showed a significant increase compared with those of the controls. However, the organs showing higher relative weights at autopsy showed no evidence of any underlying associated pathology. As such, they are not considered to be adverse effects of treatment or relevant for deriving a NOAEL.

Most types of tumours encountered occurred at a similar or higher frequency in the controls than in the treated mice and there was, therefore, no indication of any carcinogenic effect of sorbic acid.

The authors concluded that sorbic acid did not exhibit any signs of carcinogenicity in this study. The reduction in weight gain in males and females given the highest dietary level was an indication of a slight effect due to the intake of sorbic acid. No adverse effects, other than a slight enlargement of the kidney and a reduction in body weight gain, were seen in mice fed 5 or 10 % dietary sorbic acid, and these changes were not observed at the 1 % dietary concentration. On this basis, the authors concluded that the NOAEL of this study is 1 % of the diet, equivalent to 1 400 mg/kg bw/day. The Panel agreed with the NOAEL of 1 400 mg sorbic acid/kg bw/day.

3.2.4.2. Rats

JECFA (1974) described the results of an unpublished study report (Lang et al., 1967) as follows: "*The feeding experiment on groups of 100 rats (50 males and 50 females) given 0 and 5 % sorbic acid was extended to the whole life-span of the first generation. The average life-span of the group receiving sorbic acid was 811 days for the males and 789 days for the females. In the control group the life-span of the males was 709 days and for the females 804 days, possibly suggesting protection by sorbic acid against lung infection. Autopsies were performed on all rats of the first generation that died during the experiment. There were no differences in the organ weight of the individual groups nor in the distribution of the causes of death. In each group (5 % sorbic acid and controls) only two tumours were found. The animals of the second generation were sacrificed after 250 days of feeding sorbic acid. Examination of liver, kidney, heart and testes showed no abnormalities (Lang, 1960; Lang et al., 1967*)." JECFA (1974) based its ADI on this unpublished study report (Lang et al., 1967), which was not available to the Panel.

In a chronic toxicity study (Gaunt et al., 1975), groups of Wistar rats (48 per sex) were given, for two years, dietary concentrations of 0, 1.5 or 10 % sorbic acid, reported to be equal to 0, 630 and 4 330 mg/kg bw/day for males and 0, 850 and 5 690 mg/kg bw/day for females, respectively. According to the authors, these doses were selected based on the available data of the previous dose of 5 % sorbic acid in the diet used by Lang et al. (1967). The feed was made isocaloric between the groups, as a mixture of corn oil and starch (at a ratio of 1:1 by weight), which was fed to the 0 and 1.5 % sorbic acid groups. During the study, no effects on mortality were attributed to the consumption of sorbates. The rate of body weight gain of the rats given 10 % sorbic acid was less than that of the controls. The differences were small (5–10 % of the control weight) but statistically significant from week 26 onwards for females and from week 39 onwards for males. The only difference between treated and control rats in the organ weights was a higher thyroid weight ($p < 0.01$) of male rats given 10 % sorbic acid. This difference was also evident when the organ weights were expressed relative to body weight. The total tumour incidence, the incidence of malignant tumours and the distribution of affected tissues were not influenced by sorbic acid treatment. In fact, no malignant tumours were

found in the females given 10 % sorbic acid. In many cases, the incidence of tumours was similar in the control and the treated animals or the tumours occurred in only the control rats.

Taking into account that there was no increase in the rate of mortality in the treated rats; that there were no changes attributable to treatment in the haematological examinations, analyses of serum, studies of renal function or histopathological examination; that the relative liver and kidney weights increased in the rats given 10 % sorbic acid and the thyroid weight increased at the same level in males, which was not thought to be due to sorbic acid treatment; and in the absence of carcinogenic effects, the authors concluded that the NOAEL of this study was 1.5 % in the diet, equivalent to approximately 750 mg sorbic acid/kg bw/day (Gaunt et al., 1975). The Panel noted that the study was appropriately conducted and that no carcinogenic effects were reported. The Panel also identified NOAELs of 630 mg sorbic acid/kg bw/day and 850 mg sorbic acid/kg bw/day for males and females, respectively. The Panel noted that 5 % sorbic acid in the diet as used in the unavailable unpublished study of Lang et al. (1967), used by JECFA as the basis of its ADI, was not tested in the study.

3.2.5. Reproductive and developmental toxicity

3.2.5.1. Reproductive toxicity studies

Rats

JECFA (1974) very briefly reported a reproduction study from an unpublished study report which was not available to EFSA and described the study as follows: "*Feeding 5 % of sorbic acid in the diet to groups of 100 rats for 1 000 days in two generations had no effect on weight gain or reproduction. No ill effects were observed, and no sorbic acid could be found in the urine (Lang et al., 1967*)."

A two-generation reproductive toxicity study was performed in CD/Crl:CD rats (n = 30 and 25 per sex per group in F_0 and F_1, respectively) in accordance with OECD Guideline 416 (OECD, 2001a) and GLP (Cordts, 2004a). Sorbic acid (in an aqueous vehicle containing 0.5 % hydroxypropyl-methylcellulose, which also served as control) was administered by gavage (dosing volume 10 ml/kg bw) at doses of 0, 300, 1 000 and 3 000 mg/kg bw/day, expressed as sorbic acid. The F_0 group was dosed from 10 weeks before mating until termination of the mating period for males and until day 21 of lactation for females. The F_1 generation was dosed from weaning (three weeks old) and followed the same schedule for dosing as that of the F_0 generation.

In the F_0 generation, no test item-related mortality was observed. In the F_1 generation, two animals of each sex of the 3 000 mg/kg bw/day group died prematurely between test days 16 and 38. One high-dose female was sacrificed prematurely on test day 13 in a moribund condition. According to the authors, these deaths may have been due to intolerance to oral gavage after excessive doses to juveniles. The Panel noted that these deaths occurred in only the high-dose group and that a relationship with test items cannot be excluded.

Body weights of the male F_0 and F_1 animals of the 3 000 mg/kg bw/day group were significantly reduced from week 1 onwards by 4–7 % and 8–17 %, respectively. Body weight gain of the F_0 and the F_1 males of this group was reduced by 3–79 % and 5–26 %, respectively. There was no effect on body weight and body weight gain in the F_0 and F_1 females of this group at any time. Effects on body weight were not regarded by the authors as adverse but were considered to be related to the administration of an acid at a high dose. However, the Panel found this explanation to be unlikely, as reduced body weight was seen in males only and there was no effect on body weight in females, although the administration of acid was similar in males and females.

During the premating period, food consumption was slightly reduced, by 3–9 % and 4–11 % in the female F_0 and F_1 animals of the 1 000 mg/kg bw/day group, respectively. In the male (statistically significant on a few days) and female (statistically significant during the whole premating period) F_0 and F_1 animals of the 3 000 mg/kg bw/day group, food consumption was reduced by 4–17 % and 4–10 %, respectively, during the same period. In the 3 000 mg/kg bw/day group, a transient decrease was

observed during gestation and lactation (3–17 %) in the F_0 dams and in the F_1 dams (gestation 4–17 %, lactation 2–10 %), which was statistically significant on a few days. The reduced food intake was considered by the authors to be related to caloric substitution via sorbic acid. The Panel noted that reduced feed intake was observed mainly during the premating period and in females, while reduced body weight compared with controls was observed in males only.

In both generations, no effects were observed on male and female reproduction (sperm analyses, oestrus cycle, precoital time, weight and histology of the reproductive organs, male and female fertility index, duration of pregnancy, post-implantation loss, average litter size, number of viable pups at birth, and sex ratio at birth and during the lactation period).

Absolute brain weight was statistically significantly reduced (6 %) in male and female animals of the 3 000 mg/kg bw/day group of the F_1 generation. However, no significant decrease was observed in relative brain weight. Absolute adrenal weight of the females of this group was statistically significantly increased (18–20 %). Relative adrenal weight was increased, but not statistically significantly.

The dose levels had a significant influence on mean litter body weight in F_1 and F_2 pups (analysis of covariance (ANCOVA), with days of life as a covariate: $p < 0.05$). The mean litter body weight of F_1 males and females of the mid- and high-dose groups was significantly reduced compared with the body weights of control and low-dose groups (least significant difference (LSD) test, $p < 0.01$). In the F_2 pups, mean litter body weight of males was significantly reduced in the high-dose group (LSD test, $p < 0.0001$) and in the females in the low-dose ($p = 0.0001$), mid-dose ($p = 0.0003$) and high-dose ($p < 0.0001$) groups compared with controls. At postnatal day 1, mean litter body weights of the F_1 and F_2 pups were only slightly reduced (approximately 1–2 %). With increasing age, the mean litter body weight was further decreased and at 21 days of age body weight was reduced by 10–13 % in F_1 and F_2 pups of the high-dose animals compared with controls.

Milestones of physical development in treated F_1 pups in the high-dose group were statistically significantly different (by ANOVA and LSD test) from those of the control group for pinna detachment, upper incisor eruption, ear opening, eye opening, cleavage of the balanopreputial gland in males and for upper incisor eruption, eye opening and time of vaginal opening in females. These changes were considered by the authors as spontaneous, as they were within the range of normal variations for this strain. However, there was a slight trend towards a delay in occurrence of morphological landmarks (cleavage of balanopreputial gland in males and vaginal opening in females) at the high dose of 3 000 mg/kg compared with the control animals. Functional development was affected at the highest dose, as there was a statistically increased incidence of reduced reflexes for the auditory startle reflex (in both males and females) and for the mid-air righting reflex (in females). In female pups of the high-dose group, a statistically significant increase in the percentage of pups that failed in the passive avoidance test (+31 % learning and +76 % memory; $p \leq 0.01$) was also observed. No negative findings were noted for the pupillary reflex in any of the animals. No treatment-related influence was noted in the open field test (latency, rearing, sectors entered, defecation boluses). A statistically significant increase in grooming of both male and female F_1 pups from the high-dose group was observed.

Measurement of anogenital distance of F_2 pups at birth revealed a statistically significant decrease in male F_2 pups of 10.6 % and 9.2 % at 1 000 mg/kg bw/day and 3 000 mg/kg bw/day, respectively, compared with the control animals. The anogenital distance in the 300 mg/kg bw/day group was comparable to that of the control group. The anogenital distance of F_2 female pups was reduced only marginally. As the effects on pup body weight at birth were only slight, the effects could not be attributed to pup body weight only. The Panel reanalysed the data on anogenital distance by dividing by the cube root of the body weight, as recommended by OECD Guidance Document 43 (OECD, 2008b) and Gallavan et al. (1999). Similar results to those obtained without normalisation to body weight were obtained, showing statistically significant decreases in anogenital distance in male F_2 pups of 10.3 % and 9.1 % in the mid- and high-dose groups, respectively, compared with controls. At

histopathological examination, no adverse effects on reproduction organs were noted, fertility was not affected in the F_0 and F_1 generation parents and no effects on sex ratio were observed in pups of the F_1 and F_2 generations of the 3 000 mg/kg bw/day group. However, fertility and histopathology were not studied in the F_2 generation, where the effect on anogenital distance was observed.

Considering the reduced body weight in F_1 and F_2 pups during lactation in the mid- and high-dose groups; the effects on morphological landmarks and on physical development in the F_1 pups of the high-dose group; and the effect on anogenital distance in males in the mid- and high-dose groups, the Panel concluded that, by gavage, the NOAEL for developmental toxicity was 300 mg/kg bw/day. Furthermore, the Panel noted that, by gavage, the NOAEL for parental toxicity was 1 000 mg/kg bw/day based on effects on body weight of the parental male animals.

3.2.5.2. Developmental toxicity studies

Mice

The SCF described studies performed on groups of approximately 20 pregnant CD-1 mice and Wistar rats (FDRL, 1975, as referred to by SCF, 1992): "*Animals were given potassium sorbate daily by gavage on day 6–15 of gestation. The mice received doses of 3.4, 16.0, 74.0, 343.3 mg/kg bw/day expressed as sorbic acid and the rats were given 2.5, 11.8, 54.7 or 253 mg/kg bw/day expressed as sorbic acid. No significant effects were noted on implantation or on maternal or fetal survival in both species. The number of abnormalities seen in soft and skeletal tissues of potassium sorbate dosed animals did not differ from the number occurring spontaneously in the control animal*s." This study was not available to the Panel.

Rabbits

A developmental toxicity study in rabbits was performed in accordance with OECD Guideline 414 (OECD, 2001b) and GLP (Cordts, 2004b). Himalayan rabbits (24 rabbits per group) were given sorbic acid at doses of 0, 300, 1 000 or 3 000 mg/kg bw/day by gavage in an aqueous vehicle containing 0.5 % hydroxypropyl-methylcellulose, which also served as control, from day 6 to 29 of pregnancy.

