Vitenskapskomiteen for mattrygghet
Norwegian Scientific Committee for Food Safety

Risk assessments of aspartame, acesulfame K, sucralose and benzoic acid from soft drinks, “saft”, nectar and flavoured water

Opinion of the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics of the Norwegian Scientific Committee for Food Safety

VKM Report 2014: 26

Contributors

Persons working for VKM as appointed members of the Committee do this by virtue of their scientific expertise, not as representatives for their employers. The Civil Services Act instructions on legal competence apply for all work prepared by VKM.

Acknowledgements

VKM wishes to acknowledge Trine Husøy and Gro Haarklou Mathisen for their valuable contribution to this opinion. Inger Therese Laugsand Lillegaard is acknowledged for calculating the dietary exposures.

Assessed by

This opinion has been evaluated and approved by the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics of VKM.

Members of the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics assessing and approving the version published 20.12.2013:
Inger-Lise Steffensen (Chair), Jan Alexander, Mona-Lise Binderup, Knut Helkås Dahl, Berit Granum, Ragna Bogen Hetland, Trine Husøy, Jan Erik Paulsen, Vibeke Thrane.

Members of the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics assessing and approving the version published 28.11.2014:
Inger-Lise Steffensen (Chair), Ellen Bruzell, Berit Granum, Bente Brokstad Herlofson, Ragna Bogen Hetland, Trine Husøy, Jens Rohloff, Trude Wicklund.

Scientific coordinators from the secretariat
Inger Therese Laugsand Lillegaard, Gro Haarklou Mathisen

ISBN: 978-82-8259-151-5

Norwegian Scientific Committee for Food Safety (VKM)
Po 4404 Nydalen
N – 0403 Oslo
Norway

Phone: +47 21 62 28 00
Email: vkm@vkm.no

www.vkm.no
www.english.vkm.no

Summary

The Norwegian Scientific Committee for Food Safety (Vitenskapskomiteen for mattrygghet, VKM), Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics, has at the request of the Norwegian Food Safety Authority (Mattilsynet) conducted a risk assessment of the intense sweeteners aspartame, acesulfame K and sucralose and the preservative benzoic acid from soft drinks, "saft", nectar and flavoured water. The risk assessment includes exposure assessments and the calculated exposures are compared to the acceptable daily intake (ADI) for the respective sweeteners and benzoic acid. VKM was also requested to compare the current calculated intake of aspartame, acesulfame K and benzoic acid to the calculated intake reported by VKM in 2007 (from the VKM report «Impact on health when sugar is replaced with intense sweeteners in soft drinks, «saft» and nectar») (VKM, 2007).

Exposure calculations were made for four different scenarios with varying concentrations of added sweeteners (either the average concentration or the highest reported concentration for the respective sweetener) and varying consumption of beverages with sweeteners (either the actual reported consumption of beverages added sweetener or the assumption that all reported beverages were added sweeteners). Scenario 1 gives the best estimate of the current situation in the population (average content of sweeteners/benzoic acid, actual reported consumption), scenarios 2-4 is based on one or both of the following assumptions: only beverages added sweeteners are consumed, the beverages consumed are added the highest reported value of the sweeteners (scenario 2: average content of sweeteners/benzoic acid, all consumed beverages contain sweeteners; scenario 3: highest reported content of sweeteners/benzoic acid, actual reported consumption; scenario 4: highest reported content of sweeteners/benzoic acid, all consumed beverages contain sweeteners).

In the current risk assessment, the intake of sweeteners and benzoic acid for two-year-old children and 18-70 year old men and women were calculated. Due to lack of new dietary surveys, the other age groups of children and adolescents were excluded. The estimated intake of aspartame, acesulfame K and sucralose was below the ADI for all age groups, both for mean and high consumers in all scenarios. When it comes to benzoic acid, the calculated mean and high intake for adults was below the ADI in all scenarios. The mean intake for 2-year-olds was below ADI in all scenarios, as was the intake for high consumers among the 2-year-olds in scenarios 1 and 2. However, high consumers among the two-year-old children in scenario 3 and 4 reached the ADI.

Due to differences in the way the calculations were done in the current opinion and in 2007, it was not possible to compare the current calculated intake of aspartame, acesulfame K and benzoic acid to the calculated intakes reported by VKM in 2007.

VKM concludes that for all age groups in all scenarios the intake of sweeteners is well below the established ADI values, thus, there is no concern related to the intake of the sweeteners aspartame, acesulfame K or sucralose.

VKM further concludes that the benzoic acid intake in 2-year-old-children, in scenarios 3 and 4, is of concern as it reaches ADI for high consumers of soft drinks, "saft" and flavoured water, although the ADI is not a threshold for toxicity. For the other age groups, there is no concern related to the intake of benzoic acid from beverages. However, it should be noted that a considerable intake of benzoic acid also is expected from other sources such as food and cosmetics. High consumers of soft drinks, "saft" or flavoured water in all age groups could be at risk for approaching or exceeding ADI if the exposures from foods are taken into account.

This is especially of concern for 2-year-old children, since high consumers of soft drinks and "saft" already have reached the ADI.

Norsk sammendrag

Vitenskapskomiteen for mattrygghet (VKM), Faggruppen for tilsetningsstoffer, aroma, matemballasje og kosmetikk, har på oppdrag fra Mattilsynet gjennomført en risikovurdering av de intense søtstoffene aspartam, acesulfam K og sukralose og konserveringsmiddelet benzosyre i leskedrikker, saft, nektar og vann tilsatt smak. Mattilsynet ba om at vurderingen skulle inneholde inntaksberegninger for hvert stoff og at disse skulle sammenlignes med fastsatte verdier for akseptabelt daglig inntak (ADI) av stoffene. VKM ble også bedt om å sammenligne inntaksberegningene med de som ble gjort i VKMs risikovurdering fra 2007 «Impact on health when sugar is replaced with intense sweeteners in soft drinks, «saft» and nectar» hvis det var mulig (VKM, 2007).

Eksponeringsberegningene ble gjort for fire ulike scenarier hvor det som varierte var konsentrasjonen av søtstoff (konsentrasjonene som ble brukt var enten gjennomsnittskonsentrasjonen eller den høyeste rapporterte konsentrasjonen) og inntaket av drikke tilsatt søtstoff (det som ble brukt var enten inntaket som var rapportert i kostholdsundersøkelsene eller antagelsen om at alt rapportert drikke innen for kategoriene inneholdt søtstoff). Scenario 1 gir det beste estimatet av dagens situasjon i befolkningen (gjennomsnittskonsentrasjonen av søtstoff, rapportert inntak av drikkevarer). Scenariene 2-4 er basert på en eller begge av følgende forutsetninger: bare drikker tilsatt søtstoffer er konsumert, drikkene som er konsumert inneholder høyeste rapporterte mengde av søtstoffene (scenario 2: gjennomsnittskonsentrasjonen av søtstoff, kun konsum av drikkevarer tilsatt søtstoffer; scenario 3: høyeste rapporterte konsentrasjon av søtstoff, rapportert inntak av drikkevarer; scenario 4: høyesterapporterte konsentrasjon av søtstoff, kun konsum av drikkevarer tilsatt søtstoffer).

I denne vurderingen ble inntaket til toåringer og voksne (18-70 år) beregnet. På grunn av at det ikke er nye kostholdsundersøkelser tilgjengelig for de andre aldersgruppene ble ikke barn over to år og ungdom inkludert i denne risikovurderingen. Det beregnede inntaket av aspartam, acesulfam K og sukralose ligger under ADI hos alle aldersgrupper, både for gjennomsnittskonsumenter og for høykonsumenter, i alle scenariene. Når det gjelder benzosyre ligger det beregnede inntaket under ADI for gjennomsnittlig og høyt inntak hos voksne i alle scenariene. Gjennomsnittlig inntak hos toåringer var under ADI i alle scenariene, og også blant høykonsumenter av leskedrikker og saft blant toåringene i scenarioene 1 og 2. I scenarioene 3 og 4 for høykonsumentene blant to-åringene, når derimot inntaket ADI. Det var ikke mulig å sammenligne inntaksberegningene i denne risikovurderingen med de som ble gjort i VKMs risikovurdering fra 2007 på grunn av forskjeller i hvordan beregningene ble gjort.

VKM konkluderer med at for alle aldersgrupper er inntaket av de intense søtstoffene aspartam, acesulfam K og sukralose under ADI-verdiene og derfor ikke av bekymring.

VKM konkluderer videre at det beregnede inntaket av benzosyre hos høykonsumenter blant toåringene (i scenariene 3 og 4) er bekymringsfullt siden det overskrider ADI, selv om ADI ikke er en terskelverdi for toksisitet. Inntaket av benzosyre fra drikkevarer er under ADI for alle voksne. Det er viktig å merke seg at det beregnede inntaket kun omfatter drikkevarer og at man i tillegg kan få i seg benzosyre fra andre kilder, som for eksempel mat og

kroppspleieprodukter. Høykonsumenter av leskedrikker, saft og vann tilsatt smak, i alle aldersgrupper, kan være i fare for å nærme seg eller overskride ADI hvis det tas hensyn til eksponering fra mat. Dette er spesielt bekymringsfullt for høykonsumentene av leskedrikker og saft blant toåringer siden disse allerede har nådd ADI.

Keywords

Acesulfame K, aspartame, benzoic acid, flavoured water, risk assessment, sucralose

Abbreviations

ADI; Acceptable daily intake

AFC; The EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food

ANS; The EFSA Scientific Panel on Food Additives and Nutrient Sources added to Food

DKP; 5-Benzyl-3,6-dioxo-2-piperazine acetic acid

EFSA; The European Food Safety Authority

JECFA; The Joint WHO/FAO Expert Committee on Food Additives

SCF; The (former) EU Scientific Committee for Food

Glossary

Acceptable daily intake (ADI); the amount of a substance that people can consume on a daily basis during their whole life without any appreciable risk to health. ADIs are usually expressed in mg per kg of body weight (mg/kg bw).

Average concentration of sweetener or benzoic acid in each product category; reported concentrations in each product within a product category multiplied by the relative sales volume for the specific product/brand.

Flavoured water; water added flavour and benzoic acid, without sugar or sweetener.

High consumers; consumption at the 95th percentile.

Nectar; an unfermented product consisting of fruit juice, water and sugar.

Preservative; a substance that protects drinks and foods against deterioration caused by micro-organisms.

Relative sales volume of the sweetener or benzoic acid within a product category; sales volume for each product (litre/year) divided by the total sales volume for the product category.

"Saft"; a concentrate produced from fruit juice which may contain sugar (mono- and disaccharides only) or intense sweeteners at specified levels. Flavourings and water is not added. "Saft" is a traditional Norwegian product and shall be mixed with water before drinking.

Soft drinks; include sodas with or without gas (sweetened with sugar or intense sweeteners), ice tea, non-alcoholic cider, sports drinks and "energy-drinks".

Weighted average of sweetener or benzoic acid; calculated from the average concentration of sweetener or benzoic acid for all products within a category adjusted for sales volume.

Contents

Contributors **1**
Acknowledgements 2
Assessed by 2
Summary **3**
Norsk sammendrag **4**
Keywords **5**
Abbreviations **5**
Glossary **5**
Contents **7**
Background **9**
Terms of reference **10**
Assessment **11**
1 Introduction **11**
1.1 The VKM risk assessment "Impact on health when sugar is replaced with intense sweeteners in soft drinks, "saft" and nectar" 11
2 Hazard characterization of aspartame, acesulfame K, sucralose and benzoic acid **12**
2.1 Aspartame (E951) 12
Evaluations by EFSA, SCF and JECFA 12
2.2 Acesulfame K (E950) 13
Evaluations by SCF and JECFA 13
2.3 Sucralose (E955) 13
Evaluations by SCF and JECFA 13
2.4 Benzoic acid (E210, E211, E212, E213) 14
Evaluations by SCF and JECFA 14
2.5 ADI values used in the current risk assessment 14
3 Exposure assessment **14**
3.1 Exposure assessment of aspartame (E951) 18
3.2 Exposure assessment of acesulfame K (E950) 24
3.3 Exposure assessment of sucralose (E955) 30
3.4 Exposure assessment of benzoic acid (E210, E211, E212, E213) 36
4 Risk assessment of aspartame, acesulfame K, sucralose and benzoic acid **42**
4.1 Aspartame 42
4.2 Acesulfame K 44
4.3 Sucralose 47
4.4 Benzoic acid 49
4.5 Comparison of the intake of aspartame, acesulfame K, sucralose and benzoic acid with the estimated intake from the VKM risk assessment in 2007 52
5 Uncertainties regarding human risk assessment **52**
5.1 Uncertainty regarding content 52
5.2 Uncertainty regarding dietary assessment 52
5.3 Summary of uncertainties 53
6 Discussion **54**
7 Conclusions **56**
8 Data gaps **56**

References **57**
Appendices **60**
Appendix 1 ..... **60**
Appendix 2 ..... **61**

Background

Beverages with added sweeteners may be considered as a favorable alternative to sugar-containing products. It has therefore been questioned whether the tax on drinks with added sweeteners should be decreased. The Norwegian Food Safety Authority has been commissioned by the Ministry of Health and Care Services to assess whether the consumption of drinks with added sweeteners pose a health risk to the population. To investigate this issue, it is essential to get new and updated knowledge of the intake levels of sweeteners in the Norwegian population. In order to provide a basis for answering the question asked by the Ministry, the Norwegian Food Safety Authority requested the Norwegian Scientific Committee for Food Safety (VKM) to calculate the intake of sweeteners and benzoic acid in the Norwegian population from consumption of beverages, and evaluate whether the intake exceeds the acceptable daily intake (ADI). VKM was also asked to describe trends in the intake of sweeteners from beverages over time if possible. If the intake of intense sweeteners or benzoic acid is higher than the ADI this may increase the risk of adverse health effects.

In 2007, VKM published a risk assessment in which health consequences of replacing sugar with sweeteners in soft drinks, juices and nectars were considered (title: “Impact on health when sugar is replaced with intense sweeteners in soft drinks, “saft” and nectar) (VKM, 2007). It was concluded that the intake of sweeteners was below the ADI even if all added sugars in soft drinks, juices and nectars were replaced with sweeteners. However, the estimated intake of acesulfame K was close to the ADI for the youngest children. Furthermore, the ADI for benzoic acid was exceeded among children at 1-4 years of age. VKM expressed concern about the high intake of benzoic acid.

