EXPOCHI

SCIENTIFIC REPORT submitted to EFSA

Long-term dietary exposure to selenium in young children living in different European countries[1]

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Abstract

Previous EFSA exposure assessments of selenium have been based on limited data and a more detailed assessment was considered important. As part of the EXPOCHI project, long-term dietary exposure to selenium in young children living in 12 different European countries was assessed. National or regional individual food consumption data from 14 different food consumption databases were used together with selenium concentration data in food collected in eight Member States. Food consumption data were all categorised according to a harmonised system to allow for linkage with selenium concentration data in a standardised way. Two approaches were used to calculate long-term exposure to selenium: the observed individual means (OIM) and the beta-binomial normal (BBN) approach. The results showed differences in exposure between countries based on food consumption patterns and decreased exposure with increased age. Young children in the upper bound scenario commonly exceeded the tolerable upper intake level of 5 µg/kg bw per day. However, current results should be interpreted with caution since they do not necessarily represent the actual selenium exposure in the respective country. To improve reliability, consumption and occurrence results should be linked at more detailed levels, local variations in selenium concentrations explored and handling of long-term exposure calculations refined for all types of data distributions.

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Summary

The FEEDAP Panel has reviewed the safety and efficacy of selenium enriched yeast used as a feed additive in three opinions. Human exposure assessments were conducted based on a prescribed, very conservative, consumption scenario for food of animal origin, but also a more realistic consumption scenario. When using the worst-case consumption scenario for food from animals fed selenium-enriched feed, estimated exposure in children (4-6 years) of 99 µg/day was slightly above the tolerable upper intake level of 90 µg/day for this group. This was not the case for the more realistic consumption scenario, but since it was based on limited data a more detailed assessment was considered important.

In the current report, long-term dietary exposure to selenium in children aged 1 to 14 years and living in 12 different European countries was assessed. National or regional individual food consumption data from 14 different food consumption databases were used that were collected during at least two days using either the 24-h recall method or the dietary record method. Eight Member States supplied the selenium concentration data, with about 90% coming from Germany. It is known that selenium content in food varies across Europe, but it was not possible within the timeframe of the project to achieve more complete coverage of European countries. It is difficult to assess how representative these data are for evaluating selenium intake in the 14 different European countries.

To link consumption data with selenium concentration data, 42 communal food groups were used. These food groups were very diverse, for example the food group ‘vegetables’ contained all types of raw and processed vegetables, including potatoes. Assigning one mean selenium level to all foods belonging to a food group very likely affected the exposure. Linking food consumption and concentration data is a crucial step in dietary exposure assessments.

Two approaches were used to calculate long-term exposure to selenium: the deterministic observed individual means (OIM) and the stochastic beta-binomial normal (BBN) approach. The BBN model separates the within-person variation from the between-person variation to estimate exposure and can model covariates, such as age. This approach has been proven very useful for estimating long-term exposure. However, for some countries the BBN model could not be used due to lack of required normality of the transformed exposure data. In such cases the OIM approach was used, although this model cannot deal with within-person variation and results in more conservative estimates of exposure in the right tail of the exposure distribution than the BBN model.

Results of the modelling calculations showed differences in exposure between countries and a decreased exposure with age. Using the BBN model for children 1 to 10 years of age, the national long-term exposure to selenium from food across the 12 European countries, using lower bound concentrations, ranged from 1.2 to 4.1 µg/kg bw per day for median consumers, and from 2.3 to 8.6 µg/kg bw per day for 99th percentile consumers. Exposure levels in younger children were higher compared to older children in this age group. The lower bound estimates for children aged 11 to 14 years were 0.9 to 1.8 µg/kg bw per day for median consumers and 1.8 to 3.3 µg/kg bw per day for 99th percentile consumers. Using upper bound concentrations, median exposure for the age group 1 to 10 years ranged from 2.0 to 6.5 µg/kg bw per day and 99th percentile exposure from 3.7 to 14.1 µg/kg bw per day. The upper bound estimates for children aged 11 to 14 years were 1.5 to 2.7 µg/kg bw per day for median consumers and 2.8 to 5.6 µg/kg bw per day for 99th percentile consumers. Estimated exposure

levels were higher using the OIM model compared to the BBN model, particularly for high percentiles. The food groups ‘cereals’, ‘vegetables’, ‘fresh meat’ and ‘milk & dairy drinks’ contributed most to the exposure in almost all countries. An exception was the Spain-enKid study, in which the food group ‘other foods for special dietary use’ was the most important source of exposure.

To assess whether there may be a possible health risk related to the exposure to selenium in children, the proportion of children exceeding the tolerable upper intake level of 5 µg/kg bw per day was estimated in the respective age group. In the upper bound scenario, between 8 and 84% of the children in the 1-3 year old age group exceeded the tolerable upper intake level, while the proportion diminished with increasing age.

Methodological issues of an exposure study linking different national food consumption databases to one “European” selenium concentration database were addressed in the discussion. Not all age groups were present in all countries, which might have partly influenced the overall results. Due to the uncertainties related to the selenium exposure assessment presented here, as well as the exclusion of selenium exposure via food supplements, the exposure results must be interpreted with caution. To improve reliability, consumption and occurrence results should be linked at a more detailed level, occurrence results should better represent local conditions and a model should be developed that can more precisely predict long-term exposure also for non-normally distributed data.

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Background

In order to carry out their risk assessments, the EFSA Panels on additives, flavourings, processing aids and materials in contact with food (AFC), on contaminants in the food chain (CONTAM), on Biological Hazards (BIOHAZ) and on additives and products or substances used in animal feed (FEEDAP) expressed the need to have reliable and detailed individual food consumption data for children and, in particular, young children. In addition, a requirement for specific exposure assessment studies was identified for the same population groups. One of these studies should estimate the dietary exposure to selenium.

In 2006, the FEEDAP Panel adopted an opinion on the safety and efficacy of a selenized yeast as a feed additive. The exposure assessment was conducted based on the intake data from the scenario given by Commission Directive 2001/79/EC and from realistic data (European Commission within the Tasks for Scientific Cooperation, SCOOP[3]). When using the worst-case scenario it was found that the exposure in children (4-6 years) (99 µg/day) was slightly above the upper intake level (UL) for this group (90 µg/day), when food of animal origin from animal supplemented the said selenium form was considered. Therefore, EFSA asked to carry out an up-to-date exposure assessment to selenium in European children.

Keywords

Dietary exposure, children, selenium, Europe

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[3] European Commission, 2004. Reports on Tasks for Scientific Cooperation (SCOOP) Task 3.2.11. Assessment of the dietary exposures to arsenic, cadmium, lead and mercury of the population of the EU Member States Directorate General Health and Consumer Protection. http://ec.europa.eu/food/food/chemicalsafety/contaminants/scoop_3-2-11_heavy_metals_report_en.pdf

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1. Introduction

In this report, we describe the long-term exposure to selenium in children living in 12 different European countries, including Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Netherlands, Spain and Sweden.

For this exposure assessment food consumption data of children aged 1 up to 14 years were combined with selenium concentration data. To estimate the long-term exposure we used the software Monte Carlo Risk Assessment (MCRA) (de Boer and van der Voet, 2007). In this program, different (statistical) models to assess the long-term dietary exposure to chemicals have been implemented.

In section 2, we describe the input data and the methodology used to assess the long-term dietary exposure to selenium. In section 3, the results are described and listed. In the last section, these results are discussed in relation to their methodological limitations.

2. Materials and Methods

2.1. Selenium concentration data

Food items contain a number of different selenium forms. In animal foods, there are specific selenium proteins where selenium is incorporated via selenide as selenocysteine, while selenomethionine, and possibly also selenocysteine to some extent, are non-specifically incorporated as analogues to methionine and cysteine in foods both of animal and plant origin. Selenomethionine, as well as the inorganic forms selenite and selenate, are the most common forms in food supplements and fodder additives (SCF, 2000).

The selenium occurrence data were supplied to EFSA through a call for data on selenium and chromium levels in food and beverages (EFSA/DATEX/2008/013) issued by EFSA in September 2008 with a closing date of November 2008. EFSA received a total of 47,858 results from food testing from 8 Member States (Austria, Cyprus, France, Germany, Greece, Hungary, Ireland and United Kingdom). Germany was the major contributor providing 90% of the data followed by Ireland (4%) and United Kingdom (2%). The data covers the period from 2000 to 2008. No specific information is available about the form in which the selenium was present in the food and beverages.

The data were processed by EFSA and categorised in 42 communal food groups (Table 1). Two mean selenium concentrations were calculated per food group: lower bound (LB) and upper bound (UB) mean selenium concentration. The LB mean concentrations were calculated, where appropriate, by assigning zero to the samples with a level below limit of reporting (LOR), determination (LOD) or quantification (LOQ). The UB mean concentrations were calculated by assigning LOR, LOD or LOQ to the samples with a level below the respective limits. See Table 1 for the LB and UB mean selenium concentrations per food group. Mean selenium concentrations were calculated per food group because selenium is a compound that is present in foods at levels for which chronic effects are the relevant health effects. Fluctuations in daily concentrations are assumed to average out in the long run.