No treatment-related mortality occurred among the dams treated with 300 or 1 000 mg/kg bw/day. At 3 000 mg/kg bw/day, eight females died prematurely between gestation days (GDs) 8 and 28, predominantly unobserved, during the night. In addition, eight dams were sacrificed after abortion between GDs 17 and 28. Necropsy of the prematurely deceased dams revealed changes to the spleen (coarse-grained rough surface, reduced in size) and gastric lesions (haemorrhagic foci) in all animals.

In the 300, 1 000 and 3 000 mg/kg bw/day groups, slightly reduced motility was noted in all dams, starting from 20 to 60 minutes after administration. In addition, an increased respiratory rate was noted at 1 000 and 3 000 mg/kg bw/day. These symptoms lasted for up to 60 minutes at 1 000 mg sorbic acid/kg bw/day and for up to two hours at 3 000 mg sorbic acid/kg bw/day.

In the 1 000 mg/kg bw/day group, a statistically significant reduction ($p < 0.05$) in the mean body weight gain was noted for the period of gestation. At 3 000 mg/kg bw/day, the mean maternal body weight was slightly reduced during the whole treatment period. A body weight loss was observed between GDs 6 and 15, followed by a growth slope which was similar to other groups, including the control group. Statistically significant reductions were noted on GDs 16, 21 and 25 to 29 (up to 6 % below the control value). However, it should be noted that there were no statistical differences between the mean carcass weights of the treated and control groups at laparotomy. In addition, the mean net weight change between GDs 6 and 29 was similar among all groups and the observed variations were not dose related.

Feed consumption was reduced in a dose-related manner in all groups and, at 3 000 mg/kg bw/day, the difference was up to a maximum of 63 % compared with controls. The amplitude of decreased food consumption was particularly high during organogenesis, varying between 46 and 63 %.

Necropsy revealed no treatment-related changes at 300 mg/kg bw/day. At 1 000 and 3 000 mg/kg bw/day, changes to the spleen (coarse-grained rough surface, reduced size) were noted in all dams. No treatment-related lesions were noted in the gastric mucosa or small or large intestines of the surviving animals.

In the 3 000 mg/kg bw/day group, a statistically significant reduction was noted for the gravid uterus weight (52 % below the control) reflecting the lower number of fetuses/dams at this dose. From 1 000 mg/kg bw/day and higher, statistically significant reductions were noted for the mean fetal and placental weights and the viability of fetuses during a 6- or 24-hour incubator stay. At 3 000 mg/kg bw/day, post-implantation loss increased to 29.2 % (control 4.5 %). The number of early and total resorptions was significantly increased ($p > 0.01$) and the number of fetuses was significantly decreased. At 1 000 and 3 000 mg/kg bw/day, one and five runts were reported, respectively. All runts died within 0.5 to 6 hours after laparotomy. At 300 mg/kg bw/day, all fetuses survived the 24-hour incubation stay.

In the 3 000 mg/kg bw/day group, five malformed fetuses, four fetuses with malrotated fore paws and one fetus with omphalocele were noted in three different litters. This incidence of malformation was significantly different ($p > 0.01$) from the control. The omphalocele was judged to be incidental, because this observation is quite common in fetuses and well within the historical control for this strain. External examination revealed classified macroscopic variations in the form of a domed fetal head in four fetuses (two litters), which died within 0.5 to 24 hours after birth. Domed head was associated to omphalocele and malrotated fore paw in two fetuses from the same litter. Skeletal examination revealed no malformations and statistically significant increases in the fetal incidence of accessory 13th rib variation. At this high dose of 3 000 mg/kg bw/day, missing or incomplete ossification of the skull, lumbar vertebral bodies and talus were statistically significantly increased. Eventually, there were increases in the fetal and litter incidence of dilated lateral cerebral ventricles and, hence, the incidence of total soft tissue variations of the head.

In the 1 000 mg/kg bw/day group, external examination revealed a statistically significant increase ($p > 0.01$) in the incidence of unclassified macroscopic observations in the form of abdominal distension caused by an inflated gastric tract. This finding was noted in 12 fetuses (of two litters) that died during the 24-hour incubator stay. The author of the study report concluded that this effect was spontaneous and not treatment related. One fetus with a malrotated fore paw was observed in this dose group; this finding was well within the historical control findings for this species. A statistically significant increase in the fetal incidence of missing lumbar vertebral bodies, a skeletal retardation, was observed at 1 000 mg/kg bw/day. The Panel noted that the death of the 12 fetuses (two litters) and distension of the abdomen may be related to retarded development of the fetuses and can be due to treatment.

The author of the study considered that the maternal NOAEL was 300 mg sorbic acid/kg bw/day, as the minor effects at this dose (reduced motility and reduced feed intake) were not considered adverse, and the NOAEL for the fetuses was also 300 mg sorbic acid/kg bw/day based on the effect on fetal weight and retardation in development. The Panel agreed with these NOAELs.

3.2.6. Hypersensitivity, allergenicity and intolerance

Out of 20 children exposed to mayonnaise dressing preserved with potassium sorbate (0.11 %), 18 developed perioral urticaria, which was considered as a contact dermatitis induced by sorbates in the oral mucosa. The authors considered that this reaction was not of immunological origin (Clemmensen and Hjorth, 1982). In 90 persons, there were concentration-dependent reactions to sorbic acid solutions after a closed patch test. At the lowest dose (0.1 %), there was a reaction in 20 % of the participants; at a dose of 1 %, there was a reaction in 62 % of the participants; and, at the highest dose (5 %), there was a reaction in 65 % of the test persons. The skin reaction could not be reproduced on the oral mucosal surface after application of 5 or 10 % sorbic acid in water (Clemmensen and Hjorth, 1982; Clemmensen and Schiodt, 1982).

No cases of food allergy induced by the use of sorbic acid and its salts as food additives are documented.

4. Discussion

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

JECFA evaluated sorbic acid and its salts in 1961, 1965 and 1973. A group ADI of 25 mg/kg bw/day expressed as sorbic acid was allocated, covering sorbic acid, sodium sorbate, potassium sorbate and calcium sorbate (JECFA, 1974). This ADI was based on a NOAEL of 5 % in the diet equivalent to 2 500 mg/kg bw/day identified in an unpublished long-term rat study report, which was not available to the Panel. In 2003, JECFA evaluated sorbic acid for use as a food flavouring substance (JECFA, 2004).

Sorbic acid and its potassium and calcium salts were evaluated by the SCF in 1994 (SCF, 1996). Based on studies originally evaluated by JECFA (1974), as well as more recent studies, the SCF endorsed the group ADI of 25 mg/kg bw/day for sorbic acid, potassium sorbate and calcium sorbate set by JECFA based on a long-term study on sorbic acid with a NOAEL of 2 500 mg/kg bw/day. The SCF noted that there were no toxicological studies on calcium sorbate, but nevertheless included this substance in the group ADI. The group ADI including potassium and calcium sorbate was expressed as sorbic acid (SCF, 1996).

After oral administration, radiolabelled [^{14}C]sorbic acid was found to be rapidly and extensively absorbed and then metabolised by the rat and the mouse. More than 80 % of the radioactivity was found in expired carbon dioxide and 10 % was found in internal organs, skeletal muscles and other parts of the carcass. Urinary and faecal excretion of the radioactivity accounted for 1 to 2 % and around 5 %, respectively (Fingerhut et al., 1962; Westöö, 1964). The Panel considered that data available on the absorption, distribution, metabolism and excretion of sorbic acid show that sorbic acid is absorbed and mainly excreted as expired carbon dioxide. Since no data on bioavailability were available on potassium sorbate and calcium sorbate, the Panel considered that, owing to the ionisation properties of sorbic acid ($pK_a = 4.76$), the unionised forms of these sorbates should be absorbed by a diffusion process in the stomach. Potassium and calcium sorbate might dissociate into their constituents—potassium, calcium and sorbate ions—in the small intestine. Accordingly, sorbate from potassium or calcium sorbate should be bioavailable and absorbed in the same manner as from sorbic acid. The calcium and potassium ions are expected to enter normal homeostatic processes and are not expected to have an impact on the toxicity of the salts. Thus, the properties of the cations are not discussed further in the opinion.

Short-term and sub-chronic toxicity studies performed in rats did not show any adverse effects at the concentrations tested (up to 9 200 mg/kg bw/day in rats).

Numerous *in vitro* genotoxicity tests have been performed with sorbic acid; however, some of them are very old and three studies could not be taken into account owing to a lack of information on the design of the studies. Taking into account all available data, the Panel considered that the results obtained from *in vitro* tests were equivocal. The Panel observed that all *in vivo* tests were negative except one limited study using intraperitoneal injection.

Sorbic acid and potassium sorbate were investigated in *in vitro* and *in vivo* genotoxicity assays. Overall, the Panel considered that the database was sufficiently robust and that there was no evidence of genotoxic activity for sorbic acid or potassium sorbate. The Panel noted that no data on genotoxicity were available for calcium sorbate. The Panel considered that read-across from sorbic acid and potassium sorbate data on genotoxicity to calcium sorbate would be theoretically possible. However, given the available positive genotoxicity data on sodium sorbate (as reported by the SCF

(1996)), the Panel considered that genotoxicity data on calcium sorbate are needed. Therefore, the Panel considered that calcium sorbate should be excluded from the group ADI.

The Panel also noted that potential reaction products that may result from the interaction of sorbic acid with nitrites and with ascorbic acid in the presence of iron salts were demonstrated to be mutagenic *in vitro* (Namiki et al., 1980; Kitano et al., 2002) and that there are certain food categories for which the use of these food additives (sorbic acid with ascorbic acid in the presence of iron salts or sorbic acid with nitrites) is permitted in parallel. However, these reaction products have been shown to be formed under optimal experimental conditions in an aqueous environment only and may not be formed to any major extent in food matrices.

The Panel also noted that the major reaction products resulting from the interaction of sorbic acid with different amines (e.g. methylamine, ethylamine, propylamine, butylamine and benzylamine) were not mutagenic in the bacterial reverse mutation assay.

There were five long-term toxicity/carcinogenicity studies. All of them were performed before the current OECD guidelines were established. No recent long-term toxicity/carcinogenicity studies have been identified in the literature. The Panel revisited all the relevant original reports and publications, except the Lang et al. (1967) study used to allocate the ADI by JECFA (1974), which was not available.

In a study (80 weeks) in mice, a slight enlargement of the kidney and a reduction in body weight gain were observed at the highest dose tested and a NOAEL of 1 400 mg sorbic acid/kg bw/day was identified (Hendy, 1976). In a two-year study in rats (Gaunt et al., 1975), the relative liver and kidney weights were increased in the rats given 10 % sorbic acid. The thyroid weight was increased at the same level in males, but this was not thought to be due to sorbic acid treatment. This study showed no carcinogenic effect of sorbic acid at dietary levels up to 10 %. According to the authors, the NOAEL established in this study was 1.5 % in the diet (equal to 630 and 850 mg sorbic acid/kg bw/day in males and females, respectively) with changes of doubtful significance at the higher level (10 %). The Panel noted that 5 % sorbic acid in the diet, as used in the unavailable unpublished study of Lang et al. (1967) and used by JECFA as the basis of its ADI, was not tested in the study.

A two-generation reproductive toxicity study was performed in CD/Crl:CD rats (n = 30 and 25 per sex per group in F_0 and F_1, respectively) in accordance with OECD Guideline 416 and GLP (Cordts, 2004a). Sorbic acid was administered by gavage at doses of 0, 300, 1 000 or 3 000 mg/kg bw/day. Several adverse effects were described in pups, such as a decrease in mean litter body weight, milestones of physical development in F_1 pups, a delay in functional development in F_1 pups and a decrease in anogenital distance in male F_2 pups in the mid- and high-dose groups. Considering the aforementioned observations, the Panel concluded that, by gavage, the NOAEL for developmental toxicity is 300 mg/kg bw/day. Furthermore, the Panel noted that, by gavage, the NOAEL for parental toxicity is 1 000 mg/kg bw/day based on effects on body weights of the parental male animals.

In a developmental toxicity study performed in rabbits in accordance with OECD Guideline 414 and GLP (Cordts, 2004b) at doses of 0 (control), 300, 1 000 or 3 000 mg sorbic acid/kg bw/day by gavage from day 6 to 29 of gestation, maternal and fetal toxicity were observed in the mid- and high-dose groups. The Panel considered that the maternal NOAEL was 300 mg sorbic acid/kg bw/day and the NOAEL for the fetuses was also 300 mg sorbic acid/kg bw/day.

The Panel considered that the present database on reproductive and developmental toxicity gives a reason to revise the group ADI of 25 mg/kg bw/day set by the SCF in 1996. The Panel noted that there appeared to be a difference between the results obtained from studies performed by gavage and the earlier reproductive toxicity study which was a diet study. However, as the latter study performed in 1967 was not available, the Panel considered that it would be prudent to regard the gavage study as relevant.

