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## Health risk assessment of the use of sweeteners in soft drinks

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The "National Reduction and Innovation Strategy for Sugar, Fats and Salt in Processed Foods" (NRI) aims to reduce the amount of sugar in processed foods, in addition to fats and salt. In order to maintain a comparable sweet taste, food manufacturers sometimes use sweeteners. Product monitoring by the Max Rubner-Institute (MRI) shows that the sugar content in soft drinks has decreased, while the proportion of soft drinks sweetened exclusively with sweeteners has increased. Against this background, the German Federal Institute for Risk Assessment (BfR) investigated with the BfR MEAL Study (Meals for exposure assessment and analysis of food) the concentrations of sweeteners in commercially relevant non-alcoholic soft drinks. The results showed that sweeteners are mostly used in combination and, in some cases, are used at the maximum permitted levels.

In an [opinion by the BfR \(assessment status 23 September 2019\)](#) addressed to the German Federal Ministry of Agriculture, Food and Regional Identity (BMLEH), the authors predicated their findings on an assumption of a situation in which a person's entire daily fluid intake (not just soft drinks) is obtained through a drink containing a single sweetener at the maximum permitted level. In this hypothetical "worst-case" scenario based on a highly unlikely maximum risk, it was considered theoretically possible – based on the calculations at the time – that two- to eight-year-old children with a low body weight (below the 50th percentile) could exceed the *acceptable daily intake (ADI)* for acesulfame K and cyclamate. The ADI specifies the quantity of a substance that can be consumed daily over an entire lifetime without any adverse health impairments.

Based on occurrence data on the content of sweeteners in soft drinks from the BfR MEAL Study and food consumption data from KiESEL and EsKiMo II, the BfR has recently assessed whether the intake of the sweeteners acesulfame K, aspartame, cyclamate, saccharin, sucralose and steviol glycosides solely via soft drinks pose any health risks for children and adolescents aged 0.5 to 17 years. The BfR found that the consumption of soft drinks with currently market-standard levels of

sweeteners does not exceed the acceptable daily intake (ADI) of the sweeteners examined for children and adolescents. This was also evident in a scenario in which the maximum permitted levels for sweeteners were included in the calculations instead of the measured concentrations from the BfR MEAL Study. However, increased consumption of soft drinks containing sweeteners or additional sources of intake, e.g. from other processed foods such as confectionery and dairy products, could lead to the ADI for individual sweeteners being exceeded.

This opinion supports the statements made in an [opinion published by the BfR \(assessment status 30 October 2021\)](#) that sweeteners are frequently used in different combinations and that further data on potential combination effects would be desirable for an assessment.

## 1 Subject of the assessment

In consideration of the occurrence data on various sweeteners in market-relevant soft drinks submitted as part of the extension of the "*food additive*" module of the BfR MEAL Study, the BfR has examined the extent to which an update of the BfR's opinions is necessary. When reviewing the BfR's opinions "[Sweeteners: Majority of studies confirm no adverse health effects – however, the study situation is insufficient](#)" (from 23 September 2019) and "[Do mixtures of several sweeteners pose risks for human health?](#)" (from 30 October 2021), particular attention should be paid to assessing the exposure of young children and primary school pupils. The concentration data and more recent food consumption data (KiESEL and EsKiMo-II) should be taken into account.

## 2 Results

Analytical data on the concentrations of sweeteners in market-relevant soft drinks were collected as part of the expansion of the food additive module of the BfR MEAL Study. The data show that the sweeteners

- acesulfame K,
- aspartame,
- cyclamate,
- saccharin,
- sucralose and
- steviol glycosides

are used separately or in combination. In individual cases, concentrations within the maximum permitted levels for cyclamate and acesulfame K were found in cola/ cola-mixed drinks with no added sugar. In the current exposure assessment, in addition to the BfR's opinions "[Sweeteners: Majority of studies confirm no adverse health effects – however, the study situation is insufficient](#)"

(from 23 September 2019) and "Do mixtures of several sweeteners pose risks for human health?" (from 30 October 2021), the exposure of young children and primary school pupils as well as older children and adolescents up to the age of 17 was estimated, taking into account the occurrence data determined and current food consumption data (KiESEL and EsKiMo-II). The results of these estimates can be summarised as follows:

- **The exposure assessments do not indicate an increased health risk for children and adolescents from the consumption of soft drinks containing sweeteners, notwithstanding other sources of sweeteners.**

Based on occurrence data from the BfR MEAL Study or on the assumed concentrations at the maximum permitted levels and taking into account current food consumption data from KiESEL and EsKiMo II, none of the scenarios considered resulted in an exposure estimate that exceeded the acceptable daily intake for the sweeteners examined in soft drinks in the age groups considered.

The exposure assessments based on the data used therefore provide no evidence of an increased health risk for children and adolescents aged 0.5 to 17 years from the consumption of soft drinks containing sweeteners.

- **Increased consumption of soft drinks containing sweeteners (especially cyclamate and acesulfame K) or intake from additional sources of exposure could lead to an exceedance of the acceptable daily intake for certain sweeteners.**

Assuming that the maximum permitted levels for sweeteners are used instead of the analytical data from the BfR MEAL Study, it appears that the acceptable daily intake (ADI) for the sweeteners examined would not be exceeded for infants, children and adolescents even if consumed by high consumers. However, for younger children under 6 years of age, children aged 6–11 years and children and adolescents aged 12 years and older, exposure to cyclamate and acesulfame K was estimated to exceed the respective ADI by 73 % to 88 % in the case of high consumption. Increased consumption of soft drinks containing sweeteners (especially cyclamate and acesulfame K) or intake from additional sources of exposure (e.g. other food categories such as confectionery or dairy products) could lead to the respective acceptable daily intake (ADI) being exceeded in these age groups at concentrations within the maximum permitted levels.

- **An update of the BfR's opinions "Sweeteners: Majority of studies confirm no adverse health effects – however, the study situation is insufficient" (from 23 September 2019) and "Do mixtures of several sweeteners pose risks for human health?" (from 30 October 2021), is not necessary.** In the BfR opinion "Sweeteners: Majority of studies confirm no adverse health effects – however, the study situation is insufficient" (from 23 September 2019), a hypothetical worst-case scenario was assumed in which a person's entire daily fluid intake was provided by a beverage sweetened with a single sweetener containing the maximum permitted level of that sweetener. Under this assumption, it would be theoretically possible for toddlers and primary school children with a body weight below the median (P50) to exceed the ADI for acesulfame K and cyclamate. This has since been refuted by the calculations made in this report based on consumption data and analytical data.

In the BfR opinion "Do mixtures of several sweeteners pose risks for human health?" (from 30 October 2021) on the combined use of selected sweeteners in soft drinks, the BfR investigated whether the available data, specifically from animal studies, provided any evidence of health risks from the combined use of relevant sweeteners. The considerations were based on the example of the combined use of sweeteners in non-alcoholic soft drinks. The examples show that combined effects can occur in principle. The analytical data from the BfR MEAL Study show that in particular the sweeteners acesulfame K, aspartame, cyclamate, saccharin, sucralose and steviol glycosides are used separately or in combination in market-relevant soft drinks. In individual cases, concentrations approaching the specified maximum permitted levels for cyclamate and acesulfame K were found in cola/ cola-mixed drinks. This finding supports the statements made in the BfR's opinion "Do mixtures of several sweeteners pose risks for human health?" (from 30 October 2021) on the combined use of selected sweeteners in soft drinks and underlines the importance of experimental data on the potential effects of the combined use of sweeteners.

### 3 Rationale

#### 3.1 Risk assessment

##### 3.1.1 Health-based guidance values for the sweeteners investigated

In the European Union (EU), Regulation (EC) No 1333/2008 authorises the use of the aforementioned sweeteners in numerous foods. In the category relevant to the opinion, "flavoured drinks", which also includes various soft drinks, the sweeteners under consideration are only permitted in products that are energy-reduced or with no added sugar. Certain maximum permitted levels apply to the sweeteners considered here (Regulation (EC) No 1333/2008).

The basis for the authorisation of the placing on the market and use of the sweeteners considered here in food under the conditions specified therein within the framework of Regulation (EC) No 1333/2008 is provided by assessments carried out by the Scientific Committee on Food (SCF) of the European Commission and the European Food Safety Authority (EFSA). In the assessments of the individual substance by the SCF and EFSA, an *acceptable daily intake (ADI)* was derived for each sweetener from animal experimental data. The health-based guidance values for the sweeteners considered in this opinion are summarised in **Table 1**. However, it should be noted that sweeteners authorised before 20 January 2009 are currently being re-evaluated by EFSA as part of the programme for the re-evaluation of approved food additives (Regulation (EU) No 257/2010). This concerns acesulfame K, cyclamate, saccharin and sucralose, but not aspartame and steviol glycosides, which were assessed by EFSA in 2013 and 2010 respectively.

**Table 1:** Overview of health-based guidance values (HBGV) for the sweeteners examined.

Sweetener	Acesulfame K	Aspartame	Cyclamate	Saccharin	Sucralose	Steviol glycosides <sup>d</sup>
Evaluation panel	SCF	EFSA	SCF	SCF	SCF	EFSA
Year	2000	2013	2000	1995	2000	2010

<b>ADI<sup>a</sup></b>	9 <sup>e</sup>	40	7	5 <sup>e</sup>	15	4
<b>Maximum permitted levels<sup>b</sup></b>	350	600	250	80 (100 <sup>c</sup> )	300	80

<sup>a</sup> ADI (acceptable daily intake) in (mg/kg bw/day); bw (body weight); SCF (Scientific Committee on Food); EFSA (European Food Safety Authority); <sup>b</sup> in non-alcoholic flavoured drinks in mg/L according to Regulation (EC) No 1333/2008 (as of 31 October 2022), only energy-reduced products or products with no added sugar; <sup>c</sup> for flavoured drinks: gaseosa; <sup>d</sup> calculated as steviol equivalent, including steviol glycoside, rubusoside, dulcoside A, stevioside, rebaudioside A, B, C, D, E, F and M, <sup>e</sup>At the date of publication of the BfR opinion, EFSA has re-evaluated acesulfame K (<https://doi.org/10.2903/j.efsa.2025.9317>) and saccharin (<https://doi.org/10.2903/j.efsa.2024.9044>). An ADI of 15 mg/kg bw/day for acesulfame K and 9 mg/kg bw/day for saccharin was derived that replace the previous ADI's of 9 and 5 mg/kg bw/day.

### 3.1.2 Exposure assessment

#### 3.1.2.1 Data basis for exposure assessment

##### 3.1.2.1.1 Food consumption data

###### *Age group 0.5–5 years*

To update the VELS study, the BfR conducted a representative Germany-wide study on children's nutrition to record food consumption (KiESEL). KiESEL was linked as a module to the RKI's "Study on the Health of Children and Adolescents in Germany" ("KiGGS Wave 2").

A total of 1,104 children aged between six months and five years took part in KiESEL between 2014 and 2017. Based on an interview, the legal guardians completed a questionnaire on general nutrition, nutrition in the first year of life, and a *Food Propensity Questionnaire* on rarely consumed food. Of these, 1008 children and their parents also participated in the nutrition survey using a weighing/estimation protocol. The children's food consumption was documented with food records for three consecutive days and one independent day. In addition, out-of-home consumption (e.g. in childcare facilities) was recorded using a reduced estimate record (Golsong *et al.* 2017; Nowak *et al.* 2022).

###### *Age groups 6–11 years and 12–17 years*

As part of KiGGS wave 2, the Robert Koch Institute also conducted the study EsKiMo II, which examined the food consumption of 2,644 children and adolescents aged 6 to 17. Two different survey methods were used depending on the age group. To collect data on the food consumption of children aged 6–11 years, a food record was completed on four days. A complete food record is available for a total of 1,190 children.