No information was available regarding the composition of the 42 communal food groups in relation to the foods analysed. This issue will therefore not be addressed here, although it is important for a correct interpretation of the chromium exposure results.

2.2. National food consumption surveys

The national and regional food consumption databases included in the selenium dietary exposure assessments are described briefly in Table 2. Two different dietary methods were used in the different surveys. When using the dietary record method, the food items and beverages consumed, as well as the amounts were recorded at the moment of consumption. When using a 24h recall, the respondent or a proxy (parents or caretakers in the case of small children) were interviewed and needed to recall amounts of all food items and beverages consumed during the day before the interview. Only children up to the age of 14 years are included in the material. In some surveys, also ages of 15 years and older were included in the database, but these data were not included in the analyses performed in the framework of this project. For more detailed descriptions about the food consumption surveys we refer to the report 'Long-term dietary exposure to lead in young children living in different European countries' (Boon et al., 2010).

In all surveys, also non-dietary information of the children was obtained, including sex, age and body weight. When age or sex was missing the subject was excluded from the database. When weight was missing, it was replaced by the average estimated in the same group (defined by age, sex and country).

Table 1. Mean selenium concentration per food group as used in the long-term exposure assessments (LB: lower bound; UB: upper bound[a]).

Food group		**Mean selenium concentration (µg/kg)**	
Nr	**Name**	**LB**	**UB**
1	Composed foods-cereal based mixed dishes and cereal-based desserts	51.05	62.25
2	Vegetables excl. dried vegetables(b)	47.26	61.04
3	Nuts/seeds	379.13	390.61
4	Coffee/tea in concentrated and in powdered form	240.67	288.39
5	Chocolate/chocolate products	259.50	375.76
6	Fruit excl. dried fruit(b)	3.62	17.42
7	Dried fruit	0.00	0.00
8	Fresh and dried herbs, spices, seasonings and condiments	12.01	22.72
9	Food supplements	32308.72	32379.06
10	Waters	1.32	2.97
11	Sugar, sweeteners and sugar products (e.g. sugar based confectionery, chewing gum and decorations)	27.59	51.27
12	Fats, oils and fat emulsions (also e.g. rice milk (no soy milk))	65.09	87.54
13	Composed foods: meat based mixed dishes	40.10	49.37
14	Composed foods: fish based mixed dishes	255.44	258.29
15	Dried vegetables	0.00	0.00
16	Pulses/legumes	176.13	187.17
17	Soy milk/soy based dessert	76.00	91.71
18	Milk/dairy drinks	12.48	23.45
19	Cheese	58.05	80.87
20	Dairy based products	8.68	43.09
21	Salt	428.14	499.57
22	Fish	353.15	355.13
23	Molluscs	488.51	493.14
24	Cephalopods	475.10	475.10
25	Crustaceans	360.32	362.10

Food group		**Mean selenium concentration (µg/kg)**	
Nr	**Name**	**LB**	**UB**
26	Other seafood (echinoderms)	478.11	478.11
27	Beer/malt beverages	1.58	13.10
28	Wine/substitutes	0.39	8.38
29	Other alcoholic beverages	111.25	122.77
30	Fruit juices/nectars(a)	0.48	11.44
31	Vegetable juices/nectars	2.99	12.00
32	Soft drinks/edible ices	6.61	20.65
33	Cereals/cereal products (no cereal based desserts or cereal based mixed dishes)(b)	53.21	81.01
34	Other food for special dietary uses	7073.16	1098.18
35	Infant formulae, follow up formulae, food for young children and infant formulae and follow up formulae for medical purposes(b)	40.30	65.45
37	Miscellaneous foods(b)	45.35	127.69
38	Liver/kidney	490.93	492.18
39	Offal except liver/kidney	166.71	169.61
40	Types of vegetarian substitutes for meat/fish	0.00	0.00
41	Fresh meat	114.11	237.60
42	Processed meat	0.00	0.00
45	Eggs	233.63	246.80

(a) For the non-detect samples two scenarios of assigning selenium concentrations were applied: for more explanation, see text

(b) These food groups have been renamed in Tables 4, 6, 9 and 10: nr 2 = vegetables; nr 6 = fruit; nr 30 = fruit juices; nr 33 = cereals; nr 35 = infant formulae; nr 37 = miscellaneous.

Table 2. Information on the food consumption data per country used to model long-term dietary exposure to selenium.

Country	Year of survey	Representativeness	Ages (year) [a]	Number of individuals				Number of days / consecutive (yes or no)	Dietary survey method
				Total	1-2 years	3-10 years	11-14 years		
Belgium	2002-2003	Regional	2-6	661	36	625	-	3 days / Yes	Dietary record
Cyprus	2002-2006	National	11-14	268	-	-	268	3 days / Yes	Dietary record
Czech Republic	2003-2004	National	4-14	602	-	493	109	2 days / No	24-h recall
Denmark	2000-2002	National	4-10	610	-	610	-	7 days / Yes	Dietary record
Finland-DIPP	2005	Regional	1, 3, 6	1,500	500	1,000	-	3 days / Yes	Dietary record
Finland-STRIP	2000	Regional	7-8	250	-	250	-	4 days / Yes	Dietary record
France	2005-2007	National	3-10	574	-	574	-	7 days / Yes	Dietary record
Germany	2006	Regional	1-10	303	92	211	-	3 days / Yes	Dietary record
Germany	2007	Regional	1-10	311	85	226	-	3 days / Yes	Dietary record
Germany	2008	Regional	1-10	307	84	223	-	3 days / Yes	Dietary record
Greece	2004-2005	Regional	4-6	795	-	795	-	3 days / Yes	Dietary record
Italy	2005-2006	National	1-10	252	36	189	-	3 days / Yes	Dietary record
Netherlands	2005-2006	National	2-6	1,279	322	957	-	2 days / No	Dietary record
Spain-Basque	2004-2005	Regional	4-14	760	-	462	298	2 days / No	24-h recall
Spain-enKid	1998-2000	National	1-14	382	17	178	187	2 days / No	24-h recall
Sweden	2003	National	3-13	2,298	-	1,379	919	4 days / Yes	Dietary record

(a) Upper age of the range is included in the selection.

2.3. Linkage food consumption and selenium concentration data

All foods present in the national/regional food consumption databases of the participating countries were categorised according to a harmonised system to allow for linkage with selenium concentration data in a standardized way. This has been described in detail in the manual of De Neve (2009) (freely available on request). The food categorisation system used was based on that described in the SCOOP Task report Task 3.2.11 (SCOOP, 2004). In short, all foods recorded in the different national/regional food consumption databases were assigned to one of 17 main food groups, and subsequently to corresponding sub food groups depending on the information available or needed on the food. For example main food group 'dairy products and analogues' consisted of many sub food groups including 'cheese', 'butter milk', 'condensed milk', 'dairy-based desserts', etc. The categorisation of all foods in these food groups was closely supervised by Ghent University, Belgium, ensuring that this was performed in a standardized way by all countries.

However, reporting to EFSA of selenium concentration data used the 'Concise Database' system to categorise the information (EFSA, 2008). The coordinating institute, Ghent University, and EFSA agreed to use 42 'communal food groups' to make sure that the consumption data could be linked to the selenium concentration data. To link the previous defined food categories to the 42 communal food groups for which mean selenium concentration were provided by EFSA (Table 1), the different main and sub food groups were linked to the most obvious EFSA food group. Subsequently, food items that were categorised in these main and sub food groups were re-assigned to one of the 42 food groups. This re-classification was performed in close cooperation with EFSA and was run automatically by a programmed script in SPSS for Windows software program (version 15.0).

For a complete overview of consumption levels per food group for all participating countries and relevant age groups, see report 'Long-term dietary exposure to lead in young children living in different European countries' **(**Boon et al., 2009). It should be noted that not all countries had consumption levels on all food groups. Mostly that was due to non-consumption of foods belonging to these groups. An exception was the food group 'food supplements'. For example in Belgium, Czech Republic, France, Netherland and Spain (both studies), no food consumption data were included on food supplements in the national food consumption database used for the calculations described in this report. For the exposure assessment of selenium, the consumption data of food supplements were not taken into account in any of the studies in order to use a similar approach for all surveys.

2.4. Modelling of long-term dietary exposure to selenium

2.4.1. Methodology

The long-term dietary exposure was calculated using the 'Monte Carlo risk assessment' programme (MCRA), Release 6.2, available for registered users at the RIKILT website (de Boer and van der Voet, 2007)[5]. For the estimation of long-term exposure, all daily consumption patterns (e.g., 2,558 for Dutch children (2 days × 1,279 individuals)) were

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[5] For the settings used within MCRA to perform the long-term exposure calculations see Appendix A.

multiplied with the LB and UB mean selenium concentration per food group, and summed over foods consumed per day per individual. The estimated exposures were adjusted for the individual’s body weight.

A distribution of daily exposures, calculated as described above using mean concentrations per food or food group, includes both the variation between individuals and between the days of one individual. However, to assess the long-term intake within a population only the former type of variation is of interest, since in the long run the variation between different days of one individual will level out. Therefore, to calculate a long-term dietary exposure distribution, the within-person (between days) variation should first be removed from the distribution of daily exposures using statistical models. In this report, we used for that the relatively new beta-binomial-normal (BBN) model (de Boer and van der Voet, 2007; Slob, 2006). To remove the within-person variation from the daily exposures, the BBN model transforms the daily exposure distribution into a normal distribution using a logarithmic function. After removal of the within-person variation, the normal distribution is back-transformed and is then considered a long-term dietary exposure distribution.