Consequently, the Panel identified the two-generation reproductive toxicity by gavage study in rats as a point of departure for the hazard characterisation. The NOAEL of 300 mg sorbic acid/kg bw/day by gavage from this study can be used to allocate a new ADI for sorbic acid and its potassium salt. By applying a default uncertainty factor of 100, the Panel established a temporary group ADI expressed as 3 mg sorbic acid/kg bw/day for sorbic acid and its potassium salt. The Panel considered that an extended one-generation reproductive toxicity study in rats including the second generation by diet is needed to reconsider the temporary group ADI.

Exposure assessments of food additives under re-evaluation were carried out by the ANS Panel based on (1) MPLs set out in the EU legislation (defined as the *regulatory maximum level exposure assessment scenario*) and (2) usage or analytical data (defined as the *refined exposure assessment scenario*).

Based on the available dataset, 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.

Overall, the Panel considered long-term exposures based on the *regulatory maximum level exposure assessment scenario* as being conservative, as this scenario assumes that all foods and beverages contain sorbic acid – sorbates (E 200, 202, 203) as food additives at the MPL. The Panel considered that the refined exposure assessment approach resulted in more realistic long-term exposure estimates. This approach was based on the extensive range of analytical data and assumes that people, in the long term, are exposed to foods and beverages that contain the additive at a mean concentration level for all products (non-brand-loyal consumer scenario) or that one product contains sorbic acid – sorbates at the maximum concentration level (brand-loyal consumer scenario) and the remaining products contain the additive at a mean concentration level. For this refined scenario, 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 sorbic acid and sorbates. 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 sorbic acid – sorbates.

From the *regulatory maximum level exposure assessment scenario*, mean exposure to sorbic acid – sorbates (E 200, 202, 203) from their use as food additives ranged from 7.7 to 23.7 mg/kg bw/day in toddlers, 10.1 to 19.9 mg/kg bw/day in children, 4.7 to 11.5 mg/kg bw/day in adolescents, 5.0 to 8.9 mg/kg bw/day in adults and 5.0 to 7.1 mg/kg bw/day in the elderly. The high exposure to sorbic acid and sorbates ranged from 20.7 to 33.9 mg/kg bw/day in toddlers, 20.0 to 38.7 mg/kg bw/day in children, 10.1 to 25.1 mg/kg bw/day in adolescents, 9.9 to 16.3 mg/kg bw/day in adults and 9.6 to 12.8 mg/kg bw/day in the elderly. The Panel noted that this exposure estimate of sorbic acid – sorbates exceeded the temporary group ADI of 3 mg/kg bw/day for all population groups at the mean and high levels. The main contributing food categories to the total mean exposure estimates for children, adolescents and adults in this scenario were bread and rolls, fine bakery wares and flavoured drinks. For the elderly, the main contributing food categories were bread and rolls and fine bakery wares, while, for toddlers, the main contributing food categories were bread and rolls, fine bakery wares and processed cheese.

From the *refined estimated exposure scenario* using only reported use levels, in the *brand-loyal scenario*, mean exposure to sorbic acid – sorbates from their use as food additives ranged from 2.8 mg/kg bw/day in adolescents to 15.3 mg/kg bw/day in children. The high exposure to sorbic acid – sorbates ranged from 6.3 mg/kg bw/day in adolescents to 30.8 mg/kg bw/day in children. The main contributing food categories for children, adolescents, adults and the elderly were bread and rolls and

fine bakery wares. For children, the main contributing food categories were bread and rolls, fine bakery wares and processed cheese. In the *non-brand-loyal scenario*, mean exposure to sorbic acid – sorbates ranged from 2 mg/kg bw/day in adolescents to 11.3 mg/kg bw/day in children. The high exposure to sorbic acid – sorbates ranged from 4.7 mg/kg bw/day in adolescents to 23.1 mg/kg bw/day in children. The main contributing food categories for all groups were bread and rolls and fine bakery wares.

The Panel noted that using only reported use levels, the refined brand-loyal and non-brand-loyal exposure estimates exceeded the temporary group ADI of 3 mg/kg bw/day for all population groups at the mean and high levels.

From the *refined estimated exposure scenario* using reported use levels and analytical data, in the *brand-loyal scenario*, mean exposure to sorbic acid – sorbates ranged from 2.5 mg/kg bw/day in adolescents to 13.0 mg/kg bw/day in children. The high exposure to sorbic acid – sorbates ranged from 5.6 mg/kg bw/day in adolescents to 25.6 mg/kg bw/day in children. In the *non-brand-loyal scenario*, mean exposure to sorbic acid – sorbates ranged from 0.3 mg/kg bw/day in adults and the elderly to 1.8 mg/kg bw/day in toddlers. The high exposure to sorbic acid – sorbates ranged from 0.6 mg/kg bw/day in the elderly to 3.7 mg/kg bw/day in children. The main contributing food categories for all groups were bread and rolls and fine bakery wares in the *brand-loyal scenario* and bread and rolls, fine bakery wares, flavoured drinks and sauces in the *non-brand-loyal scenario*.

The Panel noted that, when using reported use levels and analytical data in the refined brand-loyal exposure estimate, all population groups exceeded the temporary group ADI of 3 mg/kg bw/day at the mean and high levels (95th percentile), whilst, for the *non-brand-loyal scenario*, the temporary group ADI was exceeded in only toddler and children population groups in one country.

The Panel noted that, for several food products for which the use of sorbic acid – sorbates is authorised such as citrus fruits, chewing gum, potato gnocchi, meat pâté, dehydrated and concentrated frozen eggs, table-top sweeteners in liquid form, protein products, dietary foods for weight control, aromatised wines and processed nuts, no usage data were reported and analytical data were reported in only limited numbers ($n < 20$). In addition, the Panel further noted that, for some other authorised food categories such as unripened, ripened and whey cheese and cheese products, processed potato products, potato gnocchi, processed meat, processed fish, processed eggs, table-top sweeteners, salads, fruit nectars, beer, wine, fruit wine and made wine, mead, aromatised wines and aromatised wine-based drinks and cocktails, potato-, cereal-, flour- or starch-based snacks, desserts and food supplements, no usage data were reported by industry, while positive analytical results (> LOQ) were submitted.

For the main contributing food categories, namely bread and rolls and fine bakery wares, the numbers of analytical data submitted were 1 625 and 2 597 samples, respectively. The mean analytical levels (all data, including the left-censored data) were found to be far below the MPL of 2 000 mg/kg (92.2 and 205 mg/kg, respectively), although a significant proportion of the values measured were close to the MPL. The mean typical reported use levels for bread and rolls and fine bakery wares were higher than the mean analytical levels from the set of monitoring data: 1 425 versus 1 200 and 1 068 versus 400 mg/kg, respectively. The difference observed in the mean levels is probably due to (1) the additive not being added systematically in these food categories (the proportion of the additive detected/quantified being 9 % in bread and rolls and 52 % in fine bakery wares) and (2) the fact that using solely analytical data means that the percentage of losses during the manufacturing process is included. It is important to mention that, for the present exposure assessment, the sub-categories within the categories "bread and rolls" and "fine bakery wares" in the FoodEx classification system were considered, but the presence of sorbic acid –sorbates in all these sub-categories is very unlikely. Therefore, the exposure to sorbic acid – sorbates for bread and rolls and fine bakery wares is probably overestimated. Given the significant importance of these two food categories to the total exposure, it can be assumed that the total exposure to sorbic acid – sorbates is likely to be overestimated.

The Panel considered that the maximum residual levels of divalent transition metals used as catalysts in the manufacturing process should be included in the EC specifications for sorbic acid (E 200). The Panel also considered that the maximum limits for the impurities of toxic elements (lead, mercury and arsenic) in the EC specification for sorbic acid and its salts (E 200, 202, 203) should be revised in order to ascertain that sorbic acid – sorbates (E 200, 202, 203) as food additives will not be a significant source of exposure to those toxic elements in food.

CONCLUSIONS

Given the lack of genotoxicity data on calcium sorbate and the available positive genotoxicity data on sodium sorbate, the Panel concluded that calcium sorbate should be excluded from the group ADI.

The Panel concluded that the present dataset on reproductive and developmental toxicity gives a reason to revise the group ADI of 25 mg/kg bw/day allocated by the SCF in 1996. The Panel considered that the NOAEL of 300 mg sorbic acid/kg bw/day from the two-generation reproductive toxicity study in rats can be used to allocate a temporary group ADI for sorbic acid and its potassium salt. By applying an uncertainty factor of 100, the Panel established a new temporary group ADI expressed as 3 mg sorbic acid/kg bw/day for sorbic acid (E 200) and potassium sorbate (E 202).

The Panel noted that the most realistic approach using reported use levels and analytical data in the *non-brand-loyal scenario* did not exceed the temporary group ADI in any population group at the mean or in adolescents, adults and the elderly at the high level, except in the toddler and children population groups in one country. The Panel noted that, in these estimates, the main food contributors were bread and rolls, fine bakery wares and flavoured drinks.

RECOMMENDATIONS

The Panel recommended that:

- genotoxicity studies on calcium sorbate need to be performed in order to consider including calcium sorbate in the group ADI;
- an extended one-generation reproductive toxicity study in rats including the second generation by diet needs to be performed in order to reconsider the temporary group ADI;
- if divalent transition metals are used as catalysts in the manufacturing process of sorbic acid, maximum residual levels of divalent transition metals should be included in the EC specifications for sorbic acid (E 200);
- the maximum limits for the impurities of toxic elements (lead, mercury and arsenic) in the EC specification for sorbic acid and its salts (E 200, 202, 203) should be revised in order to ascertain that sorbic acid – sorbates (E 200, 202, 203) as food additives will not be a significant source of exposure to those toxic elements in food;
- future research be performed on the occurrence of breakdown and reaction products of possible toxicological concern under realistic conditions of food processing and storage – especially when sorbic acid, potassium sorbate or calcium sorbate is used in parallel with ascorbic acid in the presence of iron salts or with nitrites.

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APPENDICES

Appendix A. Summary of reported use levels (mg/kg) of sorbic acid – sorbates (E 200, 202, 203) provided by industry

FCS category number	FCS food category	MPL	Restrictions/exceptions	Number of data	Reported use levels from industry		Information provided by	Comments
					Typical mean	Highest maximum level		
01.3	Unflavoured fermented milk products	1 000	Only curdled milk	1	370	–	FDE	No FoodEx linkage
01.4	Flavoured fermented milk products including heat-treated products	300	Only non-heat-treated dairy-based desserts	Typical usage level reported as a range	170	–	FDE	No FoodEx linkage
01.7.5	Processed cheese	2 000		Typical usage level reported as a range	1 450	–	FDE	
01.8	Dairy analogues, including beverage whiteners	*QS*	Only cheese analogues (surface treatment only)	Typical usage level reported as a range	1 450	–	FDE	
02.2.2	Other fat and oil emulsions	1 000	Only fat emulsions (excluding butter) with a fat content of 60 % or more	Typical usage level reported as a range	1 000	1 000	FDE	
02.2.2	Other fat and oil emulsions	2 000	Only fat emulsions with a fat content less than 60 %	Typical usage level reported as a range	2 000	2 000	FDE	
04.2.1	Dried fruit and vegetables	1 000	Only dried fruit	Typical usage level reported as a range	750	1 000	FDE	
04.2.2	Fruit and vegetables in vinegar, oil or brine	2 000	Only vegetables (excluding olives)	1	400	800	FDE	
04.2.2	Fruit and vegetables in vinegar, oil or brine	1 000	Only olives and olive-based preparations	Typical usage level reported as a range	750	1 000	FDE	

FCS category number	FCS food category	MPL	Restrictions/exceptions	Number of data	Reported use levels from industry		Information provided by	Comments
					Typical mean	Highest maximum level		
04.2.5.2/ 04.2.5.3	Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2 001/113/EC. Other similar fruit or vegetable spreads	1 000/ 1 500	Only low-sugar and similar low calorie or sugar-free products, *mermeladas*/other fruit-based spreads, *mermeladas*/only *marmelada*	1	5	6	FDE	
05.2	Other confectionery including breath-freshening microsweets	1 500	Except candied, crystallised or glacé fruit and vegetables	3	553	1 500	FDE	
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	1 000	Only toppings (syrups for pancakes, flavoured syrups for milkshakes and ice cream; similar products)	1	850	1 000	FDE	No FoodEx linkage
06.4.5	Fillings of stuffed pasta (ravioli and similar)	1 000		1	160	–	FDE	
06.7	Pre-cooked or processed cereals	2 000	Only *semmelknödelteig*	1	600	750		No FoodEx linkage
07.1	Bread and rolls	2 000	Only prepacked sliced bread and rye-bread, partially baked, prepacked bakery wares intended for retail sale and energy-reduced bread intended for retail sale	4	1 425	2 000	FDE	
07.2	Fine bakery wares	2 000	Only with a water activity of more than 0.65	5	1 068	2 000	FDE	

