Vitenskapskomiteen for mattrygghet
Norwegian Scientific Committee for Food Safety

Risk assessments of cyclamate, saccharin, neohesperidine DC, steviol glycosides and neotame from soft drinks, “saft” and nectar

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

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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.

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Assessed by

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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 cyclamate, saccharin, neohesperidine DC, steviol glycosides and neotame in soft drinks, "saft" and nectar. The risk assessment includes exposure assessments and the calculated exposures are compared to the acceptable daily intake (ADI) for the respective sweeteners. VKM was also requested to compare the current calculated intake of saccharin and cyclamate to the calculated intake reported by VKM in 2007 (the VKM report «Impact on health when sugar is replaced with intense sweeteners in soft drinks, "saft" and nectar») when possible (VKM, 2007).

Six different intake 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) were used for the exposure calculations.

- Scenario 1 gives the best estimate of the current situation in the population (average content of sweeteners, actual reported consumption).
- Scenario 2 is based on the average content of sweeteners and that all consumed beverages contain sweeteners.
- Scenario 3 is based on the highest reported content of sweeteners and the actual reported consumption.
- Scenario 4 is based on the highest reported content of sweeteners and that all consumed beverages contain sweeteners.

Scenarios 5 and 6 are based on the maximum allowed amounts of sweeteners within a category in accordance with the Regulation on food additives, within the categories soft drinks, "saft" and nectar in Norway (Regulation No 668 of 6 June 2011 on food additives, 2011).

- In scenario 5 the consumption of beverages with added sweeteners or sugar reported in dietary surveys were used for the calculations.
- In scenario 6 it was assumed that all consumed soft drinks, "saft" and nectar contained sweeteners (no sugar).

In the current risk assessment, the intake of the sweeteners was calculated for 2-year-old children and 18-70 year old men and women. Due to lack of new dietary surveys, the other age groups of children and adolescents were not included.

For all age groups in all scenarios, the intake of the sweeteners cyclamate, saccharin, neohesperidine DC, steviol glycosides and neotame was below their respective established ADI values. Due to possible differences in the calculation, it was not possible to compare the current calculated intake of saccharin and cyclamate to the calculated intake reported by VKM in 2007.

VKM concludes that there is no major health concern related to the intake of the sweeteners cyclamate, saccharin, neohesperidine DC, steviol glycosides and neotame from the beverage categories included in this risk assessment per today.

VKM further concludes that among young women who are high consumers of beverages with cyclamate, and 2-year-old children who are high consumers of beverages with steviol glycosides, the estimated intake approaches the ADI values. The high intakes approaching ADI are considered conservative estimates, as the highest reported content of sweetener or the maximum allowed amounts is used. Thus, these estimates are only relevant for the part of the population that are both loyal to beverages with sweeteners and a particular brand of sweetened beverage. It should be noted that intake of sweeteners from other foods or from tabletop sweeteners is not included in the intake estimates, and that a considerable contribution from these sources cannot be excluded.

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 cyklamat, sakkarin, neohesperidin DC, steviolglykosider og neotam i leskedrikker, saft og nektar. 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 opp til seks ulike scenarier hvor det som varierte var konsentrasjonen av søtstoff (konsentrasjonene som ble brukt var enten gjennomsnittskonsentrasjonen eller den høyeste rapporterte konsentrasjonen i produktene) 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 innenfor kategoriene inneholdt søtstoff).

- Scenario 1 gir det beste estimatet av dagens situasjon i befolkningen (gjennomsnittskonsentrasjonen av søtstoff, rapportert inntak av drikkevarer).
- Scenario 2 er basert på gjennomsnittskonsentrasjonen av søtstoff og at det kun konsumeres drikkevarer tilsatt søtstoffer.
- Scenario 3 er basert på høyeste rapporterte konsentrasjon av søtstoff og rapportert inntak av drikkevarer.
- Scenario 4 er basert på høyeste rapporterte konsentrasjon av søtstoff og at det kun konsumeres drikkevarer tilsatt søtstoffer.

Scenariene 5 og 6 er basert på den maksimale mengden søtstoff det er tillatt å sette til produkter i kategoriene leskedrikker, saft og nektar i Norge (Forskrift 6. juni 2011 nr. 668 om tilsetningsstoffer til næringsmidler, 2011).

- I scenario 5 brukes rapportert inntak av drikkevarer.
- Scenario 6 er basert på antagelsen om at det kun konsumeres drikkevarer tilsatt søtstoff.

I denne vurderingen ble inntaket til to-åringer 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 cyklamat, sakkarin, steviolglykosider, neohesperidin DC og neotam ligger under ADI hos alle aldersgrupper, både for gjennomsnittskonsumenter og for høykonsumenter, i alle scenariene. Det var ikke mulig å sammenligne inntaksberegningene med de som ble gjort i VKMs risikovurdering fra 2007 på grunn av mulige forskjeller i hvordan beregningene ble gjort.

VKM konkluderer med at for alle aldersgrupper er inntaket av de intense søtstoffene cyklamat, sakkarin, steviolglykosider, neohesperidin DC og neotam under ADI-verdiene og derfor ikke til bekymring.

VKM konkluderer videre at for unge kvinner som er høykonsumenter av drikke tilsatt cyklamat og 2-åringer som er høykonsumenter av drikke tilsatt steviolglykosider, nærmer det beregnede inntaket seg deres respektive ADI-verdier. Disse høye inntakene anses å være konservative siden de er basert på enten høyeste rapporterte innhold av søtstoff eller at det er tilsatt maksimal tillatt mengde av søtstoffet. Disse estimatene er derfor kun relevante for den delen av befolkningensom kun konsumerer drikke tilsatt søtstoff, og som holder seg til produkter med høyest innhold av søtstoff.

Det er viktig å merke seg at det beregnede inntaket kun omfatter drikkevarer og at man i tillegg kan få i seg søtstoffene fra mat eller bordsøtningsmidler. Det kan ikke utelukkes at det også kan være et betydelig bidrag fra disse kildene.

Key words

Cyclamate, neohesperidine DC, neotame, risk assessment, saccharin, “saft”, soft drink, steviol glycosides

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

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 body weight (mg/kg bw).

Average concentration of sweetener in each product category; calculated from the reported concentration in each product within a product category multiplied by the relative sales volume for the specific product/brand.

High consumers; consumption at the 95th percentile.

Relative sales volume of the sweetener 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 by the consumers before drinking.

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

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

Contents

Background

The high intake of added sugar is one of the most important health-related concerns in the diet of children and adolescents. To reduce the intake of added sugar, 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 may 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 in the Norwegian population from consumption of beverages, and evaluate whether the intake exceeds the acceptable daily intake (ADI). If the intake of intense sweeteners is higher than the ADI, this may increase the risk of adverse health effects.VKM was also asked to describe trends in the intake of sweeteners from beverages over time if possible.

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 published two new dietary surveys, Småbarnskost (data collected 2006/2007, published 2009) and Norkost 3 (data collected 2010/2011, published 2012), which is used for the intake calculations in the current risk assessment.

The assignment is divided into two parts. Part A, published the 20th of December 2013, addressed aspartame, acesulfame K, sucralose and benzoic acid. Part B (the current assessment) addresses the sweeteners cyclamate, saccharin, neohesperidine DC, steviol glycosides and neotame.

Terms of reference

The Norwegian Food Safety Authority requested the Norwegian Scientific Committee for Food Safety (VKM) to perform a risk assessment of cyclamate, saccharin, neohesperidine DC, steviol glycosides and neotame that cover the following points:

1. Estimate the intake of the sweeteners cyclamate, saccharin, neohesperidine DC, steviol glycosides and neotame from soft drinks ("leskedrikker"), "saft" and nectar according to the scheme in Table 2. Furthermore, the Norwegian Food Safety Authority requests VKM to assess whether the estimated intake levels of cyclamate, saccharin, neohesperidine DC, steviol glycosides and neotame exceeds the acceptable daily intake (ADI) for the respective sweeteners in the general population or in parts of the population. The intake estimates refer to each of the product categories separately: soft drinks, "saft" and nectar.

2. To what extent has the intake of cyclamate, saccharin, neohesperidine DC, steviol glycosides and neotame 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 foods and as table-top sweeteners. Sweeteners may be divided in two categories, the intense sweeteners and sugar alcohols. In this report, the intense sweeteners cyclamate (E952), saccharin (E954), neohesperidine DC (E959), steviol glycosides (E960) and neotame (E961) are assessed. Cyclamate, saccharin, neohesperidine DC, steviol glycosides and neotame are all low-calorie, intense sweeteners. Compared to sugar, cyclamate is approximately 30 times sweeter, saccharin is approximately 400 times sweeter, neohesperidine DC is approximately 1900 times sweeter, steviol glycosides are 200-300 times sweeter, and neotame is approximately 7000-13000 sweeter (matportalen.no, 2013, Mortensen, 2006, EFSA, 2010). It is common to use several sweeteners in combination to provide a better taste to food and drinks (matportalen.no, 2013).

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

In 2007, the risk assement «Impact on health when sugar is replaced with intense sweeteners in soft drinks, "saft" and nectar» was published by the Norwegian Scientific Committe 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 sugarfree drinks was increased compared to the level of preservatives added to sugar-containing drinks

The conclusions regarding cyclamate and saccharin, which were the only sweeteners relevant for this assessment, were reported as follows in the 2007 risk assessment (in short):

The estimated intakes of the intense sweeteners saccharin and cyclamate 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. Altogether, no health concern is connected to the use of the above-mentioned intense sweeteners in soft drinks, "saft" and nectar.

The weighted average of cyclamate and saccharin from the 2007 risk assessment and in the present risk assessment can not be directly compared, due to possible differences in the calculation.

Therefore, it is not possible to answer question number 2 in the terms of reference: "To what extent has the intake of cyclamate, saccharin, neohesperidine DC, steviol glycosides and neotame 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."

2 Hazard characterization of cyclamate, saccharin, neohesperidine DC, steviol glycosides and neotame

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.

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. Exposure above the ADI value is not desirable. An occasional exceedance of the ADI represents a reduced safety margin and increases the risk for adverse effects. The ADI is not a threshold for toxicity with immediate onset of adverse effects when exceeded.

Cyclamate (E952)

Evaluations by SCF and JECFA

JECFA evaluated cyclamate in 1977, 1980 and 1982. An ADI of 0-11 mg/kg bw was established in 1982 (JECFA, 1977b, JECFA, 1980, JECFA, 1982). The first SCF opinion on cyclamate was expressed in 1984 (SCF, 1985) and a temporary ADI of 11 mg/kg bw for cyclamate and its sodium and calcium salts was established.The ADI was temporary due to the possibility of some humans metabolising cyclamate to cyclohexylamine, for which toxicity to the testicles were found at high doses. A re-evaluation of the ADI by SCF in 2000 resulted in the establishment of a full ADI of 7 mg/kg bw for cyclamate (SCF, 2000), based on new human biotransformation data on cyclamate.