The food consumption of adolescents aged 12–17 years was recorded retrospectively over the last four weeks using the Dietary History Interview (DISHES) method. Data is available for a total of 1,353 adolescents (Mensink *et al.* 2021).

##### 3.1.2.1.2 Intake levels of beverages and soft drinks

**Table 2** shows the consumption of soft drinks from the present evaluation together with the total consumption of beverages from the respective studies. In the case of the children from KiESEL, the

calculation of the total consumption is based on our own evaluations based on the MEAL food categories (Kolbaum *et al.*2022). The figures for EsKiMo II are taken from an evaluation by the RKI (Mensink *et al.*2021). Soft drinks account for between 10 and 22 % of total beverage consumption. Other liquids, such as those found in soups, are not included.

**Table 2:** Comparison of soft drink consumption with total beverage consumption by gender and age.

Study	Gender	Consumption		Proportion
		Soft drinks [g/d] <sup>c</sup>	Total beverages [g/d] <sup>c</sup>	Soft drinks
KiESEL <sup>a</sup>	Girls	117	686	17 %
	Boys	127	703	18 %
EsKiMo II 6–11 years <sup>b</sup>	Girls	109	940	12 %
	Boys	109	1068	10 %
EsKiMo II 12–17 years <sup>b</sup>	Girls	274	1727	16 %
	Boys	438	2035	22 %

<sup>a</sup> Own evaluation; <sup>b</sup> (Mensink *et al.*2021); <sup>c</sup>For simplicity, it is assumed that one gram (g) corresponds to one milliliter, even if the density of the beverages considered only approximately corresponds to the value 1, [g/d] = grams (in this case ml) per day

### 3.1.2.1.3 Processing of food consumption data

The food consumption data from KiESEL and the food consumption data for children aged 6–11 years from EsKiMo II allow for a differentiation of the soft drinks consumed down to the product level. This would make it possible to link concentration data and consumption of soft drinks at the product level. Nevertheless, in most of the product groups considered here, and particularly in the case of energy-reduced beverages, only a few individuals who consume these products are identified (**Table 3**). For this reason, the beverages recorded were grouped into different product groups (e.g. cola drinks, lemonades or iced tea) for the exposure assessment, without any subdivision into 'no added sugar', 'energy-reduced' or 'regular'. Accordingly, a conservative scenario was chosen for the exposure assessment, in which the proportion of energy-reduced soft drinks and soft drinks with no added sugar in the total consumption of the respective product group is 100 %.

For the age groups considered, it was subsequently possible to draw on a sufficiently large ( $n > 20$ ) sub-sample for the consideration of the product groups "cola drinks", "iced tea", "fruit juice drinks", "isotonic drinks" and "lemonades". For the age group of adolescents (age 12–17 years), the product groups "energy drinks" and "flavoured water" could also be considered. Children who were partially breastfed at the time of the study protocol were excluded from further analysis.

To determine long-term consumption, food records from KiESEL and EsKiMo II were used for all participants who had consumed beverages containing sweeteners on at least one day of the study. Consumption for the corresponding food group was totaled for each day of consumption and then the mean value for all days of the study was calculated. For 12- to 17-year-old adolescents (DISHES interviews from EsKiMo II), long-term food consumption was recorded directly, which is why the data could be used directly in the corresponding age groups.

### 3.1.2.1.4 Consumption of energy-reduced soft drinks or soft drinks with no added sugar and consumption of regular soft drinks

**Table 3** shows the number of individuals consuming soft drinks depending on the respective (sub)study, differentiated by product group and whether the drinks are with no added sugar or energy-reduced or regular soft drinks. In many cases, there are less than 20 individuals consuming these products. In particular, for soft drinks with no added sugar or energy-reduced soft drinks, only the group of lemonades has more than 20 consumers in KiESEL and among adolescents aged 12- to 17-years. For this reason, the consumption of soft drinks with no added sugar, energy-reduced soft drinks and regular drinks was combined for further evaluation. Possible effects of this assumption on exposure assessments are considered in the next section.

**Table e 3:** Number of consumers by (sub)study, product group and type (energy-reduced/with no added sugar; regular).

Product group	Type	KiESEL (0.5–5 years)	EsKiMo II (6–11 years)	EsKiMo II (12–17 years)
Cola drinks	energy-reduced /with no added sugar	11	38	107
	regular	30	184	634
Lemonades	energy-reduced/with no added sugar	29	35	27
	regular	146	412	619
Fruit juice drinks	energy-reduced/with no added sugar	1	2	– <sup>a</sup>
	regular	215	229	124 <sup>a</sup>
Isotonic drinks	energy-reduced/with no added sugar	1	23	2
	regular	8	51	35
Iced tea	energy-reduced/with no added sugar	– <sup>a</sup>	4	1
	regular	21 <sup>a</sup>	141	303
Flavoured water	energy-reduced/with no added sugar	–	14	– <sup>a</sup>
	regular	–	82	144
Energy drinks	energy reduced/no added sugar	–	– <sup>a</sup>	2
	regular	–	6 <sup>a</sup>	125

<sup>a</sup> It is not possible to differentiate between "energy-reduced/no added sugar" and "regular" because no persons were identified for the "energy-reduced/no added sugar" category.

### 3.1.2.1.5 Comparison of the consumption of energy-reduced soft drinks and soft drinks with no added sugar with regular soft drinks in the cola drinks and lemonade product groups

For the product groups "cola drinks" and "lemonades", the sub-samples of consuming individuals were large enough to examine the extent to which the consumption of energy-reduced beverages or beverages with no added sugar differs from the consumption of regular beverages at the product group level (Table 4). Consumption is shown in g (or ml, whereby here and in the following it was assumed that 1 ml corresponds exactly to 1 g) in relation to body weight (BW) per day.

**Table 4:** Consumption of cola drinks and lemonades by adolescents aged 12–17 (EsKiMo II), separated into energy-reduced/with no added sugar and regular. For simplicity, it is assumed that one gram corresponds to one milliliter, even though the density of the considered beverages only approximates the value 1.

Beverage group	Number <sup>a</sup>	Mean (95% CI) [g/(kg bw d)]	Median (95% CI) [g/(kg bw d)]	95th percentile (95% CI) [g/(kg bw d)]
Cola drinks (regular)	634	2.6 (2.3–2.9)	1.0 (0.9-1.2)	10.7 (9.1-13.2)
Cola drinks (energy-reduced /with no added sugar)	107	2.2 (1.6-2.8)	0.9 (0.6-1.6)	7.9 (6.8-8.8)
Lemonades (regular)	619	3.3 (2.9-3.8)	1.2 (0.9-1.3)	14.3 (10.7-14.9)
Lemonades (energy-reduced /with no added sugar)	27	3.8 (2.2-6.2)	3.7 (0.4–4.1)	10.3 (4.4-12.0)

<sup>a</sup> Consumers only

High consumers show a higher intake of regular cola drinks compared to high consumers of energy-reduced cola drinks or cola with no added sugar. The mean consumption of energy-reduced lemonades or cola drinks and lemonades or cola drinks with no added sugar does not differ statistically from the consumption of regular lemonades or cola drinks. The small subsample size of individuals who consume energy-reduced beverages or beverages with no added sugar may influence the width of the confidence interval and obscure possible differences. The mean consumption of energy-reduced cola drinks and cola drinks with no added sugar tends to be slightly lower compared to regular cola drinks. The results cannot be directly transferred to other beverage groups (such as iced tea), but they do indicate that a non-differentiated view of energy-reduced or with no added sugar and regular beverages is conservative and may slightly overestimate the consumption of energy-reduced soft drinks or soft drinks with no added sugar.

### 3.1.2.1.6 Analytical data

The concentration of sweetener in soft drinks in the BfR MEAL Study was determined as part of the 'food additives' module. The sample was limited to market-relevant soft drinks identified from the product list in the MRI's 2019 product monitoring (BfR 2023).

After comparison with the consumption data attributable to the sampled food, those beverage groups for which a sufficient number of consumers were available were included. The remaining analytical data were categorised into the beverage groups "cola drinks" (including cola drinks and

cola-mixed drinks, n<sup>1</sup> = 36), "lemonades" (including lemon, orange, grapefruit, herbal and mixed fruit lemonades, n = 32), "fruit juice drinks" (n = 4), "isotonic drinks" (n = 4), "flavoured water" (n = 2), "iced tea, energy-reduced" (n = 5) and "iced tea with no added sugar" (n = 3). Iced tea was divided into iced tea with no added sugar and energy-reduced iced tea (in these products, the reduction in sugar is not apparent from the product description), as the two groups differ substantially in the composition of the added sweeteners. Three samples were produced from syrups for the preparation of soft drinks. The product group of syrup drinks was not included in the present evaluation.

Depending on the matrix, the limit of detection (LOD) ranged between 0.005 and 0.1 mg/L and the limit of quantification (LOQ) ranged between 0.005 and 0.3 mg/L for all substances to be examined. The quantitative analysis results were well above the limits of quantification, so that only the *lower* bound approach was used in this evaluation (i.e., all undeterminable values were set to zero and all unquantified values to the limit of quantification (LOQ); see **Table 5** for the proportion of measured values above the limit of quantification (LOQ)).

**Table 5:** Concentrations of sweeteners in product groups of soft drinks. Only sweeteners for which concentrations above the limit of quantification (LOQ) were measured in the corresponding product group are listed. The 95th percentile was only calculated for groups with a sufficient sample size (n>20).

Beverage group	Number of samples	Sweetener	Measured values > LOQ [%]	Mean value [mg/L]	Median [mg/L]	P95 [mg/L]
Cola drinks	36	Acesulfame K	100	117.2	114.5	157.0
		Aspartame	100	137.0	83.8	337.0
		Saccharin	2.8	0.02	0	0 <sup>a</sup>
		Cyclamate	75.0	150.5	196.0	238.8
Lemonades	32	Acesulfame K	71.9	69.9	59.2	181.0
		Aspartame	87.5	61.6	57.8	167.9
		Saccharin	56.3	18.1	22.5	40.2
		Cyclamate	87.5	177.1	202.8	243.8
		Sucralose	12.5	4.9	0	48.0
		Stevioside	9.4	1.1	0	0.31
		Rebaudioside A	9.4	1.8	0	5.8
Iced tea, with no added sugar	3	Acesulfame K	100	72.8	69.8	-
		Aspartame	33.3	10.6	0	-
		Cyclamate	33.3	49.7	0	-

<sup>1</sup> The number refers to the products tested for sweeteners as part of the BfR MEAL Study.

		Sucralose	66.7	62.8	86.5	-
<b>Iced tea, energy-reduced</b>	5	Stevioside	100	0.39	0.10	-
		Rebaudioside A	80.0	68.3	52.2	-
<b>Energy drinks</b>	2	Acesulfame K	100	185.0	185.0	-
		Aspartame	50.0	72.0	72.0	-
		Sucralose	50.0	120.0	120.0	-
<b>Fruit juice drinks</b>	4	Saccharin	100	29.7	29.8	-
		Cyclamate	100	194.0	193.0	-
		Sucralose	50.0	3.9	2.4	-
<b>Isotonic drinks</b>	4	Saccharin	100	12.4	12.1	-
		Cyclamate	100	210.4	204.0	-
<b>Flavoured water</b>	2	Acesulfame K	100	13.5	13.5	-
		Saccharin	100	19.4	19.4	-
		Cyclamate	100	80.4	80.4	-

*If there are only a few values above the limit of quantification (LOQ), the 95th percentile may be zero even though the mean value is > 0.*

Table 5 shows the mean, median and 95th percentile (P95) of the measured concentrations of sweeteners within each beverage group. The lemonade product group contained the largest number of different sweeteners. A total of seven sweeteners were detected in this product group, with cyclamate having the highest mean concentration in lemonades (177 mg/L). The four substances acesulfame K, aspartame, saccharin and cyclamate were detected in cola drinks. Cyclamate was also the substance with the highest mean concentration in cola drinks (150 mg/L). Within the cola drinks and lemonade product groups, it was noticeable that the composition of sweeteners can vary greatly. Therefore, an exposure assessment with regard to a scenario of brand-loyal consumers is of relevance in these groups.