FCS category number	FCS food category	MPL	Restrictions/exceptions	Number of data	Reported use levels from industry		Information provided by	Comments
					Typical mean	Highest maximum level		
08.2.3	Casings and coatings and decorations for meat	*QS*	Only collagen-based casings with water activity greater than 0.6	1	–	8 000	Cutisin	For potassium sorbate (E 202) only; it was estimated that approximately 68 mg/kg ends up in the final meat product. No FoodEx linkage
09.3	Fish roe	2 000	Only semi-preserved fish products including fish roe products	1	600	–	FDE	
12.2.2	Seasonings and condiments	1 000		1	500	500	FDE	
12.4	Mustard	1 000		1	250	500	FDE	
12.6	Sauces	2 000	Only emulsified sauces with a fat content of less than 60 %	1	500	1 000	FDE	
12.6	Sauces	1 000	Only emulsified sauces with a fat content of 60 % or more	1	500	500	FDE	
12.6	Sauces	1 000	Only emulsified sauces with a fat content of 60 % or more; non-emulsified sauces	Typical usage level reported as a range	425	500	FDE	
13.2	Dietary foods for special medical purposes	1 500		1	–	550	FDE	
14.1.2	Fruit juices as defined by Directive 2 001/112/EC[14] and vegetable juices	500	Only sød … saft and sødet … saft	1	500	500	FDE	No FoodEx linkage
14.1.4	Flavoured drinks	300	Excluding dairy-based drinks	Typical usage level reported as a range	135	300	FDE	

FCS category number	FCS food category	MPL	Restrictions/exceptions	Number of data	Reported use levels from industry		Information provided by	Comments
					Typical mean	Highest maximum level		
				Typical usage level reported as a range	175	300	UNESDA	
14.1.5.2	Other	600	Only liquid tea concentrates and liquid fruit and herbal infusion concentrates	1	8.2	8.2	FDE	No FoodEx linkage
14.2.8	Other alcoholic drinks including spirits with less than 15 % of alcohol and mixtures of alcoholic drinks with non-alcoholic drinks	200	Only alcoholic drinks with less than 15 % of alcohol and *nalewka na winie owocowym*, *aromatyzowana nalewka na winie owocowym*, *nalewka na winie z soku winogronowego*, *aromatyzowana nalewka na winie z soku winogronowego*, *napój winny owocowy lub miodowy*, *aromatyzowany napój winny owocowy lub miodowy*, *wino owocowe niskoalkoholowe and aromatyzowane wino owocowe niskoalkoholowe*	Typical usage level reported as a range	175	200	FDE	

FCS category number	FCS food category	MPL	Restrictions/exceptions	Number of data	Reported use levels from industry		Information provided by	Comments
					Typical mean	Highest maximum level		
14.2.8	Other alcoholic drinks including spirits with less than 15 % of alcohol and mixtures of alcoholic drinks with non-alcoholic drinks	200	Only alcoholic drinks with less than 15 % of alcohol and *nalewka na winie owocowym*, *aromatyzowana nalewka na winie owocowym*, *nalewka na winie z soku winogronowego*, *aromatyzowana nalewka na winie z soku winogronowego*, *napój winny owocowy lub miodowy*, *aromatyzowany napój winny owocowy lub miodowy*, *wino owocowe niskoalkoholowe and aromatyzowane wino owocowe niskoalkoholowe*	Typical usage level reported as a range	175	200	FDE	

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

Appendix B. Summary of analytical results (mg/kg) of sorbic acid provided by Members States

FCS category number	Food category	MPL	All data				All data Middle bound					Positives values Middle bound					
			N	% LC	Range LOD	Range LOQ	Min	Median	Mean	P95 (a)	Max	N	Min	Median	Mean	P95 (a)	Max
01.3	Unflavoured fermented milk products	1 000	422	98	0.004–2.0	0.01–50	0.01	0.25	3.04	2.50	669	8	0.60	6.6	141	–	669
01.4	Flavoured fermented milk products including heat-treated products	300	876	95	0.004–20	0.01–50	0.01	0.25	4.32	5.00	264	43	0.40	69.0	80.1	–	264
01.7.1	Unripened cheese excluding products falling in category 16	1 000	107	95	0.07–1.7	0.20–5.0	0.10	2.50	24.5	2.50	960	5	110	430	491	–	960
01.7.2	Ripened cheese	1 000	502	96	0.004–10	0.01–10	0.01	0.25	4.74	5.00	820	21	4.00	24.0	89.6	–	820
01.7.4	Whey cheese	1 000	123	93	0.004–33.6	0.01–101	0.01	0.25	17.7	222	297	9	133	265	238	–	297
01.7.5	Processed cheese	2 000	447	88	0.004–33.6	0.01–101	0.01	0.25	42.8	189	1 819	53	1.00	162	352	–	1 819
01.7.6	Cheese products (excluding products falling in category 16)	*QS*/ 1 000	160	88	0.07–6.7	0.20–20	0.10	2.10	54.7	305	1 363	19	12.6	199	440	–	1 363
01.8	Dairy analogues, including beverage whiteners	*QS*	2	100	14–14	15–46	7.00	7.25	7.25	–	7.50	–	–	–	–	–	–
02.2.2	Other fat and oil emulsions including spreads as defined by Regulation (EC) No 1 234/2 007[2] and liquid emulsions—only fat emulsions (excluding butter) with a fat content of 60 % or more	1 000/ 2 000	183	50	0.004–20	0.01–50	0.01	93.0	288	1 088	1 338	92	93.0	555	568	1 166	1 338
04.1.1	Entire fresh fruit and vegetables	20	83	100	0.004–10	0.01–20	0.01	2.50	2.59	2.5	5.00	–	–	–	–	–	–
	Only citrus fruits		5	100	1.7–1.7	5.0–5.0	2.50	2.50	2.50	–	2.50	–	–	–	–	–	–
04.2.1	Dried fruit and vegetables	1 000	1 266	52	0.004–20	0.01–60	0.01	10.0	199	704	999	607	1.23	409	412	829	999

FCS category number	Food category	MPL	All data				All data Middle bound					Positives values Middle bound					
			N	% LC	Range LOD	Range LOQ	Min	Median	Mean	P95 (a)	Max	N	Min	Median	Mean	P95 (a)	Max
04.2.2	Fruit and vegetables in vinegar, oil or brine—only vegetables (excluding olives)	2 000	851	87	0.004–20	0.01–50	0.01	2.50	43.8	429	1 922	111	1.31	198	315	1 000	1 922
04.2.2	Fruit and vegetables in vinegar, oil or brine—only olives and olive-based preparations	1 000	70	81	1.0–20	3.0–50	0.5	7.50	36.2	181	414	13	36	143	165	–	414
04.2.4.1	Fruit and vegetable preparations excluding compote—only fruit and vegetable preparations including seaweed-based preparations, fruit-based sauces, aspic, excluding purée, mousse, compote, salads and similar products, canned or bottled	1 000	39	97	0.3–10	0.9–30	0.15	7.50	7.25	–	24.6	1	–	–	–	–	24.6
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2 001/113/EC	1 000	1 307	66	0.004–25	0.01–75	0.01	5.0	121	600	960	445	1.0	318	350	780	960
04.2.5.3	Extra jam and extra jelly as defined by Directive 2 001/113/EEC	1 000	254	97	0.2–20	0.5–50	0.25	10.0	21.5	10.0	517	11	30.0	346	340	–	517
04.2.5.3	Other similar fruit or vegetable spreads—other fruit-based spreads, *mermeladas*	1 000	465	61	0.07–20	0.2–75	0.10	10.0	165	680	817	182	50.0	392	409	740	817
04.2.5.3	Other similar fruit or vegetable spreads—only *marmelada*	1 500	112	50	0.07–25	0.2–75	0.10	31.2	192	690	870	56	50.0	351	379	–	870

FCS category number	Food category	MPL	All data				All data Middle bound					Positives values Middle bound					
			N	% LC	Range LOD	Range LOQ	Min	Median	Mean	P95 (a)	Max	N	Min	Median	Mean	P95 (a)	Max
04.2.6	Processed potato products	2 000	105	40	0.07–20	0.2–50	0.05	932	845	1 794	1 936	63	13.0	1 585	1 410	1 805	1 936
05.2	Other confectionery including breath-freshening microsweets—except candied, crystallised or glacé fruit and vegetables	1 500	319	79	0.004–20	0.01–50	0.01	2.50	92.4	699	1 156	66	10.0	416	433	940	1 156
05.2	Other confectionery including breath-freshening microsweets—only candied, crystallised or glacé fruit and vegetables	1 000	128	82	0.004–11	0.01–30	0.005	0.50	45.0	265	775	23	1.86	212	225	–	775
05.3	Chewing gum	1 500	6	100	0.2–20	0.5–50	0.25	5.25	5.21	–	10.0	–	–	–	–	–	–
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	1 000/ 1 500	73	58	4.2–4.2	10–14	2.10	2.10	236	705	980	31	25.3	553	552	–	980
06.4.4	Potato gnocchi	1 000	12	17	3.3–20	10–20	5.00	680	594	–	904	10	496	737	712	–	904
07.1	Bread and rolls	2 000	1 625	91	0.07–50	0.2–50	0.10	5.00	92.2	858	1 999	139	6.83	1 200	1 009	1 931	1 999
07.2	Fine bakery wares	2 000	2 597	48	0.004–33.8	0.01–101	0.01	10.00	205	1 186	2 000	1 351	0.40	148	390	1 476	2 000
08.2.1	Non-heat-treated processed meat	*QS*	94	37	0.13–20	0.13–20	0.06	32.3	61.2	199	849	59	6.08	52.8	95.1	–	849
08.2.2	Heat-treated processed meat	1 000	90	76	0.004–24.8	0.01–101	0.01	2.50	72.1	609	860	22	4.30	120	290	–	860
	Only pâté		7	86	1.0–1.7	3.0–5.0	0.5	2.5	124	–	860	1	–	–	860	–	–
08.2.3	Casings and coatings and decorations for meat	*QS*	1	0	–	–		–	5.40	–	5.40	1	–	–	5.40	–	–
09.2	Processed fish and fishery products including molluscs and crustaceans	1 000/ 200/ 2 000/ 6 000	1 318	57	0.001–74.3	0.003–223	0.01	10.0	144	641	1 982	571	0.02	250	326	1 100	1 982
	Only fish meat	200	559	81	0.004–5.0	0.01–20	0.005	2.50	13.8	93.2	194	104	0.69	50.2	64.5	180	194
	Only fish products, including crustaceans	2 000	213	45	0.07–50	0.2–150	0.50	222	391	1 200	1 900	117	35.0	591	706	1 400	1 900

FCS category number	Food category	MPL	All data				All data Middle bound					Positives values Middle bound					
			N	% LC	Range LOD	Range LOQ	Min	Median	Mean	P95 (a)	Max	N	Min	Median	Mean	P95 (a)	Max
	and molluscs																
09.3	Fish roe	2 000	85	60	0.004–6.7	0.01–20	0.01	2.50	248	890	1 100	34	44.6	665	615	–	1 100
10.2	Processed eggs and egg products—only dehydrated and concentrated frozen and deep frozen egg products	1 000	1	100	–	10	–	–	5.0	–	5.0	–	–	–	–	–	–
10.2	Processed eggs and egg products—only liquid egg	5 000	60	70	0.5–24.8	1.5–101	0.25	5.00	537	2 868	3 460	18	352	1 498	1 806	–	3 460
11.4.1	Table-top sweeteners in liquid form	500	2	0	3.3–6.7	10–20	462	477	477	–	491	2	462	477	477	–	491
12.2.2	Seasonings and condiments	1 000	1 196	56	0.004–31.5	0.01–95	0.01	10.0	194	792	980	523	3.90	411	436	885	980
12.4	Mustard	1 000	431	97	0.04–30	0.01–50	0.01	0.50	10.3	7.50	859	11	1.00	183	344	–	859
12.5	Soups and broths	500	347	98	0.004–20	0.01–50	0.01	0.25	4.52	7.50	460	8	9.30	83.8	146	–	460
12.6	Sauces—only emulsified sauces	2 000	292	33	0.02–6.7	0.5–50	2.50	555	655	1 771	2 000	195	61.0	910	980	1 800	2 000
12.6	Sauces—non-emulsified sauces	1 000	490	67	0.004–20	0.01–75	0.01	2.50	153	740	952	164	3.10	447	453	860	952
12.7	Salads and savoury-based sandwich spreads	1 500	2 704	35	0.001–221	0.003–662	0.01	154	269	866	1 500	1 753	0.02	359	409	956	1 500
12.9	Protein products, excluding products covered in category 1.8	2 000	1	100	–	15–15	–	–	7.50	–	7.50	–	–	–	–	–	–
13.2	Dietary foods for special medical purposes defined in Directive 1 999/21/EC (excluding products from food category 13.1.5)	1 500	150	82	0.1–100	0.5–100	0.05	5.00	68.3	478	1 178	27	4.00	384	349	–	1 178