Transformation of the daily exposure distribution into a normal distribution is an important prerequisite to be able to use statistical models that assess the long-term exposure. We therefore checked whether this was true using the normal quantile-quantile (q-q) plot, a graphical display of residuals, as advocated by de Boer et al. (2009). In Figure 1, we have plotted two examples of such a q-q plot. In the left panel, the transformed daily exposure distribution can be considered reasonably normal, while in the right panel the assumption of normality is violated.

No models are presently available to estimate the long-term exposure on transformed daily exposure distributions that are not normally distributed. Because for some countries the assumption of normality was violated, we also calculated the long-term exposure using a simpler approach: all daily exposures are averaged per individual, and the resulting distribution of observed individual means (OIM) is interpreted as the long-term exposure distribution. However, the observed individual means are more variable than the true long-term exposures unless there are many measured days per individual (which is typically not the case). Consequently, high percentiles in the OIM distribution are expected to be conservative (too high).

The reported percentiles of the long-term exposure distribution are P50, P95 and P99. These percentiles were reported for the ages 1 up to 14 years for all countries, dependent on the ages present in the databases (Table 2).

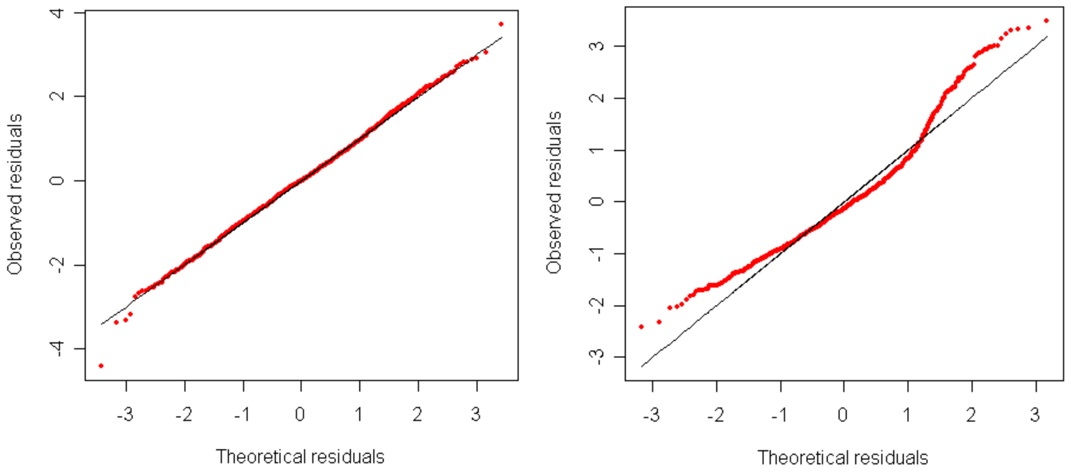

Figure 1. Two examples of the q-q-plot of selenium exposure amounts after lognormal transformation performed in the BBN (betabinomial-normal) model. Left panel the transformed daily exposure distribution can be considered reasonably normal, while in the right panel the assumption of normality is violated.

2.4.2. Age dependency of exposure

The ages included in the different national food consumption surveys differed (Table 2). Since the dietary exposure of children is expected to be a function of age with higher exposure levels at lower ages (due to a higher amount of food consumed per kg body weight), we calculated the exposure as a function of this covariable using the BBN model. The long-term exposure will therefore be reported per age using this approach and compared between countries at that level. Within the BBN model intake frequency and intake amount are modelled separately and afterwards combined to estimate the long-term exposure distribution (de Boer and van der Voet, 2007; de Boer et al., 2009). Intake frequency and amount can both be modelled as a function of age. Because a preliminary analysis showed that the intake frequency of selenium was not dependent on age (all children have an intake of selenium on all days because selenium is present in almost all consumed foods), only age dependency of intake amount was modelled.

When using the OIM approach the exposure cannot be estimated as a function of age. We therefore calculated the exposure for three age groups: 1 to 2, 3 to 10 and 11 to 14 years. Please note that the different dietary surveys do not all cover these age groups to the same extent (Table 2). For example, the age group 3 to 10 years only included the ages 4 to 6 years for Greece and 3 to 6 years for Belgium and the Netherlands. The number of individuals per age group differed also much between and within countries. For example, for Belgium 36 of the 661 children belong to the age group 1 to 2 years, all the rest to the group 3 to 10. Furthermore not all countries have consumptions for all ages. Only Belgium, Finland, Germany, Italy, Netherlands and Spain-enKid have consumption levels that cover the age group 1 to 2 years, and Czech Republic, Cyprus, Spain (both studies) and Sweden have data on children aged 11 to 14 years. All countries have consumption data covering ages within the age group 3 to 10 years, except Cyprus (only data on children older than 10 years).

2.4.3. Contribution of food groups to the total long-term exposure

Apart from exposure percentiles we also calculated for each country the relative contribution of the food groups to the total long-term exposure distribution using both the BBN and OIM method. Because it is not possible with the present software to calculate the contribution of the food groups to the long-term exposure as a function of age using the BBN model, we divided the children in two age groups: the age groups 1 to 10 and 11 to14 years. We did not divide the 1 to 10 year group in 1 to 2 and 3 to 10 years (as when using the OIM approach) due to loss of statistical power when addressing a small number of children in the 1 to 2 year group. Contributions calculated with the OIM model were reported for the three age groups examined with this approach.

We report the three food groups contributing most to the long-term exposure to selenium. This included in all cases all food groups that contributed more than 10% to the total long-term exposure.

2.5. Risk characterisation of the long-term exposure

To assess whether there is a health risk of long-term exposure to selenium in children, the P99 of exposure was compared with the Upper Level (UL) of intake of selenium. The Scientific Committee on Food (SCF) decided on an UL of 300 µg/day for adults (SCF, 2000). This value covers selenium intake via food, beverages and food supplements. An UL for children was extrapolated from adults on a body weight basis, i.e. 5 µg/kg bw per day. When the P99 of selenium exposure exceeded this UL, the exact percentage of children exceeding this level was reported.

3. Results

3.1. Long-term dietary exposure to selenium using the BBN approach

3.1.1. Long-term exposure for age range of 1 to 10 years of age

In Table 3, the estimated long-term dietary exposure to selenium in children covering the age 1 to 10 years in the different countries is listed for the LB and UB concentration scenarios. These exposure results were calculated using the BBN approach. The exposure to selenium was highest in the youngest children and decreased with age. In the LB concentration scenario, the P99 of exposure ranged from 2.3 µg/kg bw per day in 10-year olds from Sweden to 8.6 µg/kg bw per day in 1-year olds from Germany (2007 study). The P99 of exposure in the UB concentration scenario was on average about a factor 1.6 higher than in the LB concentration scenario, resulting in a range from 3.7 µg/kg bw per day in 10-year olds from Sweden to 14.1 µg/kg bw per day in 1-year olds from Finland (DIPP-study).

Table 4 lists for each country the three food groups contributing most to the long-term exposure distribution of selenium for children within the age range of 1 to 10 years for both concentration scenarios. Please note that the ages present in this age range differ per country. Important food groups that contributed most to the selenium exposure were ‘cereals’, ‘vegetables’, ‘fresh meat’ and ‘milk & dairy drinks’. For Spain (enKid study) ‘other food for special dietary use’ emerged as the most important sources of exposure. This food group has a very high selenium concentration (Table 1), but consumption levels for this group are not available in all surveys, due to non-consumption of foods belonging to this group.

3.1.2. Long-term exposure for age range of 11 to 14 years

The percentiles of long-term dietary exposure to selenium in children aged 11 to 14 years are listed in Table 5 for the LB and UB concentration scenarios. In this age group, the P99 of exposure ranged from 1.8 µg/kg bw per day in 14-year olds from Cyprus to 3.3 µg/kg bw per day in 11-year olds from the Czech Republic and Spain (enKid study) for the LB concentration scenario. Corresponding figures for the UB concentration scenario were 2.8 µg/kg bw per day in 14-year olds from Cyprus and 5.6 µg/kg bw per day in 11-year olds from the Czech Republic.

The contribution of the three most important food groups to the long-term exposure is listed in Table 6 for all countries and both concentration scenarios. As in younger children, also in the older children food groups ‘cereals’, ‘vegetables’ and ‘fresh meat’ were important food groups contributing to the exposure in both the LB and UB concentration scenario. Also ‘fish’ appear as an important contributor to the exposure in Sweden and Spain (Basque). For Spain (enKid-study) ‘other food for special dietary use’ emerged as the most important source of exposure as was the case in the younger age group (Table 6).

Table 3. Percentiles of long-term dietary exposure to selenium in children aged 1 to 10 years living in different European countries[d].