In the product group of iced tea with no added sugar, the substances acesulfame K, aspartame, cyclamate and sucralose were detected, with acesulfame K having the highest mean concentration (73 mg/L). In contrast, of the sweeteners examined, only the steviol glycosides rebaudioside A and stevioside were detected in energy-reduced iced teas, with rebaudioside A having the higher mean concentration (68 mg/L). Due to the different composition of the two product subgroups of iced tea, it is necessary to consider them separately. The energy-reduced iced teas contained sweeteners without this being apparent from the product description (the sweeteners were only listed in the ingredients). Accordingly, consumers cannot distinguish them from regular iced teas at first glance. This suggests that energy-reduced iced teas are also unknowingly consumed by people who would normally consume regular iced teas. For this reason, the concentrations of iced tea with no added sugar (with labelling as "zero") are used for the scenarios that describe different proportions of beverages containing sweeteners in total consumption. A separate exposure assessment is carried out for energy-reduced iced teas that contain rebaudioside A in particular: a

scenario in which 25 % of the iced tea consumed contains the measured concentrations of rebaudioside A and stevioside.

In the energy drinks product group acesulfame K, aspartame, and sucralose were detected, with acesulfame K being the substance with the highest mean concentration (185 mg/L). Saccharin and cyclamate were detected in the isotonic drinks product group. Acesulfame K, saccharin and cyclamate were detected in the flavoured water product group. Saccharin, cyclamate and sucralose were found in the fruit juice drinks product group. Cyclamate had the highest concentration in each of these three product groups (210 mg/L, 80 mg/L and 194 mg/L, respectively).

Cyclamate is the sweetener that was detected in most product groups (all except in energy drinks and energy-reduced iced tea) and had the highest mean concentration among sweeteners in most product groups (max. 194 mg/L in fruit juice drinks). Acesulfame K was found in five product groups, with the highest mean concentration found in energy drinks (185 mg/L). Saccharin was also found in five product groups and had the highest mean concentration in fruit juice drinks (30 mg/L). Aspartame was found in four product groups and had the highest concentration in cola drinks (137 mg/L). Sucralose was also found in four product groups and had the highest concentration in energy drinks (120 mg/L). The steviol glycosides rebaudioside A and stevioside were found in two product groups each. Rebaudioside A had the highest concentration in energy-reduced iced tea (68 mg/L), and the stevioside concentration was higher in lemonades (1.1 mg/L) than in energy-reduced iced tea.

### 3.1.2.2 Exposure scenarios

Various scenarios were used to estimate the exposure of children aged 0.5–17 years to the sweeteners acesulfame K, aspartame, cyclamate, saccharin, sucralose and steviol glycosides in soft drinks using data from the BfR MEAL Study and taking into account current intake data from KiESEL and EsKiMo II.. Exposure to steviol glycosides was summarised as steviol equivalent, with conversion factors of 0.40 and 0.33 for stevioside and rebaudioside A, respectively (EFSA 2014).

#### **Scenario I: exposure from soft drinks under the assumption of mean concentrations**

Total exposure was determined by multiplying the mean concentration of the corresponding sweetener for each beverage group by the consumption of each individual. It was assumed that the proportion of beverages containing sweeteners was 100 %. To represent total exposure, the exposure to the corresponding sweetener was then summed individually for all individuals in the respective sample.

#### *Age group 0.5–5 years*

The exposure to the sweeteners considered for children aged 0.5–5 years from KiESEL is shown in **Table 6**. It was assumed that 100 % of the beverages consumed contained sweeteners. This scenario can be considered conservative, as a substantial proportion of soft drinks are consumed in regular versions<sup>2</sup>.

<sup>2</sup> Demuth I, Busl L, Ehnle-Lossos M, Elflein A, Goos-Balling E, Werner R, Hoffmann I (2020): Product Monitoring 2019. Published by: Max Rubner Institute. URL: [https://www.mri.bund.de/fileadmin/MRI/Institute/EV/Produktmonitoring2019\\_Ergebnisbericht\\_final.pdf](https://www.mri.bund.de/fileadmin/MRI/Institute/EV/Produktmonitoring2019_Ergebnisbericht_final.pdf). Karlsruhe

Under this assumption, the highest median exposure is to cyclamate, with an exposure of 801.3 µg/(kg bw d). Acesulfame K and aspartame show the next highest median exposure at 289.2 µg/(kg bw d) and 239.4 µg/(kg bw d), respectively, followed by saccharin (100.6 µg/(kg bw d)) and sucralose (19.0 µg/(kg bw d)). The steviol glycosides rebaudioside A and stevioside (total 3.9 µg/(kg bw d)) show comparatively low exposure.

**Table 6:** Exposure to various sweeteners on the assumption that 100 % of the beverages consumed contain concentrations of sweeteners as determined in the BfR MEAL Study. Data basis: **Children aged 0.5–5 years** from KiESEL; mean concentrations from the BfR MEAL Study.

Sweetener	Number <sup>a</sup>	Mean (95% CI) [µg/(kg bw d)]	Median (95% CI) [µg/(kg bw d)]	95th percentile (95% CI) [µg/(kg bw d)]
Acesulfame K	191	490.6 (406.3-589.8)	289.2 (256.8-341.5)	1500.5 (1105.0-1637.2)
Aspartame	191	423.4 (345.9-514.4)	239.4 (205.5-295.9)	1324.1 (1146.8-1513.9)
Cyclamate	355	1227.8 (1085.2-1405.5)	801.3 (708.2-981.1)	3550.4 (2729.9-3860.8)
Saccharin	351	147.1 (128.8-169.5)	100.6 (85.9-107.9)	411.9 (340.9-500.9)
Sucralose	332	56.7 (39.7-80.6)	19.0 (16.0-22.5)	203.5 (95.8-504.0)
Steviol glycosides (rebaudioside A and stevioside) <sup>b</sup>	161	5.5 (4.4–7.0)	3.9 (3.3-4.3)	15.4 (9.9-22.9)

<sup>a</sup> Consumers only; <sup>b</sup> Calculated as steviol equivalent; [µg/(kg bw d)] = micrograms per kilogram of body weight per day

#### Age group 6–11 years

**Table 7** shows the exposure to the sweeteners investigated for children aged 6–11 years from EsKiMo II. On the assumption that 100 % of the beverages consumed contain concentrations of sweeteners as determined in the BfR MEAL Study, cyclamate again shows the highest exposure at 850.8 µg/(kg bw d). This exposure is slightly higher than that of children in the KiESEL study. The next highest exposures, at 325.5 µg/(kg bw d) and 249.7 µg/(kg bw d), are again for acesulfame K and aspartame, followed once more by saccharin at 83.3 µg/(kg bw d) and sucralose at 26.2 µg/(kg bw d). The lowest occurrence is with steviol glycosides (3.1 µg/(kg bw d)).

**Table 7:** Exposure to various sweeteners on the assumption that 100 % of the beverages consumed contain concentrations of sweeteners as determined in the BfR MEAL Study. Data basis: **Children aged 6–11 years** from EsKiMo II; mean concentrations from the BfR MEAL Study.

Sweetener	Number <sup>a</sup>	Mean (95% CI) [µg/(kg bw d)]	Median (95% CI) [µg/(kg bw d)]	95th percentile (95% CI) [µg/(kg bw d)]
Acesulfame K	656	445.3 (413.4-480.0)	325.5 (309.4-358.3)	1336.3 (1081.9-1552.1)

<b>Aspartame</b>	615	368.7 (341.0-396.7)	249.7 (218.3-285.4)	1051.0 (883.2-1248.1)
<b>Cyclamate</b>	736	1213.1 (1131.0-1303.6)	850.8 (763.3-909.7)	3749.0 (3220.7-4152.6)
<b>Saccharin</b>	690	139.6 (127.9-151.8)	83.3 (72.6-93.5)	408.3 (396.9-495.2)
<b>Sucralose</b>	625	97.6 (81.3-115.2)	26.2 (22.7-28.9)	418.2 (382.3-555.5)
<b>Steviol glycosides (rebaudioside A and stevioside)<sup>b</sup></b>	432	5.1 (4.6-5.6)	3.1 (2.9-3.6)	14.4 (13.1-17.8)

<sup>a</sup> Consumers only; <sup>b</sup> Calculated as steviol equivalent/[ $\mu\text{g}/(\text{kg bw d})$ ] = micrograms per kilogram of body weight per day

### Age group 12–17 years

**Table 8** shows the exposure to sweeteners for adolescents aged 12–17 years, on the assumption that 100 % of the beverages consumed contain the concentrations determined by the BfR MEAL Study. The proportion of individuals consuming these sweeteners is significantly higher than in other age groups, ranging from 59 % (steviol glycosides) to almost 100 % (cyclamate). This shows that the consumption of soft drinks is far more widespread in this age group than in other age groups. Once again, the highest exposure is to cyclamate, at 371.9  $\mu\text{g}/(\text{kg bw d})$ . This is much lower than in the 0.5–5-year-old and 6–11-year-old age groups. The situation is similar for acesulfame K at 206.9  $\mu\text{g}/(\text{kg bw d})$  and aspartame at 157.3  $\mu\text{g}/(\text{kg bw d})$ . Once again, sucralose (24.7  $\mu\text{g}/(\text{kg bw d})$ ) and saccharin (14.8  $\mu\text{g}/(\text{kg bw d})$ ) follow. Steviol glycosides again have the lowest exposure at 1.3  $\mu\text{g}/(\text{kg bw d})$ . Thus, all age groups show a similar ranking of exposure to sweeteners, which can be explained by the corresponding occurrence levels.

In the 95th percentile, which takes into account high consumers of soft drinks, adolescents aged 12- to 17 years show the highest exposure to acesulfame K, aspartame and sucralose compared to other age groups. For cyclamate, saccharin and steviol glycosides, exposure is similarly high (or slightly lower) than for children under 6 years of age. This is different for many foods due to the normally lower consumption in relation to body weight, but it shows that there are high consumers of soft drinks, especially in the 12–17 years age group.

**Table 8:** Exposure to various sweeteners on the assumption that 100 % of the beverages consumed contain the sweetener concentrations from the BfR MEAL Study. Data basis: **children aged 12–17 years** from EsKiMo II; mean concentrations from the BfR MEAL Study.