FCS category number	Food category	MPL	All data				All data Middle bound					Positives values Middle bound					
			N	% LC	Range LOD	Range LOQ	Min	Median	Mean	P95 (a)	Max	N	Min	Median	Mean	P95 (a)	Max
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)	1 500	1	100	–	15–15	–	–	7.50	–	7.50	–	–	–	–	–	–
14.1.2	Fruit juices as defined by Directive 2 001/112/EC[14] and vegetable juices	500/ 2 000	1 067	83	0.004–500	0.01–500	0.01	1.00	33.8	207	1 320	179	1.10	157	189	592	1 320
14.1.3	Fruit nectars as defined by Council Directive 2 001/112/EC and vegetable nectars and similar products	300/ 250	175	94	0.004–10	0.01–20	0.01	1.00	9.56	22.0	298	11	5.00	101	125	–	298
14.1.4	Flavoured drinks	300	5 022	64	0.001–500	0.003–500	0.00	3.00	40.4	185	300	1 791	0.06	110	109	229	300
14.1.5.2	Other	600	23	39	0.1–3.3	0.5–10	0.50	52.9	127	–	427	14	2.50	207	207	–	427
14.2.1	Beer and malt beverages	200	208	95	0.07–5.0	0.2–15	0.05	0.25	1.06	7.50	33.0	10	2.17	2.70	7.00	33.0	33.0
14.2.2	Wine and other products defined by Regulation (EC) No 1 234/2 007, and alcohol-free counterparts	200	879	59	0.004–10	0.01–14	0.01	5.00	43.8	160	199	359	1.08	114	102	173	199
14.2.3	Cider and perry	200	550	88	0.004–200	0.01–200	0.05	5.00	19.4	149	196	66	11.0	147	133	177	196
14.2.4	Fruit wine and made wine	200	695	71	0.004–10	0.01–15	0.01	5.00	40.3	161	192	203	1.57	138	129	172	192
14.2.5	Mead	200	83	88	0.1–10	0.5–20	0.30	0.35	11.0	122	192	10	2.15	120	86.4	–	192
14.2.7.1	Aromatised wines	200	17	18	0.004–10	0.01–10	0.25	116	88.9	–	146	14	31.3	119	108	–	146
	Only vermouth	200	4	25	0.004–0.3	0.01–1.0	0.25	81.3	76.0	–	141	3	31.3	141	101	–	141
14.2.7.2	Aromatised wine-based drinks except bitter soda, sangria, claria, zurra	200	52	79	0.004–10	0.01–15	0.30	5.00	35.3	–	197	11	57.0	163	153	–	197
14.2.7.3	Aromatised wine-product cocktails	200	35	97	5.0–10	10–10	2.50	5.00	8.73	–	138	1	–	–	138	–	–

FCS category number	Food category	MPL	All data				All data Middle bound					Positives values Middle bound					
			N	% LC	Range LOD	Range LOQ	Min	Median	Mean	P95 (a)	Max	N	Min	Median	Mean	P95 (a)	Max
14.2.8	Other alcoholic drinks including spirits with less than 15 % of alcohol and mixtures of alcoholic drinks with non-alcoholic drinks	200	324	39	0.004–10	10–10	0.01	114	90.8	180	200	199	2.21	157	146	181	200
	Alcopop		45	20	0.3–1.7	1.0–10	0.5	135	119	–	190	36	89.9	150	149	–	190
15.1	Potato-, cereal-, flour- or starch-based snacks	1 000	153	92	0.004–20	0.01–50	0.01	2.50	8.76	23.5	217	13	6.00	35.1	49.6	–	217
15.2	Processed nuts	1 000	5	100	0.3–1.7	1.0–20	0.50	2.50	3.60	–	10.0	–	–	–	–	–	–
16	Desserts excluding products covered in categories 01, 03 and 04	1 000/ 2 000/ 300	517	93	0.004–20	0.01–50	0.01	5.00	21.60	51.3	761	36	1.00	135	250	–	761
17.1/ 17.2	Food supplements	1 000/ 2 000	182	51	0.001–100	0.003–101	0.005	13.3	368	1 183	1 736	70	0.005	847	740	1 380	1 736

% 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): The 95th percentile obtained on occurrence data with fewer than 60 analytical results may not be statistically robust (EFSA, 2011a) and therefore are not reported in the table.

Appendix C. Concentration levels of sorbic acid and sorbates (E 200, 202, 203) used in the MPL scenario and refined exposure scenario using only reported use levels (mg/kg)

FCS category number	FCS food category	MPL	MPL scenario	Concentration levels used in the refined exposure assessment scenario (only reported use levels)		Comments
				Mean	Maximum	
01.3	Unflavoured fermented milk products	1 000	–	–	–	Not taken into account (no corresponding FoodEx code)
01.4	Flavoured fermented milk products including heat-treated products	300	–	–	–	Not taken into account (no corresponding FoodEx code)
01.7.1	Unripened cheese excluding products falling in category 16	1 000	1 000	–	–	Use levels not available
01.7.2	Ripened cheese—only cheese, prepacked, slices and cut; layered cheese and cheese with added foods	1 000	1 000	–	–	Use levels not available
01.7.2	Ripened cheese—only ripened products surface treatment	*QS*	–	–	–	Not taken into account (no corresponding FoodEx code)
01.7.4	Whey cheese	1 000	1 000	–	–	Use levels not available
01.7.5	Processed cheese	2 000	2 000	1 450	1 450	
01.7.6	Cheese products (excluding products falling in category 16)—only unripened products; ripened products, prepacked, sliced; layered ripened products and ripened products with added foods	1 000	–	–	–	Not taken into account (no corresponding FoodEx code)
01.7.6	Cheese products (excluding products falling in category 16)—only ripened products surface treatment	*QS*	–	–	–	Not taken into account (no corresponding FoodEx code)
01.8	Dairy analogues, including beverage whiteners—only cheese analogues (surface treatment only)	*QS*	1 450	1 450	1 450	

FCS category number	FCS food category	MPL	MPL scenario	Concentration levels used in the refined exposure assessment scenario (only reported use levels)		Comments
				Mean	Maximum	
01.8	Dairy analogues, including beverage whiteners—only analogues of cheese based on protein	2 000	–	–	–	Not taken into account (no corresponding FoodEx code)
02.2.2	Other fat and oil emulsions including spreads as defined by Regulation (EC) No 1 234/2 007[2] and liquid emulsions—only fat emulsions (excluding butter) with a fat content of 60 % or more	1 000	–	–	–	Not taken into account (not possible to distinguish between a fat content of less and more than 60 %)
02.2.2	Other fat and oil emulsions including spreads as defined by Regulation (EC) No 1 234/2 007[2] and liquid emulsions—only fat emulsions with a fat content less than 60 %	2 000	2 000	1 500	2 000	Not possible to distinguish between a fat content of less and more than 60 %; therefore, a higher MPL of 2 000 mg/kg was considered
04.1.1	Entire fresh fruit and vegetables—only citrus fruits	20	20	–	–	Use levels not available
04.2.1	Dried fruit and vegetables	1 000	1 000	750	1 000	
04.2.2	Fruit and vegetables in vinegar, oil or brine—only vegetables (excluding olives)	2 000	2 000	400	800	
04.2.2	Fruit and vegetables in vinegar, oil or brine—only olives and olive-based preparations	2 000	2 000	750	1 000	
04.2.4.1	Fruit and vegetable preparations excluding compote—only fruit and vegetable preparations including seaweed-based preparations, fruit-based sauces, aspic, excluding purée, mousse, compote, salads and similar products, canned or bottled	1 000	1 000	–	–	Use levels not available

FCS category number	FCS food category	MPL	MPL scenario	Concentration levels used in the refined exposure assessment scenario (only reported use levels)		Comments
				Mean	Maximum	
04.2.4.1	Fruit and vegetable preparations excluding compote—only olive-based preparations	1 000	–	–	–	Not taken into account (no corresponding FoodEx code)
04.2.5.1	Extra jam and extra jelly as defined by Directive 2 001/113/EC	1 000	–	–	–	Not taken into account (no corresponding FoodEx code)
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2 001/113/EC	1 000	1 000	5	6	
04.2.5.3	Other similar fruit or vegetable spreads—other fruit-based spreads, *mermeladas*	1 000	1 000	5	6	
04.2.5.3	Other similar fruit or vegetable spreads—only *marmelada*	1 500	1 500	5	6	
04.2.6	Processed potato products	2 000	–	–	–	Not taken into account (no corresponding FoodEx code)
05.2	Other confectionery including breath-freshening microsweets—except candied, crystallised or glacé fruit and vegetables	1 500	1 500	553	1 500	
05.2	Other confectionery including breath-freshening microsweets—only candied, crystallised or glacé fruit and vegetables	1 000	1 000	–	–	Use levels not available
05.3	Chewing gum	1 500	1 500	–	–	Use levels not available
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4—only toppings (syrups for pancakes, flavoured syrups for milkshakes and ice cream; similar products)	1 000	–	–	–	Not taken into account (no corresponding FoodEx code)

FCS category number	FCS food category	MPL	MPL scenario	Concentration levels used in the refined exposure assessment scenario (only reported use levels)		Comments
				Mean	Maximum	
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	1 500	–	–	–	Not taken into account (no corresponding FoodEx code)
06.4.4	Potato gnocchi	1 000	–	–	–	Not taken into account (no corresponding FoodEx code)
06.4.5	Fillings of stuffed pasta (ravioli and similar)	1 000	1 000	160	160	
06.6	Batters	2 000	–	–	–	Not taken into account (no corresponding FoodEx code)
06.7	Pre-cooked or processed cereals—only *polenta*	2 000	–	–	–	Not taken into account (no corresponding FoodEx code)
06.7	Pre-cooked or processed cereals—only *semmelknödelteig*	2 000	–	–	–	Not taken into account (no corresponding FoodEx code)
07.1	Bread and rolls	2 000	2 000	1 425	2 000	
07.2	Fine bakery wares	2 000	2 000	1 068	2 000	
08.3.1	Non-heat-treated processed meat, only surface treatment of dried meat products	*QS*	–	–	–	Not taken into account (no corresponding FoodEx code)
08.3.2	Heat-treated processed meat—only pâté	1 000	1 000	–	–	Use levels not available
08.3.2	Heat-treated processed meat—only aspic	1 000	–	–	–	Not taken into account (no corresponding FoodEx code)
08.3.2	Heat-treated processed meat—only surface treatment of dried meat products	*QS*	–	–	–	Not taken into account (no corresponding FoodEx code)
08.3.3	Casings and coatings and decorations for meat—only collagen-based casings with water activity greater than 0.6	*QS*	–	–	–	Not taken into account (no corresponding FoodEx code)
08.3.3	Casings and coatings and decorations for meat—only jelly coatings of meat products (cooked, cured or dried)	1 000	–	–	–	Not taken into account (no corresponding FoodEx code)

FCS category number	FCS food category	MPL	MPL scenario	Concentration levels used in the refined exposure assessment scenario (only reported use levels)		Comments
				Mean	Maximum	
09.2	Processed fish and fishery products including molluscs and crustaceans—aspic	1 000	–	–	–	Not taken into account (no corresponding FoodEx code)
09.2	Processed fish and fishery products including molluscs and crustaceans—only salted, dried fish	200	200	–	–	Use levels not available
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	2 000	2 000	–	–	Use levels not available
09.2	Processed fish and fishery products including molluscs and crustaceans—only cooked *Crangon crangon* and *Crangon vulgaris*	6 000	–	–	–	Not taken into account (no corresponding FoodEx code)
09.3	Fish roe	2 000	2 000	600	600	
10.2	Processed eggs and egg products—only dehydrated and concentrated frozen and deep frozen egg products	1 000	1 000	–	–	Use levels not available
10.2	Processed eggs and egg products—only liquid egg	5 000	5 000	–	–	Use levels not available
11.4.1	Table-top sweeteners in liquid form	500	–	–	–	Not taken into account (no corresponding FoodEx code)
12.2.2	Seasonings and condiments	1 000	1 000	500	500	
12.4	Mustard	1 000	1 000	250	500	
12.5	Soups and broths	500	500	–	–	Use levels not available
12.6	Sauces—only emulsified sauces with a fat content of less than 60 %	2 000	2 000	500	1 000	