The intake calculations in the 2007 VKM report was made on the basis of available dietary surveys conducted between 1997 and 2001. Since 2007 there have been two new dietary surveys, Småbarnskost and Norkost 3, which is used for the intake calculations in the current risk assessment.

The assignment is divided into two parts. Part A, the current assessment, addresses aspartame, acesulfame K, sucralose and benzoic acid. In part B (published 01.04.2014) the sweeteners cyclamate, saccharin, neohesperidine DC, steviol glycosides and neotam were addressed.

Terms of reference

The Norwegian Food Safety Authority requested the Norwegian Scientific Committee for Food Safety (VKM) to perform a risk assessment of aspartame, acesulfame K, sucralose and benzoic acid that cover the following points:

1. Estimate the intake of the sweeteners aspartame, acesulfame K, sucralose, and the preservation agent benzoic acid, from soft drinks ("leskedrikker"), "saft", nectar and flavoured water according to the scheme in Table 2. Furthermore, the Norwegian Food Safety Authority requests VKM to assess whether the estimated intake levels of acesulfame K, aspartame, sucralose and benzoic acid exceeds the acceptable daily intake (ADI) for the respective sweeteners and benzoic acid in the general population or in parts of the population. The intake estimates refer to each of the product categories separately: soft drinks, "saft", nectar and flavoured water.

2. To what extent has the intake of acesulfame K, aspartame, sucralose and benzoic acid from soft drinks, "saft", and nectar changed since the 2007 risk assessment? Describe the development over time, in the general population and also in relation to sex and age when possible.

Assessment

1 Introduction

Sweeteners are a category of food additives used to impart a sweet taste in foodstuffs and as table-top sweeteners. Sweeteners may be divided in two categories, the intense sweeteners and sugar alcohols. In this report the intense sweeteners aspartame, acesulfame K and sucralose are assessed. Aspartame (E951), acesulfame K (E950) and sucralose (E955) are all low-calorie, artificial intense sweeteners. Aspartame is 150-200 times sweeter than sugar, acesulfame K is 130-180 times sweeter than sugar, and sucralose is approximately 600 times sweeter than sugar (matportalen.no, 2013). It is common to use several sweeteners in combination to provide a better taste to food and drinks (matportalen.no, 2013). Benzoic acid (E210) and its salts sodium benzoate (E211), potassium benzoate (E212) and calcium benzoate (E213), are some of the most used preservatives in food and drinks.

1.1 The VKM risk assessment "Impact on health when sugar is replaced with intense sweeteners in soft drinks, "saft" and nectar"

In 2007, the risk assessment «Impact on health when sugar is replaced with intense sweeteners in soft drinks, «saft» and nectar» was published by the Norwegian Scientific Committee for Food Safety at a request from the Norwegian Food Safety Authority (VKM, 2007). The background for the initiation of this work was the focus on the high intake of added sugar as one of the most important health-related concerns in the diet of children and adolescents. The Norwegian Directorate for Health and Social Affairs therefore recommended a reduction in the consumption of sugar-sweetened soft drinks. This could result in a higher consumption of soft drinks with added sweeteners; therefore, the potential health risk of elevated intake of sweeteners was assessed. Since sugar has a preservative effect it was possible that the level of preservatives added to sugar-free drinks was increased compared to the level of preservatives added to sugar-containing drinks. Benzoic acid and its salts are widely used preservatives in drinks and food. Therefore, the assessment also included an evaluation of the potential health risk of elevated intake of benzoic acid.

The conclusions regarding aspartame, acesulfame K, sucralose and benzoic acid from the 2007 risk assessment were as follows (in short):

The estimated intakes of aspartame from soft drinks, "saft" and nectar were well below the acceptable daily intake (ADI) for all age groups both at the current level of intake and in the 50% and 100% scenarios (substituting 50% or 100% of the sugar in the products with sweeteners). In 2007, it was not possible to estimate the intake of sucralose because sucralose was first introduced to the Norwegian market in 2005. Altogether, no health concern was connected to the use of the above-mentioned sweeteners in soft drinks, "saft" and nectar. The estimated intake of acesulfame K for high consumers of soft drinks, "saft" and nectar in the age group 1-year-old children was close to the ADI, and the probability of exceeding ADI for acesulfame K was increased for high consumers (95th percentile) of the age groups 1- and 2-year-old children. This would represent an erosion of the safety margin for acesulfame K. The intake of acesulfame K was below ADI for all other age groups, also when shifting from the current level to the 100% scenario. The estimated total intake of benzoic acid was close to the ADI among high consumers (95th percentile) of soft drinks, "saft" and nectar in all groups

except men, and for the high consumers among 1-year-old children the estimated intake was higher than the ADI. Children (95th percentile) from 1- to 4-years of age were found to have the highest intake of benzoic acid on a body weight basis. The children's total exposure to benzoic acid was not known, and the estimated high intake of benzoic acid from foods and drinks in 1- to 4-year-old children in Norway should therefore be of special concern.

2 Hazard characterization of aspartame, acesulfame K, sucralose and benzoic acid

International bodies such as the European Food Safety Authority (EFSA), the (former) EU Scientific Committee on Food (SCF) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) have established values for the acceptable daily intake (ADI) of intense sweeteners and the preservative benzoic acid.

The ADI is an estimate of the amount that may be ingested daily over a lifetime, on a body weight basis, without appreciable health risk. The ADI is therefore expressed as the maximum acceptable intake, usually in term of mg/kg body weight (bw). In the current risk assessment, the ADI values established by EFSA are used. In cases where EFSA has not established an ADI, the ADI established by SCF are used. Due to the integrated uncertainty factors and the conservative way in which the ADI levels are derived, exceeding the ADI will initially only represent a reduced safety margin. Thus, the ADI is not a threshold for toxicity with onset of adverse effects.

2.1 Aspartame (E951)

Evaluations by EFSA, SCF and JECFA

Aspartame has been evaluated several times by JECFA (1975, 1980 and 1981), SCF (1985, 1989, 1997 and 2002) and EFSA (2006, 2009, 2011 and 2013). JECFA established an ADI of 0-40 mg/kg bw for aspartame in 1980 and 1981 (JECFA, 1981, JECFA, 1980). In 1984, SCF established 40 mg/kg bw as ADI for aspartame established from long-term studies (SCF, 1985), and this was not changed in subsequent re-evaluations. In 2006, the EFSA Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) assessed a long-term carcinogenicity study on aspartame, and based on previous and newly published literature, the AFC Panel concluded that there was no reason to revise the previously established ADI for aspartame of 40 mg/kg bw (EFSA, 2006).

The 2013 re-evaluation of aspartame by the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)

It has been decided that all food additives (including sweeteners) authorised in the EU shall be systematically re-evaluated by EFSA (anticipated under Regulation EU 257/2010), and the planned completion of this work is by 2020. In May 2011, EFSA was asked by the European Commission to bring forward the full re-evaluation of the safety of aspartame. EFSA accepted this mandate, and the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to deliver a scientific opinion on the re-evaluation of aspartame as a food additive. This is the first full risk assessment of aspartame requested of EFSA. The Panel

based its evaluation on original reports, previous evaluations, additional literature available since the previous evaluations, and the data made available following a public call for data.

Aspartame is degraded to L-phenylalanine and aspartic acid (amino acids), methanol, and 5-benzyl-3,6-dioxo-2-piperazine acetic acid (DKP). β-Aspartame, a non-sweet isomer of α-aspartame, may be present in the sweetener as impurities. In its re-evaluation of aspartame, the ANS Panel therefore considered the safety of methanol, phenylalanine, aspartic acid, DKP and β-aspartame, in addition to aspartame.

The conclusion of the 2013 assessment of aspartame was that there were no safety concerns at the current ADI of 40 mg/kg bw, and therefore no reason to revise the ADI for aspartame (EFSA, 2013). The EFSA ANS Panel emphasised that the ensuing ADI is not applicable to phenylketonuria patients (individuals homozygous for phenylalanine hydroxylase mutation resulting in a markedly reduced capacity for phenylalanine metabolism). These individuals require total control of dietary phenylalanine intake to manage the risk from elevated phenylalanine plasma levels.

For a detailed description of the 2013 establishment of the ADI, please see the EFSA report (EFSA, 2013).

2.2 Acesulfame K (E950)

Evaluations by SCF and JECFA

An ADI of 9 mg/kg bw for acesulfame K was established by SCF in 1984 (SCF, 1985). In 2000, SCF reaffirmed the ADI set in 1984 (SCF, 2000b). JECFA established an ADI of 0-9 mg/kg bw/day for acesulfame K in 1983 (JECFA, 1983). In 1991, after reviewing new data, JECFA changed the previously established ADI to 0-15 mg/kg bw (JECFA, 1991b).

For a detailed description of the SCF establishment of the ADI, please see the reports from SCF (SCF, 1985, SCF, 2000b).

2.3 Sucralose (E955)

Evaluations by SCF and JECFA

The first SCF opinion of sucralose was published in 1989, concluding that sucralose was toxicologically unacceptable due to unresolved questions concerning some of the observed treatment-related effects on body weight, organ weights and haematological parameters; it was unclear whether effects observed in laboratory animals was secondary to a cascade of events caused by impalatability of sucralose when given in the diet or if it was due to a direct toxic action of sucralose itself (SCF, 1989). In 2000, SCF re-evaluated sucralose, and an ADI of 15 mg/kg bw was established (SCF, 2000a). In 1989 and 1991, sucralose was evaluated by JECFA (JECFA, 1989, JECFA, 1991a), and the ADI of 0-15 mg/kg bw was established by JECFA in 1991 (JECFA, 1991a).

For a detailed description of the SCF establishment of the ADI, please see the SCF report (SCF, 2000a).

2.4 Benzoic acid (E210, E211, E212, E213)

Evaluations by SCF and JECFA

Benzoic acid and its salts were evaluated by SCF in 1994 and 2002, and in 2002 SCF established an ADI of 5 mg/kg bw for benzoic acid and its salts, including benzyl alcohol and related benzyl derivatives used as flavourings (SCF, 2002). Benzyl alcohol was evaluated by SCF in a separate opinion in 2002, and SCF confirmed the inclusion of benzyl alcohol in the group ADI of 5 mg/kg bw for benzoic acid and benzoates.
Benzoic acid and its salts were evaluated by JECFA in 1974 and an ADI of 0-5 mg/kg bw/day was established (JECFA, 1974). In 1996, JECFA performed a full re-evaluation of the toxicity of benzyl acetate, benzyl alcohol, benzaldehyde, and benzoic acid and its salts together in one opinion, and the group ADI of 0-5 mg/kg bw was maintained (JECFA, 1996).

For a detailed description of the SCF establishment of the ADI, please see the SCF report (SCF, 2002).

2.5 ADI values used in the current risk assessment

An overview of the ADI values used in the current risk assessment is given in Table 1.

Table 1: An overview of the ADI values used in the current risk assessment.

Substance	ADI	Reference
Aspartame	40 mg/kg bw	(EFSA, 2013)
Acesulfame K	9 mg/kg bw	(SCF, 2000b)
Sucralose	15 mg/kg bw	(SCF, 2000a)
Benzoic acid	5 mg/kg bw	(SCF, 2002)

3 Exposure assessment

The exposure assessments were performed for four different scenarios. Scenario 1 gives the best estimate of the current situation in the population. Scenario 2 gives an estimate of the exposure among the part of the population who only consume beverages added sweeteners (it is assumed that all reported consume of soft drinks, “saft” or nectar contains sweeteners, no added sugar), and the level of added sweeteners is average (based on reported content that is adjusted for sale). Scenarios 3 and 4 covers the part of the population that always consume the same brand (brand loyal customers), and it is assumed that they are loyal to the brand added the highest reported level of sweeteners or benzoic acid. Scenario 3 gives an estimate of the exposure for the part of the brand loyal population with an actual consumption of beverages as reported in dietary surveys, whereas scenario 4 gives an estimate of the exposure among the part of the brand loyal population who only consume beverages added sweeteners (it is

assumed that all reported consume of soft drinks, "saft" or nectar containsws sweeteners, no added sugar).

In this risk assessment, the intake of intense sweeteners and benzoic acid is evaluated from beverages divided in the categories soft drinks, "saft", nectar and flavoured water, based on data from 2012 received from the industry in October 2013. In Norway, the sweeteners aspartame and acesulfame K are used in the beverage categories soft drinks, "saft" and nectar, sucralose is used in the categories soft drinks and "saft", and benzoic acid is used in soft drinks, "saft" and flavoured water. Therefore, all exposure assessments include soft drinks and "saft" whereas nectar only is included in the exposure assessments for aspartame and acesulfame K, and flavoured water is only included in the exposure assessments for benzoic acid. None of the participants in the dietary surveys reported consume of nectar added aspartame or acesulfame K; therefore nectar is only included in scenario 3 and 4 for aspartame and acesulfame K. None of the 2-year-olds reported consume of flavoured water; therefore flavoured water is not included in the benzoic acid exposure assessments for this age group.

Methodological description of the calculations

In the present opinion, the calculated exposures of sweeteners from beverages are based on data from the national food consumption surveys Småbarnskost 2007 (Kristiansen *et al.*, 2009) and Norkost 3 (Totland *et al.*, 2012). The consumption of products within each product category (soft drinks, "saft", nectar and flavoured water) registered in the dietary surveys were multiplied with the products' corresponding concentration of sweeteners or benzoic acid as described. The exposure assessments are based on annual sales volumes and data on the actual content of the sweeteners and benzoic acid in specified products 2012 (reported by the manufacturers October 2013), representing the majority of brands with dominating market shares on the Norwegian market. The vast majority of soft drinks, "saft", nectar and flavoured water are produced in Norway, whereas import of these categories is very limited and not included in the current assessment. Thus, the Norwegian Food Safety Authority assumes that the reported data from the industry are representative for the majority of soft drinks, "saft", nectar and flavoured water on the Norwegian market.