Sweetener	Number <sup>a</sup>	Mean (95% CI) [ $\mu\text{g}/(\text{kg bw d})$ ]	Median (95% CI) [ $\mu\text{g}/(\text{kg bw d})$ ]	95th percentile (95% CI) [ $\mu\text{g}/(\text{kg bw d})$ ]
<b>Acesulfame K</b>	1077	472.6 (433.8-513.5)	206.9 (184.5-232.8)	1841.2 (1689.2-2180.0)
<b>Aspartame</b>	1056	392.8 (358.0–429.1)	157.3 (139.8-185.3)	1593.2 (1397.2-1928.7)

<b>Cyclamate</b>	1097	829.6 (764.3-895.3)	371.9 (328.5-412.6)	3193.0 (3040.1-3666.4)
<b>Saccharin</b>	1051	66.7 (59.3-74.5)	14.8 (12.3-17.0)	303.2 (277.7-338.1)
<b>Sucralose</b>	876	131.7 (111.2-153.6)	24.7 (20.1-32.4)	595.1 (542.7-824.5)
<b>Steviol glycosides (rebaudioside A and stevioside)<sup>b</sup></b>	641	3.6 (3.1-4.1)	1.3 (1.1-1.5)	15.2 (11.4-15.8)

<sup>a</sup> Consumers only; <sup>b</sup> Calculated as steviol equivalent; [ $\mu\text{g}/(\text{kg bw d})$ ] = micrograms per kilogram of body weight per day

### Scenario II: exposure from soft drinks under the assumption of P95 concentrations for cola drinks and lemonades

Since brand loyalty can be assumed for some products, the 95th percentile of the concentrations was used for the cola drinks and lemonades product groups instead of the mean value<sup>3</sup>. These two groups were selected because, apart from iced tea, they have the highest number of consumers and brand loyalty is very likely to be expected (see Tables 3–4).

**Tables 9–11** show the exposure to sweeteners for children aged 0.5–5 years, children aged 6–11 years and adolescents aged 12–17 years, under the assumption that 100 % of the beverages consumed contain sweeteners. In the case of steviol glycosides, the maximum concentration was used instead of the 95th percentile, as steviol glycosides were only detected in three beverages in the lemonades category (the only one of the two product groups in which steviol glycosides were determined). In addition, one beverage has a significantly higher concentration than the other two, which is why the 95th percentile is even below the mean value.

Compared to consumption at mean concentrations (see Tables 6–8), a similar picture emerges in all age groups. Median exposure is mostly 1.2–3 times higher than when considering mean concentrations, and 1.1–4 times higher in the 95th percentile. The highest median exposure occurs again for cyclamate, with the highest value of 1087.9  $\mu\text{g}/(\text{kg bw d})$  for children aged 6–11 years. Furthermore, it can be seen that in this scenario, exposure to steviol glycosides is much higher (> factor 10) in all three age groups, especially in children under 6 years of age, compared to the assumption with mean concentrations.

**Table 9:** Exposure to various sweeteners on the assumption that 100 % of the beverages consumed contain concentrations of sweeteners as determined in the BfR MEAL Study. Data basis: **Children aged 0.5–5 years** from KiESEL; 95th percentile of concentrations for cola drinks and lemonades; mean value for other beverages.

<b>Sweetener</b>	<b>Number<sup>a</sup></b>	<b>Mean (95% CI) [<math>\mu\text{g}/(\text{kg bw d})</math>]</b>	<b>Median (95% CI) [<math>\mu\text{g}/(\text{kg bw d})</math>]</b>	<b>95th percentile (95% CI) [<math>\mu\text{g}/(\text{kg bw d})</math>]</b>
<b>Acesulfame K</b>	191	1017.9 (840.2-1239.1)	688.5 (591.3-754.0)	3053.1 (1936.3-3886.7)

<sup>3</sup> In the case of stevioside, the maximum of 36 mg/L was taken, as the 95th percentile is below the mean value due to the many values below the limit of quantification (LOQ).

<b>Aspartame</b>	191	1099.5 (883.0-1365.2)	650.4 (559.5-762.9)	3605.3 (2916.7-3722.4)
<b>Cyclamate</b>	355	1434.8 (1259.1-1635.7)	989.8 (790.6-1178.1)	3967.3 (3257.0-5221.0)
<b>Saccharin</b>	351	199.8 (173.5-233.4)	125.1 (107.7-151.7)	523.8 (421.9-679.3)
<b>Sucralose</b>	332	165.0 (130.7-209.4)	56.1 (38.5-81.6)	684.1 (447.8-899.6)
<b>Steviol glycosides (rebaudioside A and stevioside)<sup>b</sup></b>	161	84.8 (67.5-105.6)	59.2 (51.3-65.7)	235.0 (152.2-350.7)

<sup>a</sup> Consumers only; <sup>b</sup> Calculated as steviol equivalent; [ $\mu\text{g}/(\text{kg bw d})$ ] = micrograms per kilogram of body weight per day

**Table 10:** Exposure to various sweeteners on the assumption that 100 % of the beverages consumed contain concentrations of sweeteners as determined in the BfR MEAL Study. Data basis: **children aged 6–11 years** from EsKiMo II; 95th percentile of concentrations for cola drinks and lemonades; mean value for other beverages.

<b>Sweetener</b>	<b>Number<sup>a</sup></b>	<b>Mean (95% CI) [<math>\mu\text{g}/(\text{kg bw d})</math>]</b>	<b>Median (95% CI) [<math>\mu\text{g}/(\text{kg bw d})</math>]</b>	<b>95th percentile (95% CI) [<math>\mu\text{g}/(\text{kg bw d})</math>]</b>
<b>Acesulfame K</b>	656	836.4 (773.8-905.0)	589.9 (508.8-618.4)	2235.7 (2047.8-2638.9)
<b>Aspartame</b>	615	941.2 (858.0-1024.8)	606.1 (559.5-723.5)	2711.9 (2207.9-3350.1)
<b>Cyclamate</b>	736	1480.2 (1385.6-1593.4)	1087.9 (939.7–1128.7)	4021.3 (3577.1-4697.0)
<b>Saccharin</b>	619	206.1 (188.8-224.4)	130.2 (116.1-138.3)	629.4 (537.1-800.2)
<b>Sucralose</b>	625	240.7 (217.7-265.6)	144.7 (131.7-158.9)	817.7 (669.7-992.0)
<b>Steviol glycosides (rebaudioside A and stevioside)<sup>b</sup></b>	432	78.3 (70.1-87.0)	48.1 (44.6-54.4)	220.4 (199.1-272.1)

<sup>a</sup> Consumers only; <sup>b</sup> Calculated as steviol equivalent; [ $\mu\text{g}/(\text{kg bw d})$ ] = micrograms per kilogram of body weight per day

**Table 11:** Exposure to various sweeteners on the assumption that 100 % of the beverages consumed contain concentrations of sweeteners as determined in the BfR MEAL Study. Data basis: **children aged 12–17 years** from EsKiMo II; 95th percentile of concentrations for cola and lemonade; mean value for other beverages.

<b>Sweetener</b>	<b>Number<sup>a</sup></b>	<b>Mean (95% CI) [<math>\mu\text{g}/(\text{kg bw d})</math>]</b>	<b>Median (95% CI) [<math>\mu\text{g}/(\text{kg bw d})</math>]</b>	<b>95th percentile (95% CI) [<math>\mu\text{g}/(\text{kg bw d})</math>]</b>
<b>Acesulfame K</b>	1077	763.5 (697.9-837.2)	329.8 (277.3-370.9)	3150.9 (2628.0-3291.3)

<b>Aspartame</b>	1056	965.5 (873.4-1058.8)	382.1 (330.7-432.8)	3919.9 (3394.3-4914.1)
<b>Cyclamate</b>	1097	1111.2 (1019.4-1206.0)	490.7 (421.4-553.8)	4371.1 (3995.7-4610.1)
<b>Saccharin</b>	766	111.9 (99.8-125.0)	29.9 (24.9-34.5)	483.6 (429.9-561.1)
<b>Sucralose</b>	876	237.2 (212.5-264.1)	80.3 (67.5-99.0)	969.1 (798.0-1076.8)
<b>Steviol glycosides (rebaudioside A and stevioside)<sup>b</sup></b>	641	54.7 (47.8-62.2)	19.9 (16.3-22.4)	233.0 (174.5-243.7)

<sup>a</sup> Consumers only; <sup>b</sup> Calculated as steviol equivalent; [ $\mu\text{g}/(\text{kg bw d})$ ] = micrograms per kilogram of body weight per day

### Scenario III: exposure at the maximum permitted levels for flavoured drinks

In scenario III, it was also assumed that the soft drinks consumed contained concentrations corresponding to the respective maximum permitted levels specified in Regulation (EC) No 1333/2008 (Tables 12–14). In most cases, exposure is 1.47 times higher than in the scenario where mean concentrations were assumed (see Tables 6–8). Compared to the scenario in which the 95th percentile of the measured concentrations for cola drinks and lemonades was assumed ("brand loyalty"; see Tables 9–11), it is a factor of 1.2–14.4.

**Tables 12:** Exposure to various sweeteners on the assumption that 100 % of the beverages consumed contain concentrations of sweeteners at the maximum permitted levels. Data basis: **children aged 0.5–5 years** from KiESEL; maximum permitted levels for sweeteners according to Regulation (EC) No 1333/2008; consumers only (n = 355).

<b>Sweetener</b>	<b>Mean (95% CI) [mg/(kg bw d)]</b>	<b>Median (95% CI) [mg/(kg bw d)]</b>	<b>95th percentile (95% CI) [mg/(kg bw d)]</b>
<b>Acesulfame K</b>	2.4 (2.1-2.8)	1.6 (1.4-2.0)	7.2 (5.6-7.7)
<b>Aspartame</b>	4.2 (3.7-4.8)	2.7 (2.3-3.4)	12.3 (9.8-12.9)
<b>Cyclamate</b>	1.7 (1.5-2.0)	1.1 (1.0-1.4)	5.1 (4.1-5.4)
<b>Saccharin</b>	0.7 (0.6–0.8)	0.5 (0.4-0.6)	2.0 (1.6-2.1)
<b>Sucralose</b>	2.1 (1.9-2.4)	1.5 (1.2–1.7)	6.4 (4.8-6.9)
<b>Steviol glycosides<sup>a</sup></b>	0.6 (0.5-0.6)	0.4 (0.3-0.5)	1.7 (1.3-1.7)

<sup>a</sup> Calculated as steviol equivalent; [ $\text{mg}/(\text{kg bw d})$ ] = milligrams per kilogram of body weight per day

**Table 13:** Exposure to various sweeteners on the assumption that 100 % of beverages consumed contain sweeteners at the maximum permitted levels. Data basis: **children aged 6–11 years** from EsKiMo II; maximum permitted levels for sweeteners according to Regulation (EC) No 1333/2008; consumers only (n = 677).

Sweetener	Mean (95% CI) [mg/(kg bw d)]	Median (95% CI) [mg/(kg bw d)]	95th percentile (95% CI) [mg/(kg bw d)]
Acesulfame K	2.6 (2.4-2.8)	1.6 (1.5–1.9)	7.8 (7.1-9.2)
Aspartame	4.4 (4.1-4.8)	2.8 (2.7-3.2)	13.3 (12.1-15.5)
Cyclamate	1.9 (1.7-2.0)	1.2 (1.1-1.3)	5.6 (5.1-6.5)
Saccharin	0.7 (0.7-0.8)	0.5 (0.4-0.5)	2.2 (2.0-2.6)
Sucralose	2.2 (2.0-2.4)	1.4 (1.3-1.6)	6.7 (6.1-7.9)
Steviol glycosides <sup>a</sup>	0.6 (0.5-0.6)	0.4 (0.3-0.4)	1.8 (1.6-2.1)

<sup>a</sup> Calculated as steviol equivalent; [mg/(kg bw d)] = milligrams per kilogram of body weight per day

**Table 14:** Exposure to various sweeteners with the assumption that 100 % of beverages consumed contain sweeteners at the maximum permitted levels. Data basis: **children aged 12–17 years** from EsKiMo II; maximum permitted levels for sweeteners according to Regulation (EC) No 1333/2008; consumers only (n = 1081).