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

Saccharin (E954)

Evaluations by SCF and JECFA

JECFA evaluated saccharin in 1967, 1974, 1977, 1980, 1984 and 1993, and in 1993 an ADI of 0-5 mg/kg bw was established (JECFA, 1993). A temporary ADI of 2.5 mg/kg bw was established for saccharin by SCF in 1977 (JECFA, 1977a), and it was maintained until 1993 (JECFA, 1993). The temporary ADI was due to findings of increased incidence of bladder cancer in rats after high exposure to saccharin. In 1995, SCF established an ADI of 5 mg/kg bw for saccharin (SCF, 1995), since it was concluded that saccharine was not genotoxic and that the development of bladder cancer was specific to rats and only observed at very high doses.

For a detailed description of the establishment of the presently applied ADI, please see the SCF report (SCF, 1995).

Steviol glycosides (E960)

Evaluations by EFSA, SCF and JECFA

The sweetener stevioside was evaluated by SCF in 1984, 1989 and 1999 (SCF, 1985, SCF, 1989, SCF, 1999). SCF concluded that the use of stevioside was not acceptable due to insufficient toxicity data, specifically on genotoxicity and reproductive toxicity, to assess the safety. JECFA evaluated the safety of steviol glycosides in 1998, and no ADI was allocated because insufficient data were available and specifications were not prepared (JECFA, 1998). In 2006, a temporary ADI of 0–2 mg/kg bw was established for steviol glycosides (JECFA, 2006). In 2009, an ADI (expressed as steviol equivalents) of 0-4 mg/kg bw/day was established (JECFA, 2009). In 2010, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) evaluated the safety of steviol glycosides, including new toxicity data available since 1999, for the proposed use as a food additive, and an ADI of 4 mg/kg bw was established (EFSA, 2010).

For a detailed description of the presently applied ADI, please see the EFSA report (EFSA, 2010).

Neohesperidine DC (E959)

Evaluations by SCF

The first SCF opinion on neohesperidine DC published in 1984 concluded that the use of neohesperidine DC was unacceptable due to lack of toxicity data (SCF, 1985). In 1988, new toxicity data was available and an ADI of 5 mg/kg bw for neohesperidine DC was established by SCF (SCF, 1989). JECFA has not evaluated neohesperidine DC.

For a detailed description of the establishment of the presently applied ADI, please see the SCF report (SCF, 1989).

Neotame (E961)

Evaluations by JECFA and EFSA

Neotame was evaluated by JECFA in 2003 and an ADI of 0-2 mg/kg bw was established (JECFA, 2003). In 2007, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) evaluated the safety of neotame as a sweetener and flavour enhancer, and an ADI of 2 mg/kg bw was established (EFSA, 2007).

For a detailed description of the presently applied ADI, please see the EFSA report (EFSA, 2007).

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

Substance	ADI	Reference
Cyclamate	7 mg/kg bw	(SCF, 2000)
Saccharin	5 mg/kg bw	(SCF, 1995)
Steviol glycosides	4 mg/kg bw	(EFSA, 2010)
Neohesperidine DC	5 mg/kg bw	(SCF, 1989)
Neotame	2 mg/kg bw	(EFSA, 2007)

3 Exposure assessment

The exposure assessments were performed according to six different scenarios, and the actual scenarios used for the respective sweetener were depending on the available data for each sweetener.

Scenario 1 gives the best estimate of the current situation in the population with respect to consumption and actual content of sweetener.

Scenario 2 includes population groups loyal to products added sweeteners. It 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 and "saft" contains sweeteners, no added sugar), and the level of added sweeteners is average (based on reported content that is adjusted for sale).

Scenario 3 includes population groups loyal to the brands added the highest reported level of sweeteners. It 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.

Scenario 4 includes the population groups loyal to products added sweeteners and loyal to the brands added the highest reported level of sweeteners. It 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 and "saft" contains sweeteners, no added sugar).

There is no reported use of neohesperidine DC or neotame in soft drinks, "saft" and nectar on the Norwegian market. Therefore, the maximum allowed amount of these sweeteners within a category (in accordance with the Regulation on food additives) was used for the exposure assessments (Regulation No 668 of 6 June 2011 on food additives, 2011).

In scenario 5 the consumption of beverages with added sweeteners reported in dietary surveys were used for the calculations. The maximum allowed amount of sweetener within the categories soft drinks, "saft" and nectar were used (Regulation No 668 of 6 June 2011 on food additives, 2011).

In scenario 6 it was assumed that all consumed soft drinks, "saft" and nectar contained sweeteners (no sugar). The maximum allowed amount of sweetener within the categories soft

drinks, “saft” and nectar were used (Regulation No 668 of 6 June 2011 on food additives, 2011).

Scenarios 5 and 6 are used for the exposure assessments of steviol glycosides, and scenario 6 is used for neohesperidine DC and neotame.

In this risk assessment, the intake of intense sweeteners from beverages divided in the categories soft drinks, “saft” and nectar, was calculated from actual use levels in 2012 as reported by the producers in October 2013. In Norway, the sweeteners cyclamate and saccharin are used in the beverage category soft drinks, and steviol glycosides are used in the beverage category “saft”. The data from the industry contained no information on the use of neohesperidine DC or neotame in products within the categories soft drinks, “saft” or nectar. For neohesperidine DC and neotame, the exposure is estimated using a scenario including the maxium allowed concentration in all three categories (scenario 6).

Table 2: An overview of the different exposure assessments.

CONTENT of sweeteners in beverages (mg/l). / **INTAKE of sweeteners from beverages (mg/kg bw/day).**	**Based om sales figures and data on the actual content of the sweeteners in specified products in 2012 (reported by the producers October 2013).**	**Based on the highest reported content of the sweeteners in a product within a category in 2012 (reported by the producers October 2013).**	**Based on the maximum amount allowed sweeteners within a category in accordance with the Regulation No 668 of 6 June 2011 on food additives (2011).**
The actual consumption of beverages with added sweetener or sugar reported in dietary surveys.	**Scenario 1** Content: The average content of sweetener (adjusted for sale). Consumption: The actual consumption of beverages with added sweetener reported in dietary surveys.	**Scenario 3** Content: The highest reported value for the content of sweetener is used for the calculation. Consumption: The actual consumption of beverages with added sweetener reported in dietary surveys.	**Scenario 5** Content: The maximum allowed content of sweetener is used for the calculation. Consumption: The consumption of beverages with added sweeteners 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 (adjusted for sale). Consumption: It is assumed that all consumed soft drinks and "saft" contained sweeteners (no sugar).	**Scenario 4** Content: The highest reported value for the content of sweetener is used for the calculation. Consumption: It is assumed that all consumed soft drinks or "saft" contained sweeteners (no sugar).	**Scenario 6** Content: The maximum allowed content of sweetener is used for the calculation. Consumption: It is assumed that all consumed soft drinks, "saft" and nectar contained sweeteners (no sugar).

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" and nectar) registered in the dietary surveys were multiplied with the products' corresponding concentration of sweeteners as described. The exposure assessments were based on annual sales volumes and data on the actual content of the sweeteners in specified products in 2012 (reported by the manufacturers October 2013), representing the majority of brands with dominating market shares on the Norwegian market, or on the maximum amount allowed sweeteners within a category in accordance with the Regulation on food additives (Regulation No 668 of 6 June 2011 on food additives, 2011). The vast majority of soft drinks, "saft" and nectar 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 drink, "saft" and nectar on the Norwegian market.

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

Relative sales volume of the sweetener 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 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 = calculated from the average concentration of sweetener for all products within a category adjusted for sales volume.

The average concentration and the weighted average of the sweeteners 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 2006/2007, 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 and "saft" 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, Matvaretabellen, 2006).

The two dietary surveys used in this risk assessment were conducted at two different time points, Småbarnskost in 2006/2007 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 in the different products used in the exposure assessment were collected from the industry in 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 mean body weight for women and men, young adults and adults).

The calculated exposure to the sweeteners cyclamate, saccharin and steviol glycosides from soft drinks and "saft" were based on the actual content in the beverages and the actual sales. The calculated exposure to neohesperidine DC and neotame were based on maximum allowed amount of these sweeteners within the categories soft drinks and "saft". 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, scenarios 1-4, were performed for cyclamate and saccharin (Table 2). Four different exposure assessments, scenarios 1, 2, 5 and 6 were performed for steviol glycosides (Table 2). One exposure assessment, scenario 6, was performed for neohesperidine DC and neotame (Table 2).

When the number of participants in a group was less than 60 persons, the 95th percentile was not calculated (EFSA, 2011).

Exposure assessment of cyclamate (E952)

The exposure assessment of cyclamate from soft drinks (shown in Tables 3-7) was based on the actual cyclamate content, the Norwegian sales volumes reported by the industry, and the dietary surveys. In Norway, cyclamate is used in the beverage category soft drinks. Four different exposure assessments were performed; scenarios 1-4.

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

Scenario 1
Content*: The average content of cyclamate (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)	0.61	1.14
Total (n=263)	0.61	1.14

Scenario 2
Content*: The average content of cyclamate (adjusted for sale).
Consumption:** It is assumed that all consumed soft drinks contain sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=530)	0.67	1.46
Total (n=530)	0.67	1.46

Scenario 3
Content*: The highest value for the amount of added cyclamate in soft drinks 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)	0.80	1.51
Total (n=263)	0.80	1.51

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

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=530)	0.89	1.94
Total (n=530)	0.89	1.94

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

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

Scenario 1
Content*: The average content of cyclamate (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)	1.19	-
Total (n=33)	1.19	-

Scenario 3
Content*: The highest value for the amount of added cyclamate in soft 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=33)	1.58	-
Total (n=33)	1.58	-

Scenario 2
Content*: The average content of cyclamate (adjusted for sale).
Consumption:** It is assumed that all consumed soft drinks contain sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=78)	1.29	5.06
Total (n=78)	1.29	5.06

Scenario 4
Content*: The highest value for the amount of added cyclamate in soft drinks is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks contain sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=78)	1.71	6.73
Total (n=78)	1.71	6.73

Based on *sales figures and data on the actual content of cyclamate in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3. ***The 95th percentile was not calculated (n<60).

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

Scenario 1
Content*: The average content of cyclamate (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)	0.97	-
Total (n=23)	0.97	-

Scenario 3
Content*: The highest value for the amount of added cyclamate in soft drinks 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=23)	1.29	-
Total (n=23)	1.29	-

Scenario 2
Content*: The average content of cyclamate (adjusted for sale).
Consumption:** It is assumed that all consumed soft drinks contain sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=88)	1.50	3.87
Total (n=88)	1.50	3.87

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

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=88)	2.00	5.14
Total (n=88)	2.00	5.14

Based on *sales figures and data on the actual content of cyclamate in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3. ***The 95th percentile was not calculated (n<60).