To get a weighted average of sweetener and benzoic acid within a category, that is the mean concentration of the sweetener or benzoic acid within the given product category adjusted for sales, the calculations below have been performed.

Table 2: An overview of the different exposure assessments.

CONTENT of sweeteners or benzoic acid in beverages (mg/l). / **INTAKE of sweeteners or benzoic acid from beverages (mg/kg bw/day).**	**Based om sales figures and data on the actual content of the sweeteners and benzoic acid in specified products in 2012 (reported by the producers October 2013).**	**Based on the highest reported content of the sweeteners and benzoic acid in a product within a category in 2012 (reported by the producers October 2013).**
The actual consumption of beverages with added sweetener, sugar or benzoic acid reported in dietary surveys.	**Scenario 1** Content: The average content of sweetener or benzoic acid (adjusted for sale). Consumption: The actual consumption of beverages with added sweetener, sugar or benzoic acid reported in dietary surveys.	**Scenario 3** Content: The highest reported value for the content of sweetener or benzoic acid is used for the calculation. Consumption: The actual consumption of beverages with added sweetener, sugar or benzoic acid reported in dietary surveys.
The 100% scenario for consumption of beverages. This is based on the total volume of consumption within a category reported in dietary surveys.	**Scenario 2** Content: The average content of sweetener or benzoic acid (adjusted for sale). Consumption: It is assumed that all consumed soft drinks, "saft" or nectar contained sweeteners (no sugar).	**Scenario 4** Content: The highest reported value for the content of sweetener or benzoic acid is used for the calculation. Consumption: It is assumed that all consumed soft drinks, "saft" or nectar contained sweeteners (no sugar).

Relative sales volume of the sweetener or benzoic acid within a product category = sales volume for each product (litre/year) divided by the total sales volume for the product category

Average concentration of sweetener or benzoic acid in each product category = reported concentrations in each product within a product category adjusted for the relative sales volume for the specific product/brand.

Weighted average of sweetener or benzoic acid = calculated from the average concentration of sweetener or benzoic acid for all products within a category adjusted for sales

The average concentration and the weighted average of the sweeteners and benzoic acid in each product category are reported in Appendix 1.

Description of the methodologies (in short) used in the consumption surveys

- 2-year-old children; Småbarnskost 2007 is based on a semi-quantitative food frequency questionnaire. In addition to predefined household units, amounts of drinks were also estimated from photographs. The study was conducted in 2007, and a total of 1674 2-year-olds participated (Kristiansen *et al.*, 2009).
- Adults; Norkost 3 is based on two 24-hour recalls by telephone at least one month apart. Amounts of drinks were presented in household measures or estimated from photographs (Totland *et al.*, 2012). The study was conducted in 2010/2011 and 1787 men and women aged 18-70 years participated.

Daily consumption of soft drinks, "saft", nectar and flavoured water was computed by using food databases in the software system (KBS) developed at the Institute of Basic Medical Sciences, Department of Nutrition, at the University of Oslo. The food databases are mainly based on various versions of the official Norwegian food composition table (Rimestad *et al.*, 2000, Mattilsynet *et al.*, 2006).

The two dietary surveys used in this risk assessment were conducted at two different time points, Småbarnskost in 2007 and Norkost 3 in 2010-2011 (Kristiansen *et al.*, 2009, Totland *et al.*, 2012). The reported sales figures were from year 2012. Both the sales figures for 2012 and the specific concentration of sweeteners and benzoic acid in the different products used in the exposure assessment were collected from the industry during the autumn 2013.

The individual body weights reported in the different dietary surveys have been used to calculate the exposure in mg/kg body weight/day. Among the 2-year-olds, 620 children (37%) did not report the individual body weight, and these were given the group's mean body weight of 12.8 kg. Among adults, 30 persons (1.7%) did not report their individual body weights and were given the group's mean body weight of 77.5 kg.

The calculated exposure to the sweeteners aspartame, acesulfame K, sucralose and the preservative benzoic acid from soft drinks, "saft", nectar and flavoured water were based on the actual content in the beverages and the actual sales. Consumption data were taken from two Norwegian dietary surveys; Småbarnskost 2007 (2-year-olds) (Kristiansen *et al.*, 2009) and Norkost 3 (18-70 year olds) (Totland *et al.*, 2012). The adult group is divided in young women and young men (18-29 years) and women and men (30-70 years). The consumption data is shown in Appendix 2.

The number of participants (n) in Småbarnskost 2007 was 1674. In Norkost 3, for young women the number of participants was 143, for young men the number of participants was 138, for women the number of participants was 782, and for men the number of participants was 724.

Four different exposure assessments for aspartame, acesulfame K, sucralose and benzoic acid were performed as shown in Table 2.

3.1 Exposure assessment of aspartame (E951)

The exposure assessment of aspartame from soft drinks, "saft" and nectar (shown in Tables 3-7) was based on the actual aspartame content, the Norwegian sales volumes reported by the industry, and the consumption data from the dietary surveys Småbarnskost 2007 (Kristiansen *et al.*, 2009) and Norkost 3 (Totland *et al.*, 2012). In Norway, aspartame is used in the beverage categories soft drinks, "saft" and nectar. None of the participants in the dietary surveys reported consume of nectar added aspartame; therefore nectar is only included in scenario 3 and 4 for aspartame. Four different exposure assessments were performed; scenarios 1-4.

Table 3: Aspartame exposure assessment (consumers only) for 2-year-olds.

Scenario 1

Content*: The average content of aspartame (adjusted for sale).
Consumption**: The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=263)	1.35	2.53
"Saft" (n=427)	1.08	4.16
Total (n=542)	1.50	4.32

Scenario 2

Content*: The average content of aspartame (adjusted for sales).
Consumption**:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=530)	1.48	3.24
"Saft" (n=1012)	1.18	4.16
Nectar (n=401)	0.29	1.12
Total (n=1216)	1.73	5.29

Scenario 3

Content*: The highest value for the amount of added aspartame in soft drinks and "saft" is used for the calculation.
Consumption**:** The actual consumption (the real distribution of consumption of beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=263)	1.60	3.01
"Saft" (n=427)	1.28	4.92
Total (n=542)	1.79	5.11

Scenario 4

Content*: The highest value for the amount of added aspartame in soft drinks, "saft" and nectar is used for the calculation.
Consumption**:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=530)	1.77	3.86
"Saft" (n=1012)	1.40	4.92
Nectar (n=401)	0.29	1.12
Total (n=1216)	2.03	6.26

Based on *sales figures and data on the actual content of aspartame in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Småbarnskost 2007.

Table 4: Aspartame exposure assessment (consumers only); young women (age18-29 years).

Scenario 1

Content*: The average content of aspartame (adjusted for sale).
Consumption**: The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=33)	2.64	9.48
"Saft" (n=10)	0.87	-
Total (n=39)	2.46	9.37

Scenario 2

Content*: The average content of aspartame (adjusted for sales).
Consumption**:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=78)	2.86	11.26
"Saft" (n=27)	0.70	-
Nectar (n=3)	0.20	-
Total (n=93)	2.61	9.61

Scenario 3

Content*: The highest value for the amount of added aspartame in soft drinks and "saft" is used for the calculation.
Consumption**:** The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=33)	3.15	11.29
"Saft" (n=10)	1.03	-
Total (n=39)	2.92	11.15

Scenario 4

Content*: The highest value for the amount of added aspartame in soft drinks, "saft" and nectar is used for the calculation.
Consumption**:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=78)	3.40	13.41
"Saft" (n=27)	0.83	-
Nectar (n=3)	0.20	-
Total (n=93)	3.10	11.45

Based on *sales figures and data on the actual content of aspartame in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3. ***The 95th percentile was not calculated (n<30).

Table 5: Aspartame exposure assessment (consumers only); young men (age18-29 years).

Scenario 1

Content*: The average content of aspartame (adjusted for sale).
Consumption**: The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=23)	2.17	-
"Saft" (n=14)	0.74	-
Total (n=31)	1.94	4.33

Scenario 3

Content*: The highest value for the amount of added aspartame in soft drinks and "saft" is used for the calculation.
Consumption**:** The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=23)	2.58	-
"Saft" (n=14)	0.87	-
Total (n=31)	2.31	5.15

Scenario 2

Content*: The average content of aspartame (adjusted for sales).
Consumption**:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=88)	3.34	8.60
"Saft" (n=37)	0.78	2.20
Nectar (n=4)	0.16	-
Total (n=100)	3.24	8.92

Scenario 4

Content*: The highest value for the amount of added aspartame in soft drinks, "saft" and nectar is used for the calculation.
Consumption**:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=88)	3.98	10.24
"Saft" (n=37)	0.93	2.61
Nectar (n=4)	0.16	-
Total (n=100)	3.85	10.61

Based on *sales figures and data on the actual content of aspartame in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3. ***The 95th percentile was not calculated (n<30).

Table 6: Aspartame exposure assessment (consumers only); women (age 30-70 years).

Scenario 1

Content*: The average content of aspartame (adjusted for sale).
Consumption**: The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=173)	2.92	8.26
"Saft" (n=49)	0.60	2.18
Total (n=209)	2.56	7.88

Scenario 3

Content*: The highest value for the amount of added aspartame in soft drinks and "saft" is used for the calculation.
Consumption**:** The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

.

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=173)	3.48	9.84
"Saft" (n=49)	0.70	2.58
Total (n=209)	3.04	9.38

Scenario 2

Content*: The average content of aspartame (adjusted for sales).
Consumption**:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=277)	2.57	6.65
"Saft" (n=124)	0.69	1.73
Nectar (n=4)	0.12	-
Total (n=350)	2.28	6.54

Scenario 4

Content*: The highest value for the amount of added aspartame in soft drinks, "saft" and nectar is used for the calculation.
Consumption**:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=277)	3.06	7.92
"Saft" (n=124)	0.81	2.05
Nectar (n=4)	0.12	-
Total (n=350)	2.71	7.79

Based on *sales figures and data on the actual content of aspartame in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3. ***The 95th percentile was not calculated (n<30).

Table 7: Aspartame exposure assessment (consumers only); men (age 30-70 years).

Scenario 1

Content*: The average content of aspartame (adjusted for sale).
Consumption**: The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=133)	2.69	7.88
"Saft" (n=48)	0.60	1.72
Total (n=165)	2.34	6.79

Scenario 2

Content*: The average content of aspartame (adjusted for sales).
Consumption**:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=285)	2.57	7.32
"Saft" (n=139)	0.56	1.53
Nectar (n=5)	0.11	-
Total (n=365)	2.22	6.53

Scenario 3

Content*: The highest value for the amount of added aspartame in soft drinks and "saft" is used for the calculation.
Consumption**:** The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=133)	3.20	9.39
"Saft" (n=48)	0.71	2.04
Total (n=165)	2.79	8.08

Scenario 4

Content*: The highest value for the amount of added aspartame in soft drinks, "saft" and nectar is used for the calculation.
Consumption**:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=285)	3.06	8.71
"Saft" (n=139)	0.66	1.81
Nectar (n=5)	0.11	-
Total (n=365)	2.64	7.78

Based on *sales figures and data on the actual content of aspartame in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3. ***The 95th percentile was not calculated (n<30).

For **scenario 1**, the mean aspartame intake totally from all beverage categories was found to be highest for women and the 95th percentile intake was found to be highest for young women. For **scenario 2**, the mean aspartame intake was found to be highest for young men and the 95th percentile intake was found to be highest for young women. For **scenario 3**, the mean aspartame intake was found to be highest for women and the 95th percentile intake was found to be highest for young women. For **scenario 4**, the mean aspartame intake was found to be highest for young men and the 95th percentile intake was found to be highest for young women (18-29 years).

3.2 Exposure assessment of acesulfame K (E950)

The exposure assessment of acesulfame K from soft drinks, "saft" and nectar (shown in Tables 8-12) was based on the actual acesulfame K content, the Norwegian sales volumes reported by the industry, and the consumption data from the dietary surveys Småbarnskost 2007 (Kristiansen *et al.*, 2009) and Norkost 3 (Totland *et al.*, 2012). In Norway, acesulfame K is used in the beverage categories soft drinks, "saft" and nectar. None of the participants in the dietary surveys reported consume of nectar added acesulfame K; therefore nectar is only included in scenario 3 and 4 for acesulfame K. Four different exposure assessments were performed; scenarios 1-4.

Table 8: Acesulfame K exposure assessment (consumers only); 2-year-olds.

Scenario 1

Content*: The average content of acesulfame K (adjusted for sale).
Consumption**: The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=263)	0.13	0.25
"Saft" (n=427)	0.91	3.49
Total (n=542)	0.78	2.78

Scenario 2

Content*: The average content of acesulfame K (adjusted for sales).
Consumption:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=530)	0.15	0.32
"Saft" (n=1012)	0.99	3.49
Nectar (n=401)	0.64	2.42
Total (n=1216)	1.10	3.91

Scenario 3

Content*: The highest value for the amount of added acesulfame K in soft drinks and "saft" is used for the calculation.
Consumption:** The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=263)	0.61	1.14
"Saft" (n=427)	1.22	4.70
Total (n=542)	1.26	4.20

Scenario 4

Content*: The highest value for the amount of added acesulfame K in soft drinks, "saft" and nectar is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=530)	0.67	1.46
"Saft" (n=1012)	1.34	4.70
Nectar (n=401)	0.64	2.42
Total (n=1216)	1.61	5.34

Based on *sales figures and data on the actual content of acesulfame K in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Småbarnskost 2007.

Table 9: Acesulfame K exposure assessment (consumers only); young women (age18-29 years)..

Scenario 1

Content*: The average content of acesulfame K (adjusted for sale).
Consumption:** The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=33)	0.26	0.93
"Saft" (n=10)	0.73	-
Total (n=39)	0.41	1.12

Scenario 2

Content*: The average content of acesulfame K (adjusted for sales).
Consumption:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=78)	0.28	1.11
"Saft" (n=27)	0.59	-
Nectar (n=3)	0.44	-
Total (n=93)	0.42	1.21

Scenario 3

Content*: The highest value for the amount of added acesulfame K in soft drinks and "saft" is used for the calculation.
Consumption:** The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=33)	1.19	4.28
"Saft" (n=10)	0.98	-
Total (n=39)	1.26	4.23

Scenario 4

Content*: The highest value for the amount of added acesulfame K in soft drinks, "saft" and nectar is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=78)	1.29	5.09
"Saft" (n=27)	0.79	-
Nectar (n=3)	0.44	-
Total (n=93)	1.33	4.34

Based on *sales figures and data on the actual content of acesulfame K in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3. ***) The 95th percentile was not calculated (n<30).