Country	Age (years) and exposure (µg/kg bw per day)																			
	Mean LB concentrations										Mean UB concentrations									
	1	2	3	4	5	6	7	8	9	10	1	2	3	4	5	6	7	8	9	10
P50 of exposure																				
Belgium		3.0	2.7	2.5	2.2	2.0						5.3	4.8	4.3	3.9	3.5				
Czech Republic				2.5	2.3	2.2	2.0	1.9	1.8	1.7				4.1	3.8	3.5	3.3	3.1	2.9	2.7
Denmark [c]				2.5	2.4	2.3	2.1	1.9	1.7	1.5				4.0	3.8	3.6	3.4	3.1	2.8	2.5
Finland-DIPP [a, c]	3.0	2.8	2.7	2.5	2.4	2.3					5.1	4.8	4.6	4.3	4.0	3.8				
Finland-STRIP							1.9	1.9									3.1	3.1		
France [c]			2.6	2.5	2.3	2.1	2.0	1.9	1.7	1.6			4.3	4.0	3.7	3.5	3.2	3.0	2.8	2.6
Germany-2008 [c]	3.0	2.6	2.2	1.9	1.7	1.5	1.4	1.3	1.3	1.2	4.9	4.2	3.5	3.1	2.8	2.5	2.3	2.2	2.1	2.0
Germany-2007 [c]	3.0	2.5	2.2	1.9	1.7	1.6	1.5	1.4	1.3	1.3	4.9	4.2	3.5	3.1	2.8	2.6	2.4	2.3	2.2	2.1
Germany-2006 [c]	2.9	2.4	2.0	1.8	1.6	1.5	1.4	1.4	1.3	1.3	4.7	4.0	3.4	2.9	2.7	2.5	2.3	2.2	2.2	2.1
Greece				2.4	2.2	2.1								3.7	3.4	3.2				
Italy	3.4	3.2	3.0	2.9	2.7	2.6	2.4	2.3	2.1	2.0	5.1	4.8	4.5	4.3	4.0	3.7	3.5	3.3	3.1	2.9
Netherlands		2.4	2.2	2.1	1.9	1.8						4.1	3.8	3.6	3.3	3.1				
Spain-enKid [c]	4.1	3.8	3.5	3.2	3.0	2.7	2.5	2.3	2.2	2.0	6.5	5.9	5.4	5.0	4.6	4.2	3.8	3.5	3.2	3.0
Spain-Basque				3.0	2.8	2.6	2.4	2.3	2.1	2.0				4.8	4.4	4.1	3.8	3.5	3.2	3.0
Sweden [b]			2.5	2.5	2.2	1.9	1.8	1.7	1.6	1.3			4.2	4.1	3.7	3.3	3.0	2.8	2.6	2.1
P95 of exposure																				
Belgium		4.4	4.0	3.6	3.3	3.0						7.7	7.0	6.3	5.7	5.2				
Czech Republic				3.8	3.5	3.3	3.1	2.9	2.7	2.5				6.1	5.7	5.3	5.0	4.6	4.3	4.0
Denmark [c]				3.8	3.7	3.5	3.2	2.9	2.6	2.4				6.0	5.8	5.5	5.1	4.7	4.2	3.8
Finland-DIPP [a, c]	5.9	5.6	5.3	5.0	4.7	4.5					10.5	9.9	9.4	8.8	8.3	7.8				
Finland-STRIP							2.7	2.7									4.3	4.4		
France [c]			4.3	4.0	3.7	3.5	3.2	3.1	2.8	2.7			7.0	6.5	6.1	5.7	5.3	4.9	4.6	4.2
Germany-2008 [c]	5.9	5.0	4.3	3.7	3.3	3.0	2.8	2.6	2.5	2.4	9.4	8.0	6.8	5.9	5.3	4.8	4.5	4.2	4.0	3.8
Germany-2007 [c]	6.4	5.4	4.5	3.9	3.5	3.3	3.1	2.9	8.8	2.7	10.2	8.7	7.3	6.4	5.8	5.4	5.1	4.8	4.6	4.4
Germany-2006 [c]	6.1	5.1	4.3	3.8	3.4	3.2	3.0	2.9	2.8	2.7	9.6	8.1	6.9	6.0	5.5	5.1	4.8	4.6	4.4	4.3
Greece				3.77	3.50	3.27								5.73	5.32	4.93				
Italy	5.5	5.2	4.9	4.6	4.4	4.1	3.9	3.7	3.5	3.3	8.3	7.7	7.2	6.8	6.4	6.0	5.6	5.3	5.0	4.7
Netherlands		3.4	3.2	2.9	2.7	2.5						5.7	5.3	4.9	4.6	4.2				

Country	Age (years) and exposure (µg/kg bw per day)																			
	Mean LB concentrations										Mean UB concentrations									
	1	2	3	4	5	6	7	8	9	10	1	2	3	4	5	6	7	8	9	10
Spain-enKid [c]	6.3	5.8	5.4	4.9	4.6	4.2	3.9	3.6	3.3	3.1	10.0	9.2	8.4	7.7	7.0	6.4	5.9	5.4	5.0	4.6
Spain-Basque				4.1	3.8	3.6	3.3	3.1	2.9	2.7				6.6	6.1	5.6	5.2	4.8	4.4	4.1
Sweden [b]			3.8	3.7	3.4	3.0	2.7	2.6	2.4	2.0			6.2	6.0	5.5	4.9	4.4	4.2	3.9	3.1
P99 of exposure																				
Belgium		5.2	4.7	4.3	3.9	3.5						8.9	7.5	6.8	6.1	5.6				
Czech Republic				4.5	4.2	3.9	3.7	3.4	3.2	3.0				7.3	6.8	6.3	5.9	5.5	5.1	4.8
Denmark [c]				4.6	4.4	4.2	3.9	3.5	3.1	2.8				7.1	6.8	6.5	6.0	5.5	5.0	4.5
Finland-DIPP [a, c]	7.8	7.4	7.0	6.6	6.2	5.9					14.1	13.4	12.5	11.8	11.2	10.5				
Finland-STRIP							3.2	3.2									5.0	5.0		
France [c]			5.2	4.9	4.6	4.3	4.0	3.8	3.5	3.2			8.5	8.0	7.4	6.9	6.4	5.9	5.6	5.1
Germany-2008 [c]	7.8	6.7	5.6	4.9	4.4	3.9	3.7	3.4	3.3	3.1	12.4	10.6	9.0	7.8	6.9	6.4	5.9	5.5	5.3	5.1
Germany-2007 [c]	8.6	7.4	6.2	5.4	4.8	4.5	4.2	4.0	3.8	3.7	13.8	11.8	9.9	8.7	7.9	7.3	6.9	6.4	6.2	5.9
Germany-2006 [c]	8.4	6.9	5.9	5.2	4.6	4.3	4.1	3.9	3.8	3.7	12.9	10.9	9.3	8.1	7.4	6.9	6.6	6.2	6.0	5.8
Greece				4.5	4.2	3.9								6.9	6.4	6.0				
Italy	6.7	6.4	6.0	5.7	5.3	5.1	4.7	4.5	4.2	4.0	10.0	9.4	8.8	8.3	7.8	7.3	6.8	6.4	6.1	5.7
Netherlands		4.0	3.7	3.4	3.1	2.9						6.5	6.1	5.6	5.2	4.8				
Spain-enKid [c]	7.5	7.0	6.4	5.9	5.5	5.1	4.7	4.3	4.0	3.7	12.0	11.0	10.0	9.2	8.5	7.7	7.1	6.5	5.9	5.4
Spain-Basque				4.7	4.4	4.1	3.8	3.5	3.3	3.0				7.5	6.9	6.4	5.9	5.5	5.1	4.7
Sweden [b]			4.5	4.4	4.0	3.5	3.2	3.0	2.9	2.3			7.3	7.1	6.5	5.7	5.2	5.0	4.6	3.7

[a] Consumption data of Finland-DIPP included the ages of 1, 3 and 6 years. The exposures reported for the other ages (2, 4 and 5 years) were estimated by interpolation.

[b] Consumption data of Sweden included the ages of 3, 4 and 7-10 years. The exposures reported for the other ages (5 and 6 years) were estimated by interpolation.

[c] Daily exposure distributions for both the LB and UB concentration scenarios were not transformed to normality in a satisfactory way. Exposure results may therefore be not correct.

[d] Following two scenarios of assigning selenium concentrations to non-detect samples (LB: lower bound; UB: upper bound). Exposures were calculated using the statistical beta-binomial-normal (BBN) model

Table 4. Contribution of the different food groups[a] to the long-term exposure to selenium in children within the age range of 1 to 10 years living in different European countries[d].