FCS category number	FCS food category	MPL	MPL scenario	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	1 000	–	–	–	Not taken into account (covered in 12.6 Sauces, only emulsified sauces with a fat content of less than 60 %)
12.6	Sauces—only emulsified sauces with a fat content of 60 % or more; non-emulsified sauces	1 000	1 000	425	500	
12.7	Salads and savoury-based sandwich spreads	1 500	1 500	–	–	Use levels not available
12.9	Protein products, excluding products covered in category 1.8	2 000	2 000	–	–	Use levels not available
13.2	Dietary foods for special medical purposes defined in Directive 1 999/21/EC (excluding products from food category 13.1.5)	1 500	1 500	550	550	
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)	1 500	1 500	–	–	Use levels not available
14.1.2	Fruit juices as defined by Directive 2 001/112/EC[14] and vegetable juices—only Sød … saft and sødet … saft	500	–	–	–	Not taken into account (no corresponding FoodEx code)
14.1.2	Fruit juices as defined by Directive 2 001/112/EC[14] and vegetable juices—only grape juice, unfermented, for sacramental use	2 000	–	–	–	Not taken into account (no corresponding FoodEx code)
14.1.3	Fruit nectars as defined by Council Directive 2 001/112/EC and vegetable nectars and similar products—only traditional Swedish and Finnish fruit syrups	300	–	–	–	Not taken into account (no corresponding FoodEx code)

FCS category number	FCS food category	MPL	MPL scenario	Concentration levels used in the refined exposure assessment scenario (only reported use levels)		Comments
				Mean	Maximum	
14.1.3	Fruit nectars as defined by Council Directive 2 001/112/EC and vegetable nectars and similar products—only traditional Swedish fruit syrups, maximum applies if E 210–213, benzoic acid — benzoates, have also been used	250	–	–	–	Not taken into account (no corresponding FoodEx code)
14.1.4	Flavoured drinks—excluding dairy-based drinks	300	300	135	300	
14.1.4	Flavoured drinks—maximum applies if E 210–213, benzoic acid — benzoates, have also been used	250	–	–	–	Not taken into account (covered by category 14.1.4)
14.1.5.2	Other—only liquid tea concentrates and liquid fruit and herbal infusion concentrates	600	–	–	–	Not taken into account (no corresponding FoodEx code)
14.2.1	Beer and malt beverages, only beer in kegs containing more than 0.5 % added fermentable sugar and/or fruit juices or concentrates	200	–	–	–	Not taken into account (no corresponding FoodEx code)
14.2.2	Wine and other products defined by Regulation (EC) No 1 234/2 007, and alcohol-free counterparts, only alcohol free	200	–	–	–	Not taken into account (no corresponding FoodEx code)
14.2.3	Cider and perry	200	200	–	–	Use levels not available
14.2.4	Fruit wine and made wine	200	–	–	–	Not taken into account (no corresponding FoodEx code)
14.2.5	Mead	200	–	–	–	Not taken into account (no corresponding FoodEx code)
14.2.7.1	Aromatised wines	200	200	–	–	Use levels not available
14.2.7.2	Aromatised wine-based drinks except bitter soda, sangria, claria, zurra	200	–	–	–	Not taken into account (no corresponding FoodEx code)

FCS category number	FCS food category	MPL	MPL scenario	Concentration levels used in the refined exposure assessment scenario (only reported use levels)		Comments
				Mean	Maximum	
14.2.7.3	Aromatised wine-product cocktails	200	–	–	–	Not taken into account (no corresponding FoodEx code)
14.2.8	Other alcoholic drinks including spirits with less than 15 % of alcohol and mixtures of alcoholic drinks with non-alcoholic drinks	200	200	175	200	
15.1	Potato-, cereal-, flour- or starch-based snacks	1 000	1 000	–	–	Use levels not available
15.2	Processed nuts	1 000	1 000	–	–	Use levels not available
16	Desserts excluding products covered in categories 01, 03 and 04—only *frugtgrød*, *rote Grütze* and *pasha*	1 000	–	–	–	Not taken into account (no corresponding FoodEx code)
16	Desserts excluding products covered in categories 01, 03 and 04—only *ostkaka*	2 000	–	–	–	Not taken into account (no corresponding FoodEx code)
16	Desserts excluding products covered in categories 01, 03 and 04—only non-heat-treated dairy-based desserts	300	–	–	–	Not taken into account (no corresponding FoodEx code)
17.1/ 17.2	Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms	1 000/2 000	2 000	–	–	Use levels not available

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

Appendix D. Summary of total estimated exposure to sorbic acid – sorbates (E 200, 202, 203) from their use as food additives per population group and survey for the MPL scenario and refined exposure scenario using only reported use levels: mean and high level (mg/kg bw/day)

	Number of subjects	MPL scenario		Brand–loyal scenario		Non–brand–loyal scenario	
		Mean	High level	Mean	High level	Mean	High level
Toddlers							
Belgium (Regional_Flanders)	36	23.7	–	13.7	–	10.6	–
Bulgaria (NUTRICHILD)	428	17.3	33.9	13.2	27.7	9.6	20.4
Germany (DONALD_2006_2008)	261	9.7	20.7	7.4	16.0	5.4	11.7
Italy (INRAN_SCAI_2005_06)	36	10.1	–	6.6	–	5.2	–
Spain (EnKid)	17	7.7	–	8.3	–	6.6	–
The Netherlands (VCP_kids)	322	14.2	30.3	9.0	21.6	6.6	15.6
Children							
Belgium (Regional_Flanders)	625	18.3	31.4	11.5	20.9	8.7	16.1
Bulgaria (NUTRICHILD)	433	19.9	38.7	15.3	30.8	11.3	23.1
Czech Republic (SISP04)	389	13.6	24.7	10.2	19.7	7.7	14.6
Denmark (Danish_Dietary_Survey)	490	16.7	27.4	12.8	20.7	9.6	15.5
Finland (STRIP)	250	15.5	25.2	9.5	17.7	7.1	12.5
France (INCA2)	482	13.0	24.0	8.6	16.6	6.1	11.7
Germany (DONALD_2006_2008)	660	10.9	20.1	7.7	15.0	5.7	11.1
Greece (Regional_Crete)	839	10.1	20.6	4.4	11.0	2.5	6.1
Italy (INRAN_SCAI_2005_06)	193	11.2	24.6	8.1	19.2	6.0	13.9
Latvia (EFSA_TEST)	189	13.6	27.9	7.5	17.8	5.4	13.8
Spain (enKid)	156	11.1	20.7	8.4	16.9	6.6	13.0
Spain (NUT_INK05)	399	11.4	20.0	8.1	14.8	6.1	11.1
Sweden (NFA)	1 473	15.2	26.4	9.0	16.8	6.7	12.2
The Netherlands (VCP_kids)	957	12.8	26.5	8.1	18.0	5.9	13.0
Adolescents							
Belgium (Diet_National_2004)	584	10.0	18.2	6.6	12.0	4.8	8.9
Cyprus (Childhealth)	303	4.7	10.1	2.8	6.3	2.0	4.7
Czech Republic (SISP04)	298	11.5	25.1	8.4	19.0	6.3	13.7
Denmark (Danish_Dietary_Survey)	479	9.6	17.3	7.1	13.0	5.3	9.6
France (INCA2)	973	7.9	15.7	5.6	11.7	4.1	8.3
Germany (National_Nutrition_Survey_II)	1 011	7.9	16.7	5.4	12.1	4.0	8.7
Italy (INRAN_SCAI_2005_06)	247	7.2	15.3	5.1	12.0	3.8	8.6
Latvia (EFSA_TEST)	470	11.2	23.5	6.5	14.7	4.8	10.8
Spain (AESAN_FIAB)	86	6.4	12.8	4.7	9.3	3.4	6.4
Spain (enKid)	209	9.1	19.4	7.0	16.3	5.2	12.4

	Number of subjects	MPL scenario		Brand–loyal scenario		Non–brand–loyal scenario	
		Mean	High level	Mean	High level	Mean	High level
Spain (NUT_INK05)	651	8.1	14.9	6.0	11.4	4.5	8.5
Sweden (NFA)	1 018	9.9	19.0	6.1	11.9	4.5	8.8
Adults							
Belgium (Diet_National_2004)	1 304	8.2	16.1	5.2	10.8	3.8	8.1
Czech Republic (SISP04)	1 666	7.5	14.4	5.5	11.1	4.2	8.4
Denmark (Danish_Dietary_Survey)	2 822	6.5	11.2	5.0	8.8	3.7	6.5
France (INCA2)	2 276	6.3	12.0	4.4	8.6	3.2	6.4
Germany (National_Nutrition_Survey_II)	1 0419	6.9	13.5	4.6	9.6	3.4	6.9
Hungary (National_Repr_Surv)	1 074	6.6	12.7	4.8	9.3	3.6	6.9
Ireland (NSIFCS)	958	6.4	12.0	4.8	9.3	3.7	7.0
Italy (INRAN_SCAI_2005_06)	2 313	5.1	10.0	3.6	7.9	2.6	5.8
Latvia (EFSA_TEST)	1 306	8.3	16.3	4.8	10.9	3.5	7.9
Spain (AESAN)	410	5.0	10.1	3.6	7.2	2.6	5.4
Spain (AESAN_FIAB)	981	5.0	10.5	3.6	7.6	2.6	5.7
Sweden (Riksmaten_1997_98)	1 210	6.8	11.8	4.0	7.3	3.0	5.5
The Netherland (DNFCS_2003)	750	8.9	15.2	6.0	10.4	4.5	7.9
United Kingdom (NDNS)	1 724	5.6	9.9	3.9	7.2	3.0	5.5
Elderly and very elderly							
Belgium (Diet_National_2004)	1 230	7.1	12.8	4.3	8.1	3.2	6.0
Denmark (Danish_Dietary_Survey)	329	5.7	9.6	4.6	7.8	3.4	5.7
France (INCA2)	348	6.4	12.2	4.5	9.0	3.4	6.5
Germany (National_Nutrition_Survey_II)	2 496	6.7	12.6	4.6	9.2	3.4	6.6
Hungary (National_Repr_Surv)	286	6.0	10.5	4.5	7.9	3.4	6.0
Italy (INRAN_SCAI_2005_06)	518	5.0	10.3	3.9	8.7	2.8	6.2

Appendix E. Main food categories contributing to exposure to sorbic acid – sorbates (E 200, 202, 203) using MPLs (> 5 % of the total mean exposure) and the number of surveys in which each food category is contributing

FCS category number	Foods	Toddlers	Children	Adolescents	Adults	The elderly [(a)]
		Range of percentage contribution to the total exposure (number of surveys)				
01.7.1	Unripened cheese excluding products falling in category 16	5.4–6.5 (4)	5.1–9.0 (3)	9.7 (1)	10.2 (1)	6.9 (1)
01.7.2	Ripened cheese	6.8–8.8 (3)	5.8 (1)	5.3–12.0 (2)	5.4–7.1 (3)	5.0–7.2 (3)
01.7.5	Processed cheese	17.7 (1)	–	–	–	–
02.2.2	Other fat and oil emulsions including spreads as defined by Regulation (EC) No 1 234/2 007 [2] and liquid emulsions	–	–	–	7.9 (1)	–
04.2	Processed fruit and vegetables	8.3 (1)	5.4 (1)	6.6 (1)	8.3–19.2 (2)	5.8–18.6 (2)
05.2	Other confectionery including breath-freshening microsweets	–	5.4–6.1 (3)	5.8–5.8 (2)	–	–
06.4.5	Fillings of stuffed pasta (ravioli and similar)	–	5.4–11.7 (2)	8.1 (1)	–	
07.1	Bread and rolls	34.4–64.0 (6)	26.1–65.4 (13)	31.7–59.6 (12)	34.9–66.5 (14)	45.6–75.0 (6)
07.2.	Fine bakery wares	8.8–31.4 (6)	11.8–39.1 (13)	14.6—34.6 (11)	10.1–24.4 (12)	5.2–23.9 (5)
09.2	Processed fish and fishery products	–	–	–	5.6 (1)	–
10.2	Processed eggs and egg products	–	16.0 (1)	5.3 (1)	–	–
12.5	Soups and broths	10.6 (1)	5.6–15.2 (3)	5.1–11.5 (2)	7.5–11.4 (2)	6.1–14.3 (2)
12.6	Sauces	–	5.2–8.6 (5)	5.0–9.6 (6)	5.3–9.2 (6)	5.1–5.8 (3)
12.7	Salads and savoury-based sandwich spreads	–	9.8–12.2 (2)	11.7 (1)	9.8–15.4 (2)	–
14.1.4	Flavoured drinks	7.2–10.7 (2)	5.9–18.0 (9)	5.1–20.7 (12)	6.0–17.5 (11)	–
15.2	Potato-, cereal-, flour- or starch-based snacks	5.2 (1)	–	–	–	–

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.