Table 10: Acesulfame K exposure assessment (consumers only); young men (age18-29 years).

Scenario 1

Content*: The average content of acesulfame K (adjusted for sale).
Consumption**: The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=23)	0.21	-
"Saft" (n=14)	0.62	-
Total (n=31)	0.44	1.40

Scenario 2

Content*: The average content of acesulfame K (adjusted for sales).
Consumption**:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=88)	0.33	0.85
"Saft" (n=37)	0.66	1.85
Nectar (n=4)	0.35	-
Total (n=100)	0.55	1.60

Scenario 3

Content*: The highest value for the amount of added acesulfame K in soft drinks and "saft" is used for the calculation.
Consumption**:** The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=23)	0.98	-
"Saft" (n=14)	0.83	-
Total (n=31)	1.10	2.47

Scenario 4

Content*: The highest value for the amount of added acesulfame K in soft drinks, "saft" and nectar is used for the calculation.
Consumption**:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=88)	1.51	3.88
"Saft" (n=37)	0.88	2.49
Nectar (n=4)	0.35	-
Total (n=100)	1.67	4.31

Based on *sales figures and data on the actual content of acesulfame K in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3. ***) The 95th percentile was not calculated (n<30).

Table 11: Acesulfame K exposure assessment (consumers only); women (age 30-70 years).

Scenario 1

Content*: The average content of acesulfame K (adjusted for sale).
Consumption**: The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=173)	0.29	0.81
"Saft" (n=49)	0.50	1.83
Total (n=209)	0.36	1.01

Scenario 2

Content*: The average content of acesulfame K (adjusted for sales).
Consumption**:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=277)	0.25	0.66
"Saft" (n=124)	0.57	1.45
Nectar (n=4)	0.25	-
Total (n=350)	0.41	1.16

Scenario 3

Content*: The highest value for the amount of added acesulfame K in soft drinks and "saft" is used for the calculation.
Consumption**:** The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=173)	1.32	3.73
"Saft" (n=49)	0.67	2.46
Total (n=209)	1.25	3.65

Scenario 4

Content*: The highest value for the amount of added acesulfame K in soft drinks, "saft" and nectar is used for the calculation.
Consumption**:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=277)	1.16	3.00
"Saft" (n=124)	0.77	1.95
Nectar (n=4)	0.25	-
Total (n=350)	1.19	3.14

Based on *sales figures and data on the actual content of acesulfame K in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3. ***) The 95th percentile was not calculated (n<30).

Table 12: Acesulfame K exposure assessment (consumers only); men (age 30-70 years).

Scenario 1

Content*: The average content of acesulfame K (adjusted for sale).
Consumption:** The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (acesulfame K) (n=133)	0.26	0.78
"Saft" (acesulfame K) (n=48)	0.51	1.44
Total acesulfame K (n=165)	0.36	0.95

Scenario 2

Content*: The average content of acesulfame K (adjusted for sales).
Consumption:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=285)	0.25	0.72
"Saft" (n=139)	0.47	1.28
Nectar (n=5)	0.24	-
Total acesulfame K (n=365)	0.38	1.03

Scenario 3

Content*: The highest value for the amount of added acesulfame K in soft drinks and "saft" is used for the calculation.
Consumption:** The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (acesulfame K) (n=133)	1.21	3.56
"Saft" (acesulfame K) (n=48)	0.68	1.94
Total acesulfame K (n=165)	1.18	3.23

Scenario 4

Content*: The highest value for the amount of added acesulfame K in soft drinks, "saft" and nectar is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks, "saft" or nectar contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=285)	1.16	3.30
"Saft" (n=139)	0.63	1.72
Nectar (n=5)	0.24	-
Total acesulfame K (n=365)	1.15	3.02

Based on *sales figures and data on the actual content of acesulfame K in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3. ***) The 95th percentile was not calculated (n<30).

For **scenarios 1 and 2**, the mean acesulfame K intake and the 95th percentile intake totally from all beverage categories was found to be highest for 2-year-olds. For **scenario 3**, the mean acesulfame K intake was found to be highest for young women and 2-year-olds, and the 95th percentile intake was found to be highest for young women. For **scenario 4**, the mean acesulfame K intake was found to be highest for young men and the 95th percentile intake was found to be highest for 2-year-olds.

3.3 Exposure assessment of sucralose (E955)

The exposure assessment of sucralose from soft drinks and "saft" (shown in Tables 13-17) was based on the actual sucralose content, the Norwegian sales volumes reported by the industry, and the consumption data from the dietary surveys Småbarnskost 2007 (Kristiansen *et al.*, 2009) and Norkost 3 (Totland *et al.*, 2012). In Norway, sucralose is used in the categories soft drinks and "saft". Four different exposure assessments were performed; scenarios 1-4.

Table 13: Sucralose exposure assessment (consumers only); 2-year-olds.

Scenario 1

Content*: The average content of sucralose (adjusted for sale).
Consumption**: The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=263)	0.22	0.41
"Saft" (n=427)	1.23	4.75
Total (n=542)	1.08	3.80

Scenario 2

Content*: The average content of sucralose (adjusted for sales).
Consumption**:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=530)	0.24	0.52
"Saft" (n=1012)	1.35	4.75
Total (n=1131)	1.32	4.80

Scenario 3

Content*: The highest value for the amount of added sucralose in soft drinks and "saft" is used for the calculation.
Consumption**:** The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=263)	0.66	1.25
"Saft" (n=427)	1.34	5.18
Total (n=542)	1.38	4.63

Scenario 4

Content*: The highest value for the amount of added sucralose in soft drinks and "saft" is used for the calculation.
Consumption**:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=530)	0.73	1.60
"Saft" (n=1012)	1.47	5.18
Total (n=1131)	1.66	5.51

Based on *sales figures and data on the actual content of sucralose in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Småbarnskost 2007.

Table 14: Sucralose exposure assessment (consumers only); young women (age18-29 years).

Scenario 1

Content*: The average content of sucralose (adjusted for sale).
Consumption**: The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=33)	0.42	1.52
"Saft" (n=10)	0.99	-
Total (n=39)	0.61	1.56

Scenario 3

Content*: The highest value for the amount of added sucralose in soft drinks and "saft" is used for the calculation.
Consumption**:** The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=33)	1.30	4.67
"Saft" (n=10)	1.08	-
Total (n=39)	1.38	4.62

Scenario 2

Content*: The average content of sucralose (adjusted for sales).
Consumption**:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=78)	0.46	1.80
"Saft" (n=27)	0.80	-
Total (n=93)	0.62	1.88

Scenario 4

Content*: The highest value for the amount of added sucralose in soft drinks and "saft" is used for the calculation.
Consumption**:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=78)	1.41	5.55
"Saft" (n=27)	0.87	-
Total (n=93)	1.43	4.74

Based on *sales figures and data on the actual content of sucralose in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3. ***) The 95th percentile was not calculated (n<30).

Table 15: Sucralose exposure assessment (consumers only); young men (age18-29 years).

Scenario 1

Content*: The average content of sucralose (adjusted for sale).
Consumption:** The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=23)	0.35	-
"Saft" (n=14)	0.84	-
Total (n=31)	0.64	1.93

Scenario 2

Content*: The average content of sucralose (adjusted for sales).
Consumption:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=88)	0.54	1.38
"Saft" (n=37)	0.89	2.52
Total (n=99)	0.81	2.40

Scenario 3

Content*: The highest value for the amount of added sucralose in soft drinks and "saft" is used for the calculation.
Consumption:** The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=23)	1.07	-
"Saft" (n=14)	0.92	-
Total (n=31)	1.21	2.72

Scenario 4

Content*: The highest value for the amount of added sucralose in soft drinks and "saft" is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=88)	1.65	4.24
"Saft" (n=37)	0.97	2.74
Total (n=99)	1.83	4.72

Based on *sales figures and data on the actual content of sucralose in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3. ***) The 95th percentile was not calculated (n<30).

Table 16: Sucralose exposure assessment (consumers only); women (age 30-70 years).

Scenario 1

Content*: The average content of sucralose (adjusted for sale).
Consumption:** The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=173)	0.47	1.32
"Saft" (n=49)	0.68	2.49
Total (n=209)	0.55	1.63

Scenario 2

Content*: The average content of sucralose (adjusted for sales).
Consumption:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=277)	0.41	1.06
"Saft" (n=124)	0.78	1.98
Total (n=350)	0.60	1.66

Scenario 3

Content*: The highest value for the amount of added sucralose in soft drinks and "saft" is used for the calculation.
Consumption:** The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=173)	1.44	4.07
"Saft" (n=49)	0.74	2.72
Total (n=209)	1.36	3.99

Scenario 4

Content*: The highest value for the amount of added sucralose in soft drinks and "saft" is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=277)	1.26	3.28
"Saft" (n=124)	0.85	2.15
Total (n=350)	1.30	3.45

Based on *sales figures and data on the actual content of sucralose in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3.

Table 17: Sucralose exposure assessment (consumers only); men (age 30-70 years).

Scenario 1

Content*: The average content of sucralose (adjusted for sale).
Consumption:** The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=133)	0.43	1.26
"Saft" (n=48)	0.69	1.97
Total (n=165)	0.55	1.45

Scenario 2

Content*: The average content of sucralose (adjusted for sales).
Consumption:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=285)	0.41	1.17
"Saft" (n=139)	0.64	1.75
Total (n=362)	0.57	1.53

Scenario 3

Content*: The highest value for the amount of added sucralose in soft drinks and "saft" is used for the calculation.
Consumption:** The actual consumption (the real distribution of consumed beverages added sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=133)	1.32	3.89
"Saft" (n=48)	0.75	2.14
Total (n=165)	1.29	3.53

Scenario 4

Content*: The highest value for the amount of added sucralose in soft drinks and "saft" is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=285)	1.27	3.61
"Saft" (n=139)	0.69	1.90
Total (n=362)	1.26	3.31

Based on *sales figures and data on the actual content of sucralose in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3.

For **scenarios 1 and 2** the mean sucralose intake and the 95th percentile intake totally from all beverage categories was found to be highest for 2-year-olds. For **scenario 3**, the mean sucralose intake and the 95th percentile intake was found to be highest for young women and 2-year-olds. For **scenario 4**, the mean sucralose intake and the 95th percentile intake was found to be highest for 2-year-olds.

3.4 Exposure assessment of benzoic acid (E210, E211, E212, E213)

The exposure assessment of benzoic acid from soft drinks, "saft" and flavoured water (shown in Tables 18-22) was based on the actual benzoic acid content, the Norwegian sales volumes reported by the industry, and the consumption data from the dietary surveys Småbarnskost 2007 (Kristiansen *et al.*, 2009) and Norkost 3 (Totland *et al.*, 2012). In Norway, the preservative benzoic acid is used in soft drinks, "saft" and flavoured water. None of the 2-year-olds reported consume of flavoured water; therefore flavoured water is not included in the benzoic acid exposure assessments for this age group. Four different exposure assessments were performed; scenarios 1-4.

Table 18: Benzoic acid exposure assessment (consumers only); 2-year-olds.

Scenario 1

Content*: The average content of benzoic acid (adjusted for sale).
Consumption**: The actual consumption (the real distribution of consumed beverages added sugar or sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (sugar) (n=360)	0.31	0.59
"Saft" (sugar) (n=746)	0.73	2.83
Soft drinks (sweetener) (n=263)	0.39	0.74
"Saft" (sweetener) (n=427)	0.99	3.80
Total benzoic acid (n=1131)	1.05	3.44

Scenario 2

Content*: The average content of benzoic acid (adjusted for sales).
Consumption:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=530)	0.43	0.95
"Saft" (n=1012)	1.08	3.80
Total benzoic acid (n=1131)	1.17	3.99

Scenario 3

Content*: The highest value for the amount of added benzoic acid in soft drinks and "saft" is used for the calculation.
Consumption:** The actual consumption (the real distribution of consumed beverages added sugar or sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (sugar) (n=360)	0.36	0.69
"Saft" (sugar) (n=746)	1.15	4.45
Soft drinks (sweetener) (n=263)	0.41	0.77
"Saft" (sweetener) (n=427)	1.26	4.87
Total benzoic acid (n=1131)	1.45	4.98

Scenario 4

Content*: The highest value for the amount of added benzoic acid in soft drinks and "saft" is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=530)	0.45	0.99
"Saft" (n=1012)	1.38	4.87
Total benzoic acid (n=1131)	1.45	4.98

Based on *sales figures and data on the actual content of benzoic acid in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Småbarnskost 2007.

Table 19: Benzoic acid exposure assessment (consumers only); young women (age 18-29 years).

Scenario 1
Content*: The average content of benzoic acid (adjusted for sale).
Consumption:** The actual consumption (the real distribution of consumed beverages added sugar or sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (sugar) (n=53)	0.67	2.37
"Saft" (sugar) (n=18)	0.42	-
Soft drinks (sweetener) (n=33)	0.77	2.76
"Saft" (sweetener) (n=10)	0.79	-
Flavoured water (n=1)	0.62	-
Total benzoic acid (n=94)	0.82	2.97

Scenario 2
Content*: The average content of benzoic acid (adjusted for sales).
Consumption:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (total) (n=78)	0.83	3.28
"Saft" (total) (n=27)	0.64	-
Flavoured water (n=1)	0.62	-
Total benzoic acid (n=94)	0.88	3.00

Scenario 3
Content*: The highest value for the amount of added benzoic acid in soft drinks, "saft" and flavoured water is used for the calculation.
Consumption:** The actual consumption (the real distribution of consumed beverages added sugar or sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (sugar) (n=53)	0.77	2.74
"Saft" (sugar) (n=18)	0.67	-
Soft drinks (sweetener) (n=33)	0.80	2.88
"Saft" (sweetener) (n=10)	1.01	-
Flavoured water (n=1)	0.74	-
Total benzoic acid (n=94)	0.96	3.45

Scenario 4
Content*: The highest value for the amount of added benzoic acid in soft drinks, "saft" and flavoured water is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (total) (n=78)	0.86	3.40
"Saft" (total) (n=27)	0.82	-
Flavoured water (n=1)	0.74	-
Total benzoic acid (n=94)	0.96	3.43

Based on *sales figures and data on the actual content of benzoic acid in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3. ***) The 95th percentile was not calculated (n<30).