Country / age range (years)	Top 3[b] food groups contributing most to the dietary exposure to selenium per scenario					
	Lower bound scenario			Upper bound scenario		
	1	2	3	1	2	3
Belgium 2-6	Cereals 19%	Vegetables 16%	Fresh meat 14%	Cereals 16%	Fresh meat 16%	Miscellaneous 12%
Czech Republic 4-10	Cereals 20%	Fresh meat 15%	Vegetables 14%	Cereals 19%	Fresh meat 19%	Vegetables 11%
Denmark [c] 4-10	Cereals 19%	Vegetables 16%	Fresh meat 12%	Cereals 18%	Fresh meat 16%	Vegetables 12%
Finland-DIPP [c] 1-6	Vegetables 23%	Fresh meat 14%	Milk & dairy drinks 12%	Vegetables 16%	Fresh meat 16%	Milk & dairy drinks 12%
Finland-STRIP 7-8	Cereals 26%	Vegetables 11%	Milk & dairy drinks 10%	Cereals 24%	Milk & dairy drinks 12%	Fresh meat 10%
France [c] 3-10	Cereals 19%	Fish 13%	Vegetables 11%	Cereals 18%	Fresh meat 13%	Miscellaneous 9%
Germany- 2008 [c] 1-10	Cereals 23%	Vegetables 16%	Milk & dairy drinks 8%	Cereals 21%	Vegetables 13%	Milk & dairy drinks 10%
Germany- 2007 [c] 1-10	Cereals 23%	Vegetables 16%	Milk & dairy drinks 9%	Cereals 21%	Vegetables 12%	Milk & dairy drinks 11%
Germany- 2006 [c] 1-10	Cereals 22%	Vegetables 14%	Infant formulae 11%	Cereals 22%	Vegetables 11%	Infant formulae 11%
Greece 4-6	Cereals 18%	Pulses/ legumes 12%	Vegetables 11%	Cereals 18%	Fresh meat 14%	Vegetables 9%

Country / age range (years)	Top 3[b] food groups contributing most to the dietary exposure to selenium per scenario					
	Lower bound scenario			Upper bound scenario		
	1	**2**	**3**	**1**	**2**	**3**
Italy 1-10	Cereals 19%	Fish 18%	Vegetables 12%	Cereals 20%	Fresh meat 17%	Fish 12%
Netherlands 2-6	Cereals 20%	Milk & dairy drinks 11%	Vegetables 11%	Cereals 18%	Milk & dairy drinks 12%	Fresh meat 10%
Spain-enKid [c] 1-10	Other food for special dietary use 18%	Fresh meat 12%	Cereals 11%	Fresh meat 17%	Other food for special dietary use 13%	Cereals 11%
Spain-Basque 4-10	Fresh meat 17%	Cereals 15%	Fish 13%	Fresh meat 18%	Cereals 15%	Fish 11%
Sweden 3-10	Cereals 19%	Vegetables 14%	Fish 11%	Cereals 18%	Fresh meat 11%	Vegetables 11%

[a] For a more elaborate description of (some of) the food groups see Table 1.

[b] Top 3 of food groups included for all countries the food groups that contributed more than 10% to the total long-term exposure.

[c] Daily exposure distributions were not transformed to normality in a satisfactory way. Contribution may therefore not be correct.

[d] Calculations were done for two scenarios (lower and upper bound) of assigning selenium concentrations to non-detect samples. Contributions were calculated with the statistical beta-binomial-normal (BBN) model

Table 5. Percentiles of long-term dietary exposure to selenium in children aged 11 to 14 years living in four European countries[c].

Country	Age (years) and exposure (µg/kg bw per day)							
	Mean LB concentrations				Mean UB concentrations			
	11	12	13	14	11	12	13	14
P50 of exposure								
Cyprus [a]	1.2	1.1	1.1	1.0	1.9	1.7	1.6	1.5
Czech Republic [b]	1.5	1.5	1.5	1.5	2.7	2.5	2.3	2.1
Spain-enKid [b]	1.7	1.7	1.7	1.7	2.5	2.5	2.5	2.5
Spain-Basque	1.8	1.7	1.6	1.5	2.7	2.6	2.4	2.3
Sweden	1.3	1.1	0.9		2.1	1.7	1.5	
P95 of exposure								
Cyprus	1.9	1.8	1.6	1.5	2.9	2.7	2.5	2.3
Czech Republic	2.6	2.6	2.6	2.6	4.5	4.1	3.8	3.5
Spain-enKid	2.7	2.7	2.7	2.7	4.1	4.1	4.0	4.1
Spain-Basque	2.6	2.4	2.3	2.2	3.8	3.6	3.5	3.3
Sweden	2.2	1.8	1.5		3.5	3.0	2.5	
P99 of exposure								
Cyprus	2.3	2.1	2.0	1.8	3.5	3.2	3.0	2.8
Czech Republic	3.3	3.3	3.3	3.3	5.6	5.1	4.7	4.3
Spain-enKid	3.3	3.3	3.3	3.3	5.0	5.0	5.0	5.0
Spain-Basque	3.0	2.9	2.7	2.6	4.4	4.2	4.1	3.8
Sweden	2.7	2.2	1.9		4.4	3.7	3.1	

[a] Daily exposure distribution for the UB concentration scenario was not transformed to normality in a satisfactory way. Exposure result may therefore not be correct.

[b] Daily exposure distributions for both the LB and UB concentration scenario were not transformed to normality in a satisfactory way. Exposure results may therefore be not correct.

[c] Following two scenarios of assigning selenium concentrations to non-detect samples (LB: lower bound; UB: upper bound). Exposures were calculated with the statistical beta-binomial-normal (BBN) model

Table 6. Contribution of the different food groups[a] to the long-term exposure to selenium in children in the age of 11 to 14 years living in different European countries for two scenarios[e].

Country	Top 3[b] food groups contributing most to the dietary exposure to selenium					
	Lower bound scenario			Upper bound scenario		
	1	2	3	1	2	3
Cyprus [c]	Cereals 19%	Fresh meat 15%	Vegetables. 15%	Fresh meat 21%	Cereals 19%	Vegetables 13%
Czech Republic [d]	Cereals 21%	Vegetables 26%	Fresh meat 15%	Cereals 20%	Fresh meat 20%	Vegetables 13%
Spain-enKid [d]	Other food for special dietary use 22%	Cereals 13%	Fresh meat 12%	Fresh meat 18%	Other food for special dietary use 16%	Cereals 14%
Spain-Basque	Fresh meat 16%	Cereals 15%	Fish 14%	Fresh meat 19%	Cereals 15%	Fish 10%
Sweden	Cereals 20%	Vegetables 15%	Fish 11%	Cereals 19%	Fresh meat 13%	Vegetables 11%

[a] For a more elaborate description of (some of) the food groups see Table 1.
[b] Top 3 of food groups included for all countries the food groups that contributed more than 10% to the total long-term exposure
[c] Daily exposure distribution for the UB concentration scenario was not transformed to normality in a satisfactory way. Contribution may therefore not be correct.
[d] Daily exposure distribution for the LB and UB concentration scenario was not transformed to normality in a satisfactory way. Contribution may therefore not be correct.
[e] Lower and upper bound of assigning selenium concentrations to non-detect samples. Contributions were calculated with the statistical beta-binomial-normal (BBN) model

3.1.3. Transformation to normality

As explained in section 2.3.1., transformation of the daily exposure distribution into a normal distribution is an important prerequisite to be able to use the BBN model to assess the long-term exposure using food consumption data collected during a limited number of days. Based on the q-q plot (i.e. a graphical method to compare two probability distributions by plotting their quantiles against each other) the transformed data for the 1- to 10-years old could be considered reasonably normal for the databases of Belgium, Czech Republic, Finland (STRIP-study), Greece, Italy, Netherlands, Spain (Basque study) and Sweden. For these countries we expect the BBN model to give an adequate exposure assessment. For the other databases, including Denmark, Finland (DIPP-study), France, Germany (all three years of the study) and Spain (enKid-study), the assumption of normality was however not met in both concentration scenarios. Based on the q-q plot the transformed data for the 11- to 14-years old could be considered reasonably normal for the databases of Sweden, Spain (Basque-study) and Cyprus (for the LB scenario). For these countries we expect the BBN model to give an adequate exposure assessment. For the other databases, including Czech Republic, Spain (enKid-study) and Cyprus (for the UB scenario) the assumption of normality was however not met in both concentration scenarios. The deviations indicated that the estimated long-term exposure was most likely underestimated. However, to which extent is unclear.

3.1.4. Risk characterisation

To assess whether there may be a possible health risk related to the exposure to selenium in children, the P99 of exposure was initially compared to the UL of 5 µg/kg bw per day and if exceeded the actual proportion of children exceeding the UL was estimated. In Table 7, the percentage of children aged 1 to 10 years exceeding the UL is given. The percentages higher than 1% varied from 1.1% for 6-year olds in Spain (enKid-study) and Italy to 22% for 1-year olds in Spain (enKid-study). In the UB concentration scenario, the P99 of exposure for children aged 1 to 10 years old exceeded the UL in the majority of countries (although not at all ages) (Table 7). Percentages of children with a level of exposure exceeding the UL in this concentration scenario ranged from 1.1% in 10-year olds from Germany (2008 study) to 84% in 1-year olds from Spain (enKid-study).

The P99 of exposure of children in the age group of 11 to 14 years did not exceed the UL for any country studied in the LB concentration scenario (Table 8). In the UB concentration scenario, the P99 of exposure for children aged 11 to 14 years old exceeded the UL in Czech Republic and Spain (enKid-study) (Table 8).

Table 7. Percentages of children aged 1 to 10 years living in different European countries with an exposure exceeding the upper level (UL) of 5 µg/kg bw per day[e].