Sweetener	Mean (95% CI) [mg/(kg bw d)]	Median (95% CI) [mg/(kg bw d)]	95th percentile (95% CI) [mg/(kg bw d)]
Acesulfame K	2.1 (2.0-2.3)	1.0 (0.8-1.1)	7.9 (7.1-8.7)
Aspartame	3.7 (3.4-4.0)	1.7 (1.4-1.9)	13.5 (12.2-14.8)
Cyclamate	1.5 (1.4-1.7)	0.7 (0.6-0.8)	5.6 (5.1-6.2)
Saccharin	0.6 (0.6-0.7)	0.3 (0.2-0.3)	2.2 (2.1-2.5)
Sucralose	1.8 (1.7-2.0)	0.8 (0.7-0.9)	6.7 (6.1-7.4)
Steviol glycosides <sup>a</sup>	0.5 (0.5-0.5)	0.2 (0.2-0.2)	1.8 (1.6-2.0)

<sup>a</sup> Calculated as steviol equivalent; [mg/(kg bw d)] = milligrams per kilogram of body weight per day

#### Scenario IV: exposure to steviol glycosides from iced tea

A separate exposure assessment was carried out for the product subgroup of energy-reduced iced tea because it has different sweetener profiles compared to iced tea with no added sugar. Compared to "iced tea with no added sugar", the "energy-reduced iced tea" samples examined contained only the sweeteners stevioside and rebaudioside A (calculated as steviol equivalent) (see Table 5).

To estimate exposure to steviol glycosides (calculated as steviol equivalent), the determined iced tea consumption was multiplied by the corresponding mean concentrations in energy-reduced iced teas. It was assumed that 25 % of the iced tea consumed contained steviol glycosides at concentrations determined in the BfR MEAL Study. This assumption was based on research in the MINTEL-GNPD. According to this, 10 of 36 products that were on the market in the previous year contained steviol glycosides. It should be noted that this figure does not represent an overall view of the market.

**Table 15** shows the exposure to steviol glycosides (calculated as steviol equivalent) from iced tea for different age groups. The highest median exposure is shown by children aged 0.5–5 years, with an exposure of 172.7 µg/(kg bw d). However, only a small number of individuals from KiESEL (n = 21) consume this product group. More reliable figures based on a higher number of consumers are shown for children aged 6–11 years and adolescents aged 12–17 years, with a median exposure of 71.3 µg/(kg bw d) and 41.7 µg/(kg bw d) respectively. In the 95th percentile, the figures are 429.4 µg/(kg bw d) and 410.2 µg/(kg bw d).

**Table 15:** Exposure to steviol glycosides (calculated as steviol equivalent) from energy-reduced iced tea for different age groups.

Age group	Number <sup>a</sup>	Mean (95% CI) [µg/(kg bw d)]	Median (95% CI) [µg/(kg bw d)]	95th percentile (95% CI) [µg/(kg bw d)]
0.5–5 years	21	174.4 (110.8–267.1)	172.7 (57.4–240.8)	249.0 (249.0–1189.3)
6–11 years	141	114.0 (94.1–133.3)	71.3 (58.4–88.0)	429.4 (245.2–454.2)
12–17 years	303	103.9 (84.4–123.4)	41.7 (29.3–53.2)	410.2 (349.4–527.2)

<sup>a</sup> Consumers only; [µg/(kg bw d)] = micrograms per kilogram of body weight per day

### 3.1.2.3 Summary

Exposure to the six sweeteners acesulfame K, aspartame, cyclamate, saccharin, sucralose and steviol glycosides (calculated as steviol equivalent) from soft drinks for children and adolescents aged 0.5–17 years was calculated using various scenarios.

For all age groups, cyclamate resulted in the highest exposure and the highest number of consumers. This was evident assuming both mean concentrations of sweetener in all beverages

and sweetener concentrations at the 95th percentile in cola drinks and lemonades ("brand loyalty"). Acesulfame K and aspartame have the second and third highest exposure.

In terms of median (P50), children aged 6–11 years generally have the highest exposure to the sweeteners examined. Saccharin and steviol glycosides are exceptions. For these substances, the age group 0.5–5 years is most exposed. This observation depends on whether mean sweetener concentrations in all beverages, concentrations in the 95th percentile for cola drinks and lemonades, or maximum permitted levels were included. However, exposure levels for these two age groups are mostly very similar.

In the case of high consumption (P95), it can be seen that the age group 12–17 years is most exposed to acesulfame K, aspartame and sucralose, both in terms of mean sweetener concentration in all beverages, 95th percentile concentration in cola drinks and lemonades, and with the assumption of maximum permitted levels. For steviol glycosides, individuals aged 0.5–5 years have the highest exposure when consuming large quantities, with exposure levels being very similar across all age groups. For cyclamate, depending on the assumptions, either children aged 6–11 years or 12–17 years are most exposed when consuming large quantities, while no clear trend can be identified for saccharin.

In the case of iced tea, products have been identified that are not easily identifiable to consumers as energy-reduced but contain sweeteners. A separate exposure assessment was made for these product group (scenario IV). Individuals aged 0.5–5 years have the highest median exposure (P50) to steviol glycosides, while among high consumers (P95), children aged 6–11 years has the highest exposure. The exposure of high consumers aged 12–17 years to steviol glycosides from energy-reduced iced tea is only slightly lower in this scenario.

#### 3.1.2.4 Uncertainty analysis

##### 3.1.2.4.1 Food consumption data

In many cases, food consumption data could be used to determine whether a soft drink consumed was energy-reduced, with no added sugar or regular. However, it is reasonable that such consumption was not documented completely and/or accurately by all individuals. However, as the consumption of energy-reduced soft drinks, soft drinks with no added sugar and regular soft drinks with added sugar was combined for most of the evaluations, this uncertainty has no direct impact on the results presented here.

Due to the low number of cases in the groups of soft drinks aggregation of the consumption for each product group was necessary. This, together with the considered scenarios, leads to uncertainty regarding exposure to sweeteners from energy-reduced soft drinks and soft drinks with no added sugar. As shown, the mean individual consumption of energy-reduced lemonades and cola drinks or lemonades and colas drinks with no added sugar does not differ significantly from the corresponding regular soft drinks with added sugar. For the other product groups, such an evaluation could not be carried out due to the small number of individuals who consume energy-reduced soft drinks and soft drinks with no added sugar. Possible age-related differences could also not be investigated.

The consumption studies used are relatively recent, with survey periods from 2014 to 2017. However, changes in the consumption of soft drinks since this period cannot be ruled out.

For some product groups ("energy drinks" and "flavoured water"), there were not enough consumers in KiESEL and in the sub-study from EsKiMo II, which looked at the consumption of children aged 6–11 years, to provide a sufficient description of consumption. As a result, the exposure assessment lacks contributions from these product groups for these age groups. Consumption of energy drinks in these age groups is probably low, but a contribution from flavoured water cannot be completely ruled out. There are also other beverages that may contain sweeteners but were not included in the present estimate (e.g. syrup drinks).

#### 3.1.2.4.2 Exposure data

For the exposure estimate in scenario II "Brand loyalty", the 95th percentile of the analytical data for cola drinks and lemonades was used in accordance with the usual procedure of the BfR. Since artificial sweeteners in soft drinks are not naturally occurring contaminants, but are instead used as ingredients in recipes, the 95th percentile may underestimate exposure in individual cases. It cannot be ruled out that individuals repeatedly consume the product with the maximum concentration. For these individuals, the scenario II underestimate exposure to sweeteners.

Scenario III, which uses the maximum permitted levels for all beverages, is very likely to severely overestimate the actual exposure. It is assumed that all soft drinks consumed contain the respective sweetener at the maximum permitted level. It was therefore assumed that all sweeteners were present simultaneously in all beverages considered here. It is not likely that such a combination is used in the recipes.

### 3.1.3 Risk characterisation

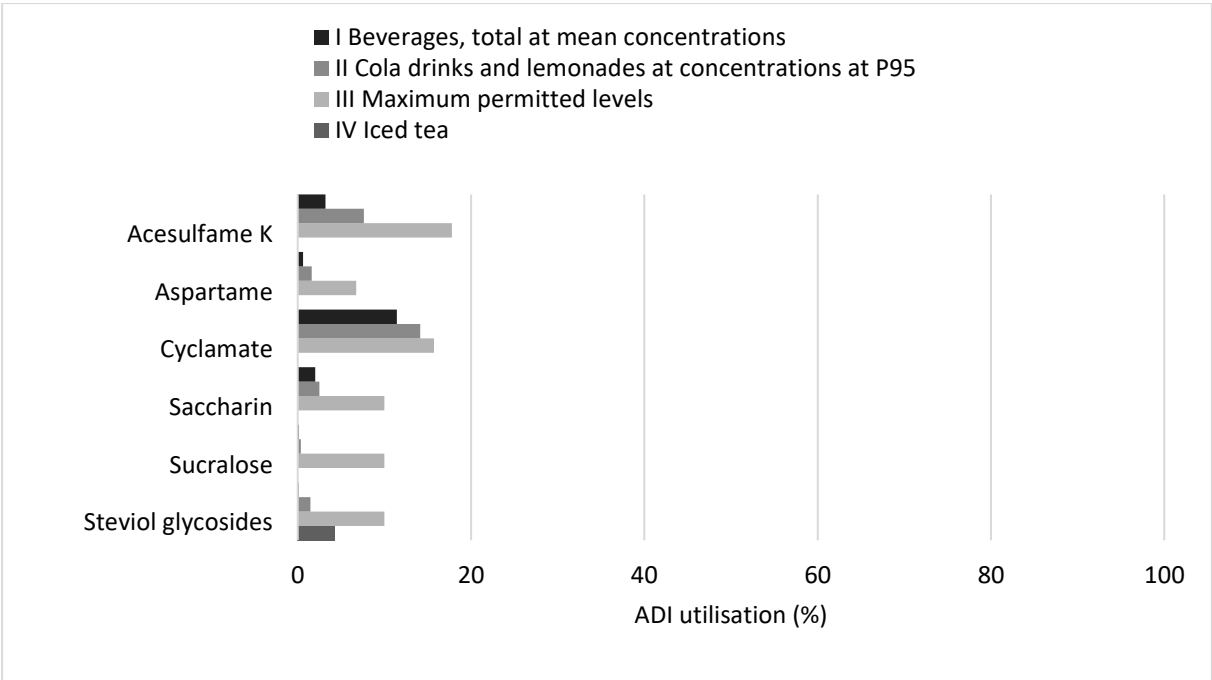
#### 3.1.3.1 ADI utilisation of individual sweeteners

##### *Age group 0.5–5 years*

With a median consumption (P50) of soft drinks, children under 6 years of age achieve an exposure to all sweeteners examined that utilises less than 20 % of the ADI in each scenario considered.

