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Dietary exposure assessment to perchlorate in the European population

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Abstract

EFSA performed a human exposure assessment for perchlorate taking into account occurrence data in the EFSA database from samples taken after 1 September 2013. A data set of 18,217 analytical results provided by governmental organisations of 16 European countries was available. Some data were also provided by food business operators. Several food groups were represented in the data set. Relatively high mean middle bound occurrence values were found in dried products, like 'Tea and herbs for infusion' (324 μg/kg) and 'Herbs, spices and condiments' (63 μg/kg), and in some fresh vegetables, like 'Radishes' (117 μg/kg), 'Rocket salad, rucola' (75 μg/kg) and 'Spinach (fresh)' (132 μg/kg). The mean and P95 of exposure to perchlorate across dietary surveys were estimated using chronic and short-term scenarios across different population groups. In the chronic scenario, infants, toddlers and other children showed exposure in the range (minimum lower bound (LB)–maximum upper bound (UB)) 0.04–0.61 μg/kg body weight (bw) per day, while in the older population groups, the range was 0.04–0.19 μg/kg bw per day; similarly, in the young population groups, the P95 of chronic exposure range was 0.09–1.0 μg/kg bw per day, while in the older population groups, it was 0.07–0.34 μg/kg bw per day. 'Vegetable and vegetable products', 'Milk and dairy products' and 'Fruit and fruit products' were found to be important contributors to the exposure across all population groups. Other food groups were relevant for specific population groups. The mean short-term exposure of infants, toddlers and other children was in the range of 0.40–2.3 μg/kg bw per day, while in the older population groups, the range was 0.26–1.3 μg/kg bw per day; similarly, in the young population groups, the P95 short-term exposure range was 0.94–6.5 μg/kg bw per day, while in the older population groups, the range was 0.67–3.6 μg/kg bw per day.

Keywords: perchlorate, occurrence, exposure

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Summary

The risk to public health related to the presence of perchlorate as a contaminant of food, in particular fruits and vegetables, was the subject of EFSA scientific opinion of the CONTAM delivered in 2014. In 2015, the European Commission issued a Recommendation on the monitoring of the presence of perchlorate in food, in particular from food sampled after 1 September 2013, when mitigation measures were put in place.

In accordance with Article 31 (1) of Regulation (EC) No 178/2002, in 2016, the European Commission has asked the European Food Safety Authority (EFSA) for an updated human exposure assessment to perchlorate taking into account the occurrence data available in the EFSA database from samples taken after 1 September 2013 (Mandate number M-2016–0181).

Following this mandate, EFSA extracted from the database of analytical results on chemical contaminants the data complying with the requested criteria: data on perchlorate in food in Europe with sampling date after 1 September 2013. Analytical results with limit of quantification (LOQ) > 50 μg/kg were excluded from the data set because of the low sensitivity of the method.

The data were checked for potential errors or inconsistencies and cleaned. A final data set of 18,217 analytical results was used for the analysis of occurrence and the estimation of human dietary exposure. The few suspect samples present in the data set (N = 179) were used only for estimating the short-term exposure. The analytical results were provided by 16 European countries, but more than 80% of the data were provided by only two countries (68% from one country alone). Most of the data (93.7%) were provided by governmental organisations while 6.3% were from food business organisations.

Almost 77% of the results were left-censored (LC), namely, reported as less than the limit of detection (LOD) or than the LOQ. For calculating the occurrence statistics, values were imputed for the LC data using the substitution method (EFSA, 2010b). In this approach, a comparison is done between the lower bound (LB) scenario where a value of 0 is input (assuming that the substance is absent) and the upper bound (UB) scenario where the value of the left-censoring limit is assigned (assuming that the substance is at the level of the limit). Additionally, as a point estimate between the two extremes, the middle bound (MB) scenario is calculated by assigning to the LC results a value of LOD/2 or LOQ/2.

The data were organised according to the FoodEx1 food classification at the available level of detail. FoodEx1 is a provisional food classification system developed by the EFSA's Dietary and Chemical Monitoring Unit in 2009 with the objective to link occurrence and food consumption data at a detailed level to assess exposure to hazardous substances. Several detailed food groups where a preliminary analysis revealed comparable (and not unusually high) perchlorate levels were aggregated into existing higher level FoodEx1 groups or into ad hoc food groups.

Relatively high mean MB occurrence values were found for products in dried form, like 'Tea and herbs for infusion (solids)' (324 μg/kg) and 'Herbs, spices and condiments' (63 μg/kg); among the fresh vegetables, relatively high mean MB occurrence levels were found in 'Radishes' (117 μg/kg), 'Rocket slad, rucola' (75 μg/kg) and 'Spinach (fresh)' (132 μg/kg).

The human dietary exposure to perchlorate was estimated using both chronic and short-term scenarios. For the chronic exposure, the mean occurrence value for the relevant food groups was used; for the short-term scenario, the highest reliable percentile of occurrence was used instead of the mean. Both exposure scenarios were estimated using consumption data at the individual level taken from the EFSA Comprehensive food consumption database; the calculation was done per individual and food group, based on the relevant (LB, MB and UB) occurrence levels, on the daily individual consumption and using the individual's body weight (bw). The distributions of exposure were then summarised by population group as minimum, median and maximum across dietary surveys of the average and P95 of exposure.

In the chronic exposure scenario, the young population groups (infants, toddlers and other children) showed higher exposure levels than the older groups: the range across dietary surveys of mean chronic exposure (minimum LB–maximum UB) was overall in these groups 0.04–0.61 μg/kg bw per day, while in the older population groups, the range was 0.04–0.19 μg/kg bw per day. Similarly, in the young population groups, the range of P95 of chronic dietary exposure was 0.09–1.0 μg/kg bw per day, while in the older population groups, it was 0.07–0.34 μg/kg bw per day.

'Vegetable and vegetable products', 'Milk and dairy products' and 'Fruit and fruit products' were found to be important contributors to the exposure across all population groups. Other food groups were also relevant for specific population groups, like 'Food for infants and small children' among Infants and Toddlers, 'Fruit and vegetable juices' among toddlers, other children and adolescents or 'Teas and herbal infusion (beverage)' among Adults.

Regarding the short-term exposure scenario, the range across dietary surveys of mean short-term dietary exposure (minimum LB–maximum UB) for young population groups (infants, toddlers and other children) was overall 0.40–2.3 μg/kg bw per day, while in the older population groups, the range was 0.26–1.3 μg/kg bw per day. Similarly, in the young population groups, the range of P95 of short-term dietary exposure was 0.94–6.5 μg/kg bw per day, while in the older population groups, it was 0.67–3.6 μg/kg bw per day.