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

Scenario 1
Content*: The average content of cyclamate (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)	1.31	3.72
Total (n=173)	1.31	3.72

Scenario 2
Content*: The average content of cyclamate (adjusted for sale).
Consumption:** It is assumed that all consumed soft contain sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=277)	1.15	2.99
Total (n=277)	1.15	2.99

Scenario 3
Content*: The highest value for the amount of added cyclamate in soft drinks 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=173)	1.74	4.94
Total (n=173)	1.74	4.94

Scenario 4
Content*: The highest value for the amount of added cyclamate in soft drinks is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks contain sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=277)	1.53	3.97
Total (n=277)	1.53	3.97

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

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

Scenario 1
Content*: The average content of cyclamate (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)	1.21	3.55
Total (n=133)	1.21	3.55

Scenario 2
Content*: The average content of cyclamate (adjusted for sale).
Consumption:** It is assumed that all consumed soft drinks contain sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=285)	1.16	3.29
Total (n=285)	1.16	3.29

Scenario 3
Content*: The highest value for the amount of added cyclamate in soft drinks 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=133)	1.61	4.71
Total (n=133)	1.61	4.71

Scenario 4
Content*: The highest value for the amount of added cyclamate in soft drinks is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks contain sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=285)	1.54	4.37
Total (n=285)	1.54	4.37

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

For **scenario 1**, the mean cyclamate and the 95th percentile intake from soft drinks was found to be highest for women. For **scenario 2**, the mean cyclamate 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 and the 95th percentile cyclamate intake was found to be highest for women. For **scenario 4**, the mean cyclamate intake was found to be highest for young men and the 95th percentile intake was found to be highest for young women.

Exposure assessment of saccharin (E954)

The exposure assessment of saccharin from soft drinks (shown in Tables 8-12) was based on the actual saccharin content, the Norwegian sales volumes reported by the industry, and the dietary surveys. In Norway, saccharin is used in the beverage category soft drinks. Four different exposure assessments were performed; scenarios 1-4.

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

Scenario 1
Content*: The average content of saccharin (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)	0.15	0.29
Total (n=263)	0.15	0.29

Scenario 2
Content*: The average content of saccharin (adjusted for sale).
Consumption:** It is assumed that all consumed soft drinks contain sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=530)	0.17	0.37
Total (n=530)	0.17	0.37

Scenario 3
Content*: The highest value for the amount of added saccharin in soft drinks 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)	0.22	0.41
Total (n=263)	0.22	0.41

Scenario 4
Content*: The highest value for the amount of added saccharin in soft drinks is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks contain sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=530)	0.24	0.53
Total (n=530)	0.24	0.53

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

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

Scenario 1
Content*: The average content of saccharin (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)	0.30	-
Total (n=33)	0.30	-

Scenario 3
Content*: The highest value for the amount of added saccharin in soft drinks 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)	0.43	-
Total (n=33)	0.43	-

Scenario 2
Content*: The average content of saccharin (adjusted for sale).
Consumption:** It is assumed that all consumed soft drinks contain sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=78)	0.33	1.30
Total (n=78)	0.33	1.30

Scenario 4
Content*: The highest value for the amount of added saccharin in soft drinks is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks contain sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=78)	0.46	1.83
Total (n=78)	0.46	1.83

Based on *sales figures and data on the actual content of saccharin in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3. *** The 95th percentile was not calculated (n<60).

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

Scenario 1
Content*: The average content of saccharin (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)	0.25	-
Total (n=23)	0.25	-

Scenario 3
Content*: The highest value for the amount of added saccharin in soft drinks 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)	0.35	-
Total (n=23)	0.35	-

Scenario 2
Content*: The average content of saccharin (adjusted for sale).
Consumption:** It is assumed that all consumed soft drinks contain sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=88)	0.38	0.99
Total (n=88)	0.38	0.99

Scenario 4
Content*: The highest value for the amount of added saccharin in soft drinks is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks contain sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=88)	0.54	1.39
Total (n=88)	0.54	1.39

Based on *sales figures and data on the actual content of saccharin in specified products (for 2012; reported by the producers October 2013) and **the dietary survey Norkost 3. *** The 95th percentile was not calculated (n<60).

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

Scenario 1
Content*: The average content of saccharin (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)	0.34	0.95
Total (n=173)	0.34	0.95

Scenario 2
Content*: The average content of saccharin (adjusted for sale).
Consumption**:** It is assumed that all consumed soft drinks contain sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=277)	0.30	0.76
Total (n=277)	0.30	0.76

Scenario 3
Content*: The highest value for the amount of added saccharin in soft drinks 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)	0.47	1.34
Total (n=173)	0.47	1.34

Scenario 4
Content*: The highest value for the amount of added saccharin in soft drinks is used for the calculation.
Consumption**:** It is assumed that all consumed soft drinks contain sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=277)	0.42	1.08
Total (n=277)	0.42	1.08

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

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

Scenario 1
Content*: The average content of saccharin (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)	0.31	0.91
Total (n=133)	0.31	0.91

Scenario 3
Content*: The highest value for the amount of added saccharin in soft drinks 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)	0.44	1.28
Total (n=133)	0.44	1.28

Scenario 2
Content*: The average content of saccharin (adjusted for sale).
Consumption:** It is assumed that all consumed soft drinks contain sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=285)	0.30	0.84
Total (n=285)	0.30	0.84

Scenario 4
Content*: The highest value for the amount of added saccharin in soft drinks is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks contain sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=285)	0.42	1.19
Total (n=285)	0.42	1.19

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

For **scenario 1**, the mean and the 95th percentile saccharin intake from soft drinks was found to be highest for women. For **scenario 2**, the mean saccharin 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 and the 95th percentile cyclamate intake was found to be highest for women. For **scenario 4**, the mean cyclamate and the 95th percentile intake was found to be highest for young men.

Exposure assessment of steviol glycosides (E960)

In Norway, the sweetener steviol glycosides is used in "saft". The exposure assessment of steviol glycosides from "saft" (scenarios 1 and 2, shown in Tables 13-17) was based on the actual content of steviol glycosides, the Norwegian sales volumes reported by the industry, and the dietary surveys. In addition, the maximum allowed amount of steviol glycosides within a category was used for the exposure assessments in the scenarios 5 and 6 (Regulation No 668 of 6 June 2011 on food additives, 2011).

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

Scenario 1
Content*: The average content of steviol glycosides (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)
"Saft" (n=427)	0.18	0.68
Total (n=427)	0.18	0.68

Scenario 2
Content*: The average content of steviol glycosides (adjusted for sale).
Consumption:** It is assumed that all consumed "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
"Saft" (n=1012)	0.19	0.68
Total (n=1012)	0.19	0.68

Scenario 5
Content***: The maximum allowed content of steviol glycosides in soft drinks and "saft" is used for the calculation (80 mg/l for soft drinks, 100 mg/l for "saft").
Consumption:** The consumption of beverages with added sweeteners or sugar reported in dietary surveys.

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=263)	0.22	0.42
"Saft" (n=427)	0.73	2.81
Total (n=542)	0.68	2.38

Scenario 6
Content*: The maximum allowed content of steviol glycosides in soft drinks, "saft" and nectar is used for the calculation (80 mg/l for soft drinks, 100 mg/l for "saft" and nectar).
Consumption:** It is assumed that all consumed soft drinks, "saft" and nectar contained sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=530)	0.24	0.53
"Saft" (n=1012)	0.80	2.81
Nectar (n=401)	0.49	1.86
Total (n=1216)	0.93	3.18

*Based on sales figures and data on the actual content of steviol glycosides in specified products (for 2012; reported by the producers October 2013). ** Based on the dietary survey Småbarnskost 2007. *** Based on the maximum amount allowed steviol glycosides within a category in accordance with the Regulation No 668 of 6 June 2011 on food additives (2011).

Table 14: Steviol glycosides exposure assessment (consumers only); young women (age 18-29 years).

Scenario 1
Content*: The average content of steviol glycosides (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)
"Saft" (n=10)	0.14	-
Total (n=10)	0.14	-

Scenario 2
Content*: The average content of steviol glycosides (adjusted for sale).
Consumption**:** It is assumed that all consumed "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile**** (mg/kg bw/day)
"Saft" (n=27)	0.11	-
Total (n=27)	0.11	-

Scenario 5
Content*: The maximum allowed content of steviol glycosides in soft drinks and "saft" is used for the calculation (80 mg/l for soft drinks, 100 mg/l for "saft").
Consumption**:** The consumption of beverages with added sweeteners or sugar reported in dietary surveys.

	Mean (mg/kg bw/day)	95-percentile**** (mg/kg bw/day)
Soft drinks (n=33)	0.43	-
"Saft" (n=10)	0.59	-
Total (n=39)	0.52	-

Scenario 6
Content*: The maximum allowed content of steviol glycosides in soft drinks, "saft" and nectar is used for the calculation (80 mg/l for soft drinks, 100 mg/l for "saft" and nectar).
Consumption**:** It is assumed that all consumed soft drinks, "saft" and nectar contained sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile**** (mg/kg bw/day)
Soft drinks (n=78)	0.47	1.85
"Saft" (n=27)	0.47	-
Nectar (n=3)	0.34	-
Total (n=93)	0.54	1.87

*Based on sales figures and data on the actual content of steviol glycosides in specified products (for 2012; reported by the producers October 2013). ** Based on the dietary survey Norkost 3. *** Based on the maximum amount allowed steviol glycosides within a category in accordance with the Regulation No 668 of 6 June 2011 on food additives (2011). **** The 95th percentile was not calculated (n<60).

Table 15: Steviol glycosides exposure assessment (consumers only); young men (age 18-29 years).

Scenario 1
Content*: The average content of steviol glycosides (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)
"Saft" (n=14)	0.12	-
Total (n=)	0.12	-

Scenario 2
Content*: The average content of steviol glycosides (adjusted for sale).
Consumption:** It is assumed that all consumed "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile**** (mg/kg bw/day)
"Saft" (n=37)	0.13	-
Total (n=37)	0.13	-

Scenario 5
Content*: The maximum allowed content of steviol glycosides in soft drinks and "saft" is used for the calculation (80 mg/l for soft drinks, 100 mg/l for "saft").
Consumption:** The consumption of beverages with added sweeteners or sugar reported in dietary surveys.

	Mean (mg/kg bw/day)	95-percentile**** (mg/kg bw/day)
Soft drinks (n=23)	0.36	-
"Saft" (n=14)	0.50	-
Total (n=31)	0.49	-

Scenario 6
Content*: The maximum allowed content of steviol glycosides in soft drinks, "saft" and nectar is used for the calculation (80 mg/l for soft drinks, 100 mg/l for "saft" and nectar).
Consumption:** It is assumed that all consumed soft drinks, "saft" and nectar contained sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile**** (mg/kg bw/day)
Soft drinks (n=88)	0.55	1.41
"Saft" (n=37)	0.53	-
Nectar (n=4)	0.27	-
Total (n=100)	0.69	1.67

*Based on sales figures and data on the actual content of steviol glycosides in specified products (for 2012; reported by the producers October 2013). ** Based on the dietary survey Norkost 3. *** Based on the maximum amount allowed steviol glycosides within a category in accordance with the Regulation No 668 of 6 June 2011 on food additives (2011). **** The 95th percentile was not calculated (n<60).