Table 20: Benzoic acid exposure assessment (consumers only); young men (age 18-29 years).

Scenario 1

Content*: The average content of benzoic acid (adjusted for sale).
Consumption:** The actual consumption (the real distribution of consumed beverages added sugar or sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (sugar) (n=77)	0.83	2.21
"Saft" (sugar) (n=28)	0.49	-
Soft drinks (sweetener) (n=23)	0.63	-
"Saft" (sweetener) (n=14)	0.67	-
Flavoured water (n=3)	0.43	-
Total benzoic acid (n=100)	1.03	2.64

Scenario 2

Content*: The average content of benzoic acid (adjusted for sales).
Consumption:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (total) (n=88)	0.97	2.51
"Saft" (total) (n=37)	0.71	2.01
Flavoured water (n=3)	0.43	-
Total benzoic acid (n=100)	1.13	2.95

Scenario 3

Content*: The highest value for the amount of added benzoic acid in soft drinks, "saft" and flavoured water is used for the calculation.
Consumption:** The actual consumption (the real distribution of consumed beverages added sugar or sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (sugar) (n=77)	0.96	2.56
"Saft" (sugar) (n=28)	0.78	-
Soft drinks (sweetener) (n=23)	0.66	-
"Saft" (sweetener) (n=14)	0.86	-
Flavoured water (n=3)	0.52	-
Total benzoic acid (n=100)	1.24	3.06

Scenario 4

Content*: The highest value for the amount of added benzoic acid in soft drinks, "saft" and flavoured water is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (total) (n=88)	1.01	2.59
"Saft" (total) (n=37)	0.91	2.58
Flavoured water (n=3)	0.52	-
Total benzoic acid (n=100)	1.24	3.06

Based on *sales figures and data on the actual content of benzoic acid in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3. ***) The 95th percentile was not calculated (n<30).

Table 21: Benzoic acid exposure assessment (consumers only); women (age 30-70 years).

Scenario 1

Content*: The average content of benzoic acid (adjusted for sale).
Consumption**: The actual consumption (the real distribution of consumed beverages added sugar or sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (sugar) (n=122)	0.44	0.95
"Saft" (sugar) (n=83)	0.50	1.29
Soft drinks (sweetener) (n=173)	0.85	2.41
"Saft" (sweetener) (n=49)	0.54	1.99
Flavoured water (n=13)	0.69	
Total benzoic acid (n=357)	0.78	2.19

Scenario 2

Content*: The average content of benzoic acid (adjusted for sales).
Consumption**:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=277)	0.75	1.94
"Saft" (n=124)	0.63	1.58
Flavoured water (n=13)	0.69	-
Total benzoic acid (n=357)	0.82	2.31

Scenario 3

Content*: The highest value for the amount of added benzoic acid in soft drinks, "saft" and flavoured water is used for the calculation.
Consumption**:** The actual consumption (the real distribution of consumed beverages added sugar or sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (sugar) (n=122)	0.51	1.09
"Saft" (sugar) (n=83)	0.79	2.02
Soft drinks (sweetener) (n=173)	0.89	2.51
"Saft" (sweetener) (n=49)	0.70	2.55
Flavoured water (n=13)	0.83	-
Total benzoic acid (n=357)	0.91	2.54

Scenario 4

Content*: The highest value for the amount of added benzoic acid in soft drinks, "saft" and flavoured water is used for the calculation.
Consumption**:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=277)	0.77	2.01
"Saft" (n=124)	0.80	2.03
Flavoured water (n=13)	0.83	-
Total benzoic acid (n=357)	0.91	2.53

Based on *sales figures and data on the actual content of benzoic acid in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3. ***) The 95th percentile was not calculated (n<30).

Table 22: Benzoic acid exposure assessment (consumers only); men (age 30-70 years).

Scenario 1

Content*: The average content of benzoic acid (adjusted for sale).
Consumption:** The actual consumption (the real distribution of consumed beverages added sugar or sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (sugar) (n=174)	0.56	1.52
"Saft" (sugar) (n=98)	0.37	0.87
Soft drinks (sweetener) (n=133)	0.78	2.30
"Saft" (sweetener) (n=48)	0.55	1.57
Flavoured water (n=9)	0.52	-
Total benzoic acid (n=367)	0.73	1.97

Scenario 2

Content*: The average content of benzoic acid (adjusted for sales).
Consumption:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=285)	0.75	2.13
"Saft" (n=139)	0.51	1.39
Flavoured water (n=9)	0.52	-
Total benzoic acid (n=367)	0.79	2.08

Scenario 3

Content*: The highest value for the amount of added benzoic acid in soft drinks, "saft" and flavoured water is used for the calculation.
Consumption:** The actual consumption (the real distribution of consumed beverages added sugar or sweeteners from the dietary survey).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (sugar) (n=174)	0.65	1.76
"Saft" (sugar) (n=98)	0.58	1.38
Soft drinks (sweetener) (n=133)	0.82	2.40
"Saft" (sweetener) (n=48)	0.71	2.01
Flavoured water (n=9)	0.62	-
Total benzoic acid (n=367)	0.87	2.43

Scenario 4

Content*: The highest value for the amount of added benzoic acid in soft drinks, "saft" and flavoured water is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks and "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=285)	0.78	2.21
"Saft" (n=139)	0.65	1.79
Flavoured water (n=9)	0.62	-
Total benzoic acid (n=367)	0.86	2.42

Based on *sales figures and data on the actual content of benzoic acid in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3. ***) The 95th percentile was not calculated (n<30).

For **scenarios 1 - 4**, the mean and the 95th percentile for the total benzoic acid intake from all beverage categories were found to be highest for 2-year-olds.

4 Risk assessment of aspartame, acesulfame K, sucralose and benzoic acid

The intake estimates from the exposure assessments in chapter 3, for the age groups 2-year-olds, young women (age 18-29 years), young men (age 18-29 years), women (age 30-70 years) and men (age 30-70 years) for the different exposure scenarios (scenarios 1-4), were compared with the ADI values described in section 2 (an overview is given in Table 1) for the respective substances in the risk characterization.

4.1 Aspartame

The ADI for aspartame is 40 mg/kg bw (EFSA, 2013).

The total mean intake of aspartame for the 2-year-olds ranged from 1.50 to 2.03 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 4.32 to 6.26 mg/kg bw/day (Table 3). The exposure scenarios for aspartame for 2-year-olds do not exceed the ADI for aspartame, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the sweetener (scenario 4). The change from actual consumption (scenario 1 and 3) of beverages containing sweeteners to the prediction (scenarios 2 and 4) that all the consumed beverages contained sweeteners increased the intake of aspartame in this age group with approximately 1 mg/kg bw/day for the high consumers (scenario 4).

The total mean intake of aspartame for young women (age 18-29 years) ranged from 2.46 to 3.10 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 9.37 to 11.45 mg/kg bw/day (Table 4). The exposure estimates for aspartame for young women do not exceed the ADI for aspartame, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the sweetener (scenario 4). The change from actual consumption (scenarios 1 and 3) of beverages containing sweeteners to the prediction that all the consumed beverages contained sweeteners (scenarios 2 and 4) did not increase the intake of aspartame in this age group considerably, indicating that a large part of this group already drink beverages with sweeteners.

The total mean intake of aspartame for young men (age 18-29 years) ranged from 1.94 to 3.85 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 4.33 to 10.61 mg/kg bw/day (Table 5). The exposure estimates for aspartame for young men do not exceed the ADI for aspartame, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the sweetener (scenario 4). The change from actual consumption (scenarios 1 and 3) of beverages containing sweeteners to the prediction that all the consumed beverages contained sweeteners (scenarios 2 and 4) increased the intake of aspartame in this age group with approximately 5 mg/kg bw/day for the high consumers (scenario 4).

The total mean intake of aspartame for women (age 30-70 years) ranged from 2.28 to 3.04 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 6.54 to 9.38 mg/kg bw/day (Table 6). Note that the highest intake is estimated for scenario 3 based on the actual consumption of beverages with sweeteners. The exposure estimates for aspartame for women do not exceed the ADI for aspartame, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the sweetener (scenarios 3 and 4). The change from actual consumption (scenarios 1 and 3) of beverages containing sweeteners to the prediction that all the consumed beverages contained sweeteners (scenarios 2 and 4) reduces the intake of aspartame in this age group with approximately 1.5 mg/kg bw/day, indicating that individuals with actual consumption of beverages containing sweeteners have a higher consumption than those drinking sugar-sweetened beverages.

The total mean intake of aspartame for men (age 30-70 years) ranged from 2.22 to 2.79 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 6.53 to 8.08 mg/kg bw/day (Table 7). Note that the highest intake is estimated for scenario 3 based on the actual consumption of beverages with sweeteners. The exposure estimates for aspartame for men do not exceed the ADI for aspartame, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the sweetener (scenarios 3 and 4). The change from actual consumption (scenarios 1 and 3) of beverages containing sweeteners to the prediction that all the consumed beverages contained sweeteners (scenarios 2 and 4) reduces the intake of aspartame in this age group with approximately 0.3 mg/kg bw/day, indicating that individuals with actual consumption of beverages with sweeteners have a higher consumption than those that drink sugar-sweetened beverages.

The intake of aspartame among mean consumers is shown in Figure 1, and the intake among high consumers (the 95th percentile) is shown in Figure 2.

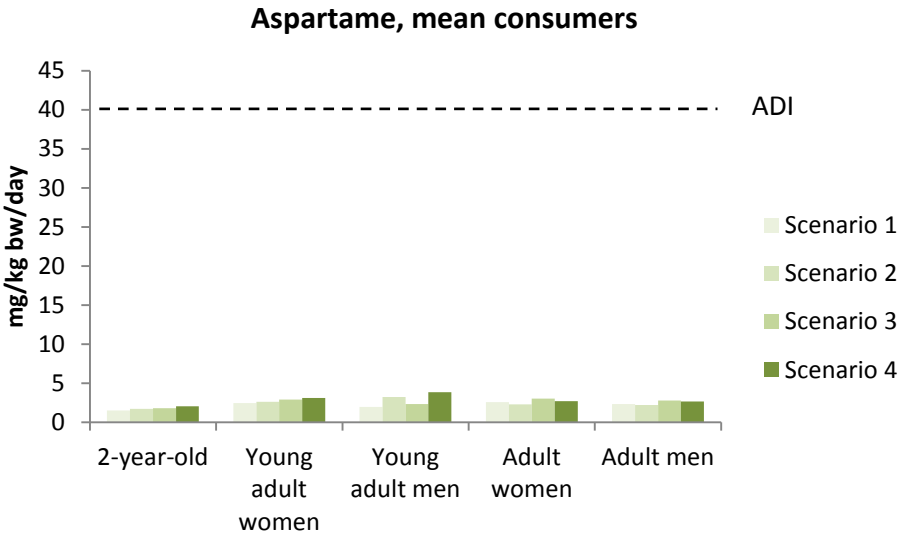

Figure 1. Intake of aspartame among mean consumers from soft drinks, "saft" and nectar from scenarios 1-4.

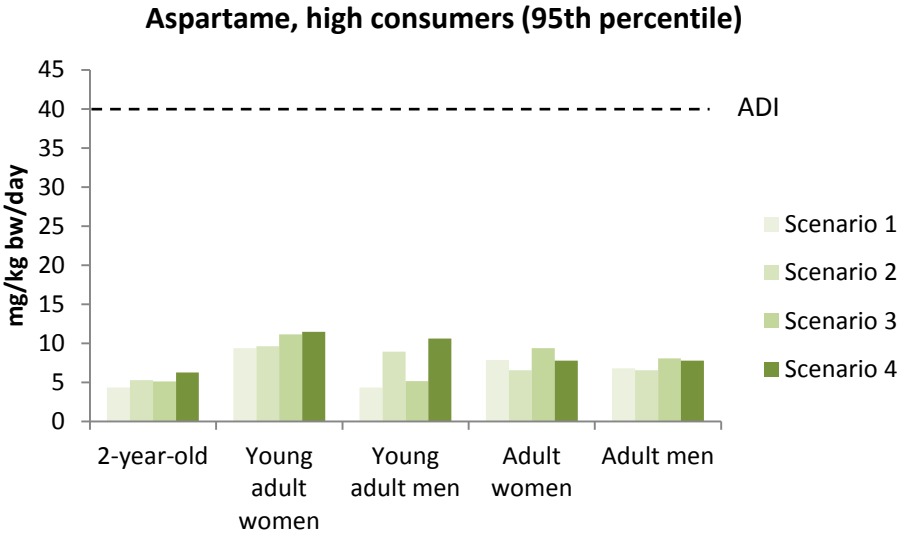

Figure 2. Intake of aspartame among high consumers from soft drinks, "saft" and nectar from scenarios 1-4.

4.2 Acesulfame K

The ADI for acesulfame K is 9 mg/kg bw (SCF, 1985, SCF, 2000b).

The total mean intake of acesulfame K for the 2-year-olds ranged from 0.78 to 1.61 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged

from 2.78 to 5.34 mg/kg bw/day (Table 8). The exposure estimates for acesulfame K for 2-year-olds do not exceed the ADI for acesulfame K, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the sweetener (scenario 4). The change from actual consumption (scenarios 1 and 3) of beverages containing sweeteners to the prediction that all the consumed beverages contained sweeteners (scenarios 2 and 4) increased the intake of acesulfame K in this age group with approximately 1.1 mg/kg bw/day for the high consumers.