Appendix F. Main food categories contributing to the exposure to sorbic acid – sorbates (E 200, 202, 203) using reported use levels 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	Foods	Toddlers	Children	Adolescents	Adults	The elderly [(a)]
		Range of percentage contribution to the total exposure (number of surveys)				
01.7.5	Processed cheese	19.7 (1)	6.5 (1)	–	–	–
02.2.2	Other fat and oil emulsions including spreads as defined by Regulation (EC) No 1 234/2 007 [2] and liquid emulsions	–	–	–	7.9 (1)	–
04.2	Processed fruit and vegetables	–	–	–	7.6 (1)	6.7 (1)
07.1	Bread and rolls	52.0–82.9 (6)	38.2–85.7 (13)	47.0–79.8 (12)	56.4–85.8 (14)	65.9–92.4 (6)
07.2.	Fine bakery wares	8.4–38.5 (6)	11.6–85.5 (13)	14.6–41.4 (11)	7.8–26.9 (12)	5.3–28.3 (5)
12.6	Sauces	–	5.6 (1)	5.3 (1)	5.2 (1)	–
14.1.4	Flavoured drinks	6.8–9.6 (2)	5.7–19.3 (9)	5.4–23.2 (8)	5.7–17.6 (9)	–

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.

Appendix G. Main food categories contributing to the exposure to sorbic acid – sorbates (E 200, 202, 203) using reported use levels 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	Foods	Toddlers	Children	Adolescents	Adults	The elderly [(a)]
		Range of percentage contribution to the total exposure (number of surveys)				
01.7.5	Processed cheese	25.2–40.1 (2)	5.3–11.8 (4)	–	–	–
02.2.2	Other fat and oil emulsions including spreads as defined by Regulation (EC) No 1 234/2 007 [2] and liquid emulsions	–	–	–	10.2 (1)	–
04.2	Processed fruit and vegetables	–	–	–	9.6 (1)	8.9 (1)
07.1	Bread and rolls	38.6–82.2 (6)	42.0–81.2 (13)	49.3–76.5 (12)	56.6–83.0 (14)	67.1–89.6 (6)
07.2.	Fine bakery wares	8.4–25.4 (6)	12.0–82.4 (13)	14.3–35.6 (11)	9.3–25.4 (12)	6.5–25.7 (4)
12.6	Sauces	–	6.0–7.6 (2)	6.2–7.0 (2)	5.7–6.7 (2)	–
14.1.4	Flavoured drinks	7.0–10.7 (2)	6.1–18.3 (9)	5.0–19.2 (11)	5.0–15.7 (10)	–

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.

Appendix H. Concentration levels of sorbic acid – sorbates (E 200, 202, 203) used in the refined exposure scenario using reported use levels and analytical data (mg/kg)

FCS category number	FCS food category	MPL	Concentration levels used in the refined exposure assessment scenario (reported use levels and analytical data)		Data source/comments
			Mean	Maximum	
01.3	Unflavoured fermented milk products	1 000	–	–	Not taken into account (no corresponding FoodEx code)
01.4	Flavoured fermented milk products including heat-treated products	300	–	–	Not taken into account (no corresponding FoodEx code)
01.7.1	Unripened cheese excluding products falling in category 16	1 000	24.5	960	Analytical data
01.7.2	Ripened cheese—only cheese, prepacked, slices and cut; layered cheese and cheese with added foods	1 000	4.74	820	Analytical data
01.7.2	Ripened cheese—only ripened products surface treatment	*QS*	–	–	Not taken into account (no corresponding FoodEx code)
01.7.4	Whey cheese	1 000	17.7	297	Analytical data
01.7.5	Processed cheese	2 000	42.8	1 819	Analytical data
01.7.6	Cheese products (excluding products falling in category 16)—only unripened products; ripened products, prepacked, sliced; layered ripened products and ripened products with added foods	1 000	–	–	Not taken into account (no corresponding FoodEx code)
01.7.6	Cheese products (excluding products falling in category 16)—only ripened products surface treatment	*QS*	–	–	Not taken into account (no corresponding FoodEx code)
01.8	Dairy analogues, including beverage whiteners—only cheese analogues (surface treatment only)	*QS*	1 450	1 450	Usage levels
01.8	Dairy analogues, including beverage whiteners—only analogues of cheese based on protein	2 000	–	–	Not taken into account (no corresponding FoodEx code)

FCS category number	FCS food category	MPL	Concentration levels used in the refined exposure assessment scenario (reported use levels and analytical data)		Data source/comments
			Mean	Maximum	
02.2.2	Other fat and oil emulsions including spreads as defined by Regulation (EC) No 1 234/2 007[2] and liquid emulsions—only fat emulsions (excluding butter) with a fat content of 60 % or more	1 000	–	–	Not taken into account (not possible to distinguish between a fat content of less and more than 60 %)
02.2.2	Other fat and oil emulsions including spreads as defined by Regulation (EC) No 1 234/2 007[2] and liquid emulsions—only fat emulsions with a fat content less than 60 %	2 000	288	1 338	Analytical data used for mean; typical usage levels reported as a range, and therefore it was not possible to calculate the mean; use level used for maximum, as it was higher than the maximum analytical level
03	Edible ices [(a)]	–	20	20	–
04.1.1	Entire fresh fruit and vegetables—only citrus fruits	20	2.50	2.50	Analytical data
04.2.1	Dried fruit and vegetables	1 000	199	999	Analytical data
04.2.2	Fruit and vegetables in vinegar, oil or brine—only vegetables (excluding olives)	2 000	43.8	1 922	Analytical data
04.2.2	Fruit and vegetables in vinegar, oil or brine—only olives and olive-based preparations	2 000	36.2	414	Analytical data
04.2.4.1	Fruit and vegetable preparations excluding compote—only fruit and vegetable preparations including seaweed-based preparations, fruit-based sauces, aspic, excluding purée, mousse, compote, salads and similar products, canned or bottled	1 000	7.50	24.6	Analytical data
04.2.4.1	Fruit and vegetable preparations excluding compote—only olive-based preparations	1 000	–	–	Not taken into account (no corresponding FoodEx code)
04.2.5.1	Extra jam and extra jelly as defined by Directive 2 001/113/EC	1 000	–	–	Not taken into account (no corresponding FoodEx code)
04.2.5.2	Jam, jellies and marmalades and sweetened chestnut purée as defined by Directive 2 001/113/EC	1 000	121	960	Analytical data
04.2.5.3	Other similar fruit or vegetable spreads—other fruit-based spreads, *mermeladas*	1 000	156	817	Analytical data

FCS category number	FCS food category	MPL	Concentration levels used in the refined exposure assessment scenario (reported use levels and analytical data)		Data source/comments
			Mean	Maximum	
04.2.5.3	Other similar fruit or vegetable spreads—only *marmelada*	1 500	192	870	Analytical data
04.2.6	Processed potato products	2 000	–	–	Not taken into account (no corresponding FoodEx code)
05.1	Cocoa and chocolate products [(a)]	–	20	20	–
05.2	Other confectionery including breath-freshening microsweets—except candied, crystallised or glacé fruit and vegetables	1 500	92.4	1 156	Analytical data
05.2	Other confectionery including breath-freshening microsweets—only candied, crystallised or glacé fruit and vegetables	1 000	45.0	775	Analytical data
05.3	Chewing gum	1 500	5.21	10.0	Analytical data
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4—only toppings (syrups for pancakes, flavoured syrups for milkshakes and ice cream; similar products)	1 000	–	–	Not taken into account (no corresponding FoodEx code)
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	1 500	–	–	Not taken into account (no corresponding FoodEx code)
06.4.4	Potato gnocchi	1 000	–	–	Not taken into account (no corresponding FoodEx code)
06.4.5	Fillings of stuffed pasta (ravioli and similar)	1 000	160	160	Usage data
06.6	Batters	2 000	–	–	Not taken into account (no corresponding FoodEx code)
06.7	Pre-cooked or processed cereals—only *polenta*	2 000	–	–	Not taken into account (no corresponding FoodEx code)
06.7	Pre-cooked or processed cereals—only *semmelknödelteig*	2 000	–	–	Not taken into account (no corresponding FoodEx code)
07.1	Bread and rolls	2 000	92.2	1 999	Analytical data
07.2	Fine bakery wares	2 000	205	2 000	Analytical data
08.3.1	Non-heat-treated processed meat, only surface treatment of dried meat products	*QS*	–	–	Not taken into account (no corresponding FoodEx code)
08.3.2	Heat-treated processed meat— only pâté	1 000	124	860	Analytical data

FCS category number	FCS food category	MPL	Concentration levels used in the refined exposure assessment scenario (reported use levels and analytical data)		Data source/comments
			Mean	Maximum	
08.3.2	Heat-treated processed meat—only aspic	1 000	–	–	Not taken into account (no corresponding FoodEx code)
08.3.2	Heat-treated processed meat—only surface treatment of dried meat products	*QS*	–	–	Not taken into account (no corresponding FoodEx code)
08.3.3	Casings and coatings and decorations for meat—only collagen-based casings with water activity greater than 0.6	*QS*	–	–	Not taken into account (no corresponding FoodEx code)
08.3.3	Casings and coatings and decorations for meat—only jelly coatings of meat products (cooked, cured or dried)	1 000	–	–	Not taken into account (no corresponding FoodEx code)
09.2	Processed fish and fishery products including molluscs and crustaceans—aspic	1 000	–	–	Not taken into account (no corresponding FoodEx code)
09.2	Processed fish and fishery products including molluscs and crustaceans—only salted, dried fish	200	13.8	194	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	2 000	391	1 900	Analytical data
09.2	Processed fish and fishery products including molluscs and crustaceans—only cooked *Crangon crangon* and *Crangon vulgaris*	6 000	–	–	Not taken into account (no corresponding FoodEx code)
09.3	Fish roe	2 000	248	1 100	Analytical data
10.2	Processed eggs and egg products—only dehydrated and concentrated frozen and deep frozen egg products	1 000	5.00	5.00	Analytical data
10.2	Processed eggs and egg products—only liquid egg	5 000	537	3 460	Analytical data
11.4.1	Table-top sweeteners in liquid form	500	–	–	Not taken into account (no corresponding FoodEx code)
12.2.2	Seasonings and condiments	1 000	194	980	Analytical data
12.4	Mustard	1 000	10.3	859	Analytical data

FCS category number	FCS food category	MPL	Concentration levels used in the refined exposure assessment scenario (reported use levels and analytical data)		Data source/comments
			Mean	Maximum	
12.5	Soups and broths	500	4.52	460	Analytical data
12.6	Sauces—only emulsified sauces with a fat content of less than 60 %	2 000	655	2 000	Analytical data
12.6	Sauces—only emulsified sauces with a fat content of 60 % or more	1 000	–	–	Not taken into account (covered in category 12.6 Sauces, only emulsified sauces with a fat content of less than 60 %)
12.6	Sauces—only emulsified sauces with a fat content of 60 % or more; non-emulsified sauces	1 000	153	952	Analytical data
12.7	Salads and savoury-based sandwich spreads	1 500	269	1 500	Analytical data
12.9	Protein products, excluding products covered in category 1.8	2 000	7.50	7.50	Analytical data
13.2	Dietary foods for special medical purposes defined in Directive 1 999/21/EC (excluding products from food category 13.1.5)	1 500	68.3	1 178	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)	1 500	7.50	7.50	Analytical data
14.1.2	Fruit juices as defined by Directive 2 001/112/EC[14] and vegetable juices—only Sød … saft and sødet … saft	500	–	–	Not taken into account (no corresponding FoodEx code)
14.1.2	Fruit juices as defined by Directive 2 001/112/EC[14] and vegetable juices—only grape juice, unfermented, for sacramental use	2 000	–	–	Not taken into account (no corresponding FoodEx code)
14.1.3	Fruit nectars as defined by Council Directive 2 001/112/EC and vegetable nectars and similar products—only traditional Swedish and Finnish fruit syrups	300	–	–	Not taken into account (no corresponding FoodEx code)