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

Scenario 1
Content*: The average content of steviol glycosides (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)
"Saft" (n=49)	0.10	-
Total (n=49)	0.10	-

Scenario 2
Content*: The average content of steviol glycosides (adjusted for sale).
Consumption**:** It is assumed that all consumed "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
"Saft" (n=124)	0.11	0.28
Total (n=124)	0.11	0.28

Scenario 5
Content***: The maximum allowed content of steviol glycosides in soft drinks and "saft" is used for the calculation (80 mg/l for soft drinks, 100 mg/l for "saft").
Consumption**:** The consumption of beverages with added sweeteners or sugar reported in dietary surveys.

	Mean (mg/kg bw/day)	95-percentile**** (mg/kg bw/day)
Soft drinks (n=173)	0.48	1.36
"Saft" (n=49)	0.40	-
Total (n=209)	0.49	1.37

Scenario 6
Content*: The maximum allowed content of steviol glycosides in soft drinks, "saft" and nectar is used for the calculation (80 mg/l for soft drinks, 100 mg/l for "saft" and nectar).
Consumption**:** It is assumed that all consumed soft drinks, "saft" and nectar contained sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile**** (mg/kg bw/day)
Soft drinks (n=277)	0.42	1.09
"Saft" (n=124)	0.46	1.17
Nectar (n=4)	0.20	-
Total (n=350)	0.50	1.36

*Based on sales figures and data on the actual content of steviol glycosides in specified products (for 2012; reported by the producers October 2013). ** Based on the dietary survey Norkost 3. *** Based on the maximum amount allowed steviol glycosides within a category in accordance with the Regulation No 668 of 6 June 2011 on food additives (2011).**** The 95th percentile was not calculated (n<60).

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

Scenario 1
Content*: The average content of steviol glycosides (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)
"Saft" (n=48)	0.10	-
Total (n=48)	0.10	-

Scenario 2
Content*: The average content of steviol glycosides (adjusted for sale).
Consumption:** It is assumed that all consumed "saft" contains sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
"Saft" (n=139)	0.09	0.25
Total (n=139)	0.09	0.25

Scenario 5
Content*: The maximum allowed content of steviol glycosides in soft drinks and "saft" is used for the calculation (80 mg/l for soft drinks, 100 mg/l for "saft").
Consumption:** The consumption of beverages with added sweeteners or sugar reported in dietary surveys.

	Mean (mg/kg bw/day)	95-percentile**** (mg/kg bw/day)
Soft drinks (n=133)	0.44	1.30
"Saft" (n=48)	0.41	-
Total (n=165)	0.47	1.37

Scenario 6
Content*: The maximum allowed content of steviol glycosides in soft drinks, "saft" and nectar is used for the calculation (80 mg/l for soft drinks, 100 mg/l for "saft" and nectar).
Consumption:** It is assumed that all consumed soft drinks, "saft" and nectar contained sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile**** (mg/kg bw/day)
Soft drinks (n=285)	0.42	1.20
"Saft" (n=139)	0.38	1.03
Nectar (n=5)	0.19	-
Total (n=365)	0.48	1.39

*Based on sales figures and data on the actual content of steviol glycosides in specified products (for 2012; reported by the producers October 2013). ** Based on the dietary survey Norkost 3. *** Based on the maximum amount allowed steviol glycosides within a category in accordance with the Regulation No 668 of 6 June 2011 on food additives (2011). **** The 95th percentile was not calculated (n<60).

For **scenario 1, 2, 5 and 6** the mean and the 95th percentile intake of steviol glycosides were highest for the 2-year-old childen.

Exposure assessment of neohesperidine DC (E959)

The exposure assessment of neohesperidine DC from soft drinks, "saft" and nectar (shown in Tables 18-22) was based on the maximum allowed amount of neohesperidine DC within a category in accordance with the Regulation No 668 of 6 June 2011 on food additives (2011), and the consumption data from the dietary surveys. Neohesperidine DC is not reported used in Norwegian products. One exposure assessment was performed for the categories soft drinks, "saft" and nectar; scenario 6.

Table 18: Neohesperidine DC exposure assessment (consumers only); 2-year-olds.

Scenario 6
Content*: The maximum allowed content of neohesperidine DC in soft drinks, "saft" and nectar (30 mg/l) is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks, "saft" and nectar contained sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=530)	0.09	0.20
"Saft" (n=1012)	0.24	0.84
Nectar (n=401)	0.15	0.56
Total (n=1216)	0.29	0.97

Based on * the maximum amount allowed neohesperidine DC within a category in accordance with the Regulation No 668 of 6 June 2011 on food additives (2011) and **the dietary survey Småbarnskost 2007.

Table 19: Neohesperidine DC exposure assessment (consumers only); young women (age18-29 years).

Scenario 6
Content*: The maximum allowed content of neohesperidine DC in soft drinks, "saft" and nectar (30 mg/l) is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks, "saft" and nectar contained sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=78)	0.18	0.69
"Saft" (n=27)	0.14	-
Nectar (n=3)	0.10	-
Total (n=93)	0.19	0.66

Based on * the maximum amount allowed neohesperidine DC within a category in accordance with the Regulation No 668 of 6 June 2011 on food additives (2011) and **the dietary survey Norkost 3. *** The 95th percentile was not calculated (n<60).

Table 20: Neohesperidine DC exposure assessment (consumers only); young men (age18-29 years).

Scenario 6
Content*: The maximum allowed content of neohesperidine DC in soft drinks, "saft" and nectar (30 mg/l) is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks, "saft" and nectar contained sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=88)	0.21	0.53
"Saft" (n=37)	0.16	-
Nectar (n=4)	0.08	-
Total (n=100)	0.24	0.62

Based on * the maximum amount allowed neohesperidine DC within a category in accordance with the Regulation No 668 of 6 June 2011 on food additives (2011) and **the dietary survey Norkost 3. *** The 95th percentile was not calculated (n<60).

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

Scenario 6
Content*: The maximum allowed content of neohesperidine DC in soft drinks, "saft" and nectar (30 mg/l) is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks, "saft" and nectar contained sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=277)	0.16	0.41
"Saft" (n=124)	0.14	0.35
Nectar (n=4)	0.06	-
Total (n=350)	0.18	0.49

Based on * the maximum amount allowed neohesperidine DC within a category in accordance with the Regulation No 668 of 6 June 2011 on food additives (2011) and **the dietary survey Norkost 3. *** The 95th percentile was not calculated (n<60).

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

Scenario 6
Content*: The maximum allowed content of neohesperidine DC in soft drinks, "saft" and nectar (30 mg/l) is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks, "saft" and nectar contained sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=285)	0.16	0.45
"Saft" (n=139)	0.11	0.31
Nectar (n=5)	0.06	-
Total (n=365)	0.17	0.46

Based on * the maximum amount allowed neohesperidine DC within a category in accordance with the Regulation No 668 of 6 June 2011 on food additives (2011) and **the dietary survey Norkost 3. *** The 95th percentile was not calculated (n<60).

For **scenario 6**, the mean and the 95th percentile for total intake of neohesperidine DC from all three product categories was found to be highest for 2-year-old children.

Exposure assessment of neotame (E961)

The exposure assessment of neotame from soft drinks, "saft" and nectar (shown in Tables 23-27) was based on the maximum allowed amount of neotame within a category in accordance with the Regulation No 668 of 6 June 2011 on food additives (2011), and the consumption data from the dietary surveys Småbarnskost 2007 (Kristiansen et al., 2009) and Norkost 3 (Totland et al., 2012). Neotame is not reported used in Norwegian products. One exposure assessment was performed for the categories soft drinks, "saft" and nectar; scenario 6.

Table 23: Neotame exposure assessment (consumers only); 2-year-olds.

Scenario 6

Content*: The maximum allowed content of neotame (20 mg/l) in soft drinks, "saft" and nectar is used for the calculation.

Consumption:** It is assumed that all consumed soft drinks, "saft" and nectar contained sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile (mg/kg bw/day)
Soft drinks (n=530)	0.06	0.13
"Saft" (n=1012)	0.16	0.56
Nectar (n=401)	0.10	0.37
Total (n=1216)	0.19	0.64

Based on * the maximum amount allowed neotame within a category in accordance with the Regulation No 668 of 6 June 2011 on food additives (2011) and **the dietary survey Småbarnskost 2007.

Table 24: Neotame exposure assessment (consumers only); young women (age18-29 years).

Scenario 6
Content*: The maximum allowed content of neotame (20 mg/l) in soft drinks, "saft" and nectar is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks, "saft" and nectar contained sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=78)	0.12	0.46
"Saft" (n=27)	0.09	-
Nectar (n=3)	0.07	-
Total (n=93)	0.13	0.44

Based on * the maximum amount allowed neotame within a category in accordance with the Regulation No 668 of 6 June 2011 on food additives (2011) and **the dietary survey Norkost 3. *** The 95th percentile was not calculated (n<60).

Table 25: Neotame exposure assessment (consumers only); young men (age18-29 years).

Scenario 6
Content*: The maximum allowed content of neotame (20 mg/l) in soft drinks, "saft" and nectar is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks, "saft" and nectar contained sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=88)	0.14	0.35
"Saft" (n=37)	0.11	-
Nectar (n=4)	0.05	-
Total (n=100)	0.16	0.42

Based on * the maximum amount allowed neotame within a category in accordance with the Regulation No 668 of 6 June 2011 on food additives (2011) and **the dietary survey Norkost 3. *** The 95th percentile was not calculated (n<60).

Table 26: Neotame exposure assessment (consumers only); women (age 30-70 years).

Scenario 6
Content*: The maximum allowed content of neotame (20 mg/l) in soft drinks, "saft" and nectar is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks, "saft" and nectar contained sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=277)	0.11	0.27
"Saft" (n=124)	0.09	0.23
Nectar (n=4)	0.04	-
Total (n=350)	0.12	0.33

Based on * the maximum amount allowed neotame within a category in accordance with the Regulation No 668 of 6 June 2011 on food additives (2011)and **the dietary survey Norkost 3. *** The 95th percentile was not calculated (n<60).

Table 27: Neotame exposure assessment (consumers only); men (age 30-70 years).

Scenario 6
Content*: The maximum allowed content of neotame (20 mg/l) in soft drinks, "saft" and nectar is used for the calculation.
Consumption:** It is assumed that all consumed soft drinks, "saft" and nectar contained sweeteners (no sugar).

	Mean (mg/kg bw/day)	95-percentile*** (mg/kg bw/day)
Soft drinks (n=285)	0.11	0.30
"Saft" (n=139)	0.08	0.21
Nectar (n=5)	0.04	-
Total (n=365)	0.11	0.30

Based on * the maximum amount allowed neotame within a category in accordance with the Regulation No 668 of 6 June 2011 on food additives (2011) and **the dietary survey Norkost 3. *** The 95th percentile was not calculated (n<60).

For **scenario 6**, the mean and the 95th percentile for the total intake of neotame from all three product categories was found to be highest for 2-year-old children.