The total mean intake of acesulfame K for young women (age 18-29 years) ranged from 0.41 to 1.33 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 1.12 to 4.34 mg/kg bw/day (Table 9). The exposure estimates for acesulfame K for young women do not exceed the ADI for acesulfame K, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the sweetener (scenario 4). The change from actual consumption (scenarios 1 and 3) of beverages containing sweeteners to the prediction that all the consumed beverages contained sweeteners (scenarios 2 and 4) do not increase the intake of acesulfame K in this age group considerably, with an approximately increase of 0.1 mg/kg bw/day for the high consumers.

The total mean intake of acesulfame K for young men (age 18-29 years) ranged from 0.44 to 1.67 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 1.40 to 4.31 mg/kg bw/day (Table 10). The exposure estimates for acesulfame K for young men do not exceed the ADI for acesulfame K, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the sweetener (scenario 4). The change from actual consumption (scenarios 1 and 3) of beverages containing sweeteners to the prediction that all the consumed beverages contained sweeteners (scenarios 2 and 4) increased the intake of acesulfame K in this age group with approximately 1.8 mg/kg bw/day for the high consumers (scenario 4).

The total mean intake of acesulfame K for women (age 30-70 years) ranged from 0.36 to 1.25 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 1.01 to 3.65 mg/kg bw/day (Table 11). Note that the highest intake is estimated for scenario 3 based on the actual consumption of beverages with sweeteners. The exposure estimates for acesulfame K for women do not exceed the ADI for acesulfame K, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the sweetener (scenarios 3 and 4). The change from actual consumption (scenarios 1 and 3) of beverages containing sweeteners to the prediction that all the consumed beverages contained sweeteners (scenarios 2 and 4) reduced the intake of acesulfame K in this age group with approximately 0.5 mg/kg bw/day This indicates that the individuals with actual consumption of beverages containing sweeteners have a higher consumption than those drinking sugar-sweetened beverages.

The total mean intake of acesulfame K for men (age 30-70 years) ranged from 0.36 to 1.18 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 0.95 to 3.23 mg/kg bw/day (Table 12). The exposure estimates for acesulfame K

for men do not exceed the ADI for acesulfame K, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the sweetener (scenarios 3 and 4). The change from actual consumption (scenarios 1 and 3) of beverages containing sweeteners to the prediction that all the consumed beverages contained sweeteners (scenarios 2 and 4) reduced the intake of acesulfame K in this age group with approximately 0.2 mg/kg bw/day. This indicates that the individuals with actual consumption of beverages containing sweeteners have a higher consumption than those that consume sugar-sweetened beverages.

The intake of acesulfame K among mean consumers is shown in Figure 3, and the intake among high consumers (95th percentile) is shown in Figure 4.

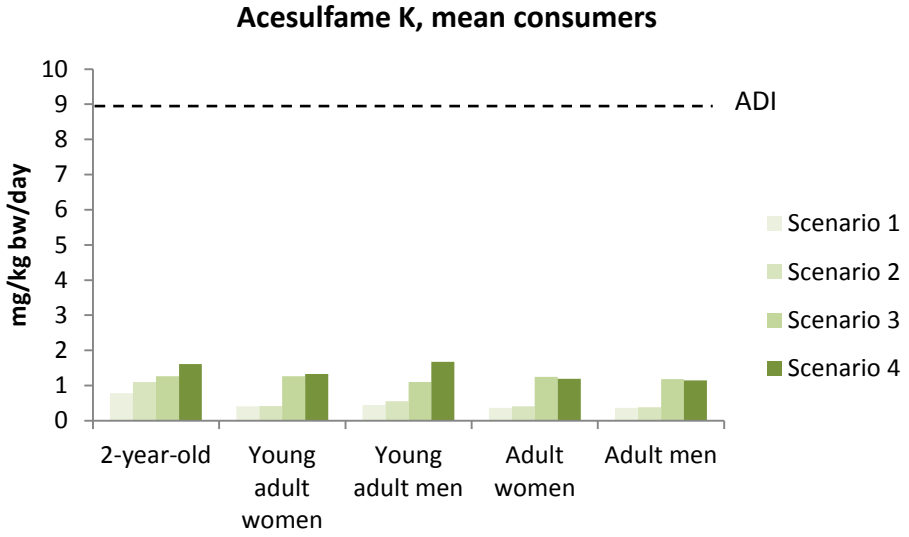

Figure 3. Intake of acesulfame K among mean consumers from soft drinks, "saft" and nectar from scenarios 1-4.

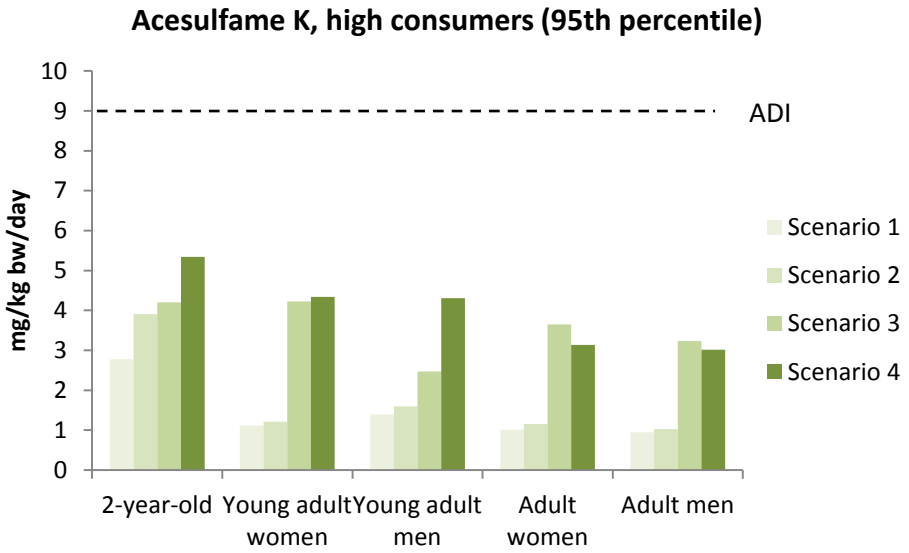

Figure 4. Intake of acesulfame K among high consumers from soft drinks, "saft" and nectar from scenarios 1-4.

4.3 Sucralose

The ADI for sucralose is 15 mg/kg bw (SCF, 2000a).

The total mean intake of sucralose for the 2-year-olds ranged from 1.08 to 1.66 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 3.80 to 5.51 mg/kg bw/day (Table 13). The exposure estimates for sucralose for 2-year-olds do not exceed the ADI for sucralose, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the sweetener (scenario 4). The change from actual consumption (scenarios 1 and 3) of beverages containing sweeteners to the prediction that all the consumed beverages contained sweeteners (scenarios 2 and 4) increased the intake of sucralose in this age group with approximately 0.9 mg/kg bw/day for the high consumers (scenario 4).

The total mean intake of sucralose for young women (age 18-29 years) ranged from 0.61 to 1.43 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 1.56 to 4.74 mg/kg bw/day (Table 14). The exposure estimates for sucralose for young women do not exceed the ADI for sucralose, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the sweetener (scenario 4). The change from actual consumption (scenarios 1 and 3) of beverages containing sweeteners to the prediction that all the consumed beverages contained sweeteners (scenarios 2 and 4) do not increased the intake of sucralose in this age group considerably, with an approximately increase of 0.1 mg/kg bw/day for the high consumers (scenario 4).

The total mean intake of sucralose for young men (age 18-29 years) ranged from 0.64 to 1.83 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile)

ranged from 1.93 to 4.72 mg/kg bw/day (Table 15). The exposure estimates for sucralose for young men do not exceed the ADI for sucralose, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the sweetener (scenario 4). The change from actual consumption (scenarios 1 and 3) of beverages containing sweeteners to the prediction that all the consumed beverages contained sweeteners (scenarios 2 and 4) increased the intake of sucralose in this age group with approximately 2.0 mg/kg bw/day the high consumers (scenario 4).

The total mean intake of sucralose for women (age 30-70 years) ranged from 0.55 to 1.36 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 1.63 to 3.99 mg/kg bw/day (Table 16). The exposure estimates for sucralose for women do not exceed the ADI for sucralose, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the sweetener (scenarios 3 and 4). The change from actual consumption (scenarios 1 and 3) of beverages containing sweeteners to the prediction that all the consumed beverages contained sweeteners (scenarios 2 and 4) reduced the intake of sucralose in this age group with approximately 0.5 mg/kg bw/day. This indicates that the individuals with actual consumption of beverages containing sweeteners have a higher consumption than those drinking sugar-sweetened beverages.

The total mean intake of sucralose for men (age 30-70 years) ranged from 0.55 to 1.29 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 1.45 to 3.53 mg/kg bw/day (Table 17). The exposure estimates for sucralose for men do not exceed the ADI for sucralose, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the sweetener (scenarios 3 and 4). The change from actual consumption (scenarios 1 and 3) of beverages containing sweeteners to the prediction that all the consumed beverages contained sweeteners reduced the intake of sucralose in this age group with approximately 0.2 mg/kg bw/day. This indicates that the individuals with actual consumption of beverages containing sweeteners have a higher consumption than those drinking sugar-sweetened beverages.

The intake of sucralose among mean consumers is shown in Figure 5, and the intake among high consumers (95th percentile) is shown in Figure 6.

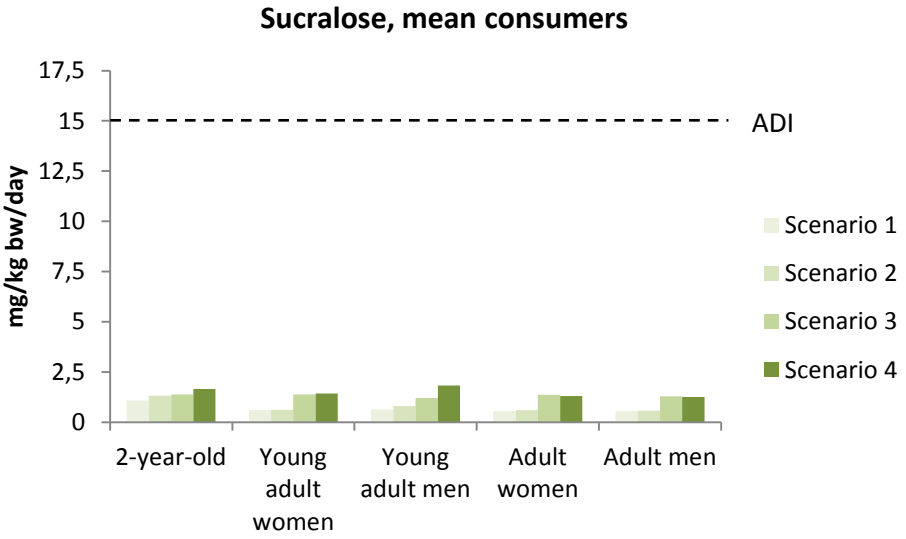

Figure 5. Intake of sucralose among mean consumers from soft drinks and "saft" from scenarios 1-4.

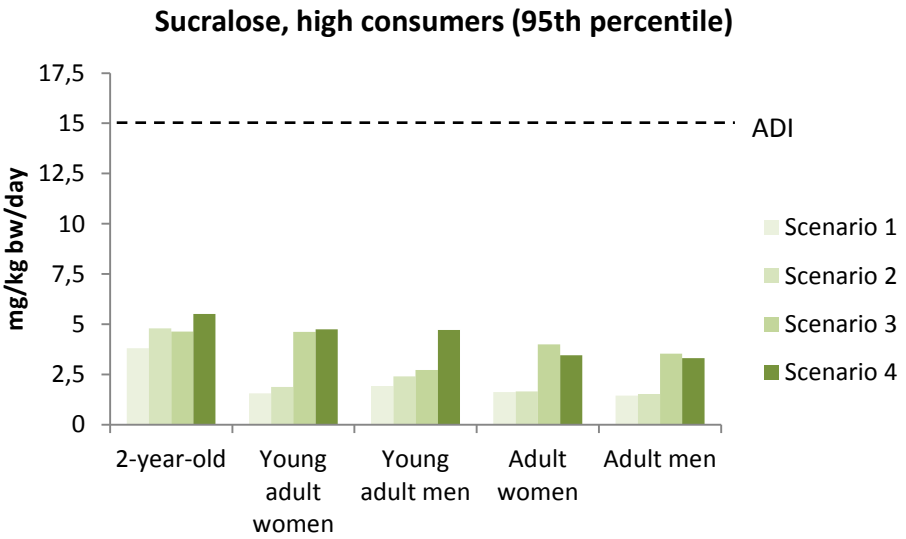

Figure 6. Intake of sucralose among high consumers from soft drinks and "saft" from scenarios 1-4.

4.4 Benzoic acid

The ADI for benzoic acid is 5 mg/kg bw/day (SCF, 2002).

The total mean intake of benzoic acid for the 2-year-olds ranged from 1.05 to 1.45 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 3.44 to 4.98 mg/kg bw/day (Table 18). The exposure estimates for benzoic acid for 2-year-olds reached the ADI for benzoic acid for high consumers with actual consumption

(scenario 3) and high consumers that are assumed to only consume beverages containing the highest reported concentration of the preservative (scenario 4). The change from actual consumption of beverages containing sweetener (scenario 1 and 3) to the prediction that all the consumed beverages contained sweetener (scenario 2 and 4), did not increase the intake of benzoic acid in this age group.

The total mean intake of benzoic acid for young women (age 18-29 years) ranged from 0.82 to 0.96 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 2.97 to 3.45 mg/kg bw/day (Table 19). The exposure estimates for benzoic acid for young women do not exceed the ADI for benzoic acid, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the preservative (scenario 4). The change from actual consumption of beverages containing sweetener (scenario 1 and 3) to the prediction that all the consumed beverages contained sweetener (scenario 2 and 4), did not increase the intake of benzoic acid in this age group.

The total mean intake of benzoic acid for young men (age 18-29 years) ranged from 1.03 to 1.24 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 2.64 to 3.06 mg/kg bw/day (Table 20). The exposure estimates for benzoic acid for young men do not exceed the ADI for benzoic acid, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the preservative (scenario 4). The change from actual consumption of beverages containing sweetener (scenario 1 and 3) to the prediction that all the consumed beverages contained sweetener (scenario 2 and 4), did not increase the intake of benzoic acid in this age group.