FCS category number	FCS food category	MPL	Concentration levels used in the refined exposure assessment scenario (reported use levels and analytical data)		Data source/comments
			Mean	Maximum	
14.1.3	Fruit nectars as defined by Council Directive 2 001/112/EC and vegetable nectars and similar products—only traditional Swedish fruit syrups, maximum applies if E 210–213, benzoic acid — benzoates, have also been used	250	–	–	Not taken into account (no corresponding FoodEx code)
14.1.4	Flavoured drinks—excluding dairy-based drinks	300	40.4	300	Analytical data
14.1.4	Flavoured drinks—maximum applies if E 210–213, benzoic acid — benzoates, have also been used	250	–	–	Not taken into account (covered by category 14.1.4)
14.1.5.2	Other—only liquid tea concentrates and liquid fruit and herbal infusion concentrates	600	–	–	Not taken into account (no corresponding FoodEx code)
14.2.1	Beer and malt beverages, only beer in kegs containing more than 0.5 % added fermentable sugar and/or fruit juices or concentrates	200	–	–	Not taken into account (no corresponding FoodEx code)
14.2.2	Wine and other products defined by Regulation (EC) No 1 234/2 007, and alcohol-free counterparts, only alcohol-free	200	–	–	Not taken into account (no corresponding FoodEx code)
14.2.3	Cider and perry	200	19.4	196	Analytical data
14.2.4	Fruit wine and made wine	200	–	–	Not taken into account (no corresponding FoodEx code)
14.2.5	Mead	200	–	–	Not taken into account (no corresponding FoodEx code)
14.2.7.1	Aromatised wines	200	81.3	141	Analytical data (only ‘Vermouth’ taken into account)
14.2.7.2	Aromatised wine-based drinks except bitter soda, sangria, claria, zurra	200	–	–	Not taken into account (no corresponding FoodEx code)
14.2.7.3	Aromatised wine-product cocktails	200	–	–	Not taken into account (no corresponding FoodEx code)
14.2.8	Other alcoholic drinks including spirits with less than 15 % of alcohol and mixtures of alcoholic drinks with non-alcoholic drinks	200	135	190	Analytical data (only “Alcopop” taken into account)
15.1	Potato-, cereal-, flour- or starch-based snacks	1 000	8.76	217	Analytical data
15.2	Processed nuts	1 000	3.60	10.0	Analytical data

FCS category number	FCS food category	MPL	Concentration levels used in the refined exposure assessment scenario (reported use levels and analytical data)		Data source/comments
			Mean	Maximum	
16	Desserts excluding products covered in categories 01, 03 and 04—only *frugtgrød*, *rote Grütze* and *pasha*	1 000	–	–	Not taken into account (no corresponding FoodEx code)
16	Desserts excluding products covered in categories 01, 03 and 04—only *ostkaka*	2 000	–	–	Not taken into account (no corresponding FoodEx code)
16	Desserts excluding products covered in categories 01, 03 and 04—only non-heat-treated dairy-based desserts	300	–	–	Not taken into account (no corresponding FoodEx code)
17.1/ 17.2	Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms	1 000/2 000	368	1 736	Analytical data
18	Processed food not covered by categories 1 to 17, excluding foods for infants and young children [(a)]	–	20	20	–

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

(a): Food category for which direct addition of sorbic acid is not authorised according to Annex II to Regulation (EC) No 1 333/2 008; however, the use of sorbic acid may result in its presence in these food categories because of carry-over.

Appendix I. Summary of total estimated exposure to sorbic acid and sorbates (E 200, 202, 203) from their use as food additives per population group and survey for the refined exposure scenario using reported use levels and analytical data: mean and high level (mg/kg bw/day)

	Number of subjects	Brand-loyal scenario		Non-brand-loyal scenario	
		Mean	High level	Mean	High level
Toddlers					
Belgium (Regional_Flanders)	36	11.9	–	1.8	–
Bulgaria (NUTRICHILD)	428	11.8	23.4	1.5	3.1
Germany (DONALD_2006_2008)	261	7.4	15.2	1.2	2.2
Italy (INRAN_SCAI_2005_06)	36	6.0	–	0.7	–
Spain (EnKid)	17	5.6	–	0.9	–
The Netherlands (VCP_kids)	322	8.1	19.0	1.5	2.9
Children					
Belgium (Regional_Flanders)	625	9.8	18.2	1.4	2.8
Bulgaria (NUTRICHILD)	433	13.0	26.5	1.7	3.7
Czech Republic (SISP04)	389	8.2	14.6	1.4	2.6
Denmark (Danish_Dietary_Survey)	490	12.0	19.8	1.5	2.5
Finland (STRIP)	250	7.1	12.8	1.5	2.5
France (INCA2)	482	7.0	13.4	1.3	2.5
Germany (DONALD_2006_2008)	660	6.6	12.6	1.1	2.0
Greece (Regional_Crete)	839	5.4	11.3	1.1	2.4
Italy (INRAN_SCAI_2005_06)	193	7.2	17.7	0.9	1.8
Latvia (EFSA_TEST)	189	7.0	15.3	1.1	2.6
Spain (enKid)	156	7.4	14.7	1.1	2.2
Spain (NUT_INK05)	399	7.5	13.5	1.1	2.0
Sweden (NFA)	1 473	6.9	12.9	1.6	2.9
The Netherlands (VCP_kids)	957	7.0	14.9	1.3	2.5
Adolescents					
Belgium (Diet_National_2004)	584	5.3	9.4	1.0	1.8
Cyprus (Childhealth)	303	2.5	5.6	0.4	0.9
Czech Republic (SISP04)	298	6.8	14.5	1.1	2.4
Denmark (Danish_Dietary_Survey)	479	6.4	12.0	0.9	1.6
France (INCA2)	973	4.5	9.4	0.8	1.6
Germany (National_Nutrition_Survey_II)	1 011	4.6	10.2	0.7	1.6
Italy (INRAN_SCAI_2005_06)	247	4.5	10.0	0.6	1.3
Latvia (EFSA_TEST)	470	6.1	13.3	0.9	2.0
Spain (AESAN_FIAB)	86	4.2	7.3	0.6	1.4
Spain (enKid)	209	6.0	14.8	0.9	1.8

	Number of subjects	Brand-loyal scenario		Non-brand-loyal scenario	
		Mean	High level	Mean	High level
Spain (NUT_INK05)	651	5.4	10.7	0.8	1.5
Sweden (NFA)	1 018	4.8	9.1	1.0	2.1
Adults					
Belgium (Diet_National_2004)	1 304	4.4	8.8	0.7	1.7
Czech Republic (SISP04)	1 666	4.8	9.3	0.7	1.3
Denmark (Danish_Dietary_Survey)	2 822	4.8	8.5	0.7	1.2
France (INCA2)	2 276	3.8	7.8	0.6	1.2
Germany (National_Nutrition_Survey_II)	1 0419	4.0	8.1	0.6	1.3
Hungary (National_Repr_Surv)	1 074	4.4	8.5	0.3	0.7
Ireland (NSIFCS)	958	4.1	7.8	0.6	1.1
Italy (INRAN_SCAI_2005_06)	2 313	3.4	7.3	0.4	0.8
Latvia (EFSA_TEST)	1 306	4.7	10.0	0.7	1.4
Spain (AESAN)	410	3.3	6.6	0.5	1.2
Spain (AESAN_FIAB)	981	3.2	6.6	0.5	1.2
Sweden (Riksmaten_1997_98)	1 210	3.4	5.9	0.8	1.4
The Netherland (DNFCS_2003)	750	4.9	8.7	0.8	1.5
United Kingdom (NDNS)	1 724	3.3	6.1	0.6	1.1
Elderly					
Belgium (Diet_National_2004)	1 230	3.9	7.4	0.5	1.1
Denmark (Danish_Dietary_Survey)	329	4.6	7.8	0.5	1.0
France (INCA2)	348	4.1	8.2	0.6	1.1
Germany (National_Nutrition_Survey_II)	2 496	4.0	7.8	0.5	1.2
Hungary (National_Repr_Surv)	286	4.1	7.1	0.3	0.6
Italy (INRAN_SCAI_2005_06)	518	3.7	8.0	0.3	0.7

Appendix J. Main food categories contributing to the exposure to sorbic acid – sorbates (E 200, 202, 203) using reported use levels and analytical data 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	Foods	Toddlers	Children	Adolescents	Adults	The elderly [(a)]
		Range of percentage contribution to the total exposure (number of surveys)				
01.7.1	Unripened cheese excluding products falling in category 16	5.5 (1)	–	–	–	–
01.7.5	Processed cheese	11.7 (1)	–	–	–	–
04.2	Processed fruit and vegetables	–	–	–	7.7 (1)	5.4 (1)
07.1	Bread and rolls	50.2–79.1 (6)	30.0–91.0 (13)	46.7–85.7 (12)	54.0–88.0 (14)	66.5–92.5 (6)
07.2.	Fine bakery wares	5.4–35.8 (5)	8.0–64.0 (13)	10.4–42.7 (11)	5.5–23.3 (11)	12.1–24.8 (3)
10.2	Processed eggs and egg products	–	12.2 (1)	–	–	–
12.6	Sauces	–	–	5.4–5.7 (2)	5.1–5.1 (2)	–
12.7	Salads and savoury-based sandwich spreads	–	11.3–11.4 (2)	10.1 (1)	6.6–13.9 (2)	–
14.1.4	Flavoured drinks	5.2 (1)	6.5–16.7 (6)	7.0–22.7 (5)	6.0–15.3 (6)	–
18	Processed food not covered by categories 1 to 17, excluding foods for infants and young children	5.0–8.3 (3)	5.3 (1)	–	5.1 (1)	–

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.

Appendix K. Main food categories contributing to the exposure to sorbic acid –sorbates (E 200, 202, 203) using reported use levels and analytical data 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	Foods	Toddlers	Children	Adolescents	Adults	The elderly [(a)]
		Range of percentage contribution to the total exposure (number of surveys)				
01.7.5	Processed cheese	5.3 (1)	–	–	–	–
01.8	Dairy analogues	5.0–13.4 (2)	6.0–9.3 (2)	–	–	–
02.2.2	Other fat and oil emulsions including spreads as defined by Regulation (EC) No 1 234/2 007 [2] and liquid emulsions	–	–	–	12.5 (1)	–
04.2	Processed fruit and vegetables	–	–	–	11.1 (1)	6.2–11.7 (3)
06.4.5	Fillings of stuffed pasta (ravioli and similar)	–	8.9–17.3 (2)	16.5 (1)	–	–
07.1	Bread and rolls	15.5–29.3 (6)	11.4–32.8 (13)	14.1–32.0 (12)	14.0–56.9 (14)	27.4–61.9 (6)
07.2	Fine bakery wares	7.2–31.4 (6)	12.1–37.5 (13)	15.0–35.2 (11)	5.3–25.8 (13)	5.1–31.1 (6)
09.2	Processed fish and fishery products	5.2 (1)	5.0 (1)	7.0–7.0 (2)	6.8–7.8 (3)	–
10.2	Processed eggs and egg products	–	15.9 (1)	7.3 (1)	–	–
12.2.2	Seasonings and condiments	–	–	–	5.3 (1)	–
12.6	Sauces	8.2–10.8 (2)	8.0–15.2 (10)	7.7–23.0 (8)	7.4–23.1 (9)	5.9–17.3 (4)
12.7	Salads and savoury-based sandwich spreads		16.1–26.4 (2)	5.5–26.0 (2)	15.2–34.3 (2)	
14.1.4	Flavoured drinks	9.5–19.0 (2)	5.0–22.9 (12)	8.0–28.8 (12)	6.1–25.3 (12)	6.1–6.6 (2)
18	Processed food not covered by categories 1 to 17, excluding foods for infants and young children	27.8–50.6 (5)	5.5–35.3 (12)	5.0–32.3 (10)	8.1–35.6 (11)	6.2–11.7 (3)

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.

ABBREVIATIONS

ADI	Acceptable Daily Intake
ANOVA	analysis of covariance
ANS	Scientific Panel on Food Additives and Nutrient Sources added to Food
BA	benzoic acid and benzoates
BrdU	5-bromo-2′-deoxyuridine
bw	body weight
CAS	Chemical Abstracts Service
CHO	Chinese hamster ovary
DAD	diode array detector
DNA	deoxyribonucleic acid
EC	European Commission
EDTA	ethylenediaminetetraacetic acid
EINECS	European Inventory of Existing Commercial chemical Substances
ENA	ethylnitrolic acid
FAO/WHO	Food and Agriculture Organization/World Health Organization
FCS	Food Categorisation System
FDA	Food and Drug Administration
FDE	FoodDrinkEurope
FDRL	Food and Drug Research Laboratories
FEEDAP	Scientific Panel on Additives and Products or Substances used in Animal Feed
GC	chromatography gas
GD	gestation day
GLP	Good Laboratory Practice
GMP	good manufacturing practice
GRAS	generally recognised as safe
HPLC	high-performance liquid chromatography
HPRT	hypoxanthine-guanine phosphoribosyl transferase
JECFA	Joint FAO/WHO Expert Committee on Food Additives
LD_{50}	lethal dose, 50 %, i.e. dose that causes death among 50 % of treated animals
LOD	limit of detection
LOQ	limit of quantification
LSD	least significant difference
MPL	maximum permitted level
MS	mass spectrometry
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development

PHB	*p*-hydroxybenzoates
QS	*quantum satis*
SA	sorbic acid and sorbates
SCE	sister chromatid exchange
SCF	EU Scientific Committee on Food
SHE	Syrian hamster embryo
UDS	unscheduled DNA synthesis
UNESDA	Union of European Soft Drinks Associations
UV	ultraviolet