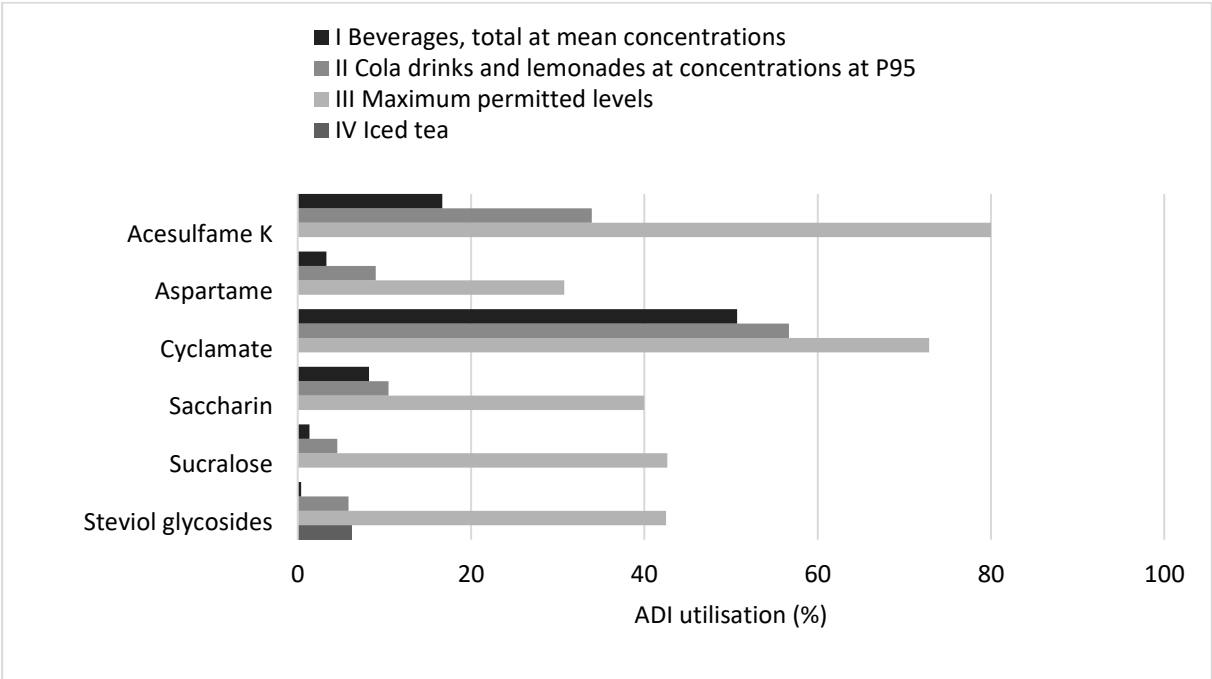
However, when considering high consumers (P95) in this age group, exposure to cyclamate reaches a value that utilises the ADI by around 51 % if 100 % of the beverages consumed have mean concentrations from the BfR MEAL Study. On the assumption of "brand loyalty" behaviour, using the 95th percentile of concentrations for cola drinks and lemonades, or using the maximum permitted levels, exposure is in a domain that utilises 57 % and 73 % of the ADI for cyclamate, respectively. Exposure to acesulfame K utilises up to 80 % of the ADI when using the maximum permitted levels. When considering mean concentrations from the BfR MEAL Study or P95 concentrations in cola drinks and lemonades, exposure would utilise around 17 % and 34 % of the ADI, respectively. For the sweeteners aspartame, saccharin, sucralose and steviol glycosides, exposure would utilise the ADI by a maximum of 43 % when using the maximum permitted levels, or by less than 11 % when considering the other three scenarios (**Figures 1 and 2, Appendix Table 1**).

**Median consumption (P50)**



**Figure 1:** ADI utilisation for median consumption of soft drinks in the age group 0.5–5 years for sweeteners in four different exposure scenarios (I–IV)

**High consumption (P95)**



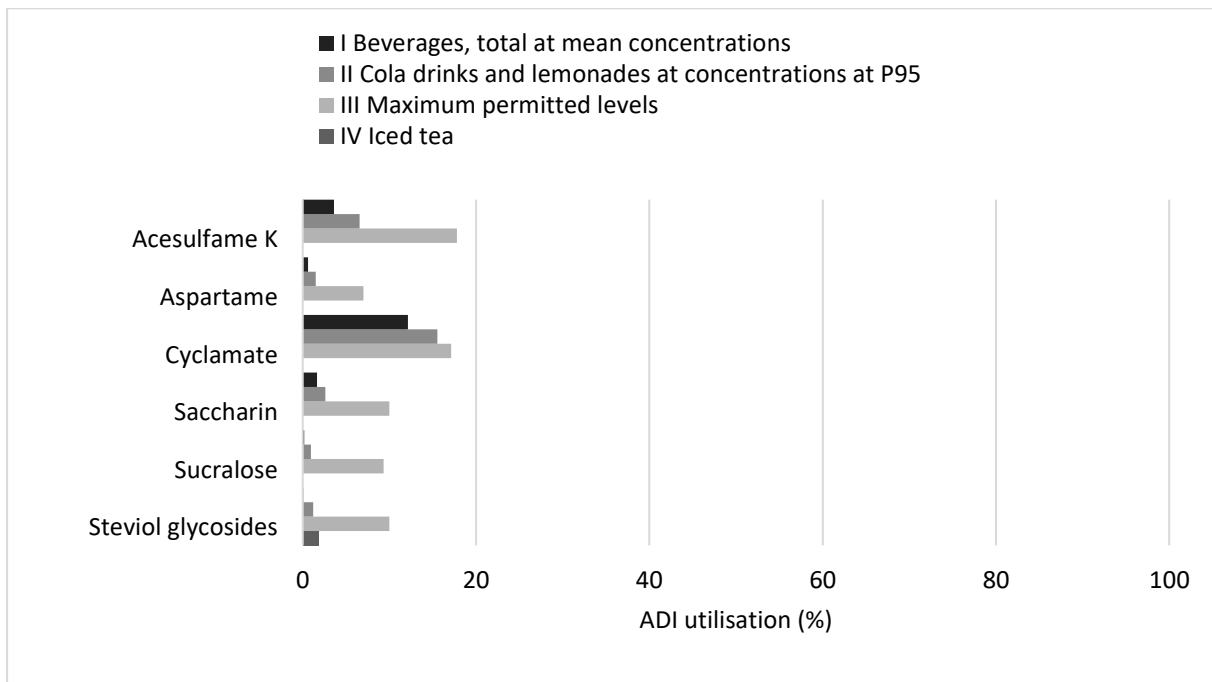
**Figure 2:** ADI utilisation by high consumers of soft drinks (P95) in the age group 0.5–5 years for sweeteners in four different exposure scenarios (I–IV)

### Age group 6–11 years

For children aged 6–11 years, the exposure utilises the ADI of different sweeteners by a maximum of 18 % at a median consumption (P50) of soft drinks in all scenarios considered.

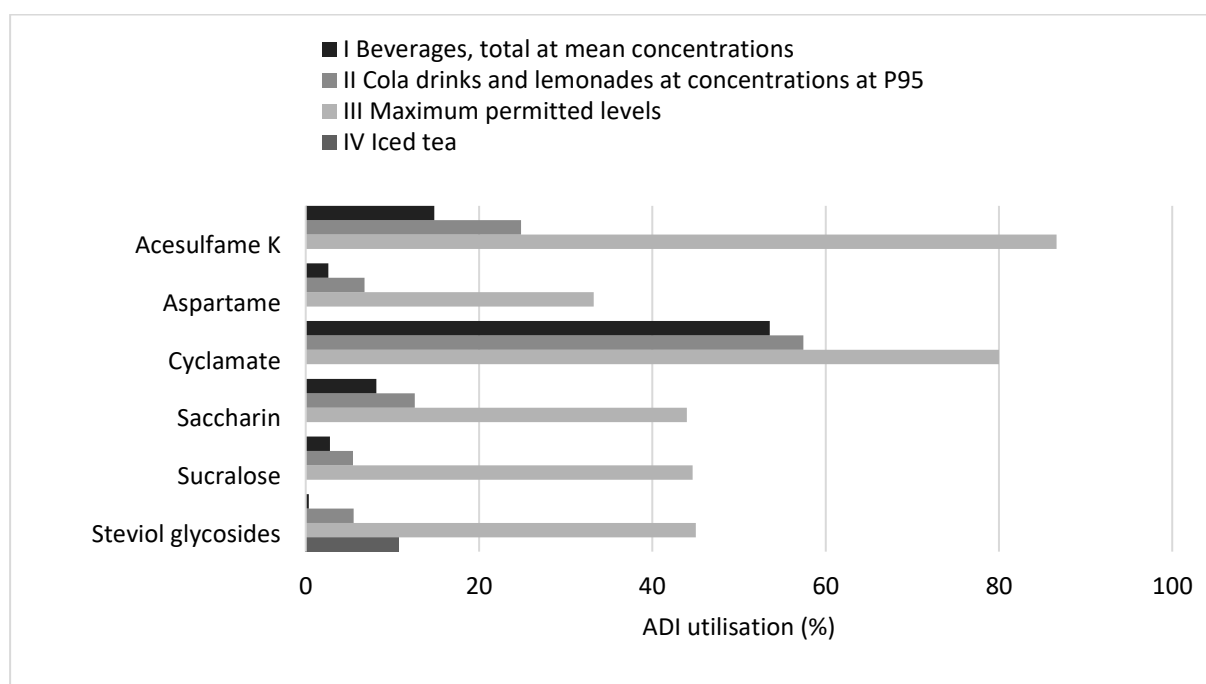
For high consumers (P95) in this age group, exposure was estimated to utilise 54 % and 57 % of the ADI for cyclamate, with the assumption that 100 % of the beverages consumed have mean concentrations from the BfR MEAL Study, or "brand loyalty behaviour", where the 95th percentile of concentrations is used for cola drinks and lemonades. Considering these two scenarios, exposure to the other five sweeteners would utilise a maximum of 25 % of the ADI. For steviol glycosides, exposure would utilise a maximum of 11 % of the ADI, on the assumption of the iced tea scenario. When using the maximum permitted levels, exposure to cyclamate and acesulfame K would utilise a maximum of 80 % and 87 % of the ADI, respectively, while for the sweeteners aspartame, saccharin, sucralose and steviol glycosides, the ADI is utilised to a maximum of 45 % (Figures 3 and 4, Appendix Table 1).

### Median consumption (P50)



**Figure 3:** ADI utilisation for median consumption of soft drinks in the age group 6–11 years for sweeteners in four different exposure scenarios (I–IV)

### High consumption (P95)



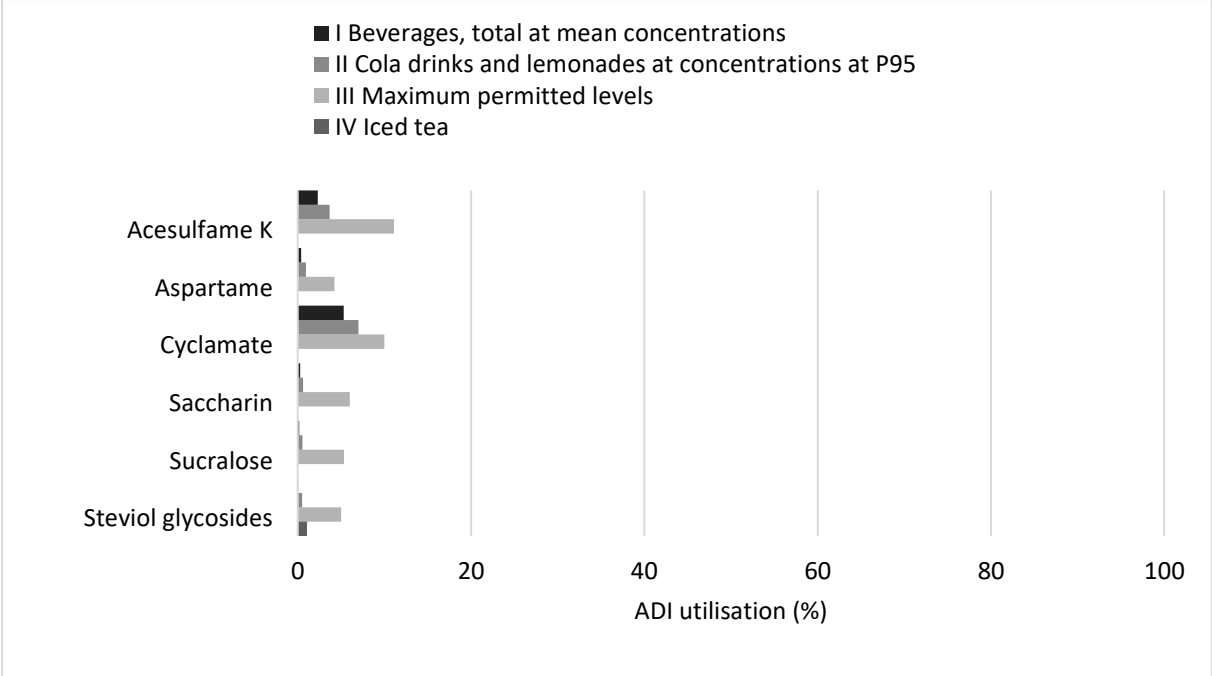
**Figure 4:** ADI utilisation by heavy consumers of soft drinks (P95) in the age group 6–11 years for sweeteners in four different exposure scenarios (I–IV)