Factors influencing the uncertainty in the exposure assessment were examined. These were found to be in particular limitations of the analytical data set in terms of balanced coverage of the European market, representativeness of all relevant food groups and representativeness of the potential variability in regions, seasons and agricultural practices. Another source of uncertainty was the limited availability of only a few food consumption surveys specific to particular population groups such as infants.

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1. Introduction

Perchlorate (ClO4-) is a food and drinking water contaminant present in the environment both from natural and anthropogenic sources. Cases of high levels of contamination have been the result of industrial release of perchlorate into the environment, in particular related to the use of ammonium perchlorate in solid propellants for rockets and missiles (Urbansky, 1998; Amitai et al., 2007; Brandhuber et al., 2009). Recent biomonitoring studies indicated the presence of background levels of perchlorate in a large part of the US population and a similar trend is also observed in Europe, suggesting the ubiquitous presence of perchlorate in the environment. Perchlorate is a well-known component of fertilisers of natural origin, such as Chilean nitrates. Therefore, the use of these fertilisers is likely to be a main source of contamination in water and food, in particular in vegetables. The formation of perchlorate from the degradation of chlorinated products used for water potabilisation could be another notable source of exposure. Finally, minor or negligible routes of contamination could include the photochemical formation of perchlorate in the atmosphere or the use of chlorinated biocides or plant protection products.

The main biochemical activity of perchlorate is related to its ability to competitively inhibit thyroid iodine uptake via the sodium-iodide symporter protein (NIS). For this reason, potassium perchlorate has also been used for the medical treatment of hyperthyroidism at daily doses up to 2,000 mg per person administered for prolonged periods.

The risks to public health related to the presence of perchlorate in food, in particular fruit and vegetables, were evaluated by the EFSA Panel on Contaminants in the Food Chain (CONTAM Panel) in a Scientific opinion issued in 2014 (from now on: EFSA CONTAM opinion) (EFSA CONTAM Panel, 2014).

The most relevant toxic effects of perchlorate are mediated by its goitrogenic properties, causing possible disruption of the hypothalamic–pituitary–thyroid axis homoeostasis. In humans, severe thyroid iodine depletion resulting from insufficient iodine intake or exposure to goitrogenic substances such as perchlorate can lead to hypothyroidism. However, even mild to moderate iodine deficiency can lead to adaptive changes in the thyroid, eventually resulting in the development of toxic multinodular goitre and hyperthyroidism. The CONTAM Panel concluded that sustained inhibition of thyroid iodine uptake resulting from chronic exposure to perchlorate could lead to long-term effects such as the development of toxic multinodular goitre, in particular in populations with mild to moderate iodine deficiency. Based on the inhibition of radioactive iodine uptake observed in a study with human volunteers exposed to perchlorate for 2 weeks, the CONTAM Panel derived a chronic tolerable daily intake (TDI) of 0.3 μg/kg body weight (bw) per day.

The CONTAM Panel concluded that a single acute dietary exposure to perchlorate is unlikely to cause adverse effects even in the most vulnerable parts of the population and therefore determined that the establishment of an acute reference dose was not warranted. The Panel noted that short-term exposure to perchlorate at levels sufficiently high to cause a severe depletion of the iodine thyroid depot would be critical for breast-fed infants and young children. However, due to the lack of relevant dose–response data, the CONTAM Panel could not establish a health-based guidance value for short-term effects of perchlorate.

In its scientific opinion, the CONTAM Panel assessed the exposure levels to perchlorate, considering approximately 12,000 results on occurrence of perchlorate, mainly on fruit and vegetables submitted by eight European Union (EU) Member States as well as literature occurrence data on infant formula, milk and dairy products, alcoholic beverages, fruit juices and breast milk.

After the exclusion of suspect samples, the highest mean perchlorate concentrations were observed in turnips (350 μg/kg, upper bound (UB)) and in lettuce (120 μg/kg, UB).

The mean chronic dietary exposure levels, reported as minimum lower bound (LB)–maximum UB, ranged from 0.04 to 0.20 μg/kg bw per day in adolescents and adults and from 0.07 to 0.54 μg/kg bw per day in infants and children. The 95th percentile chronic dietary exposure ranged from 0.10 to 0.51 μg/kg bw per day in adolescents and adults and from 0.19 to 0.97 μg/kg bw per day for children and infants.

Exposure to perchlorate for breast-fed infants was estimated to range between 0.76 and 6.5 μg/kg bw per day based on mean concentrations of perchlorate in breast milk measured in the USA.

The possibility of being exposed to relatively high levels of perchlorate for 2–3 consecutive weeks was also considered by the CONTAM Panel in two specific scenarios (one excluding and one including suspect samples) to take into account consumption of local produce which contains higher levels of perchlorate. The scenario excluding suspect samples resulted in mean and 95th percentile short-term exposure levels ranging across the different age groups from 0.38 to 3.0 μg/kg bw per day and from

0.94 to 7.2 μg/kg bw per day, respectively. For the scenario including suspect samples, the respective exposure estimates across the different age groups ranged from 0.54 to 5.3 μg/kg bw per day and from 1.3 to 18 μg/kg bw per day.

The CONTAM Panel concluded that the chronic dietary exposure to perchlorate is of potential concern for the high percentile consumers in the younger age groups of the population with mild to moderate iodine deficiency, and possible concern was also expressed for breast-fed infants of mothers with low iodine intake. Furthermore, the Panel identified a possible concern related to short-term exposure to relatively high levels of perchlorate for young children with low iodine intake.

1.1. Background and Terms of Reference as provided by the requestor

1.1.1. Background

Following the outcome of EFSA's scientific opinion on the risks for public health related to the presence of perchlorate in food, the European Commission adopted on 29 April 2015 Commission Recommendation (EU) 2015/682 on the monitoring of the presence of perchlorate in food[1] to collect more occurrence data on the presence of perchlorate in food in particular from food sampled after 1 September 2013. Mitigation measures have been put in place since 1 September 2013 and the data on perchlorate from samples taken thereafter reflect better the principle 'as low as reasonably achievable' following good practices (i.e. use of fertilisers containing low levels of perchlorate) and the current presence of perchlorate in food.

Divergent approaches as regards the issue of perchlorate in fruits and vegetables have resulted in problems/tensions in intra-Union trade, and therefore, a harmonised enforcement approach was adopted by the Standing Committee on Plants, Animals, Food and Feed.[2] This harmonised enforcement approach has taken into account the consumer health protection and what is feasible and achievable taking also into account good practices and regional differences.