4 Risk characterization of cyclamate, saccharin, steviol glycosides, neohesperidine DC and neotame

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, were compared with the ADI values described in section 2 (an overview is given in Table 1) for the respective sweeteners in the risk characterization.

Cyclamate

The ADI for cyclamate is 7 mg/kg bw (SCF, 2000).

The total mean intake of cyclamate for the 2-year-olds ranged from 0.61 to 0.89 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 1.14 to 1.94 mg/kg bw/day (Table 3). The exposure scenarios for cyclamate for 2-year-olds do not exceed the ADI for cyclamate, 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 of beverages containing sweeteners (scenario 1 and 3) to the prediction that all the consumed beverages contained sweeteners (scenarios 2 and 4) increased the intake of cyclamate in this age group with approximately 0.3-0.4 mg/kg bw/day for the high consumers (scenario 4).

The total mean intake of cyclamate for young women (age 18-29 years) ranged from 1.19 to 1.71 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) for scenarios 2 and 4 ranged from 5.06 to 6.73 mg/kg bw/day (Table 4). High exposure in scenario 1 and 3 were not calculated due to low number (n<60) of consumers. The exposure estimates for cyclamate for young women do not exceed the ADI for cyclamate. However, the high consumers in scenario 4 have an intake estimate of 6.73 mg/kg bw/day, which approaches the ADI of 7 mg/kg bw for cyclamate. The change from actual consumption of beverages containing sweeteners (scenarios 1 and 3) to the prediction that all the consumed beverages contained sweeteners (scenarios 2 and 4) did not increase the mean intake of cyclamate in this age group considerably, indicating that a large part of this group already drink beverages with sweeteners.

The total mean intake of cyclamate for young men (age 18-29 years) ranged from 0.97 to 2.00 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) for scenarios 2 and 4 ranged from 3.87 to 5.14 mg/kg bw/day (Table 5). High exposure in scenario 1 and 3 were not calculated due to low number (n<60) of consumers. The exposure estimates for cyclamate for young men do not exceed the ADI for cyclamate, 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 of beverages containing sweeteners (scenarios 1 and 3) to the prediction that all the consumed beverages contained sweeteners (scenarios 2 and 4) increased the intake of cyclamate in this age group with approximately 0.7 mg/kg bw/day for the mean consumers (scenario 4).

The total mean intake of cyclamate for women (age 30-70 years) ranged from 1.15 to 1.74 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 2.99 to 4.94mg/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 cyclamate for women do not exceed the ADI for cyclamate, 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 (of

beverages containing sweeteners (scenarios 1 and 3) to the prediction that all the consumed beverages contained sweeteners (scenarios 2 and 4) for high consumers reduces the intake of cyclamate in this age group with approximately 0.7-1.0 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 cyclamate for men (age 30-70 years) ranged from 1.16 to 1.61 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 3.29 to 4.71 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 cyclamate for men do not exceed the ADI for cyclamate, 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 of beverages containing sweeteners (scenarios 1 and 3) to the prediction that all the consumed beverages contained sweeteners (scenarios 2 and 4) reduces the intake of cyclamate for high consumers 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 cyclamate among mean consumers is shown in Figure 1, and the intake among high consumers (the 95th percentile) is shown in Figure 2.

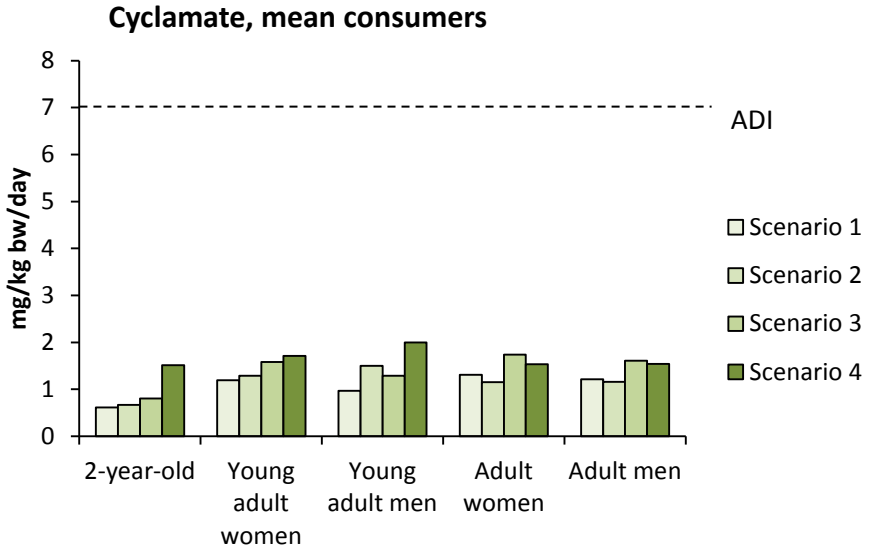

Figure 1. Intake of cyclamate among mean consumers of soft drinks from scenarios 1-4.

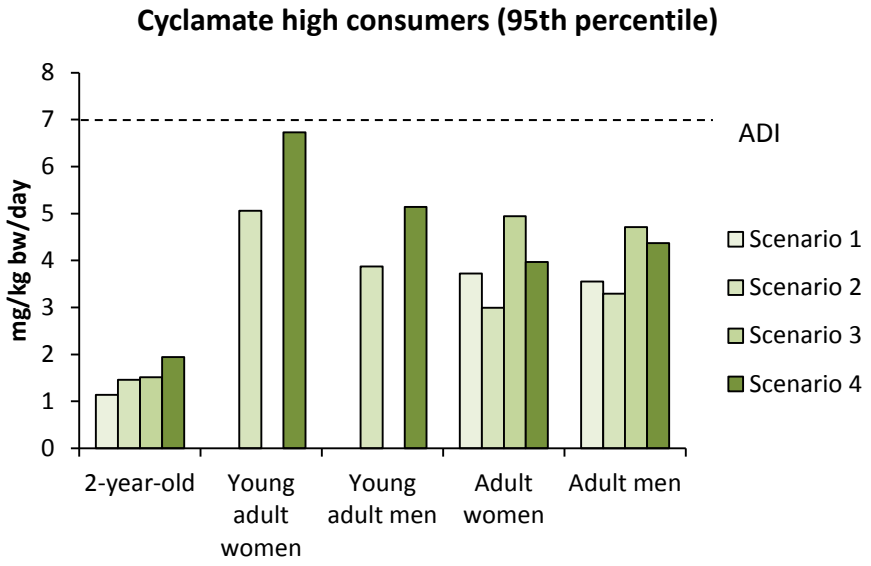

Figure 2. Intake of cyclamate among high consumers of soft drinks from scenarios 1-4. Due to few participants, the 95th percentile was not calculated for scenarios 1 and 3 for young adult women and young adult men.

Intake of cyclamate from food or the use as table top sweetener is not included in this intake estimate. Cyclamate has been used as a table top sweetener for many years, and the intake from table top sweeteners may contribute considerably, especially for persons with diabetes.

Saccharin

The ADI for saccharin is 5 mg/kg bw (SCF, 1995).

The total mean intake of saccharin for the 2-year-olds ranged from 0.15 to 0.24 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 0.29 to 0.53 mg/kg bw/day (Table 8). The exposure estimates for saccharin for 2-year-olds do not exceed the ADI for saccharin, 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 cyclamate in this age group considerably.

The total mean intake of saccharin for young women (age 18-29 years) ranged from 0.30 to 0.46 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 1.30 to 1.83 mg/kg bw/day (Table 9). High exposure in scenario 1 and 3 were not calculated due to low number (n<60) of consumers. The exposure estimates for saccharin for young women do not exceed the ADI for saccharin, even for high consumers who 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 saccharin in this age group considerably.

The total mean intake of saccharin for young men (age 18-29 years) ranged from 0.25 to 0.54 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 0.99 to 1.39 mg/kg bw/day (Table 10). High exposure in scenario 1 and 3 were not calculated due to low number (n<60) of consumers. The exposure estimates for saccharin for young men do not exceed the ADI for saccharin, 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 saccharin in this age group considerably.

The total mean intake of saccharin for women (age 30-70 years) ranged from 0.30 to 0.47 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 0.76 to 1.34 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 saccharin for women do not exceed the ADI for saccharin, even for high consumers who 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) do not increase the intake of saccharin in this age group.

The total mean intake of saccharin for men (age 30-70 years) ranged from 0.30 to 0.44 mg/kg bw/day for scenarios 1-4, respectively, whereas the total high intake (95th percentile) ranged from 0.84 to 1.28 mg/kg bw/day (Table 12). The exposure estimates for saccharin for men do not exeed the ADI for saccharin, 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) do not increase the intake of saccharin in this age group.

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

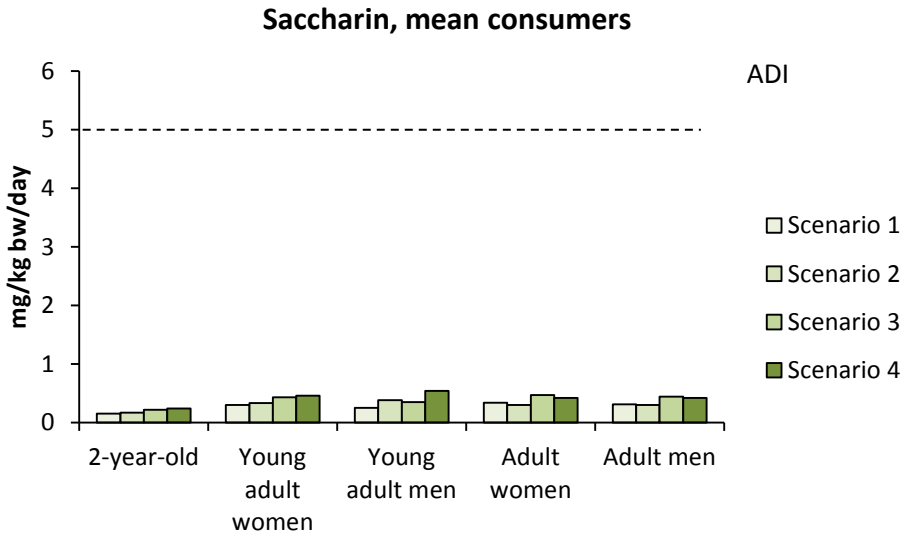

Figure 3. Intake of saccharin among mean consumers of soft drinks from scenarios 1-4.