### Age group 12–17 years

The estimated exposure for adolescents aged 12–17 years, based on median consumption of soft drinks, utilises a maximum of 11 % of the ADI for the individual sweeteners when considering the various scenarios. The exposure of high consumers (P95) utilises 46 % of the ADI for cyclamate if 100 % of the soft drinks considered have mean concentrations from the BfR MEAL Study. On the assumption that the 95th percentile of concentrations or the maximum permitted levels are used for cola drinks and lemonades, the utilisation of the ADI for cyclamate is 62 % and 80 % respectively. The estimated exposure for acesulfame K would utilise 88 % of the ADI if the maximum permitted levels were used. With the assumption of mean concentrations from the BfR MEAL Study or P95 concentrations in cola drinks and lemonades, the ADI for acesulfame K for this sweetener is utilised at around 20 % and 35 %, respectively. For the sweeteners aspartame, saccharin, sucralose and steviol glycosides, the exposure of high consumers utilise the ADI with a maximum of 45 % when using the maximum permitted levels. For the other three scenarios, the

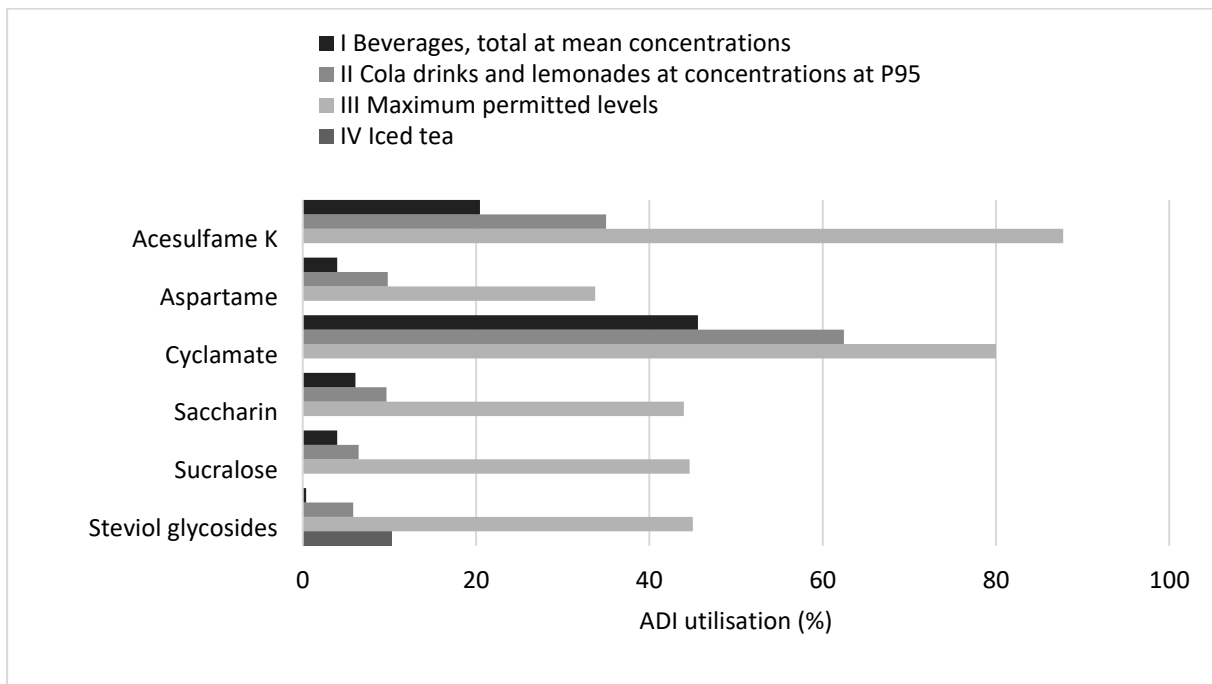
utilisation of the ADI for the sweeteners aspartame, saccharin, sucralose and steviol glycosides show a maximum of 10 % (Figures 5 and 6, Appendix Table 1).

**Median consumption (P50)**



**Figure 5:** ADI utilisation for median consumption of soft drinks in the age group 12-17 years for sweeteners in four different exposure scenarios (I – IV)

**High consumption (P95)**



**Figure 6:** ADI utilisation by high consumers of soft drinks (P95) in the age group 12-17 years for sweeteners in four different exposure scenarios (I – IV)

### 3.1.4 Conclusions

As additional part of the food additive module of the BfR MEAL Study, analytical data on concentrations of sweeteners in market-relevant soft drinks were collected. The data show that the sweeteners acesulfame K, aspartame, cyclamate, saccharin, sucralose and steviol glycosides are used separately or in combination in commercially available soft drinks. In individual cases, concentrations within the maximum permitted levels for cyclamate and acesulfame K were found in cola/ cola-mixed drinks with no added sugar.

In addition to the BfR's opinions "Sweeteners: Majority of studies confirm no adverse health effects – however, the study situation is insufficient" (from 23 September 2019) and "Do mixtures of several sweeteners pose risks for human health?" (from 30 October 2021), the exposure of young children and children aged 6–11 years and adolescents aged 12–17 years was estimated, taking into account the analytical data determined and current food consumption data (KiESEL and EsKiMo II). The results of these estimates can be summarised as follows:

- **The exposure assessments do not indicate an increased health risk for children and adolescents from the consumption of soft drinks containing sweeteners, notwithstanding other sources of sweeteners.**

Based on analytical data from the BfR MEAL Study or on assumed concentrations at the maximum permitted levels and taking into account current food consumption data from KiESEL and EsKiMo II, none of the scenarios considered resulted in an estimated exposure exceeding the acceptable daily intake for the sweeteners examined in soft drinks in the age groups considered.

The exposure assessments based on the data used therefore provide no evidence of an increased health risk for children and adolescents aged 0.5 to 17 years from the consumption of soft drinks containing sweeteners.

- **Based on the available data, exceeding the acceptable daily intake for certain sweeteners would only be possible in a hypothetical scenario of increased consumption of soft drinks containing sweeteners at the maximum permitted levels and/or additional sources of exposure (in particular cyclamate and acesulfame K).**

Assuming that the maximum permitted levels for sweeteners are used instead of the analytical data from the BfR MEAL Study, it can be seen that the acceptable daily intake (ADI) for the sweeteners examined would not be exceeded for infants, children and adolescents even if consumed in large quantities. However, for younger children under 6 years of age, children aged 6–11 years and children and adolescents aged 12 years and above, exposure to cyclamate and acesulfame K was estimated to exceed the respective ADI by 73 % to 88 % in the case of high consumption. Increased consumption of soft drinks containing sweeteners (especially cyclamate and acesulfame K) or intake from additional sources of exposure could lead to the respective acceptable daily intakes (ADI) being exceeded in these age groups at concentrations within the maximum permitted levels.

According to food consumption data from KiESEL and EsKiMo II, soft drinks account for 10 to 22 % of total beverage consumption. However, energy-reduced soft drinks and soft drinks with no added sugar account for only a small proportion of the sweetened soft drinks consumed by children and adolescents (Mensink *et al.* 2018).

In addition to flavoured non-alcoholic beverages, other sources contribute to the intake of sweeteners that are not considered in this opinion. A product search conducted by the BfR using the GNPD Mintel database (period 2015-2020) shows that sweeteners were listed as ingredients in new product launches not only in soft drinks but also in other food categories consumed by children and adolescents, such as confectionery and dairy products. Sucralose and acesulfame K were the most frequently used sweeteners in new product launches.

Data from other EU countries also show that, in addition to non-alcoholic beverages, other product groups such as dairy products, confectionery and cereals can also be relevant sources of exposure to sweeteners (Chazelas *et al.* 2021; Samaniego-Vaesken *et al.* 2021; Carvalho *et al.* 2022). For steviol glycosides, for example, EFSA concluded in its 2014 exposure assessment that exposure for young children could exceed the ADI if consumption is high and exposure from different food categories is taken into account (EFSA 2014).

In a pilot project as part of the Federal Monitoring Plan (BÜp), sweeteners in flavoured fermented milk products were investigated, so that analytical data for this food additive subcategory is now available and can be evaluated. As part of EFSA's re-evaluation of sweeteners, a re-evaluation of some of the sweeteners considered here (with the exception of aspartame and steviol glycosides) is also planned (EFSA 2020).

- **An update of the BfR opinions "Sweeteners: Majority of studies confirm no adverse health effects – however, the study situation is insufficient" (from 23 September 2019) and "Do mixtures of several sweeteners pose risks for human health?" (from 30 October 2021) is not necessary.**

In the BfR opinion "Sweeteners: Majority of studies confirm no adverse health effects – however, the study situation is insufficient" (from 23 September 2019) , a hypothetical worst-case scenario was assumed in which a person's entire daily fluid intake was provided by a beverage sweetened with a single sweetener containing the maximum permitted level of the sweetener. Under this assumption, it would be theoretically possible for toddlers and primary school children with a body weight below the median (P50) to exceed the exposure limit for acesulfame K and cyclamate. This estimate is not supported by the calculations made in this report based on consumption data and actual analytical data.

In its opinion entitled "Do mixtures of several sweeteners pose risks for human health?" (from 30 October 2021),, the BfR examined whether the available data, particularly from animal studies, provided any evidence of health risks arising from the combined use of relevant sweeteners. The considerations were based on the example of the combined use of sweeteners in non-alcoholic soft drinks. The examples show that combination effects can occur in principle. The analytical data from the BfR MEAL Study show that the sweeteners acesulfame K, aspartame, cyclamate, saccharin, sucralose and steviol glycosides are used separately or in combination in commercially relevant soft drinks. In individual cases, concentrations within the maximum permitted levels for cyclamate and acesulfame K were found in cola/ cola-mixed drinks with no added sugar. This finding supports the statements made in the BfR opinion "Do mixtures of several sweeteners pose risks for human health?" (from 30 October 2021) and underlines the importance of experimental data on the potential effects of the combined use of sweeteners.