Levels of perchlorate as reference for intra-Union trade have been determined and Member States agreed not to take action below these levels. In the meanwhile, they can determine to which extent they enforce these levels for their domestic production/products placed on their domestic market. This enforcement approach is provisional awaiting the availability of more data on the occurrence of perchlorate in food, following the recommendation to monitor the presence of this contaminant in food.

It is appropriate to perform an updated human exposure assessment taking into account the occurrence data obtained from samples taken after 1 September 2013, in view of the consideration of the need of further regulatory measures to prevent and reduce the presence of perchlorate in food to ensure a high level of human health protection.

1.1.2. Terms of Reference

In accordance with Art 31 (1) of Regulation (EC) No 178/2002, the Commission asks the European Food Safety Authority (EFSA) for an updated human exposure assessment to perchlorate taking into account the occurrence data available in the EFSA database from samples taken after 1 September 2013.

2. Data and methodologies

2.1. Data Sources

2.1.1. Occurrence data

The data used for the present report were submitted to EFSA by different data provider organisations and stored in the EFSA scientific data warehouse (SDWH). These data are organised according to the data model 'Standard sample description version 1' (SSD1) (EFSA, 2010a). The model foresees different data elements (database fields) and several coded standard terminologies for non-free-text data elements. The field names and terms mentioned in the report refer to the SSD1 data model.

[1] Commission Recommendation (EU) 2015/682 of 29 April 2015 on the monitoring of the presence of perchlorate in food (OJ L 111, 30.4.2015, p. 32).

[2] Statement as regards the presence of perchlorate in food endorsed by the Standing Committee on Plants, Animals, Food and Feed on 10 March 2015, updated on 23 June 2015. Available at: http://ec.europa.eu/food/safety/docs/cs_contaminants_catalogue_perchlorate_statement_food_update_en.pdf

Based on the mandate received from the European Commission (M-2016-0181), data with PARAMCODE 'RF-00001336-PAR' (Perchlorate) and sampling date from 1 September 2013 onwards were extracted from the SDWH on 6 April 2017. The extraction included 18,304 analytical results. The data set was subsequently analysed in order to exclude non-pertinent data, identify possible issues and prepare the data for occurrence and exposure analysis. The process is described in Section 2.2.1.

2.1.2. Consumption data

The EFSA Comprehensive European Food Consumption Database (Comprehensive Database) provides a compilation of existing national information on food consumption at individual level. It was first built in 2010 (EFSA, 2011a; Huybrechts et al., 2011; Merten et al., 2011). Details on how the Comprehensive Database is used are published in the Guidance of EFSA (EFSA, 2011a). The latest version of the Comprehensive Database[3] was used and contains results from a total of 51 different dietary surveys carried out in 23 different Member States covering 94,532 individuals.

Within the dietary studies, subjects are classified in different age classes as follows:

Infants:	< 12 months old
Toddlers:	≥ 12 months to < 36 months old
Other children:	≥ 36 months to < 10 years old
Adolescents:	≥ 10 years to < 18 years old
Adults:	≥ 18 years to < 65 years old
Elderly:	≥ 65 years to < 75 years old
Very elderly:	≥ 75 years old

Two additional surveys provided information on specific population groups: 'Pregnant women' (≥ 15 years to ≤ 45 years old; Latvia) and 'Lactating women' (≥ 28 years to ≤ 39 years old; Greece).

For the chronic exposure assessment, food consumption data were available from 44 different dietary surveys carried out in 19 different European countries. When for one particular country and population group, two different dietary surveys were available; only the most recent one was used. This choice results in a total of 35 dietary surveys selected to estimate chronic dietary exposure. In Annex A, Table A.1, these dietary surveys and the number of subjects available for the chronic exposure assessment are described.

Overall, the food consumption data gathered by EFSA in the Comprehensive Database are the most complete and detailed data currently available in the EU. Consumption data were collected using single or repeated 24- or 48-h dietary recalls or dietary records covering from 3 to 7 days per subject. Owing to the differences in the methods used for data collection, a direct country-to-country comparison can be misleading.

2.2. Methodologies

2.2.1. Management of occurrence data

After the extraction from the SDWH, the data were analysed in order to identify and address possible issues. The following sections describe the checks performed and their outcome.

2.2.1.1. Duplicated data and errors in the unit of measurement

The reported concentration values were checked in order to identify potential duplicate data and possible errors in the unit of measurement. The potential duplicates were searched comparing several elements of the database (sampling country, sampling area, origin area, FoodEx1 code, text describing the product, product treatment, sampling year, sampling month, sampling year, year of analysis, evaluation of results, limit of detection (LOD), limit of quantification (LOQ), concentration value (RESVAL), sample code and data transmission ID). No duplicate records were identified.

The check of the unit of measurement was performed by comparing the order of magnitude of the values provided for RESVAL, LOD and LOQ across the database. All data were expressed in μg/kg and no error in the unit of measurement was identified.

[3] http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb

2.2.1.2. Analytical results not relevant for the present assessment

The data set was checked for the presence of analytical results not relevant for the present assessment.

A total of 7 results on feed were found and removed from the data set. Similarly, 22 analytical results on samples of soil and fertilisers were excluded. In the food group of drinking water, 12 samples originated from South Africa; they were considered not relevant for the European assessment and therefore excluded, in analogy with what was done in the opinion of the EFSA CONTAM Panel.

2.2.1.3. Left-censored results – censoring limits

Left-censored results are analytical results reported either as < LOD or < LOQ. The limit (LOD or LOQ) applied for each specific result is called the left-censoring limit. Depending on the analytical method, the left-censored limits may vary. The analysis of the left-censoring limits in the perchlorate data set revealed the presence of 46 analytical results with an LOQ (100 μg/kg) much higher than the remaining results. In order to avoid negative influence of the high LOQ on the imputation of left-censored results, in analogy with what was done in the EFSA CONTAM opinion, a cut-off at 50 μg/kg was applied to the LOQ, thus excluding 46 analytical results. At this point, the application of the exclusion criteria so far described reduced the initially extracted data set (N = 18,304) to 18,217 analytical results.

2.2.1.4. Management of left-censored results

For the assessment of perchlorate occurrence, left-censored results were treated by the substitution method (EFSA, 2010b). This approach, based on the consideration that the true value for left-censored results may actually be any value between 0 and the left-censoring limit, compares the two extreme scenarios. The LB scenario assumes that the substance is absent; thus, to left-censored results, a value of 0 is used as input. The UB scenario assumes that the substance is present at the level of the limit; thus, to results reported as < LOD or < LOQ, the value of the respective left-censoring limit is assigned. Additionally, as a point estimate between the two extremes, the middle bound (MB) scenario is calculated by assigning to the left-censored results a value of LOD/2 or LOQ/2.