	Age (years) and percentage of children exceeding the UL (%)																			
	Mean LB concentrations										Mean UB concentrations									
Country	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Belgium		1.5	-[a]	-	-	-						59	42	26	14	6.6				
Czech Republic				-	-	-	-	-	-	-				20	13	8.1	4.7	2.4	1.2	-
Denmark [b]				-	-	-	-	-	-	-				18	14	10	6.1	2.8	-	-
Finland-DIPP[b,c]	12	9.6	5.4	5.0	3.7	2.8					52	47	42	33	31	27				
Finland-STRIP							-	-									-	-		
France [b]			1.5	-	-	-	-	-	-	-			31	23	16	11	7	4.2	2.5	1.3
Germany-2008 [b]	11	5.2	2.1	-	-	-	-	-	-	-	8	32	20	11	6.5	4.2	2.8	1.9	1.7	1.1
Germany-2007 [b]	13	6.8	3.1	1.5	-	-	-	-	-	-	49	34	22	14	9.6	6.9	5.2	4.1	3.3	2.0
Germany-2006 [b]	11	5.4	2.5	1.2	-	-	-	-	-	-	45	30	18	11	7.7	5.5	4.3	3.3	2.7	2.3
Greece				-	-	-								13	7.8	4.5				
Italy	9.6	6.6	4.4	2.9	1.8	1.1	-	-	-	-	54	45	36	29	21	15	11	7.2	4.8	2.9
Netherlands		-	-	-	-	-						16	8.7	4.1	1.7	-				
Spain-enKid [b]	22	14	8.2	4.5	2.3	1.1	-	-	-	-	84	74	62	49	36	25	16	9.0	4.7	2.3
Spain-Basque				-	-	-	-	-	-	-				41	26	14	7.1	3.1	1.2	-
Sweden [d]			-	-	-	-	-	-	-	-			23	19	11	4.0	1.4	-	-	-

[a] To assess whether there is a possible health risk related to the long-term exposure to selenium in children, the P99 levels of exposure (as reported in Table 3) were compared with the UL of selenium (5 µg/kg bw per day). When the P99 of exposure exceeded the UL of selenium, the exact percentage of children exceeding this limit value was reported. Notation '-' means that the percentage of children exceeding this value was 1% or less.

[b] Daily exposure distributions for both the LB and UB concentration scenario were not transformed to normality in a satisfactory way. Exposures may therefore not be correct.

[c] Consumption data of Finland-DIPP included the ages of 1, 3 and 6 years. The exposures reported for the other ages (2, 4 and 5 years) were estimated by interpolation.

[d] Consumption data of Sweden included the ages of 3, 4 and 7-10 years. The exposures reported for the other ages (5 and 6 years) were estimated by interpolation.

[e] Following two scenarios of assigning selenium concentrations to non-detect samples (LB: lower bound; UB: upper bound). Exposures were calculated using the statistical beta-binomial-normal (BBN) model.

Table 8. Percentages of children aged 11 to 14 years living in different European countries with an exposure exceeding the upper level (UL) of 5 µg/kg bw per day[d].

	Age (years) and percentage of children exceeding the UL (%)							
	Mean LB concentrations				Mean UB concentrations			
Country	11	12	13	14	11	12	13	14
Cyprus [c]	-[a]	-	-	-	-	-	-	-
Czech Republic [b]	-	-	-	-	2.3	1.2	-	-
Spain-enKid [b]	-	-	-	-	-	1.0	1.0	-
Spain-Basque	-	-	-	-	-	-	-	-
Sweden	-	-	-		-	-	-	

[a] To assess whether there is a possible health risk related to the long-term exposure to selenium in children, the P99 levels of exposure (as reported in Table 3) were compared with the UL of selenium (5 µg/kg bw per day). When the P99 of exposure exceeded the UL of selenium, the exact percentage of children exceeding this limit value was reported. Notation '-' means that the percentage of children exceeding this value was 1% or less.

[b] Daily exposure distributions for both the LB and UB concentration scenario were not transformed to normality in a satisfactory way. Exposures may therefore not be correct.

[c] Daily exposure distributions for both the UB concentration scenario were not transformed to normality in a satisfactory way. Exposures may therefore not be correct

[d] Following two scenarios of assigning selenium concentrations to non-detect samples (LB: lower bound; UB: upper bound). Exposures were calculated using the statistical beta-binomial-normal (BBN) model.

3.2. Long-term dietary exposure to selenium using the OIM approach

3.2.1. Long-term exposure for age groups 1 to 2, 3 to 10 and 11 to 14 years

In Table 9, the estimated long-term dietary exposure to selenium in children covering the age ranges of 1 to 2, 3 to 10 and 11 to 14 years in the different countries is listed for the LB and UB concentration scenarios. This exposure was calculated using the OIM approach. As in the BBN approach, the exposure to selenium was highest in the youngest age group and decreased with age. In the LB concentration scenario, the P99 of exposure for 1- to 2-year olds ranged from 5.7 µg/kg bw per day in Italy and Netherlands to 16.9 µg/kg bw per day in Germany (2007 study). For 3- to 10-year olds, corresponding exposure levels were 3.5 µg/kg bw per day in Finland (STRIP study) and 14.0 µg/kg bw per day in Spain (enKid study), and for 11- to 14-year olds 2.3 µg/kg bw per day in Cyprus and 7.9 µg/kg bw per day in Spain (enKid study). In the UB concentration scenario, the P99 of exposure for 1- to 2-year olds ranged from 8.4 µg/kg bw per day in Netherlands to 27.7 µg/kg bw per day in Germany (2007 study). For 3- to 10-year olds, corresponding exposure levels were 5.3 µg/kg bw per day in Finland (STRIP study) and 16.5 µg/kg bw per day in Spain (enKid study), and for 11- to 14-year olds 3.3 µg/kg bw per day in Cyprus and 9.4 µg/kg bw per day in Spain (enKid study) (Table 9).

Table 10 lists for each country the three food groups contributing most to the long-term exposure distribution of selenium for the three age groups and the LB concentration scenario. As with the BBN model, the food groups contributing most to the exposure were ‘cereals’, ‘vegetables’, ‘fresh meat’ and ‘milk and dairy drinks’. Other important food groups were ‘infant formulae’ and ‘fish’. For the UB concentration scenario, the same food groups appeared to contribute largely to the exposure as in the LB concentration scenario (Table 10). However, also the food group ‘miscellaneous’ emerged as an important contributor to the exposure. This food group was absent as an important source of exposure in the LB concentration scenario.

3.2.2. Risk characterisation

It is clear from Table 9 that in the LB concentration scenario the P99 of exposure for 1- to 2-year olds exceeded the UL in all countries having data for this age group, with the highest percentage in Germany and the lowest in Netherlands. Of the 3- to 10-year olds, only in Belgium, Finland (DIPP study), Germany (all three years of the study), Italy and Spain (enKid study) did the P99 exposure level exceed the UL, while of the 11- to 14-year olds only Spain (enKid study) had a P99 exposure that exceeded this value. In the UB concentration scenario, the P99 exposure of the majority of countries with consumption data of 1- to 2-year and 3- to 10-year olds exceeded the UL. Of the 11- to 14-year olds, only Czech Republic exceeded the UL at the P99 of exposure. In Table 12, we listed the percentage of children that exceeded the UL for those countries and age groups where the P99 of exposure was exceeded.

Table 9. Percentiles of long-term dietary exposure to selenium in children in the age classes 1 to 2, 3 to 10 and 11 to 14 years living in different European countries[a].

Country and concentration scenario	Age range (years) and exposure (µg/kg bw per day)								
	P50			P95			P99		
	1-2	3-10	11-14	1-2	3-10	11-14	1-2	3-10	11-14
Lower bound scenario									
Belgium	2.9	2.4		6.0	3.8		7.2	5.6	
Cyprus			1.1			1.8			2.3
Czech Republic		1.9	1.5		3.7	2.6		4.5	3.2
Denmark		2.0			3.3			4.1	
Finland-DIPP	2.9	2.4		6.8	4.8		9.3	9.3	
Finland-STRIP		1.8			2.9			3.5	
France		2.0			3.4			4.1	
Germany-2008	2.1	1.6		9.3	2.7		10.9	5.3	
Germany-2007	2.1	1.6		9.7	3.2		16.9	6.9	
Germany-2006	2.1	1.5		9.4	2.7		12.6	7.1	
Greece		2.2			3.8			4.7	
Italy	3.4	2.4		5.0	4.5		5.7	5.6	
Netherlands	2.3	1.9		4.2	3.2		5.7	4.3	
Spain-Basque		2.3	1.6		4.0	2.6		4.7	3.6
Spain-enKid	3.2	2.5	1.5	7.3	4.8	2.8	9.6	14.0	7.9
Sweden		1.9	1.2		3.4	2.1		4.3	2.7
Upper bound scenario									
Belgium	5.2	4.2		9.4	6.6		12.4	8.2	
Cyprus			1.6			2.8			3.3
Czech Republic		3.1	2.3		5.8	4.2		7.0	5.0
Denmark		3.3			5.2			6.5	
Finland-DIPP	5.0	4.1		11.3	7.8		15.9	16.3	
Finland-STRIP		3.1			4.5			5.3	
France		3.2			5.5			6.8	
Germany-2008	3.7	2.7		14.3	4.1		17.1	8.9	
Germany-2007	3.3	2.8		15.6	4.7		27.7	10.9	
Germany-2006	3.6	2.6		15.5	4.2		18.3	12.1	
Greece		3.4			5.4			6.7	
Italy	5.1	3.6		7.5	6.4		8.5	7.4	
Netherlands	3.9	3.4		6.8	5.4		8.4	7.0	
Spain-Basque		3.6	2.5		5.8	3.9		6.6	4.9
Spain-enKid	5.7	3.9	2.3	9.3	6.9	4.0	12.0	16.5	9.4
Sweden	-	3.2	2.0	-	5.3	3.4	-	6.6	3.9

[a] Following two scenarios of assigning selenium concentrations to non-detect samples (lower and upper bound). Exposures were calculated using the deterministic observed individual means (OIM) approach.