The total mean intake of benzoic acid for women (age 30-70 years) ranged from 0.78 to 0.91 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 2.19 to 2.54 mg/kg bw/day (Table 21). The exposure estimates for benzoic acid for women do not exceed the ADI for benzoic acid, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the preservative (scenarios 3 and 4). The change from actual consumption of beverages containing sweetener (scenario 1 and 3) to the prediction that all the consumed beverages contained sweetener (scenario 2 and 4), did not increased the intake of benzoic acid in this age group.

The total mean intake of benzoic acid for the men (age 30-70 years) ranged from 0.73 to 0.87 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 1.97 to 2.43 mg/kg bw/day (Table 22). The exposure estimates for benzoic acid for men do not exceed the ADI for benzoic acid, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the preservative (scenarios 3 and 4). The change from actual consumption of beverages containing sweetener (scenario 1 and 3) to the prediction that all the consumed beverages contained sweetener (scenario 2 and 4), did not increased the intake of benzoic acid in this age group.

The intake of benzoic acid among mean consumers is shown in Figure 7, and the intake among high consumers (95th percentile) is shown in Figure 8.

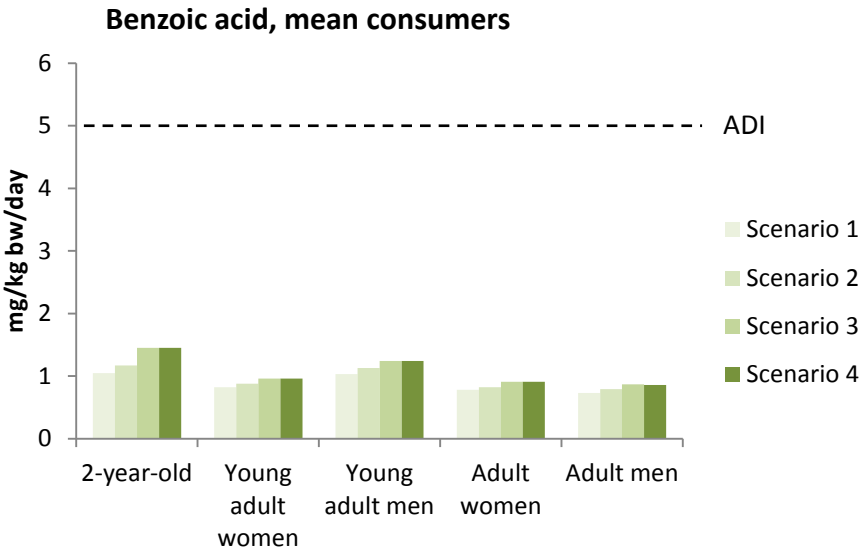

Figure 7. Intake of benzoic acid among mean consumers from soft drinks, "saft" and flavoured water from scenarios 1-4.

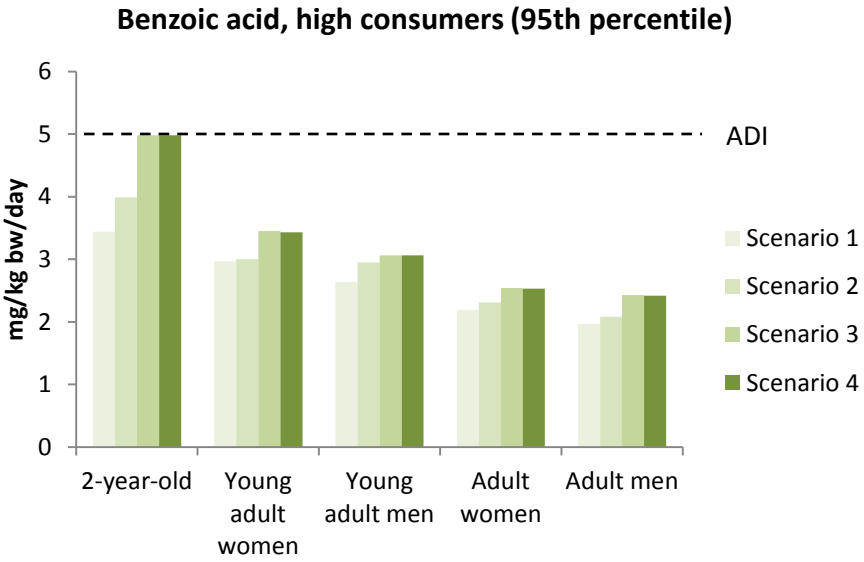

Figure 8. Intake of benzoic acid among high consumers from soft drinks, "saft" and flavoured water from scenarios 1-4.

The intake of benzoic acid for high consumers among 2-year-olds reached the ADI of 5 mg/kg bw/day for benzoic acid when it was assumed that all consumed soft drinks and "saft" contained sweeteners, while for the high consumers of the other age groups the intake was below ADI for all scenarios (Figure 8). In the scenarios with actual consumption (scenarios 1

and 2), none of the intake estimates from the age groups exceeded the ADI. The major source for benzoic acid in 2-year-old children is "saft" and the contribution of benzoic acid intake from saft containing sweeteners were only slightly higher than the contribution from sugar-sweetened saft (Table 18).

4.5 Comparison of the intake of aspartame, acesulfame K, sucralose and benzoic acid with the estimated intake from the VKM risk assessment in 2007

Due to differences in the way the calculations were done in the current opinion and in 2007, it was not possible to compare the current calculated intake of aspartame, acesulfame K and benzoic acid to the calculated intakes reported by VKM in 2007.

5 Uncertainties regarding human risk assessment

This risk assessment is based on data describing intake in population groups, data describing the content/occurrence of sweeteners and benzoic acid in specific products and the sales of these products, and data describing the toxicology of the sweeteners and benzoic acid. There are uncertainties associated with all data used to perform the risk assessment.

5.1 Uncertainty regarding content

There are uncertainties related to the representativeness of the sampling. The use of average content of sweetener adjusted for sales volume (scenarios 1 and 2), or the use of the highest reported level of sweetener used in a product within a category (scenarios 3 and 4) adds a level of uncertainty to the concentration used in each scenario.

5.2 Uncertainty regarding dietary assessment

Every dietary assessment is connected with uncertainty. A description of the most important uncertainties and assumptions in the dietary exposure calculations is described below.

Three concepts are fundamental to understanding the limitations of dietary assessment: habitual consumption, validity and precision (Livingstone and Black, 2003).

The habitual consumption of an individual is the person's consumption averaged over a prolonged period of time, such as weeks and months rather than days. However, this is a largely hypothetical concept; the consumption period covered in a dietary assessment is a compromise between desired goal and feasibility. In the Norwegian dietary surveys, the time period covered is 14-days among the 2-year-olds (Småbarnskost 2007), and two none-consecutive days among the adults (Norkost 3) (Kristiansen *et al.*, 2009, Totland *et al.*, 2012).

When evaluating high consumers, the uncertainty associated with the 95th percentile is higher than for the mean value, especially among the age groups with a low number of participants. When the number of participants in a group is less than 30 persons, a 95th percentile is not calculated. With 30 persons in one group, the 95th percentile is the mean of the two highest

reported values in the group, and the value is strongly associated with uncertainties of measurement errors and outliers. However, with a small group of participants with only two days of dietary intake measures, it is also probable that the highest consumer groups are not covered. The high consumers might not be included in the study, or the two recall days were unusual days according to beverage intake. This might lead to an underestimation of the 95th percentile consumption of sweetener in the scenarios used in this risk assessment.

The validity of a dietary assessment method refers to the degree to which the method actually measures the aspect of diet that it was designed to measure (Nelson and Margetts, 1997). Lack of validity is strongly associated with systematic errors (Burema *et al.*, 1988). With systematic errors all respondents in a dietary study or each subgroup in a population produce the same type of error, like systematic underestimation or overestimation of intake. The two different dietary assessment methods used in this risk assessment have limitations when it comes to validity. The validation studies among 2-year-olds were performed on a previously established questionnaire, but the results showed a significantly higher energy intake with the FFQ than with the weighted record reference method (Andersen *et al.*, 2004, Andersen *et al.*, 2009). The Norwegian 24-hour recall method used among adults in Norkost 3 has not been validated. However, other similar 24-hour recall methods have been validated and show an underestimation in energy intake of around 15% (Subar *et al.*, 2003, Poslusna *et al.*, 2009). Underestimation of energy intake indicates that not all foods eaten are reported, but not which foods that are underreported. It has been shown that foods perceived as unhealthy such as fats, sweets, desserts and snacks tend to be underreported to a larger degree than foods perceived as healthy (Olafsdottir *et al.*, 2006). Soft drinks and "saft" with sugar can be perceived as unhealthy and sweetened soft drinks and "saft" can be perceived as both healthy and unhealthy depending on the consumer groups. Studies have shown that drinks are more accurate estimated, probably due to regular consumption in defined portion sizes (e.g. glasses, cans or bottles) (Lillegaard *et al.*, 2012). If underreporting of soft drinks and "saft" is of the same magnitude as for total energy, the estimates for sweetener exposure are more likely to be underreported than overreported. However, if drinks are more accurately reported than other foods, the underreporting can be reduced (less than 15%) at group level.

The precision of a technique is high when a repeated administration gives the same results (Livingstone and Black, 2003). Poor precision derives from large random errors in the techniques of dietary assessment. The effect of random errors can be reduced by increasing the number of observations, but cannot be entirely eliminated (Rothman, 2002).

Dietary patterns are constantly changing. The data collections of the different dietary surveys were performed from 2007 till 2011. It has been shown that health conscious people are more likely to participate in a dietary survey. This can indicate a somewhat different dietary pattern among the participants than among the whole population. The direction of the uncertainty is difficult to estimate.

It is unclear to which extent a low participation rate will influence the assessment of sweetener exposure. A total of 68% among the 2-year-olds, 69% among adults 18-29 years, and 48% among adults 30-70 years reported drinking some kind of soft drinks, "saft" or nectar. Individual consumption data reported in the dietary surveys have been paired with person-specific self-reported body weights for the same individuals. However, where no body weight was given the mean body weight from the study was imputed.

5.3 Summary of uncertainties

Evaluations of the overall effect of identified uncertainties are presented in Table 23, highlighting the main sources introducing uncertainty, and indicating whether the respective source of uncertainty might have led to an over- or underestimation of the exposure and/or the resulting risk.

Table 23: Qualitative evaluation of influences of uncertainties on the assessment of exposure to sweeteners and benzoic acid.

Source of uncertainty	Direction
Dietary exposure assessment	
Different dietary assessment methods	+/-
Bias due to mis-reporting/underreporting	+/-
Småbarnskost 2007	
Use of 95-percentile	+/-
FFQ time span is 14 days	+/-
Norkost 3, Adults	
Participation rate	+/-
Two registration days	+/-
Use of 95-percentile, especially among the smallest group of 18-29 year-olds	+/-
Content of sweeteners	
Sampling of content data from producers	+/-
Scenario 1 Average content of sweetener adjusted for sales figures	+/-
Scenario 2 Average content of sweetener adjusted for sales volume It is assumed that all consumed beverages are added sweeteners	+
Scenario 3 Use of highest content of sweetener	+
Scenario 4 Use of highest content of sweetener It is assumed that all consumed beverages are added sweeteners	+

+: uncertainty likely to cause over-estimation of exposure.
-: uncertainty likely to cause under-estimation of exposure.

The intake of sweeteners and benzoic acid is considered realistic for each age group, despite the limitations in assessing the beverage consumptions and the uncertainties related to estimating the exposures as outlined in Table 26. Taking all sources of uncertainty into consideration, an over-estimation is most likely.

6 Discussion

The Norwegian Food Safety Authority requested VKM to estimate intake levels of acesulfame K, aspartame, sucralose and benzoic acid for the age groups 2-year-old children, young women (age 18-29 years), young men (age 18-29 years), women (age 30-70 years) and

men (age 30-70 years) based on the dietary surveys Norkost 3 and Småbarnskost 2007. The intake estimates were compared with the ADI values for the respective additives.

The exposure assessments were performed for four different scenarios:

- **Scenario 1** gives the best estimate of the current situation in the population.

None of the intake estimates for the sweeteners aspartame, acesulfame K, sucralose or benzoic acid exceeded the respective ADIs either for mean consumers or for the high consumers for any of the age groups in this scenario.

- **Scenario 2** gives an estimate of the exposure among the part of the population who only consume beverages added sweeteners (it is assumed that all reported consume of soft drinks, "saft" or nectar contains sweeteners, no added sugar), and the level of added sweeteners is average (based on reported content that is adjusted for sale).

When it was assumed that all consumed soft drinks, "saft" or nectar contained the average content of sweeteners, the estimated intake for mean or high consumption for all three sweeteners and benzoic acid were still well below the respective ADIs for all age groups.

- **Scenario 3** gives an estimate of the exposure among the part of the brand loyal population (loyal to the brand added the highest reported level of sweeteners or benzoic acid) that have an actual consumption of beverages as reported in dietary surveys.

Based on the actual consumption from the dietary surveys and the highest reported content of sweetener or benzoic acid, none of the intake estimates for the sweeteners aspartame, acesulfame K or sucralose exceeded the respective ADIs for mean consumers or for the high consumers for any of the age groups. The mean consumers of soft drinks, "saft" and flavoured water had a benzoic acid intake below the ADI values for all age groups. For high consumers of beverages in this scenario, the 2-year old children had an estimated intake of benzoic acid that reached ADI. The main source for the benzoic acid intake for this age group was "saft". For the other age groups, the high intake was below ADI in this scenario.

- **Scenario 4** gives an estimate of the exposure among the part of the brand loyal population (loyal to the brand added the highest reported level of sweeteners or benzoic acid) who only consume beverages added sweeteners (it is assumed that all reported consume of soft drinks, "saft" or nectar contains sweeteners, no added sugar).

When it was assumed that all consumed soft drinks, "saft" or nectar contained sweeteners with the highest reported content, the estimated intake for mean or high consumption for all three sweeteners were still below the respective ADIs for all age groups. The mean consumers of beverages had a benzoic acid intake below ADI for all age groups. For high consumers of soft drinks the 2-year old children had an estimated intake of benzoic acid that reached ADI. The main source for the benzoic acid intake for this age group was "saft".