2.2.1.5. Sampling method and sampling strategy

Almost all data were from analysis of individual samples. For 292 results, the sampling method was reported as pooled/batch, but the number of individual samples was not provided; they were considered like individual samples, assuming a low number of pooled individual samples and considering the overall small number of these results. With respect to the sampling strategy,[4] a large majority (N = 14,186) of the results originated from objective or selective sampling. A total of 179 results on perchlorate were reported as from suspect sampling. The remaining results (N = 3,852) were mostly from industrial sampling (sampling performed along the production chain; N = 3,627). Convenient sampling was reported for 125 results. The sampling strategy for the few remaining analytical results (N = 100) was not specified.

Overall, 18,217 analytical results were included in the final data set on perchlorate occurrence in food.

2.2.1.6. Expression of reported analytical results

All results were expressed as whole weight, in μg/kg, therefore, no further conversion was required.

In some cases (N = 135), values were reported in the RESVAL field in the case of left-censored results; of these, 114 repeated in the RESVAL field the left-censoring limit (UB imputation), while the remaining 21 results were values estimated in the range between LOD and LOQ. For consistency with the other data, these results were considered left-censored and the values used for the assessment were imputed according to the standard method described in Section 2.2.1.4.

[4] Objective sampling is based on the selection of a random sample from a population on which the data are reported; Selective sampling is based on the selection of a random sample from a subpopulation (or more frequently from subpopulations) of a population on which the data are reported. The subpopulations are often determined on a risk basis;
Convenient sampling is based on the selection of a sample for which units are selected only on the basis of feasibility or ease of data collection;
Suspect sampling is based on samples taken repeatedly from the same site as a consequence of evidence or suspicion of (illegal) contamination. Suspect samples are usually taken as a follow-up of demonstrated non-compliance with legislation.

2.2.1.7. Recovery rates

Recoveries were only reported for 2,897 analytical results, and in this case, it was in the range of 80–132%. Due to the lack of information, no selection of data based on the recovery was possible and it was assumed that the results were the best possible estimate, depending on the analytical method.

2.2.2. Food classification

The analytical results were classified according to the FoodEx1 food classification system. FoodEx1 is a provisional food classification system developed by the EFSA's Dietary and Chemical Monitoring Unit in 2009 with the objective to link occurrence and food consumption data at a detailed level to assess exposure to hazardous substances. It contains about 1,800 food descriptors (food codes) organised in four hierarchical levels. This allows grouping foods according to the needs of a specific analysis (EFSA, 2011b). The occurrence analysis was performed for food groups in the levels 1–3. For the purpose of estimating the dietary exposure, level 1 food groups were considered too generic and the level 2 groups were considered suitable. When the preliminary analysis provided evidence of some level 3 food groups with higher average levels of perchlorate, than the other groups under the same level 2 parent group, the level 3 groups with higher levels were considered separately, while the remaining were merged in an ad hoc level 3 group; similarly, the groups with high average value in the EFSA CONTAM opinion were kept separate from the ad hoc group. When the preliminary data analysis revealed that all analytical results in a food group were left-censored, the eventual subgroups of this group were not considered separately in the occurrence analysis.

According to these criteria, a recoding of food groups was performed as summarised in Table 1

Table 1: Grouping of left-censored food groups and creation of ad hoc food groups

Reported food groups[(a)]	Action[(b)]	Name of resulting group[(c)]	Level[(d)]
All root vegetables with the exclusion of beetroot, radishes and turnips	Grouped in ad hoc group	Root vegetables excluding beetroot, radishes and turnips	3
All fruiting vegetables with the exclusion of cucumbers, courgettes and melons	Grouped in ad hoc group	Fruiting vegetables excluding cucumbers, courgettes and melons	3
All brassica vegetables with the exclusion of Chinese cabbage, kale and kohlrabi	Grouped in ad hoc group	*Brassica* vegetables excluding Chinese cabbage, kale and kohlrabi	3
All leaf vegetables with the exclusion of spinach (fresh), rocket and beet leaves	Grouped in ad hoc group	Leaf vegetables excluding fresh spinach, rocket and beet leaves	3
All teas and herbs for infusions (solid) with the exclusion of Camomile flowers and Peppermint	Grouped in ad hoc group	Tea and herbs for infusions (Solid) excluding camomile and peppermint	3
Herbs, spices and condiments	Two entries reported at level 1 were recoded as a level 2 group	Herb and spice mixtures	2

(a): Reported food groups to which a recoding action is applied.
(b): Type or recoding done.
(c): Name of the recoded (ad hoc) food group.
(d): Level of the recoded (ad hoc) food group.

2.2.3. Estimation of chronic dietary exposure

For estimating the chronic dietary exposure to perchlorate, food consumption and body weight data at the individual level were accessed from the Comprehensive Food Consumption Database. The occurrence data of perchlorate in food and consumption data were linked at FoodEx1 level. Table A.3 in Annex A shows the FoodEx1 groups considered for the chronic dietary exposure estimate.

For each country, exposure estimates were calculated per dietary survey and population group. Chronic exposure estimates were calculated for 35 different dietary surveys carried out in 19 different European countries. Not all countries provided consumption information for all age groups, and in some cases, the same country provided more than one consumption survey; the dietary surveys available for the different population groups are reported in Table A.1 in Annex A. The distribution of individual chronic dietary exposures (in μg/kg bw per day) was calculated by multiplying the mean occurrence values excluding suspect samples, as shown in Table A.4 in Annex A, with the average daily consumption for each food at individual level, summing up the intakes throughout the diet, and finally dividing the results by the individual's body weight. Only subjects with more than one reporting day were considered appropriate for calculating chronic exposure. The mean and the high (95th percentile) chronic dietary exposures were then calculated choosing the mean and the 95th percentile (P95) of individual exposures for each population group in each dietary survey.

Perchlorate levels in water were used also for non-alcoholic beverages (with the exception of milk beverages and teas) for which a sufficient number of occurrence data was not available. For milk-based beverages, the occurrence in liquid milk was used, while for teas and infusions (as beverage), the occurrence in the solid infusion material divided by 100 was used (a bag of 2.5 g of infusion material for 250 g of infusion) in addition to the levels in drinking water.

'Grains and grain-based products' were excluded from the dietary exposure assessment considering that all available analytical results were below the LOD. The same approach was followed with 'Tree nuts'.