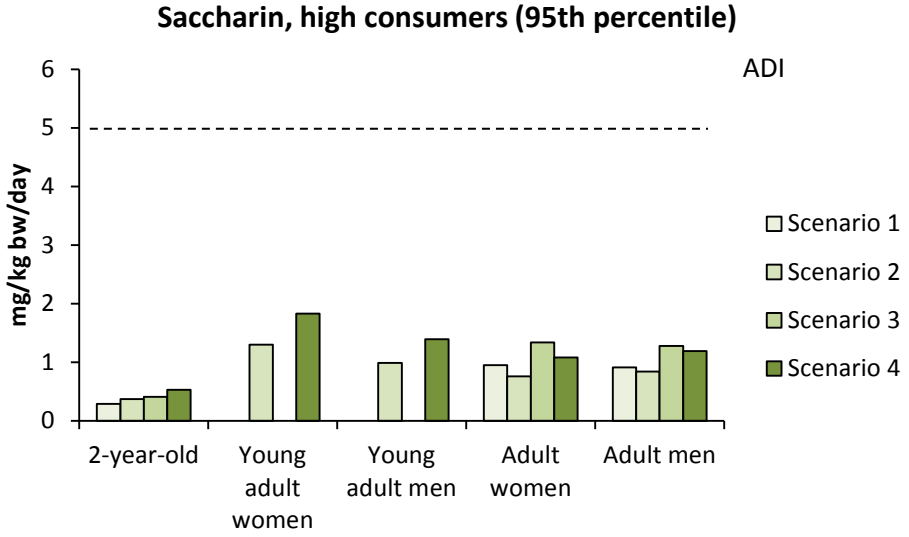

Figure 4. Intake of saccharin among high consumers of soft drinks from scenarios 1-4. Due to few participants, the 95th percentile was not calculated for scenarios 1 and 3 for young adult women and young adult men.

Intake of saccharin from food or the use as table top sweetener is not included in this intake estimate. Saccharin has been used as a table top sweetener for many years, and the intake from table top sweeteners may contribute considerably, especially for persons with diabetes.

Steviol glycosides

The ADI for steviol glycosides is 4 mg/kg bw/day (EFSA, 2010).

The total mean intake of steviol glycosides for the 2-year-olds ranged from 0.18 to 0.93 mg/kg bw/day for scenarios 1-2 and 5-6, whereas the total high intake (95th percentile) ranged from 0.68 to 3.18 mg/kg bw/day (Table 13). The exposure scenarios for 2-year-olds do not exceed the ADI for steviol glycoside, even for high consumers in the scenario 1-2 and 5. However, for high consumers who are assumed to only consume beverages containing the highest allowed concentration of the sweetener (scenario 6), the estimated intake in 2-year-olds approach ADI. The change from actual consumption of beverages containing sweeteners (scenario 1 and 5) to the prediction that all the consumed beverages contained sweeteners (scenarios 2 and 6) increased the intake of cyclamate in this age group with approximately 0.8 mg/kg bw/day for the high consumers (scenario 6).

The total mean intake of steviol glycosides for young women (age 18-29 years) ranged from 0.11 to 0.54 mg/kg bw/day for scenarios 1-2 and 5-6, whereas the total estimated high intake (95th percentile) was calculated to be 1.87 mg/kg bw/day for scenario 6 (Table 14). High exposure was only calculated for scenario 6 with contribution from soft drinks due to low number (n<60) of consumers in the other scenarios.The exposure estimates for steviol glycosides for young women do not exceed the ADI for steviol glycosides, even for high

consumers that are assumed to only consume beverages containing the highest reported concentration of the sweetener (scenario 6). The change from actual consumption of beverages containing sweetener (scenario 1 and 5) to the prediction that all the consumed beverages contained sweetener (scenario 2 and 6), did not increase the intake of steviol glycosides in this age group.

The total mean intake of steviol glycosides for young men (age 18-29 years) ranged from 0.12 to 0.69 mg/kg bw/day for scenarios 1-2 and 5-6, whereas the total estimated high intake (95th percentile) was calculated to be 1.67 mg/kg bw/day for scenario 6 (Table 15). High exposure were only calculated for scenario 6 with contribution from soft drinks due to low number (n<60) of consumers in the other scenarios.The exposure estimates for steviol glycosides for young men do not exceed the ADI for steviol glycosides, even for high consumers that are assumed to only consume beverages containing the highest reported concentration of the sweetener (scenario 6). The change from actual consumption of beverages containing sweetener (scenario 1 and 5) to the prediction that all the consumed beverages contained sweetener (scenario 2 and 6), did not increase the intake of steviol glycosides in this age group considerably.

The total mean intake of steviol glycosides for women (age 30-70 years) ranged from 0.1 to 0.50 mg/kg bw/day for scenarios 1-2 and 5-6, whereas the total high intake (95th percentile) ranged from 0.28 to 1.37 mg/kg bw/day (Table 16). High exposure in scenario 1 was not calculated due to low number (n<60) of consumers, and the contribution from nectar, “saft” and nectar were not included in the high consumption for scenario 6 and 5, respectively. The exposure estimates for steviol glycosides for women do not exceed the ADI for steviol glycosides, even for high consumers that are assumed to only consume beverages containing the highest allowed concentration of the sweetener (scenarios 6). The change from actual consumption of beverages containing sweetener (scenario 1 and 5) to the prediction that all the consumed beverages contained sweetener (scenario 2 and 6), did not increase the intake of steviol glycosides in this age group considerably.

The total mean intake of steviol glycosides for men (age 30-70 years) ranged from 0.09 to 0.48 mg/kg bw/day for scenarios 1-2 and 5-6, whereas the total high intake (95th percentile) ranged from 0.25 to 1.39 mg/kg bw/day (Table 17). High exposure in scenario 1 was not calculated due to low number (n<60) of consumers, and the contribution from soft drinks, “saft” and nectar were not included in the high consumption for scenarios 5 and 6, respectively. The exposure estimates for steviol glycosides for men do not exceed the ADI for steviol glycosides, even for high consumers that are assumed to only consume beverages containing the highest allowed concentration of the sweetener (scenarios 6). The change from actual consumption of beverages containing sweetener (scenario 1 and 5) to the prediction that all the consumed beverages contained sweetener (scenario 2 and 6), did not increase the intake of steviol glycosides in this age group.

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

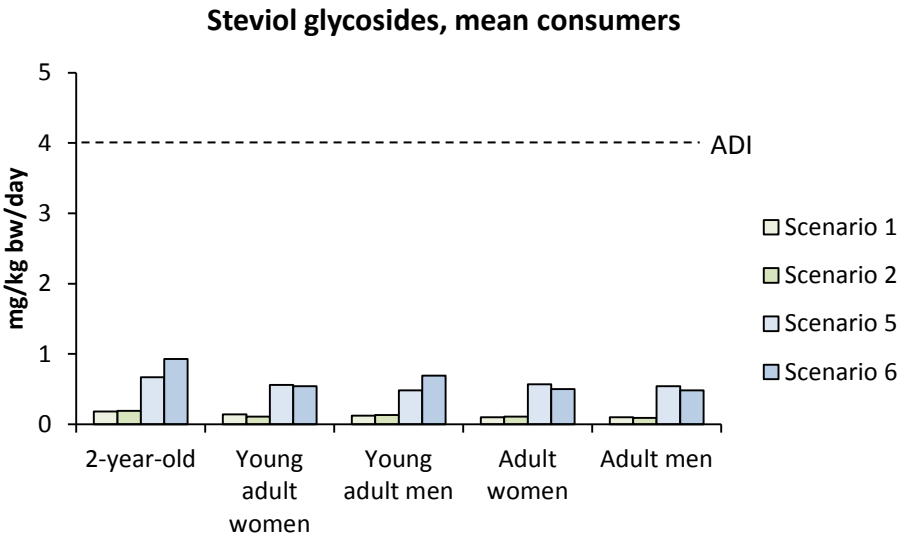

Figure 5. Intake of steviol glycosides among mean consumers of "saft" from scenarios 1 and 2, and soft drinks, "saft" and nectar for scenarios 5 and 6.

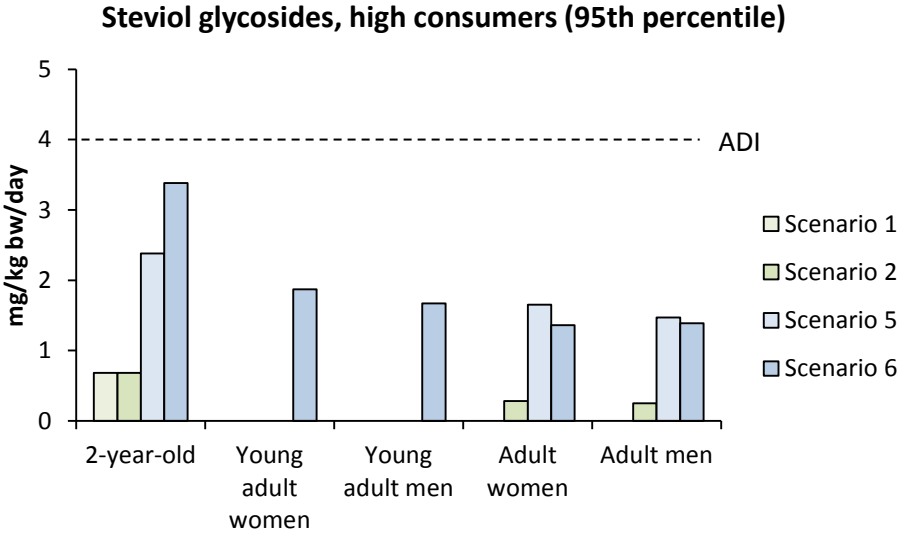

Figure 6. Intake of steviol glycosides among mean consumers of "saft" from scenarios 1 and 2, and soft drinks, "saft" and nectar for scenarios 5 and 6. Due to few participants, the 95th percentile was not calculated for scenarios 1, 2 and 3 for young adultwomen and young adult men, and for scenario 1 for adult women and men.

Intake of steviol glycoside from food or the use as table top sweetener is not included in this intake estimate. Although steviol glycoside is a relatively new sweetener, an additional contribution from food and as a table top sweetener cannot be excluded.

Neohesperidine DC

The ADI for neohesperidine DC is 5 mg/kg bw (SCF, 1989).

The total mean intake of neohesperidine DC for 2-year-olds was estimated to be 0.29 mg/kg bw/day (scenarios 6), whereas the total high intake (95th percentile) was estimated to be 0.97 mg/kg bw/day (Table 18). The exposure estimates for neohesperidine DC for 2-year-olds do not exceed the ADI for neohesperidine DC, even for high consumers that are assumed to only consume beverages containing the highest allowed concentration of the sweetener (scenario 6).

The total mean intake of neohesperidine DC for young women (age 18-29 years) was estimated to be 0.19 mg/kg bw/day (scenarios 6), whereas the total high intake (95th percentile) was estimated to be 0.66 mg/kg bw/day (Table 19). High exposure from "saft" and nectar was not calculated due to low number (n<60) of consumers.The exposure estimates for neohesperidine DC for young women do not exceed the ADI for neohesperidine DC, even for high consumers that are assumed to only consume beverages containing the highest allowed concentration of the sweetener (scenario 6).

The total mean intake of neohesperidine DC for young men (age 18-29 years) was estimated to be 0.24 mg/kg bw/day (scenarios 6), whereas the total high intake (95th percentile) was estimated to be 0.62 mg/kg bw/day (Table 20). High exposure from "saft" and nectar was not calculated due to low number (n<60) of consumers.The exposure estimates for neohesperidine DC for young men do not exceed the ADI for neohesperidine DC, even for high consumers that are assumed to only consume beverages containing the highest allowed concentration of the sweetener (scenario 6).