**Further information on the BfR website on sweeteners:**

Questions and answers on sweeteners in food

<https://www.bfr.bund.de/en/service/frequently-asked-questions/topic/sweeteners-in-food-selected-questions-and-answers/>

BfR communication, BfR opinions on sweeteners

<https://www.bfr.bund.de/cm/349/bfr-opinions-on-sweeteners.pdf>

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## Appendix

### ADI utilisation of sweeteners

**Table 1:** Utilisation of the ADI of acesulfame K, aspartame, cyclamate, saccharin, sucralose and steviol glycosides, taking into account various exposure scenarios for median consumption (P50) and high consumers (P95) (for details on scenarios, see section 2.1.2.2)

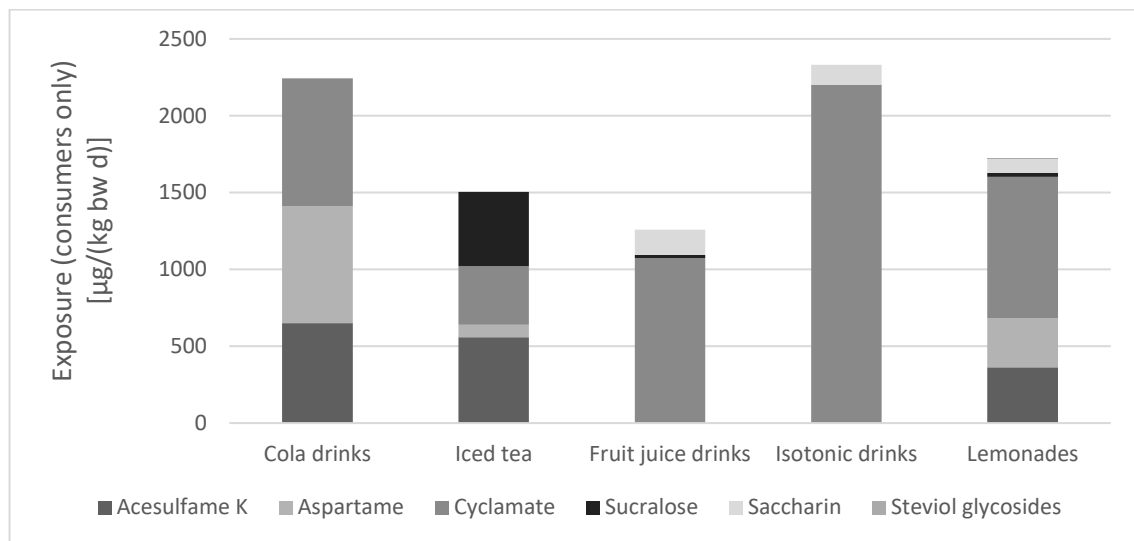
			Exposure scenario							
			I Beverages, total		II Cola drinks and lemonades		III		IV Iced tea	
			at mean concentrations		at concentrations at P95		Maximum permitted levels			
Sweeteners	ADI [mg/(kg bw d)]	Age group	ADI utilisation in %							
			P50	P95	P50	P95	P50	P95	P50	P95
<b>Acesulfame K</b>	9	0.5–5 years	3.2	16.7	7.7	33.9	17.8	80.0		
		6–11 years	3.6	14.8	6.6	24.8	17.8	86.7		
		12–17 years	2.3	20.5	3.7	35.0	11.1	87.8		
<b>Aspartame</b>	40	0.5–5 years	0.6	3.3	1.6	9.0	6.8	30.8		
		6–11 years	0.6	2.6	1.5	6.8	7.0	33.3		
		12–17 years	0.4	4.0	1.0	9.8	4.3	33.8		
<b>Cyclamate</b>	7	0.5–5 years	11.4	50.7	14.1	56.7	15.7	72.9		
		6–11 years	12.2	53.6	15.5	57.4	17.1	80.0		
		12–17 years	5.3	45.6	7.0	62.4	10.0	80.0		
<b>Saccharin</b>	5	0.5–5 years	2.0	8.2	2.5	10.5	10.0	40.0		

		6–11 years	1.7	8.2	2.6	12.6	10.0	44.0		
		12–17 years	0.3	6.1	0.6	9.7	6.0	44.0		
		0.5–5 years	0.1	1.4	0.4	4.6	10.0	42.7		
<b>Sucralose</b>	15	6–11 years	0.2	2.8	1.0	5.5	9.3	44.7		
		12–17 years	0.2	4.0	0.5	6.5	5.3	44.7		
		0.5–5 years	0.1	0.4	1.5	5.9	10.0	42.5	4.3	6.2
<b>Steviol- glycosides</b>	4	6–11 years	0.1	0.4	1.2	5.5	10.0	45.0	1.8	10.7
		12–17 years	0.0	0.4	0.5	5.8	5.0	45.0	1.0	10.3

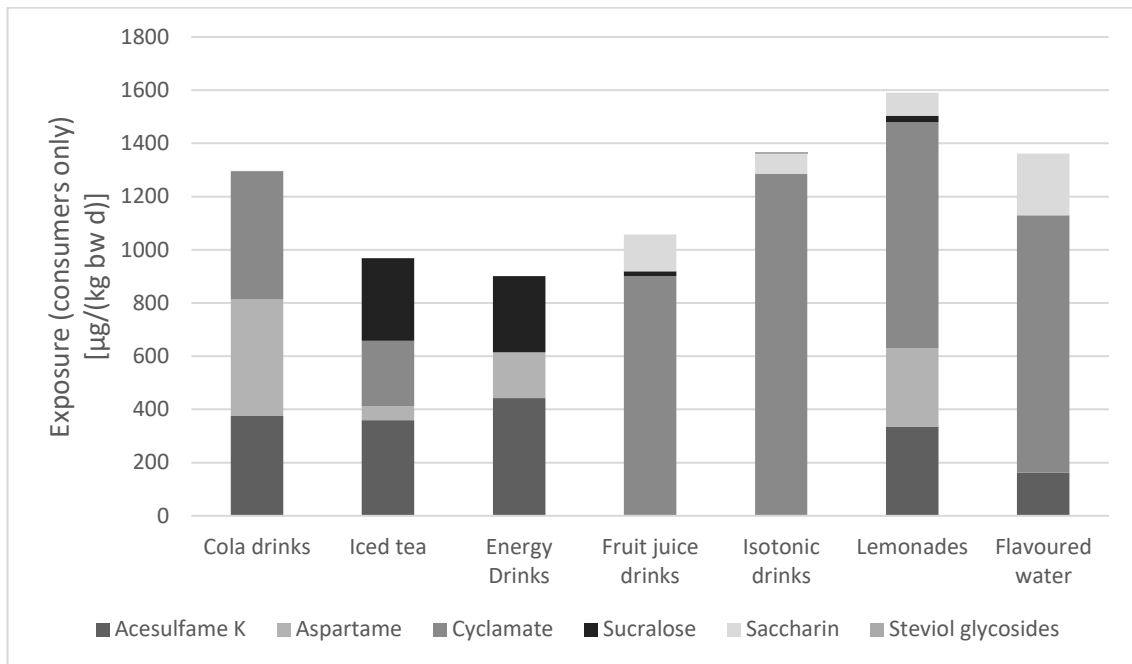
[mg/(kg bw d)] = milligrams per kilogram of body weight per day

### Median exposure (P50) by product group

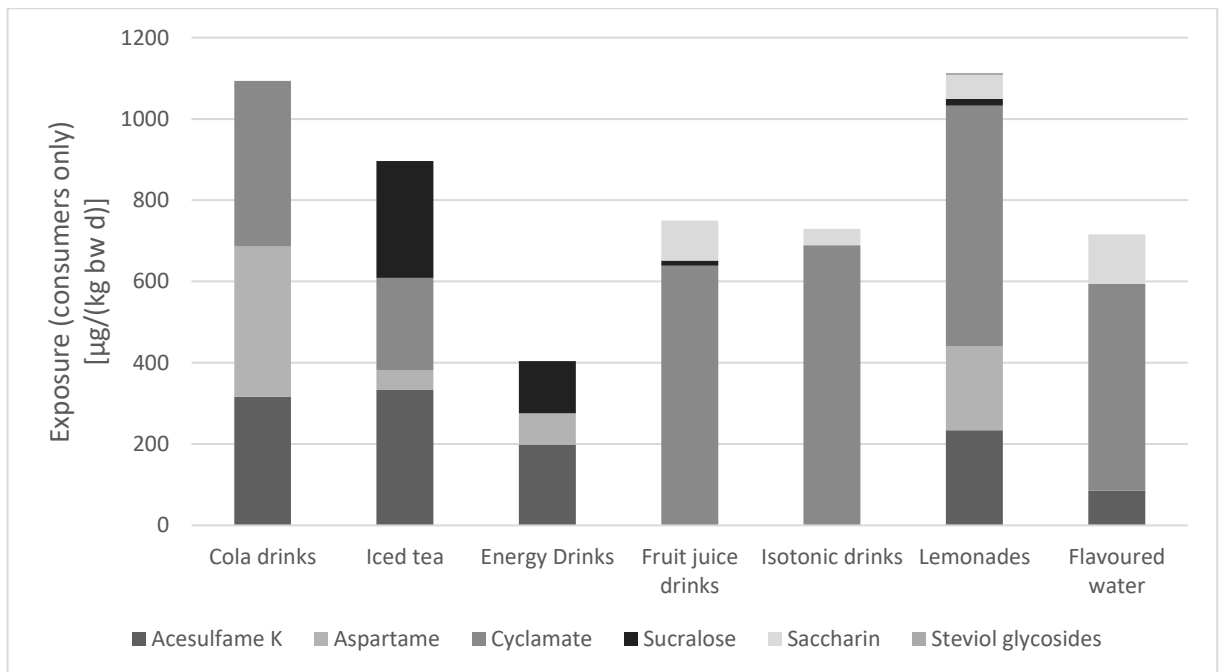
The median exposure of individual sweeteners within the various product groups is shown in **Figure 1-3**. Here, assumptions were made regarding mean concentrations and beverages containing 100 % sweeteners. Due to the global assumption, the proportions of the respective sweeteners do not change depending on the second assumption, only the level of exposure. Only the exposure of consumers of the respective product group is shown, which is why the values are higher than in the previous sections. The relative proportions do not differ between age groups, as the same concentrations were used for all of them.



**Figure 1:** Exposure for consumers of product groups broken down by sweetener. Data basis: Children aged 0.5–5 years from KiESEL; mean concentrations from the BfR MEAL Study. Assumption of 100 % share of beverages containing sweeteners; [µg/(kg bw d)] = micrograms per kilogram of body weight per day



**Figure 2:** Exposure for consumers product groups broken down by sweetener. Data basis: Children aged 6–11 years from EsKiMo II; mean concentrations from the BfR MEAL Study. Assumption of 100 % share of beverages containing sweeteners;  $[\mu\text{g}/(\text{kg bw d})]$  = micrograms per kilogram of body weight per day



**Figure 3:** Exposure for consumers of individual beverage groups broken down by sweetener. Data basis: adolescents aged 12–17 years from EsKiMo II; mean concentrations from the BfR MEAL Study. Assumption of 100 % share of beverages containing sweeteners;  $[\mu\text{g}/(\text{kg bw d})]$  = micrograms per kilogram of body weight per day

For cola drinks, exposure is divided relatively evenly between acesulfame K, aspartame and cyclamate. Values from a single sample with detected saccharin are negligible (< 0.1 % share). The situation is similar for iced tea, although here aspartame has a lower proportion (around 5 %) and the remaining exposure is divided relatively evenly between acesulfame K, cyclamate and sucralose. In fruit juice drinks, exposure to cyclamate is vast (85 %), with smaller contributions from sucralose and saccharin. Cyclamate also dominates exposure in isotonic drinks, with the remaining contribution coming from saccharin. In the case of lemonades, cyclamate again accounts for the largest share, but at 53 % it is lower. Other major contributions of around 20 % each come from acesulfame K and aspartame, followed by saccharin with a share of around 5 %. Sucralose, stevioside and rebaudioside A contribute only very little (1 % or less) to exposure via lemonades.

Energy drinks and "flavoured water" were also considered for children and adolescents aged 6 to 17 years. In energy drinks, acesulfame K accounts for the highest proportion of exposure at 49 %. This is followed by sucralose with 32 % and aspartame with 19 %. In the case of "flavoured water", the highest proportion is 71 % and comes from cyclamate. Saccharin accounts for 17 % and acesulfame K for 12 %.

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