In the group 'Products for special nutritional use', a few results with relatively high values were reported, in the subgroups 'Dietary supplements' and 'Food for sports people'. It was not possible to gather more information on the detailed nature of the samples in these groups. In order to avoid unwanted overestimation of the exposure (some foods in these groups are consumed in relatively high amounts), some assumptions were made:

- Dietary supplements and foods for sports people of probable synthetic origin or anyway not directly related to plant or dairy origin were excluded from the exposure calculation;
- Carbohydrate-electrolyte solutions for sports people were considered in the same way as soft drinks and the occurrence levels in water were attributed to them.

In the group 'Food for infants and small children', taking into account the sensitivity of the population group, all Level 2 food groups, including those with entirely left-censored results, were kept into consideration, to allow evaluating the impact of the UB occurrence data.

In the absence of analytical data on beer, the value of 1 μg/kg used in the EFSA CONTAM opinion (EFSA CONTAM Panel, 2014) was also used in this report.

2.2.4. Estimation of short-term dietary exposure

In the EFSA CONTAM opinion (EFSA CONTAM Panel, 2014), the CONTAM Panel developed a 'short-term' dietary exposure assessment, to evaluate the exposure for a short period (2–3 weeks) to relatively high levels of perchlorate; this may be the case when a single lot of highly contaminated products is repeatedly consumed in a short-time period. Short-time dietary exposure to high levels of perchlorate was calculated for each individual for each food group by multiplying the mean daily consumption by the highest reliable percentile of occurrence, summing up the intakes throughout the diet and dividing by the individual's body weight. Only individuals with more than one reporting consumption day were considered. Regarding the highest reliable percentile, the criteria described in the Section 2.2.5 were applied; in case of less than 11 analytical results for the occurrence in a food group, the mean occurrence in that food group was used instead of a percentile.

The same approach was used in this report, using all the data, including the results from suspect samples, based on the consideration that the occasional consumption may refer to any available instance of a food. In the absence of analytical data on beer, the value of 6 μg/kg used in the EFSA CONTAM opinion was also used in this report.

2.2.5. Statistical analysis

All analyses were run using the SAS® Statistical Software (SAS software, 1999). Frequency tables per sampling year, sampling country and food group were produced to describe the perchlorate data collection. Descriptive summary statistics of concentration levels per food group were calculated. The Guidance on the use of the Comprehensive Food Consumption Database indicates that the 95th percentile estimates obtained with less than 60 observations may not be statistically robust (EFSA, 2011a), and therefore, they should be considered with caution. Applying the same rationale to evaluate other percentiles, the minimum number of data points needed for considering the percentiles statistically robust was defined as 300 for the P99, 60 for the P95, 30 for the P90, 11 for the P75 and 6 for the median (P50). These criteria were adopted while compiling the occurrence table and while defining the highest reliable percentiles for the short-term exposure (Sections 2.2.4 and 3.2.2).

The number of digits reported in the tables, in particular in the occurrence tables, should not be misunderstood as overall accuracy of the value since it is only due to the standardisation of the settings in the statistical calculation routines.

3. Assessment

3.1. Occurrence of perchlorate in Food

A total of 18,217 analytical results with a sampling date from 1 September 2013 and suitable for estimating human exposure to perchlorate were considered for the present assessment. The extraction was performed in April 2017, as explained in Section 2.1.1. The analytical results were provided by 16 European countries; however, the distribution of data among countries was not balanced, considering that more than 80% of the data were provided by only two countries (68% from one country alone); some data provided by European food business association were tagged as 'European Union'. Table 2 shows the distribution of analytical results by country of the data provider and year of sampling.

Table 2: Number of analytical results on perchlorate in food per reporting country and year of sampling

Country	N by Sampling Year				TOTAL
	2013	2014	2015	2016	N
Austria			169		169
Belgium			122		122
Czech Republic			23		23
Denmark		21			21
European Union (EU food business associations)		10	495	635	1 140
Finland		158	50		208
France		211	148		359
Germany	1,086	6,148	5,202		12,436
Ireland			90	35	125
Italy	143		2,381	8	2,532
Lithuania			9		9
Luxembourg			50		50
Malta		20			20
Netherlands		82			82
Spain			52		52
Switzerland		586	1		587
United Kingdom	20	132	130		282
----TOTAL	1,249	7,368	8,922	678	18,217

N: Number of analytical results.

Most of the data (93.7%) were submitted by governmental organisations and the remaining data (6.3%) were from food business organisations.

For many results (N = 11,551), the analytical technique applied was not specified; for all the others, the analytical technique was based on high-performance liquid chromatography with different types of detector.

The value for LOQ was reported for a large majority of results (N = 17,496) and ranged between 0.6 and 50 μg/kg. The value for LOD was reported for 11,935 results and was in the range 0.3–20 μg/kg.

As explained in Section 2.2.1.5, most of the data originated from objective or selective sampling (78.6,%). A small amount of data (around 1%) was reported as suspect sampling.

An overall proportion of 23.2% of the results was quantified, while the remaining 76.8% was left-censored. For calculating statistics on the occurrence of perchlorate in food, the substitution approach was used for left censored data as described in Section 2.2.1.4.

The number of suspect samples was limited; it was decided to calculate the occurrence of perchlorate in food excluding the data from suspect sampling. For comparison, the occurrence including suspect samples was also calculated and is reported in Table A.2 and Table A.4 in Annex A;

the impact of suspect samples is almost negligible for most of the food groups. Results from suspect samples were further considered only for estimating the short-term exposure as described in Section 2.2.4 and summarised in Section 3.2.2.

The occurrence of perchlorate in the different food groups is shown in Table 3. The occurrence is presented according to the substitution approach for left-censored data described in Section 2.2.1.4 as MB, followed by the range LB–UB. Values of median with less than six data points or P95 with less than 60 data points were considered not robust enough and were not reported in the table.

In cases where the LB and UB values of statistical descriptors of occurrence are coincident, a single value is reported instead of the range. A similar approach is adopted for the range of LOQ.

Among fresh vegetables, the highest mean MB values were found in 'Radishes (*Raphanus sativus* var. *sativus*)' (117 μg/kg), 'Rocket, Rucola (*Eruca sativa*, Diplotaxis spec.)' (75 μg/kg) and 'Spinach (fresh) (*Spinacia oleracea*)' (132 μg/kg). Compared to other food groups, high values were found in 'Tea and herbs for infusion (solids)' (324 μg/kg); this is probably due to the dry status of these foods. Several other food groups, for example, Herbs, spices and condiments' (63 μg/kg) show mean perchlorate MB occurrence values higher than the remaining food groups. In the above-mentioned food groups, the difference between LB and UB average occurrence is limited, in the range 1–5.5%. While considering these results, it must be taken into account that some of the food groups include dried products. Additionally, the number of results available in each of the different food groups should be considered because it influences the robustness of the statistics.