The total mean intake of neohesperidine DC for women (age 30-70 years) was estimated to be 0.18 mg/kg bw/day (scenarios 6), whereas the total high intake (95th percentile) was estimated to be 0.46 mg/kg bw/day (Table 21). High exposure from nectar was not calculated due to low number (n<60) of consumers.The exposure estimates for neohesperidine DC for women do not exceed the ADI for neohesperidine DC, even for high consumers that are assumed to only consume beverages containing the highest allowed concentration of the sweetener (scenario 6).

The total mean intake of neohesperidine DC for men (age 30-70 years) was estimated to be 0.17 mg/kg bw/day (scenarios 6), whereas the total high intake (95th percentile) was estimated to be 0.46 mg/kg bw/day (Table 22). High exposure from nectar was not calculated due to low number (n<60) of consumers.The exposure estimates for neohesperidine DC for men do not exceed the ADI for neohesperidine DC, even for high consumers that are assumed to only consume beverages containing the highest allowed concentration of the sweetener (scenario 6).

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

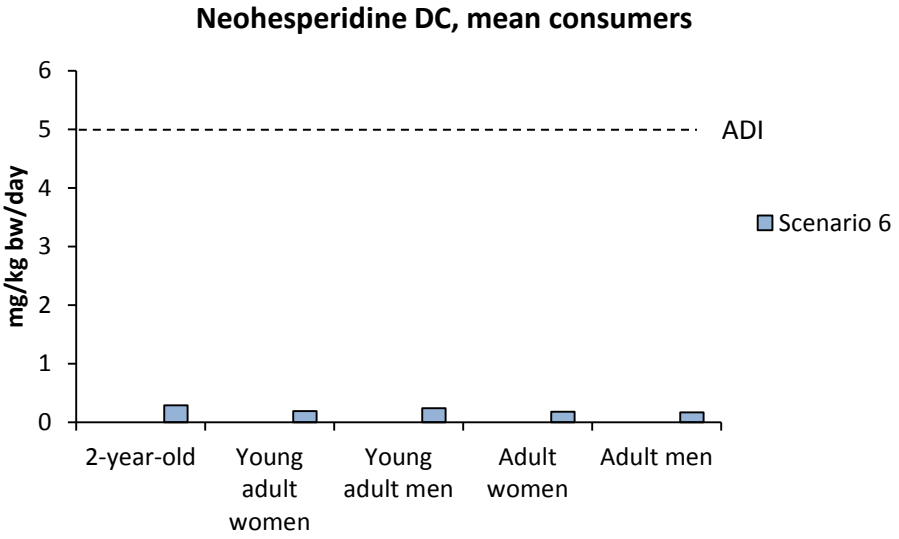

Figure 7. Intake of neohesperidine DC among mean consumers of soft drinks, "saft" and nectar from scenario 6.

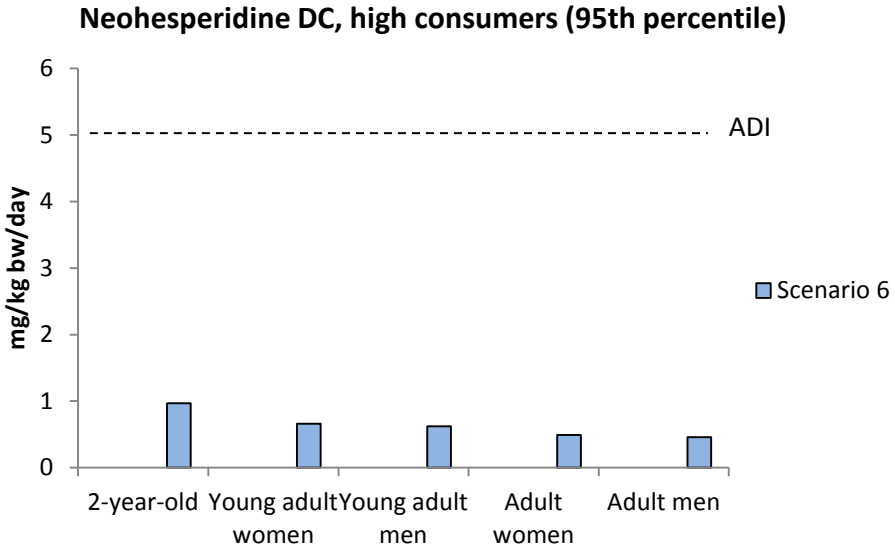

Figure 8. Intake of neohesperidine DC among high consumers of soft drinks, "saft" and nectar from scenario 6.

Neotame

The ADI for neotame is 2 mg/kg bw/day (EFSA, 2007).

The total mean intake of neotame for 2-year-olds was estimated to be 0.19 mg/kg bw/day (scenario 6), whereas the total high intake (95th percentile) was estimated to be 0.64 mg/kg bw/day (Table 23). The exposure estimates for neotame for 2-year-olds do not exceed the ADI for neotame, even for high consumers that are assumed to only consume beverages containing the highest allowed concentration of the sweetener (scenario 6).

The total mean intake of neotame for young women (age 18-29 years) was estimated to be 0.13 mg/kg bw/day (scenario 6), whereas the total high intake (95th percentile) was estimated to be 0.44 mg/kg bw/day (Table 24). High exposure from "saft" and nectar were not calculated due to low number (n<60) of consumers. The exposure estimates for neotame for young women do not exceed the ADI for neotame, even for high consumers that are assumed to only consume beverages containing the highest allowed concentration of the sweetener (scenario 6).

The total mean intake of neotame for young men (age 18-29 years) was estimated to be 0.16 mg/kg bw/day (scenario 6), whereas the total high intake (95th percentile) was estimated to be 0.42 mg/kg bw/day (Table 25). High exposure from "saft" and nectar were not calculated due to low number (n<60) of consumers. The exposure estimates for neotame for young men do not exceed the ADI for neotame, even for high consumers that are assumed to only consume beverages containing the highest allowed concentration of the sweetener (scenario 6).

The total mean intake of neotame for women (age 30-70 years) was estimated to be 0.12 mg/kg bw/day (scenario 6), whereas the total high intake (95th percentile) was estimated to be 0.33 mg/kg bw/day (Table 26). High exposure from nectar were not calculated due to low number (n<60) of consumers. The exposure estimates for neotame for women do not exceed the ADI for neotame, even for high consumers that are assumed to only consume beverages containing the highest allowed concentration of the sweetener (scenario 6).

The total mean intake of neotame for men (age 30-70 years) was estimated to be 0.11 mg/kg bw/day (scenario 6), whereas the total high intake (95th percentile) was estimated to be 0.30 mg/kg bw/day (Table 27). High exposure from nectar were not calculated due to low number (n<60) of consumers. The exposure estimates for neotame for men do not exceed the ADI for neotame, even for high consumers that are assumed to only consume beverages containing the highest allowed concentration of the sweetener (scenario 6).

The intake of neotame among mean consumers is shown in Figure 9, and the intake among high consumers (95th percentile) is shown in Figure 10.

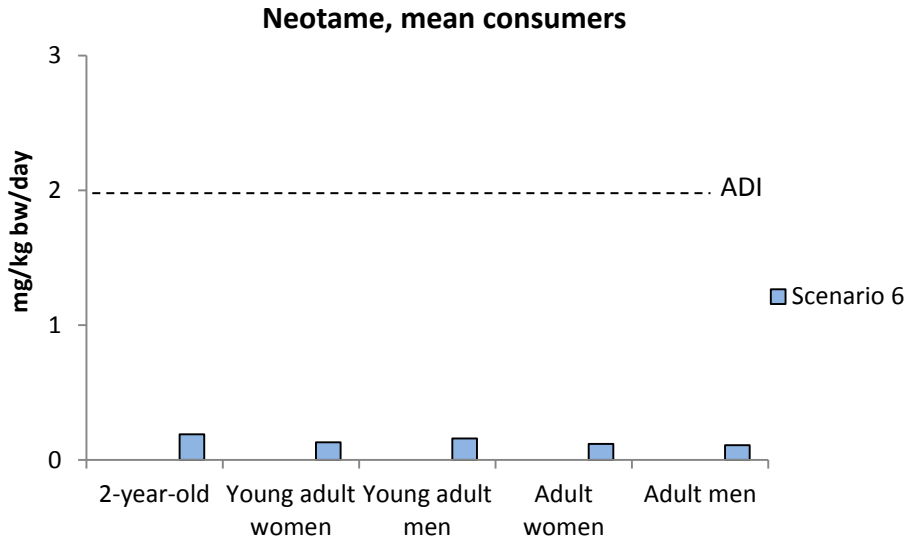

Figure 9. Intake of neotame among mean consumers of soft drinks, "saft" and nectar from scenario 6.

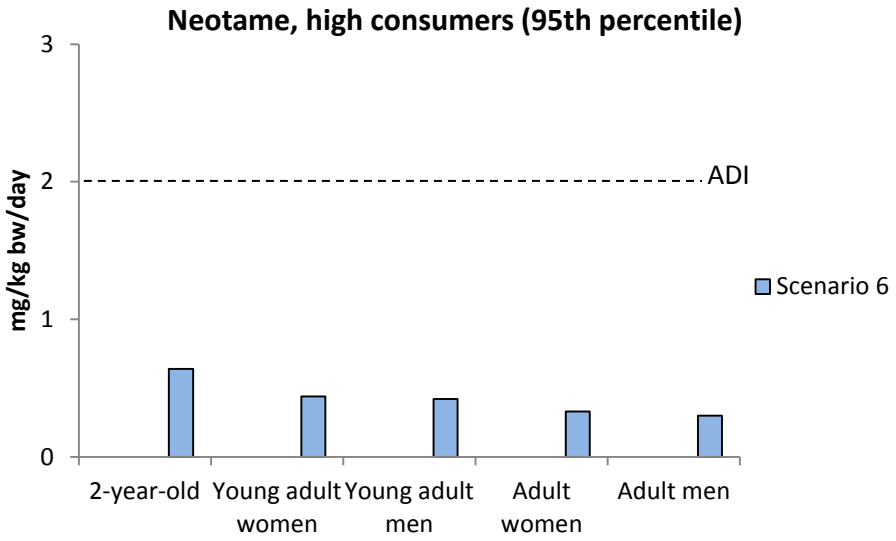

Figure 10. Intake of neotame among high consumers of soft drinks, "saft" and nectar from scenario 6.

5 Uncertainties regarding the human risk assessment

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

Uncertainty regarding content of sweeteners

There are uncertainties related to the representativeness of the samples. The use of average content of sweetener adjusted for sales volume (scenarios 1 and 2), the use of the highest reported level of sweetener used in a product within a category (scenarios 3 and 4), or the use of the maximum allowed amount of sweetener within a category (scenarios 5 and 6) adds a level of uncertainty to the concentration used in each scenario.