Table 10. Contribution of the different food groups[a] to the long-term exposure to selenium for the lower bound concentration scenario of assigning selenium concentrations to non-detect samples[c].

Country	Top 3[b] food groups contributing most to the dietary exposure to selenium per age class								
	1-2 years			3-10 years			11-14 years		
	1	2	3	1	2	3	1	2	3
Belgium	Cereals 17%	Vegetables 15%	Fresh meat 13%	Cereals 19%	Vegetables 16%	Fresh meat 14%			
Cyprus							Cereals 19%	Fresh meat 15%	Vegetables 15%
Czech Republic				Cereals 19%	Fresh meat 19%	Vegetables 11%	Cereals 21%	Vegetables 16%	Fresh meat 15%
Denmark				Cereals 19%	Vegetables 16%	Fresh meat 12%			
Finland-DIPP	Vegetables 29%	Fresh meat 16%	Milk & dairy drinks 11%	Vegetables 20%	Fresh meat 13%	Milk & dairy drinks 13%			
Finland-STRIP				Cereals 26%	Vegetables 11%	Milk & dairy drinks 10%			
France				Cereals 19%	Fish 13%	Vegetables 11%			
Germany-2008	Cereals 19%	Infant formulae 19%	Vegetables 17%	Cereals 26%	Vegetables 15%	Chocolate & chocolate products 10%			
Germany-2007	Cereals 20%	Vegetables 17%	Infant formulae 16%	Cereals 25%	Vegetables 15%	Chocolate & chocolate products 11%			
Germany-2006	Infant formulae 22%	Cereals 18%	Vegetables 14%	Cereals 25%	Vegetables 14%	Chocolate & chocolate products 11%			
Greece				Cereals 18%	Pulses/legumes 12%	Vegetables 11%			

Country	Top 3[b] food groups contributing most to the dietary exposure to selenium per age class								
	1-2 years			3-10 years			11-14 years		
	1	2	3	1	2	3	1	2	3
Italy	Fish 26%	Cereals 18%	Vegetables 9%	Cereals 19%	Fish 16%	Fresh meat 13%			
Netherlands	Cereals 19%	Milk & dairy drinks 12%	Vegetables 12%	Cereals 20%	Milk & dairy drinks 11%	Vegetables 10%			
Spain-Basque				Fish 17%	Cereals 15%	Fresh meat 13%	Fish 16%	Cereals 15%	Fresh meat 14%
Spain-enKid	Fish 15%	Fresh meat 13%	Eggs 10%	Other food for special dietary use 20%	Fresh meat 11%	Cereals 11%	Other food for special dietary use 22%	Cereals 13%	Fresh meat 12%
Sweden				Cereals 19%	Vegetables 14%	Fish 11%	Cereals 20%	Vegetables 15%	Fish 11%

[a] For a more elaborate description of (some of) the food groups see Table 1.

[b] Top 3 of food groups included for all countries the food groups that contributed more than 10% to the total long-term exposure.

[c] Contributions were calculated for three different age groups using the observed individual means (OIM) approach.

Table 11. Contribution of the different food groups[a] to the long-term exposure to selenium for the upper bound concentration scenario of assigning selenium concentrations to non-detect samples[c].

Country	Top 3[b] food groups contributing most to the dietary exposure to selenium per age class								
	1-2 years			3-10 years			11-14 years		
	1	2	3	1	2	3	1	2	3
Belgium	Fresh meat 16%	Cereals 15%	Miscellaneous 13%	Cereals 16%	Fresh meat 16%	Miscellaneous 12%			
Cyprus							Fresh meat 21%	Cereals 19%	Vegetables 13%
Czech Republic				Cereals 20%	Fresh meat 15%	Vegetables 14%	Cereals 20%	Fresh meat 20%	Vegetables 13%
Denmark				Cereals 18%	Fresh meat 16%	Vegetables 12%			
Finland-DIPP	Vegetables 22%	Fresh meat 20%	Milk & dairy drinks 13%	Fresh meat 16%	Vegetables 15%	Milk & dairy drinks 14%			
Finland-STRIP				Cereals 24%	Milk & dairy Drinks 12%	Fresh meat 10%			
France				Cereals 18%	Fresh meat 13%	Miscellaneous 10%			
Germany-2008	Infant formulae 19%	Cereals 18%	Vegetables 13%	Cereals 24%	Vegetables 12%	Chocolate & chocolate products 9%			
Germany-2007	Cereals 19%	Infant formulae 16%	Milk & dairy drinks 13%	Cereals 23%	Vegetables 12%	Chocolate & chocolate products 10%			
Germany-2006	Infant formulae 22%	Cereals 16%	Vegetables 11%	Cereals 22%	Vegetables 11%	Chocolate & chocolate products 9%			

Country	Top 3[b] food groups contributing most to the dietary exposure to selenium per age class								
	1-2 years			3-10 years			11-14 years		
	1	2	3	1	2	3	1	2	3
Greece				Cereals 18%	Fresh meat 14%	Vegetables 9%			
Italy	Cereals 18%	Fish 17%	Fresh meat 12%	Cereals 20%	Fresh meat 19%	Vegetables 11%			
Netherlands	Cereals 17%	Milk & dairy drinks 13%	Fresh meat 10%	Cereals 18%	Milk & dairy drinks 12%	Fresh meat 10%			
Spain-Basque				Fresh meat 18%	Cereals 15%	Fish 11%	Fresh meat 19%	Cereals 15%	Fish 10%
Spain-enKid	Fresh meat 17%	Milk and dairy drinks 10%	Fish 9%	Fresh meat 17%	Other food for special dietary 14%	Cereals 12%	Fresh meat 18%	Other food for special dietary 16%	Cereals 14%
Sweden				Cereals 18%	Fresh meat 11%	Vegetables 11%	Cereals 19%	Fresh meat 13%	Vegetables 11%

[a] For a more elaborate description of (some of) the food groups see Table 1.

[b] Top 3 of food groups included for all countries the food groups that contributed more than 10% to the total long-term exposure.

[c] Contributions were calculated for three different age groups using the observed individual means (OIM) approach.

Table 12. Percentage of children in the age classes 1-2, 3-10 and 11-14 years living in different European countries that exceeded the upper level (UL) of 5 µg/kg bw per day[b].

Country and concentration scenario	Age range (years) and percentage		
	1-2	3-10	11-14
Lower bound concentration scenario			
Belgium	8.3	- [a]	
Cyprus			-
Czech Republic		-	-
Denmark		-	
Finland-DIPP	12	4.3	
Finland-STRIP		-	
France		-	
Germany-2008	28	1.4	
Germany-2007	22	3.1	
Germany-2006	23	2.4	
Greece		-	
Italy	5.6	2.8	
Netherlands	1.9	-	
Spain-Basque		-	-
Spain-enKid	18	5.1	1.1
Sweden		-	-
Upper bound concentration scenario			
Belgium	64	27	
Cyprus			-
Czech Republic		11	1.7
Denmark		7.2	
Finland-DIPP	49	26	
Finland-STRIP		1.6	
France		9.1	
Germany-2008	30	2.2	
Germany-2007	27	4.4	
Germany-2006	26	3.8	
Greece		-	
Italy	56	15	
Netherlands	22	8.3	
Spain-Basque		15	-
Spain-enKid	65	21	1.6
Sweden		8.0	

[a] To assess whether there is a possible health risk related to the long-term exposure to selenium in children, the P99 levels of exposure (as reported in Table 3) were compared with the UL of selenium (5 µg/kg bw per day). When the P99 of exposure exceeded the UL of selenium, the exact percentage of children exceeding this limit value was reported. '-' means that the percentage of children exceeding this value was 1% or less.

[b] Following two scenarios of assigning selenium concentrations to non-detect samples. Exposures were calculated using the observed individual means (OIM) approach.

4. Discussion

In this document, we report on the long-term dietary exposure to selenium in children aged 1 to 14 years living in 12 different European countries. For this we used national/regional individual food consumption data collected among children during at least two days using either the 24-h recall method or the dietary record method. We addressed children because they are known to have a higher exposure level than adults given their higher consumption levels per kg body weight. Furthermore there are few data published in children. Selenium concentrations were obtained from EFSA, and were used by all countries to assess the exposure.