Due to high brand loyalty for beverages, it is reasonable to anticipate that some parts of the population will repeatedly drink the beverages with the highest content of a sweetener or benzoic acid, and that these might be high consumers of beverages.

Changing from scenario 1 and 3 based on the actual consumption of beverages with sweeteners, to scenario 2 and 4 representing the population only consuming beverages with added sweeteners did not result in the exceedance of ADI for the sweeteners for mean or high consumers. Although 2-year old children reached the ADI for benzoic acid for high consumers of beverages, the change from scenario 1 and 3 to scenario 2 and 4 did not have a large impact on the intake estimate. The estimated high intake of benzoic acid from soft

drinks and “saft” in Norwegian 2-year-old children are of concern, especially noting that the intake of benzoic acid from other sources are not known, and likely will result in an exceedance of ADI. It should be noted that a considerable intake of benzoic acid also is expected from food. High consumers of soft drinks, “saft” or flavoured water in all age groups could be at risk for approaching or exceeding ADI if the exposures from foods are taken into account. This is especially of concern for 2-year-old children, since high consumers of soft drinks and “saft” already have reached the ADI. Intake estimates of benzoic acid from food were outside the scoop of this risk assessment, as well as other sources such as cosmetics. However, in 2007 VKM estimated the contribution of benzoic acid from food to be approximately 2 mg/kg bw/day for 2-year old children (VKM, 2007).

Benzoic acid is conjugated in the body with the amino acid glycine before excretion, and the glycine capacity might be exceeded during very high intakes of benzoic acid. This is mainly a concern for organisms in growth, such as children, where absence of glycine might lead to reduced weight gain. The capacity of glycine conjugation in children is not known. It is likely to be dependent on the nutritional status and intake of glycine. On average, Norwegian children have a sufficient intake of protein. The total benzoic acid exposure to 2-year-old children have not been estimated in the present risk assessment, however, due to the estimated high intake of benzoic acid from soft drinks and “saft” in children this is of special concern.

7 Conclusions

VKM concludes that for all age groups in all scenarios, the intake of sweeteners is well below the established ADI values, thus, there is no concern related to the intake of the sweeteners aspartame, acesulfame K or sucralose.

VKM further concludes that the benzoic acid intake in 2-year-old-children, in scenarios 3 and 4, is of concern, as it reached ADI for high consumers of soft drinks, “saft” and flavoured water, although the ADI is not a threshold for toxicity. For the other age groups, there is no concern related to the intake of benzoic acid from beverages. However, it should be noted that a considerable intake of benzoic acid also is expected from other sources such as food and cosmetics. High consumers of soft drinks, “saft” or flavoured water in all age groups could be at risk for approaching or exceeding the ADI if the exposures from foods are taken into account. This is especially of concern for 2-year-old children, since high consumers of soft drinks and “saft” already have reached the ADI.

8 Data gaps

- There is a need for regularly updated dietary surveys in all age groups in the Norwegian population. In this risk assessment, the age group from 3- to 18-years are missing due to lack of updated data since 2000-2001.
- More data is needed to understand under-/over-reporting of consumption in dietary surveys.
- Further research is needed to evaluate the impact of variations in number of registration days in the dietary surveys.

References

ANDERSEN, L. F., LANDE, B., TRYGG, K. & HAY, G. 2004. Validation of a semi-quantitative food-frequency questionnaire used among 2-year-old Norwegian children. *Public Health Nutr,* 7**,** 757-64.

ANDERSEN, L. F., LANDE, B., TRYGG, K. & HAY, G. 2009. Validation of a semi-quantitative food-frequency questionnaire used among 2-year-old Norwegian children (vol 7, pg 757, 2004). *Public Health Nutrition,* 12**,** 1026-1027.

BUREMA, J., STAVEREN, W. A. & BRANDT, P. A. V. D. 1988. Validity and reproducibility. *In:* CAMERON, M., STAVEREN, W. A. & SCIENCES, N. U. T. E. A. I. U. O. N. (eds.) *Manual on methodology for food consumption studies.* Oxford University Press.

EFSA, P. O. F. A., FLAVOURINGS, PROCESSING AIDS AND MATERIALS IN CONTACT WITH FOOD 2006. Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) related to a new long-term carcinogenicity study on aspartame EFSA journal: EFSA.

EFSA, P. O. F. A. A. N. S. A. T. F. 2013. Scientific Opinion on the re-evaluation of aspartame (E 951) as a food additive. http://www.efsa.europa.eu/en/efsajournal/doc/3496.pdf: EFSA.

JECFA, T. J. W. F. E. C. O. F. A. 1974. Toxicological evaluation of some food additives including anticaking agents, antimicrobials, emulsifiers, and thickening agents. Benzoic acid an its potassium and sodium salts *In:* WHO, W. H. O., GENEVA (ed.) *WHO Food Additives Series No 15.* http://www.inchem.org/documents/jecfa/jecmono/v05je06.htm.

JECFA, T. J. W. F. E. C. O. F. A. 1980. Toxicological evaluation of certain food additives: Aspartame. http://www.inchem.org/documents/jecfa/jecmono/v15je03.htm: World Health Organization.

JECFA, T. J. W. F. E. C. O. F. A. 1981. Toxicological evaluation of certain food additives: Aspartame. *WHO food additives series no 16.* http://www.inchem.org/documents/jecfa/jecmono/v16je03.htm: World Health Organizaton.

JECFA, T. J. W. F. E. C. O. F. A. 1983. Toxicological evaluation of certain food additives: Acesulfame potassium. *WHO Food Additives Series 18.* http://www.inchem.org/documents/jecfa/jecmono/v18je02.htm: WHO, World Health Organization, Geneva.

JECFA, T. J. W. F. E. C. O. F. A. 1989. Toxicological Evaluation of certain food additives and contaminants: Trichlorogalactosucrose. http://www.inchem.org/documents/jecfa/jecmono/v024je05.htm: WHO, World Helath Organization, Geneva.

JECFA, T. J. W. F. E. C. O. F. A. 1991a. Toxicological evaluation of certain food additives and contaminants: Trichlorogalactosucrose. http://www.inchem.org/documents/jecfa/jecmono/v28je14.htm: WHO, World Health Organization, Geneva.

JECFA, T. J. W. F. E. C. O. F. A. 1991b. Toxicological evaluation of certain food addtives and contaminants: Acesulfame Potassium *In:* WHO, W. H. O., GENEVA (ed.) *WHO Food Additives Series 28.* http://www.inchem.org/documents/jecfa/jecmono/v28je13.htm.

JECFA, T. J. W. F. E. C. O. F. A. 1996. Toxicological evaluation of certain food and additives: Benzyl acetate, benzyl alcohol, benzaldehyde, and benzoic acid and its salts. *In:* WHO, W. H. O., GENEVA (ed.) *WHO Food Additives Series No 37.* WHO, World Health Organization, Geneva.

KRISTIANSEN, A. L., ANDERSEN, L. F. & LANDE, B. 2009. Småbarnskost – 2 år Landsomfattende kostholdsundersøkelse blant 2 år gamle barn. http://www.helsedirektoratet.no/publikasjoner/rapport-smabarnskost-2-aringer-2009/Publikasjoner/rapport-smabarnskost-2-aringer-2009.pdf: Helsedirektoratet.

LILLEGAARD, I. T., OVERBY, N. C. & ANDERSEN, L. F. 2012. Evaluation of a short food frequency questionnaire used among Norwegian children. *Food Nutr Res,* 56.

LIVINGSTONE, M. B. & BLACK, A. E. 2003. Markers of the validity of reported energy intake. *J Nutr,* 133 Suppl 3**,** 895S-920S.

MATPORTALEN.NO. 2013. *Merking av søtstoffer* [Online]. http://www.matportalen.no/merking/tema/merking_av_mat/merking_av_sotstoffer .

MATTILSYNET, HELSEDIREKTORATET & OSLO, U. I. 2006. *Matvaretabellen* [Online]. http://www.matvaretabellen.no/?language=en.

NELSON, M. & MARGETTS, B. M. 1997. Overview of the principles of nutritional epidemiology. *In:* NELSON, B. M. M. A. M. (ed.) *Design concepts in nutritional epidemiology.* 2nd edition ed.: Oxford University Press.

OLAFSDOTTIR, A. S., THORSDOTTIR, I., GUNNARSDOTTIR, I., THORGEIRSDOTTIR, H. & STEINGRIMSDOTTIR, L. 2006. Comparison of women's diet assessed by FFQs and 24-hour recalls with and without underreporters: associations with biomarkers. *Ann Nutr Metab,* 50**,** 450-60.

POSLUSNA, K., RUPRICH, J., DE VRIES, J. H., JAKUBIKOVA, M. & VAN'T VEER, P. 2009. Misreporting of energy and micronutrient intake estimated by food records and 24 hour recalls, control and adjustment methods in practice. *Br J Nutr,* 101 Suppl 2**,** S73-85.

RIMESTAD, A. H., LØKEN, E. B. & NORDBOTTEN, E. 2000. Den norske matvaretabellen og beregningsdatabasen ved Institutt for ernæringsforskning. *Norsk Epidemiologi,* 10**,** 7-16.

ROTHMAN, K. J. 2002. *Random error and the role of statistics*, Oxford University Press.

SCF, T. S. C. F. F. 1985. Sweeteners. Food - science and techniques. Reports of the Scientific Committee for Food (Sixteenth series). http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_16.pdf: Commission of the European Communities.

SCF, T. S. C. F. F. 1989. Sweeteners. Food Science and Techniques. Reports of the Scientific Committee for Food (Twenty-first series). http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_21.pdf: Commission of the European Communities.

SCF, T. S. C. F. F. 2000a. Opinion of the Scientific Committee on Food on sucralose. http://ec.europa.eu/food/fs/sc/scf/out68_en.pdf: European Comission, Health & Consumer Protection Directorate-General.

SCF, T. S. C. F. F. 2000b. Opinion Re-evaluation of acesulfame K with reference to the previous SCF opinion of 1991. *In:* FINAL, S. C. O. F. S. C. A. E. (ed.). http://ec.europa.eu/food/fs/sc/scf/out52_en.pdf: European Commission, Health & Consumer Protection Directorate-General.

SCF, T. S. C. F. F. 2002. Opinion of the Scientific Committee on Food on Benzoic acid and its salts. *In:* EUROPEAN COMMISSION, H. C. P. D.-G. (ed.). http://ec.europa.eu/food/fs/sc/scf/out137_en.pdf.

SUBAR, A. F., KIPNIS, V., TROIANO, R. P., MIDTHUNE, D., SCHOELLER, D. A., BINGHAM, S., SHARBAUGH, C. O., TRABULSI, J., RUNSWICK, S., BALLARD-BARBASH, R., SUNSHINE, J. & SCHATZKIN, A. 2003. Using intake biomarkers to evaluate the extent of dietary misreporting in a large sample of adults: the OPEN study. *Am J Epidemiol,* 158**,** 1-13.

TOTLAND, T. H., MELNÆS, B. K., LUNDBERG-HALLÉN, N., HELLAND-KIGEN, K. M., LUND-BLIX, N. A., MYHRE, J. B., JOHANSEN, A. M. W., LØKEN, E. B. & ANDERSEN, L. F. 2012. Norkost 3. En landsomfattende kostholdsundersøkelse blant menn og kvinner i Norge i alderen 18-70 år, 2010-2011. http://www.helsedirektoratet.no/publikasjoner/norkost-3-en-landsomfattende-kostholdsundersokelse-blant-menn-og-kvinner-i-norge-i-alderen-18-70-ar/Publikasjoner/norkost-3-is-2000.pdf: Helsedirektoratet.

VKM 2007. Impact on health when sugar is replaced with intense sweeteners in soft drinks, "saft" and nectar. http://www.vkm.no/dav/cc9df01349.pdf: Vitenskapskomiteen for mattrygghet/the Norwegian scientific committee for food safety.

Appendices

Appendix 1

The number of products within a category used for the exposure assessments and the concentrations of aspartame, acesulfame K, sucralose and benzoic acid (the weighted average and the highest reported value) in mg/l.

Aspartame

	Weighted average (mg/l)	Highest reported value (mg/l)
Soft drinks, sugar (n=0)	-	-
«Saft», sugar (n=0)	-	-
Soft drinks, sweetener (n=32)	487	580
«Saft», sweetener (n=8)	148	175
Nectar, sweetener (n=1)	60	60
Flavoured water (n=0)	-	-

Acesulfame K

	Weighted average (mg/l)	Highest reported value (mg/l)
Soft drinks, sugar (n=0)	-	-
«Saft», sugar (n=0)	-	-
Soft drinks, sweetener (n=32)	48	220
«Saft», sweetener (n=8)	124	167
Nectar, sweetener (n=1)	130	130
Flavoured water (n=0)	-	-

Sucralose

	Weighted average (mg/l)	Highest reported value (mg/l)
Soft drinks, sugar (n=0)	-	-
«Saft», sugar (n=0)	-	-
Soft drinks, sweetener (n=11)	78	240
«Saft», sweetener (n=10)	169	184
Nectar, sweetener (n=0)	-	-
Flavoured water (n=0)	-	-

Benzoic acid

	Weighted average (mg/l)	Highest reported value (mg/l)
Soft drinks, sugar (n=26)	127	147
«Saft», sugar (n=17)	110	173
Soft drinks, sweetener (n=15)	142	148
«Saft», sweetener (n=15)	135	173
Nectar, sweetener (n=0)	-	-
Flavoured water (n=12)	109	131

Appendix 2

The reported intake of beverages (from the dietary surveys used in the current report).

Reported intake of soft drinks and "saft" with added sugar (g/day), consumers only.

	Mean	95-percentile
2-year-olds	86	294
Young women (18-29)	347	1069
Young men (18-29)	546	1483
Women (30-70)	295	720
Men (30-70)	380	1000
Women (18-70)	-	-
Men (18-70)	-	-

Reported intake of soft drinks and "saft" with added sweetener (g/day), consumers only.

	Mean	95-percentile
2-year-olds	91	360
Young women (18-29)	413	1400
Young men (18-29)	427	937
Women (30-70)	427	1204
Men (30-70)	506	1450
Women (18-70)	-	-
Men (18-70)	-	-