Uncertainty regarding intake assessments

A description of the most important uncertainties and assumptions in the dietary exposure calculations is described below.

Three concepts are fundamental to understand 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. Therefore, the 95th percentile is not calculated if the number of participants in a group is less than 60 persons (EFSA, 2011). With a small group of participants with only two days of dietary intake measures, it is 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 at 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.

Summary of uncertainties

Evaluations of the overall effect of identified uncertainties are presented in Table 30, 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 30: Qualitative evaluation of influences of uncertainties on the assessment of exposure to sweeteners.

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	+
Scenario 5 Use of maximum allowed amount of sweetener	+
Scenario 6 Use of maximum allowed amount of sweetener It is assumed that all consumed beverages are added sweeteners	+
Overall	+

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

The intake of sweeteners 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 30. Taking all sources of uncertainty into consideration, an over-estimation of the exposures is most likely.

6 Discussion

The Norwegian Food Safety Authority requested VKM to estimate intake levels of cyclamate, saccharin, neohesperidine DC, steviol glycosides and neotame 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 (conducted in 2010/2011) and Småbarnskost conducted in (2006/2007). The intake estimates were compared with the ADI values for the respective intense sweeteners (food additives).

Six different scenarios were used for the exposure assessments:

Scenario 1 gives the best estimate of the current situation in the population. None of the intake estimates for the sweeteners cyclamate, saccharin or steviol glycoside exceeded the respective ADIs either for mean consumers or for the high consumers for any of the age groups in this scenario. The intake of neohesperidine DC and neotame were not calculated for 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 and "saft" 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 or "saft" contained the average content of the sweeteners cyclamate, saccharin or steviol glycoside, the estimated intake for mean and high consumers were still well below the respective ADIs for all age groups. The intake estimate for neohesperidine DC and neotame were not calculated for this scenario.

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) 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 the respective sweeteners, none of the intake estimates for the sweeteners cyclamate or saccharin exceeded the respective ADIs for mean or high consumers for any of the age groups. The intake estimate for neohesperidine DC, steviol glycoside and neotame were not calculated for 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) who only consume beverages added sweeteners (it is assumed that all reported consume of soft drinks and "saft" contains sweeteners, no added sugar). When it was assumed that all consumed soft drinks or "saft" contained the highest reported content of the respective sweeteners, the estimated intake for mean and high consumers of cyclamate or saccharin were still below the respective ADIs for all age groups. However, the high consumers among young women in scenario 4 have an intake estimate which approaches the ADI for cyclamate. The intake estimates for neohesperidine DC, steviol glycoside and neotame were not calculated for this scenario.

Scenario 5 gives an estimate of the exposure among the part of the brand loyal population (loyal to the brand anticipated to use the maximum allowed level of sweeteners) who have a consumption of beverages as reported in dietary surveys.
Based on the consumption from the dietary surveys and the maximum allowed content of sweetener, the intake estimates for steviol glycosides were still below ADI for mean and high

consumers for all age groups. The intake of cyclamate, saccharin, neohesperidine DC and neotame were not calculated for this scenario.

Scenario 6 gives an estimate of the exposure among the part of the brand loyal population (loyal to the brand anticipated to use the maximum allowed level of sweeteners) who only consume beverages added sweeteners (it is assumed that all reported consume of soft drinks and "saft" contains sweeteners, no added sugar).
No information of use levels in beverages was available for neohesperidine DC and neotame. Therefore, the maximum allowed level of these sweeteners were used for the intake calculations. When it was assumed that all consumed soft drinks, "saft" or nectar contained sweeteners added the maximum allowed level, the estimated intake of steviol glycoside, neohesperidine DC, and neotame for mean and high consumers were still below the respective ADIs. However, for high consumers among the 2-year-olds, the estimated intake approaches the ADI for steviol glycoside.The intake of cyclamate and saccharin were not calculated for this scenario.

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, and that these might be high consumers of beverages.

It should be noted that the intake of sweeteners from food is not included in the present risk assessment. In addition, cyclamate, saccharin and steviol glycosides are all used as table top sweeteners, and an additional intake from this would be expected, but this source of exposure is not included in this risk assessment.

7 Conclusions

VKM concludes that for all age groups in all scenarios, the intake of the sweeteners cyclamate, saccharin, neohesperidine DC, steviol glycosides and neotame is below the established ADI values, thus, there is no major health concern related to the intake of the sweeteners from the beverage categories included in this risk assessment per today. However, among young women who are high consumers of beverages with cyclamate, and 2-year-old children who are high consumers of beverages with steviol glycosides, the estimated intake approaches the ADI values. These high intakes approaching ADI are considered conservative estimates, as the highest reported content of sweetener or the maximum allowed amounts is used, and therefore only relevant for the part of the population that are both loyal to beverages with sweeteners and a particular brand of sweetened beverage.

Intake of sweeteners from other food or from table top sweeteners is not included in the intake estimates, and a considerable contribution from these sources cannot be excluded.

There is little known regarding the use of the sweeteners steviol glycosides, neohesperidine DC and neotame in Norway.

When it comes to the use of steviol glycosides, neohesperidine DC and neotame, there is a need for more knowledge with regard to the use of these sweeteners.

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 groups from 3- to 18-years were not included due to lack of updated data since 2000-2001.
- More data is needed to understand underreporting/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.
- More data is needed on the use of the sweeteners neohesperidine DC, steviol glycoside and neotame in beverages on the Norwegian market.

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 2007. Neotame as a sweetener and flavour enhancer. Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (Question No EFSA-Q-2003-137). Adopted on 27 September 2007. *The EFSA Journal, 581, 1.* http://www.efsa.europa.eu/en/efsajournal/doc/581.pdf: European Food Safety Authority.

EFSA 2010. Scientific Opinion on the safety of steviol glycosides for the proposed uses as a food additive. EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)2. *The EFSA Journal, 8 (4), 1537.* http://www.efsa.europa.eu/en/efsajournal/doc/1537.pdf: European Food Safety Authority.

EFSA 2011. GUIDANCE of EFSA. Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment. European Food Safety Authority. This guidance published on 15th April 2011 replaces the earlier version published on 2nd March 20114. *The EFSA Journal, 9 (3), 2097.* http://www.efsa.europa.eu/en/efsajournal/doc/2097.pdf: European Food Safety Authority.

FORSKRIFT 6. JUNI 2011 NR. 668 OM TILSETNINGSSTOFFER TIL NÆRINGSMIDLER. 2011. Vedlegg II, del E: Unionsliste over tilsetningsstoffer som kan brukes i næringsmidler, og vilkårene for bruken av dem.

JECFA 1977a. Evaluation Of Certain Food Additives: Saccharin, Potassium And Sodium Salts. WHO Technical Report Series 617 http://whqlibdoc.who.int/trs/WHO_TRS_617.pdf: World Health Organization.

JECFA 1977b. Summary Of Toxicological Data Of Certain Food Additives. WHO Food Additives Series No. 12. http://www.inchem.org/documents/jecfa/jecmono/v12je21.htm: World Health Organization.

JECFA 1980. Evaluation of certain food additives. Twenty-fourth Report of the Joint FAO/WHO Expert Committee on Food Additives. World Health Organization Technical Report Series 653 http://whqlibdoc.who.int/trs/WHO_TRS_653.pdf: World Health Organization.

JECFA 1982. Toxicological Evaluation Of Certain Food Additives: Calcium Cyclamate, Sodium Cyclamate And Cyclohexylamine. WHO Food Additives Series No 17. http://www.inchem.org/documents/jecfa/jecmono/v17je08.htm: World Health Organization.

JECFA 1993. Toxicological Evaluation Of Certain Food Additives: Saccharin And Its Salts. WHO Food Additives Series No 32. http://www.inchem.org/documents/jecfa/jecmono/v32je09.htm: World Helath Organization.

JECFA 1998. Summary of Evaluations Performed by the Joint FAO/WHO Expert Committee on Food Additives: STEVEOSIDE http://www.inchem.org/documents/jecfa/jeceval/jec_2201.htm: World Health Organization.
JECFA 2003. Neotame. http://www.fao.org/ag/agn/jecfa-additives/specs/Monograph1/Additive-294.pdf: World Health Organization.
JECFA 2006. Safety evaluation of certain food additives (including Steviol glycosides). Prepared by the sixty-third meeting of the joint FAO/WHO Expert Committee on Food Additives (JECFA) . WHO food additives series: 54. http://whqlibdoc.who.int/publications/2006/9241660546_eng.pdf: World Health Organization.
JECFA 2009. Safety evaluation of certain food additives. Prepared by the Sixty-ninth meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). http://www.inchem.org/documents/jecfa/jecmono/v60je01.pdf: World Health Organization.
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.
MATVARETABELLEN. 2006. *Matvaretabellen* [Online]. http://www.matvaretabellen.no/?language=en.
MORTENSEN, A. 2006. Sweeteners permitted in the European Union: safety aspects. *Scandinavian Journal of Food and Nutrition,* 50**,** 104-116.
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.
REGULATION NO 668 OF 6 JUNE 2011 ON FOOD ADDITIVES. 2011. Annex II, part E. Union list of food additives approved for use in foods and their conditions of use.
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 1985. Sweeteners. Food - science and techniques. Reports of the Scientific Committee for Food (Sixteenth series), Opinion expressed on 14 September 1984. http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_16.pdf: Commission of the European Communities.

SCF 1989. Food - science and techniques. Reports of the Scientific Committee for Food on Sweeteners. 21th series. Opinion expressed 11 December 1987 and 10 November 1988, and adopted 10 November 1988. http://ec.europa.eu/food/fs/sc/scf/reports/scf_reports_21.pdf: Commission of the European Communities.

SCF 1995. Opinion on Saccharin And Its Sodium, Potassium And Calcium Salts. Expressed by Scientific Committee For Food on 2 June 1995. http://ec.europa.eu/food/fs/sc/oldcomm7/out26_en.pdf: European Commission.

SCF 1999. Opinion on Stevioside as a Sweetener (Adopted on 17/6/99). http://www.efsa.europa.eu/en/efsajournal/doc/1537.pdf: European Commission.

SCF 2000. Revised Opinion On Cyclamic Acid And Its Sodium And Calcium Salts. Opinion of the Scientific Committee on Food expressed on 9 March 2000. http://ec.europa.eu/food/fs/sc/scf/out53_en.pdf: European Commission.

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 cyclamate, saccharin, and steviol glycosides (the weighted average and the highest reported value) in mg/l.

Cyclamate

	Weighted average (mg/l)	Highest reported value (mg/l)
Soft drinks, sweetener (n=3)	219	291

Saccharin

	Weighted average (mg/l)	Highest reported value (mg/l)
Soft drinks, sweetener (n=3)	56	79

Steviol glycosides

	Weighted average (mg/l)	Highest reported value (mg/l)
«Saft», sweetener (n=2)	24	24

Appendix 2

The reported intake of soft drinks and "saft" (in g/day) from the dietary surveys used in the current report, consumers only.

Reported intake of soft drinks and "saft"

	Current assessment	
	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