Table 3: Concentration values (μg/kg) of perchlorate in food categories (FoodEx1 or ad hoc) related to the Comprehensive Food Consumption database (Levels 1–3) – excluding suspect samples

FoodEx1 code	Food groups levels 1–3[(a)]	N[(b)]	% LC[(c)]	LC (min–max)[(e)] (μg/kg)	Mean[(d)] occurrence MB (LB–UB)[(e)] (μg/kg)	Median[(d)] of occurrence MB (LB–UB)[(e)] (μg/kg)	P95[(d)] of occurrence MB (LB–UB)[(e)] (μg/kg)
A.01.000001	Grains and grain-based products	179	100	(2–50)	5 (0–10)	2.50 (0–5)	25 (0–50)
A.01.000317	Vegetables and vegetable products (including fungi)	9,546	68	(0.5–50)	63 (60–65)	5 (0–10)	230
A.01.000318	Root vegetables	753	85	(2–50)	33 (31–36)	2.50 (0–5)	25 (23–30)
A.01.000320	Beetroot (*Beta vulgaris* subsp. *vulgaris*)	45	82	(2–10)	45 (42–47)	2.50 (0–5)	–
A.01.000326	Radishes (*Raphanus sativus* var. *sativus*)	171	77	(2–30)	117 (115–120)	2.50 (0–5)	800
A.01.000330	Turnips (*Brassica rapa*)	7	86	10	12 (8.28–16)	5 (0–10)	–
ad hoc	Root vegetables excluding beetroot, radishes and turnips	530	88	(2–50)	6.24 (3.26–9.21)	2.50 (0–5)	15 (13–15)
A.01.000331	Bulb vegetables	135	95	(2–30)	2.67 (0.51–4.82)	1 (0–2)	6 (2–10)
A.01.000337	Fruiting vegetables	2,144	73	(0.5–50)	10 (8.56–13)	2.50 (0–5)	39 (39–48)
A.01.000343	Cucumbers (*Cucumis sativus*)	297	63	(0.5–50)	18 (16–20)	2.50 (0–5)	70
A.01.000345	Courgettes (Zucchini) (*Cucurbita pepo* var. *melopepo*)	241	51	(0.5–20)	20 (18–21)	5 (0–10)	93
A.01.000346	Melons (*Cucumis melo*)	154	53	(0.5–50)	16 (14–18)	5 (0–9)	48 (48–50)
ad hoc	Fruiting vegetables excluding cucumbers, courgettes and melons	1,452	82	(0.5–50)	7.06 (4.54–9.59)	2.50 (0–5)	25 (20–25)
A.01.000350	*Brassica* vegetables	703	83	(0.5–50)	9.78 (7.52–12)	2.50 (0–5)	32 (32–39)
A.01.000355	Chinese cabbage (*Brassica pekinensis*)	62	87	(2–10)	18 (16–20)	2.50 (0–5)	34
A.01.000356	Kale (*Brassica oleracea* convar. *acephala*)	84	42	(2–10)	21 (20–22)	10	81
A.01.000357	Kohlrabi (*Brassica oleracea* convar. *acephala*, var. *gongylodes*)	70	84	(2–10)	14 (12–16)	2.50 (0–5)	19
ad hoc	*Brassica* vegetables excluding chinese cabbage, kale and kohlrabi	487	89	(0.5–50)	6.03 (3.46–8.60)	2.50 (0–5)	25 (16–27)
A.01.000359	Leaf vegetables	3,589	66	(0.5–50)	42 (39–45)	5 (0–10)	110
A.01.000366	Rocket, Rucola (*Eruca sativa*, Diplotaxis spec.)	715	44	(0.5–20)	75 (73–77)	11 (11–13)	220
A.01.000369	Spinach (fresh) (*Spinacia oleracea*)	388	49	(3–20)	132 (130–134)	6.60 (5.70–10)	385
A.01.000372	Beet leaves (*Beta vulgaris*)	80	61	(2–10)	64 (61–66)	5 (0–10)	107
ad hoc	Leaf vegetables excluding fresh spinach, rocket and beet leaves	2,406	75	(0.5–50)	17 (14–20)	5 (0–10)	53
A.01.000382	Legume vegetables	81	70	(1–10)	7.35 (5.84–8.86)	2.50 (0–5)	41