In a recent report on the exposure to lead (Boon et al., 2009), different methodological issues related to an exposure study addressing different national food consumption databases and one "European" chemical concentration database were addressed in relation to lead. Since this discussion is also applicable to the study described in that report, we refer for some methodological topics (methodology used to assess the long term exposure and uncertainties) to this report and only highlight here the most important aspects to consider in the framework of the results presented in this report.

In this project, 14 different food consumption databases were used. These databases were collected using different dietary assessment methods, and cover different age ranges. An important difference is the way in which the dietary information was aggregated into food groups. Due to these differences it is difficult to compare the food consumption data, and consequently the resulting exposure levels between countries.

To link the consumption data with the selenium concentration data, 42 communal food groups were used. These food groups were very diverse, for example the food group 'vegetables' contained all types of raw and processed vegetables, including potatoes. Assigning one mean selenium level to all foods belonging to a food group very likely affected the exposure. Linking food consumption and concentration data is a very crucial step in dietary exposure assessments

4.1. Selenium concentration data

To assess exposure, a critical examination of the concentration data is needed. The selenium concentration data used in this report to estimate the dietary exposure were supplied by EFSA (who received the selenium concentration data from eight different Member States). Important to mention is that about 90% of all submitted data originated from Germany, followed by 4% from Ireland and 1% from Italy. This illustrates that the concentration data used for this exposure assessment do not cover in an equal way all European countries. However, no information is currently available about the difference in selenium concentration in food items in different European countries. Therefore, it is hard to assess how representative these data are for evaluating the selenium intake in 14 different European countries.

Moreover, it is hard to judge the reliability of the exposure assessments described in this report since no detailed information about the collection of concentration data was available, for example about the following topics:

- Are the concentration data resulting from targeted versus non-targeted sampling?

- How well do the analysed commodities cover those expected to contain selenium?
- How well does the grouping of the analysed commodities in the different food groups match the grouping of the food consumption data?
- What is the effect of differences in LODs/LOQs/LOR between laboratories and countries on the exposure results?

Due to the uncertainties related to the selenium concentration data used, the exposure results presented in this report should be interpreted with caution and do not necessarily represent the intake of selenium at the respective national level.

4.2. Exposure to selenium

Exposure to selenium was calculated using national/regional food consumption databases and one ‘European’ selenium concentration database. Because of this, differences in exposure between countries were due to differences in consumption data, including real national differences in consumption patterns, but also partly due to methodological differences, differences in age ranges covered in these studies, and differences in detail in which the food consumption data was collected. This last difference affected the categorisation of foods consumed in the different food categories and thus the resulting exposure levels. Due to all of this, it is difficult to compare the exposures between countries. Moreover, it is known that the amount of selenium available in the soil for plant growth and resulting variations in concentrations present in plants varies considerably among regions and countries. This variation is not reflected in the exposure results presented in this report, since one ‘European’ selenium concentration database was used.

Generally however we can conclude from the results that the exposure to selenium was highest in the youngest children and decreased with age. Countries with the highest exposure levels were Germany and Finland. Furthermore, the main sources of exposure were, for almost all countries, the food groups ‘cereals’, ‘vegetables’, ‘fresh meat’ and ‘milk and dairy drinks’. This was not due to high levels of selenium present in these food groups, but due to high levels of consumption of these food groups by children living in Europe.

In the Spain enKid study the food group ‘foods special dietary uses’ was an important source of exposure, due to a high level of selenium assigned to this food group (Table 1) and a high level of consumption (115 g per day). In the total survey, however, only two children up to the age of 10 consumed foods belonging to this food group. Their selenium intake levels were much higher than those of children not consuming foods belonging to this food group.

In this assessment, we did not include the intake of selenium via food supplements. Selenium is a widely used supplement, and therefore the intake may have been underestimated. In a number of databases the intake of food supplements was included, such as in the Italian database. To estimate the effect of not including food supplements in the assessment, we calculated the exposure to selenium for 1 to 10 year-olds living in Italy using a mean selenium concentration level of 32.3 and 32.4 mg/kg, as supplied by EFSA for the LB and UB concentration scenarios, respectively. The mean consumption of food supplements in this age group was 0.30 g per day, and consumption of food supplements occurred on 4.4% (= 33 days) of all possible consumption days (= 756 days). The P99 of long-term exposure to selenium increased, on average, by 36% (range of 51% in 1 year-olds to 23% in 10 year-olds) in the LB concentration scenario and 25% (range of 35% in 1 year-olds to 15% in 10 year-olds) in the UB concentration scenario. How large this underestimation will be depends, among others, on whether the food supplements ingested contain selenium. In this example, we assumed that all supplements contained selenium, but in reality this may not be the case, especially because food supplements including selenium in their formulation are mostly distributed to adults and elderly people. Furthermore, inclusion of children consuming food supplements in the exposure calculations resulted in the introduction of relatively high intake levels (so-called outliers) in the exposure distribution. Due to this, the distribution became skewed, making the use of the BBN approach to assess the long-term exposure no longer feasible.

The SCF report on selenium indicates mean selenium intakes of non-vegetarian adults in different European countries (data published in the nineties) ranging from 24 to 110 µg/day (SCF, 2000). Assuming a mean body weight of 60 kg for an adult, this is equal to 0.4 to 1.8 µg/kg bw per day. The P50 of exposure that we found in this study ranged from 1.2 (10-years old children) to 4.1 µg/kg bw per day (1-year old children) in the LB concentration scenario and from 2.0 (10-years old children) to 6.5 (1-year old children) in the UB concentration scenario. A recent EFSA opinion reports data on selenium intake in 2- to 17-years old children: an average intake ranging from 23 to 42 µg/day, with a high intake (P95 or P97.5) of 32 to 77 µg/day (EFSA, 2009). Unfortunately, it is difficult to compare the data of the SCF and EFSA report with the results obtained in this exposure assessment study, since they are focusing on other age groups and not expressed per kg bw.

4.3. Dietary exposure assessment

We used two approaches to calculate the long-term exposure to selenium: the observed individual mean (OIM) and the beta-binomial normal (BBN) approach. For a discussion on these approaches see section 4.4 of the lead report (Boon et al., 2009). As for lead, BBN is the preferred method to estimate the long-term exposure to selenium. This model separates the within-person variation from the between-person variation to estimate the exposure. This approach has been proven very useful for the estimation of long-term exposure (Dodd et al., 2006; Hoffmann et al., 2002). Another advantage of the BBN model is that it can model covariates, such as age. This is important when assessing the exposure in children, because it is known that the exposure decreases with age. However, we showed that for some countries BBN could not be used in a satisfactory way, due to lack of normality of the transformed exposure data. In those cases, the exposure results may be wrong. We therefore also used the 'OIM' approach. In this approach, the within-person variation is not dealt with, resulting in more conservative estimates of exposure in the right tail of the exposure distribution compared to models that do, such as BBN.

4.4. Conclusion and recommendations for future analysis

In this study, we calculated the long-term dietary exposure to selenium in children for different European countries and regions using the same selenium concentration data and the same models to assess the exposure. To establish this, the foods recorded in the different surveys were categorised in a harmonised way, so that the consumption data could be linked to the selenium concentration levels. The results showed that the selenium exposure differed between the participating countries as well as between the different age groups, with very likely higher selenium exposures in younger children (exceeding the UL).

Due to the uncertainties related to the selenium exposure assessment presented here, as well as the exclusion of the selenium exposure via food supplements, the exposure results presented here should be interpreted with caution and do not necessarily represent the selenium intake at the national level.

Based on the work performed so far and the restrictions and uncertainties encountered, we recommend refining the risk assessment of the dietary exposure to selenium in young children in European countries by:

- Gaining insight into the grouping of the analysed commodities in the different food groups, and to improve consequently the linkage between food consumed and those analysed;
- Gaining insight in the representativity of the selenium concentration data used in the assessment for Europe, since the data used originated to 90% from only one Member State, i.e. Germany;
- Developing a long-term model, such as the BBN model, that can deal with non-normally distributed transformed exposure data, including cofactor and covariable analysis.

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APPENDIX A

This appendix shows the settings for the software Monte Carlo Risk Assessment as they were applied for calculating the dietary intake of selenium as described in this report. This information is valuable when one would like to do similar analyses.

BBN model

EXPOSURE SECTION
Chronic risk assessment
Beta-binomial-normal model (BBN)

Intake frequency model is based on beta-binomial model

No effect of cofactor included
No effect of covariable included

Model for **intake amounts** is based on Maximum Likelihood

No effect of cofactor included	
Include effect of covariable	age
Transformation	Logarithmic
Function of covariable	spline
Minimum degrees of freedom	0
Maximum degrees of freedom	4
DF selection	backward
Testing at level	0.01

OIM model

EXPOSURE SECTION
Chronic risk assessment
Observed individual means (OIM)

Glossary / Abbreviations

BBN	Beta-binominal-normal
bw	Body weight
EFSA	European Food Safety Authority
LB	Lower bound
LOD	Limit of detection
LOQ	Limit of quantification
LOR	Limit of reporting
MCRA	Monte Carlo Risk Assessment
OIM	Observed individual means
Q-q plot	Quantile-quantile plot
SCF	Scientific Committee on Food
UB	Upper bound