FoodEx1 code	Food groups levels 1–3[(a)]	N[(b)]	% LC[(c)]	LC (min–max)[(e)] (µg/kg)	Mean[(d)] occurrence MB (LB–UB)[(e)] (µg/kg)	Median[(d)] of occurrence MB (LB–UB)[(e)] (µg/kg)	P95[(d)] of occurrence MB (LB–UB)[(e)] (µg/kg)
A.01.000385	Stem vegetables (Fresh)	472	94	(0.5–50)	3.45 (0.79–6.11)	2.50 (0–5)	6 (5–10)
A.01.000395	Sugar plants	192	96	(5–10)	5.83 (1.17–10)	5 (0–10)	5 (0–10)
A.01.000404	Tea and herbs for infusions (Solid)	1,193	24	(5–20)	324 (322–325)	110	910
A.01.000407	Camomile flowers (*Matricaria recutita*)	18	6	10	3,448	147	–
A.01.000408	Peppermint (*Mentha* × *piperita*)	99	5	10	1,068	180	6,800
ad hoc	Tea and herbs for infusions (solid) excluding camomile and peppermint	1,076	26	(5–20)	203 (201–205)	100	720
A.01.000440	Vegetable products	4	–	–	67	–	–
A.01.000452	Hops (dried), including hop pellets and unconcentrated powder (*Humulus lupulus*)	4	–	–	67	–	–
A.01.000453	Fungi, cultivated	199	94	(2–50)	7.11 (5.12–9.10)	2.50 (0–5)	44 (44–48)
A.01.000458	Fungi, wild, edible	68	79	(2–8)	3.33 (2.05–4.61)	1(0–2)	13
A.01.000467	Starchy roots and tubers	295	96	(2–10)	4.28 (1.88–6.69)	2.50 (0–5)	5 (0–10)
A.01.000468	Potatoes and potatoes products	276	96	(2–10)	4.43 (2.01–6.85)	2.50 (0–5)	5 (0–10)
A.01.000480	Other starchy roots and tubers	19	100	(2–5)	2.18 (0–4.36)	2.50 (0–5)	–
A.01.000486	Legumes, nuts and oilseeds	308	80	(2–50)	10 (8.31–12)	2.50 (0–5)	29 (29–50)
A.01.000487	Legumes, beans, green, without pods	233	78	(2–50)	12 (10–14)	2.50 (0–5)	50
A.01.000491	Legumes, beans, dried	38	87	(2–10)	5.97 (3.63–8.31)	2.50 (0–5)	–
A.01.000513	Tree nuts	18	100	2	1 (0–2)	1 (0–2)	–
A.01.000527	Oilseeds	19	79	(2–5)	4.57 (2.73–6.42)	2.50 (0–5)	–
A.01.000544	Fruit and fruit products	5,690	90	(0.5–50)	5.13 (2.74–7.52)	2.50 (0–5)	20 (18–20)
A.01.000545	Citrus fruits	971	68	(0.5–50)	10 (8.07–12)	2.50 (0–5)	40 (40–45)
A.01.000552	Pome fruits	866	99	(0.5–50)	3.76 (1.06–6.46)	2.50 (0–5)	5 (0–10)
A.01.000562	Stone fruits	888	98	(2–50)	2.72 (0.49–4.95)	2.50 (0–5)	5 (0–10)
A.01.000575	Berries and small fruits	1,917	93	(0.5–50)	4.35 (1.79–6.90)	2.50 (0–5)	17 (10–17)
A.01.000611	Miscellaneous fruits	866	92	(2–50)	4.42 (2.19–6.65)	2.50 (0–5)	16 (13–17)
A.01.000647	Dried fruits	139	73	(2–20)	9.35 (7.56–11)	2.50 (0–5)	26
A.01.000657	Jam, marmalade and other fruit spreads	22	95	(2–10)	5.09 (0.50–9.68)	5 (0–10)	–
A.01.000682	Other fruit products (excluding beverages)	18	100	(2–10)	1.63 (0–3.27)	1 (0–2)	–
A.01.000948	Milk and dairy products	287	78	(2–20)	4.57 (1.80–7.33)	2.50 (0–5)	14 (14–19)

FoodEx1 code	Food groups levels 1–3[(a)]	N[(b)]	% LC[(c)]	LC (min–max)[(e)] (μg/kg)	Mean[(d)] occurrence MB (LB–UB)[(e)] (μg/kg)	Median[(d)] of occurrence MB (LB–UB)[(e)] (μg/kg)	P95[(d)] of occurrence MB (LB–UB)[(e)] (μg/kg)
A.01.000949	Liquid milk	166	82	(2–10)	3.07 (0.56–5.58)	2.50 (0–5)	5 (3.80–10)
A.01.000973	Concentrated milk	2	100	5	2.50 (0–5)	–	–
A.01.000985	Whey and whey products (excluding whey cheese)	13	92	(5–20)	7.92 (1–14)	10 (0–20)	–
A.01.001000	Cream and cream products	2	100	5	2.50 (0–5)	–	–
A.01.001027	Fermented milk products	46	78	(5–10)	2.86 (0.42–5.31)	2.50 (0–5)	–
A.01.001053	Cheese	39	49	(5–10)	10 (8.63–12)	5 (1–10)	–
A.01.001346	Animal and vegetable fats and oils	4	100	8	4 (0–8)	–	–
A.01.001367	Vegetable oil	4	100	8	4 (0–8)	–	–
A.01.001394	Fruit and vegetable juices	142	99	(2–10)	3.36 (0.70–6.03)	2.50 (0–5)	5 (0–10)
A.01.001395	Fruit juice	114	100	(2–10)	2.50 (0–5)	2.50 (0–5)	5 (0–10)
A.01.001434	Fruit nectar	11	100	(2–10)	2 (0–4)	1 (0–2)	–
A.01.001442	Mixed fruit juice	6	83	(2–10)	5.16 (1.66–8.66)	5 (0–10)	–
A.01.001454	Vegetable juice	2	100	10	5 (0–10)	–	–
A.01.001463	Mixed vegetable juice	1	100	10	5 (0–10)	–	–
A.01.001467	Mixed fruit and vegetable juice	3	100	10	5 (0–10)	–	–
A.01.001470	Non-alcoholic beverages (excepting milk-based beverages)	2	50	2	1 (0.50–1.50)	–	–
A.01.001471	Soft drinks	2	50	2	1 (0.50–1.50)	–	–
A.01.001534	Alcoholic beverages	52	92	(2–10)	2.56 (1.40–3.73)	1 (0–2)	–
A.01.001541	Wine	52	92	(2–10)	2.56 (1.40–3.73)	1 (0–2)	–
A.01.001573	Drinking water (water without any additives except carbon dioxide; includes water ice for consumption)	120	95	(1–10)	1.54 (0.04–3.03)	0.50 (0–1)	5 (0.05–10)
A.01.001580	Herbs, spices and condiments	557	41	(2–50)	63 (62–64)	11 (11–12)	233
A.01.001581	Herbs	502	40	(2–50)	67 (65–68)	11 (11–12)	233
A.01.001593	Spices	48	58	(2–50)	25 (23–27)	4.25 (0–5.50)	–
A.01.001625	Herb and spice mixtures	6	17	2	58	57	–
A.01.001684	Savoury sauces	1	100	2	1 (0–2)	–	–
A.01.001715	Food for infants and small children	676	95	(0.5–20)	4.12 (1.55–6.69)	2.50 (0–5)	5 (0–10)
A.01.001716	Infant formulae, powder	46	100	(2–10)	3.13 (0–6.26)	2.50 (0–5)	–
A.01.001722	Follow-on formulae, powder	9	100	(5–10)	3.05 (0–6.11)	2.50 (0–5)	–
A.01.001728	Cereal-based food for infants and young children	152	99	(2–10)	2.69 (0.07–5.31)	2.50 (0–5)	5 (0–10)

FoodEx1 code	Food groups levels 1–3[(a)]	N[(b)]	% LC[(c)]	LC (min–max)[(e)] (µg/kg)	Mean[(d)] occurrence MB (LB–UB)[(e)] (µg/kg)	Median[(d)] of occurrence MB (LB–UB)[(e)] (µg/kg)	P95[(d)] of occurrence MB (LB–UB)[(e)] (µg/kg)
A.01.001733	Ready-to-eat meal for infants and young children	359	92	(0.5–10)	3.09 (0.80–5.39)	2.50 (0–5)	11
A.01.001739	Yoghurt, cheese and milk-based dessert for infants and young children	2	100	5	2.50 (0–5)	–	–
A.01.001743	Fruit juice and herbal tea for infants and young children	44	98	(2–10)	2.90 (0.04–5.77)	2.50 (0–5)	–
A.01.002000	Infant formulae, liquid	13	100	(5–10)	4.80 (0–9.61)	5 (0–10)	–
A.01.001748	Products for special nutritional use	10	40	(2–5)	274 (274–275)	280	–
A.01.001752	Dietary supplements	5	80	(2–5)	65 (64–67)	–	–
A.01.001765	Food for sports people (labelled as such)	5	–	–	484	–	–
A.01.001789	Composite food (including frozen products)	170	73	(0.5–10)	16 (14–19)	5 (0–10)	67
A.01.001839	Vegetable-based meals	1	100	2	1 (0–2)	–	–
A.01.001866	Prepared salads	169	73	(0.5–10)	17 (14–20)	5 (0–10)	67

(a): The names are provided in indented form to show the hierarchical relationship of the food groups.
(b): N = number of analytical results reported.
(c): LC % = percentage of left-censored results; the values are rounded to the nearest integer.
(d): Mean = arithmetic mean; median = 50th percentile (when the number of data points is less than 11, the median is not reported); P95 = 95th percentile; the Guidance on the use of the Comprehensive food consumption database indicates that the 95th percentile estimates obtained with less than 60 observations may not be statistically robust (EFSA, 2011c). Applying the same rationale to evaluate other percentiles, the minimum number of observations for the median (50th percentile) is 6; P95 in groups with less than 60 data points and median in groups with less than 6 data points are not shown in the table.
(e): In cases where the LB and UB values of statistical descriptors of occurrence are coincident, a single value is reported instead of the range. A similar approach is adopted for the range of applied left-censoring value (LC).

3.2. Chronic and short-term dietary exposure assessment in humans

3.2.1. Chronic exposure

The chronic dietary exposure to perchlorate was calculated for the different dietary surveys by individual subject and food group, as explained in Section 2.2.3, using the occurrence values from Table 3. For FoodEx1 food groups thought to potentially contain perchlorate but not having measured samples in the occurrence data set, the occurrence values for the estimation of chronic exposure were imputed using those available in Table 3 for similar or related food groups, as summarised in Table A.3 in Annex A.

The analytical results originating from suspect sampling were excluded from the assessment of chronic human dietary exposure to perchlorate. The mean LB, MB and UB occurrence values attributed to the FoodEx1 food groups of relevance for perchlorate exposure were based on the values reported in Table 3 and are summarised in Table A.4 in Annex A (columns excluding suspect samples; the values including suspect samples are also reported, but only for reference and comparison).

Tables 4 and 5 show the statistics for the mean and P95 of exposure, respectively. For the different population groups, the minimum, median and maximum across dietary surveys of the estimated mean and P95 of exposure are reported, expressed in μg/kg bw per day. The dietary surveys where the number of subjects was less than 60 were excluded from the evaluation of the P95 of exposure. The median in Tables 4 and 5 is not shown for those population groups where the number of available surveys is less than 6. Taking into account the LB, MB and UB values for the occurrence, each exposure statistic is given as MB, followed in brackets by the range LB–UB.

Additionally, Table A.7 in Annex A provides the detail of the mean and P95 of chronic dietary exposure (μg/kg bw per day) to perchlorate by population groups and national dietary surveys.

Table 4: Mean chronic dietary exposure (μg/kg bw per day) to perchlorate (excluding suspect samples) across national dietary surveys

Population groups[(a)]	N of surveys	Min MB (LB–UB) (μg/kg bw per day)	Median MB (LB–UB) (μg/kg bw per day)	Max MB (LB–UB) (μg/kg bw per day)
Infants	6	0.15 (0.04–0.26)	0.28 (0.09–0.47)	0.35 (0.10–0.61)
Toddlers	10	0.23 (0.08–0.35)	0.26 (0.11–0.42)	0.33 (0.15–0.54)
Other children	18	0.13 (0.06–0.18)	0.17 (0.09–0.25)	0.25 (0.13–0.42)
Adolescents	17	0.06 (0.03–0.09)	0.09 (0.05–0.13)	0.13 (0.09–0.19)
Adults	17	0.06 (0.04–0.08)	0.09 (0.05–0.13)	0.11 (0.08–0.15)
Elderly	14	0.07 (0.04–0.09)	0.09 (0.05–0.13)	0.12 (0.08–0.16)
Very elderly	12	0.07 (0.04–0.10)	0.09 (0.05–0.13)	0.12 (0.08–0.16)
Lactating women	1	0.08 (0.05–0.12)	–	0.08 (0.05–0.12)
Pregnant women	1	0.10 (0.07–0.14)	–	0.10 (0.07–0.14)

bw: body weight; LB: lower bound; MB: middle bound; UB: upper bound.
(a): Details on the dietary surveys in the different population groups are in Table A.1 in Annex A.

Table 5: P95 of chronic dietary exposure (μg/kg bw per day) to perchlorate (excluding suspect samples) across national dietary surveys

Population groups[(a)]	N of surveys	Min MB (LB–UB) (μg/kg bw per day)	Median MB (LB–UB) (μg/kg bw per day)	Max MB (LB–UB) (μg/kg bw per day)
Infants	5	0.28 (0.09–0.49)	–	0.54 (0.30–0.81)
Toddlers	7	0.39 (0.15–0.60)	0.43 (0.22–0.66)	0.57 (0.34–1.0)
Other children	18	0.25 (0.12–0.34)	0.33 (0.18–0.48)	0.47 (0.32–0.79)
Adolescents	17	0.13 (0.07–0.19)	0.18 (0.11–0.25)	0.26 (0.22–0.34)
Adults	17	0.12 (0.08–0.15)	0.17 (0.10–0.23)	0.24 (0.20–0.30)
Elderly	14	0.11 (0.07–0.15)	0.17 (0.11–0.24)	0.25 (0.22–0.30)
Very elderly	9	0.15 (0.08–0.20)	0.16 (0.11–0.23)	0.26 (0.22–0.32)

Population groups[(a)]	N of surveys	Min MB (LB–UB) (μg/kg bw per day)	Median MB (LB–UB) (μg/kg bw per day)	Max MB (LB–UB) (μg/kg bw per day)
Lactating women	1	0.15 (0.11–0.21)	–	0.15 (0.11–0.21)
Pregnant women	1	0.19 (0.14–0.24)	–	0.19 (0.14–0.24)

bw: body weight; LB: lower bound; MB: middle bound; UB: upper bound.
(a): Details on the dietary surveys in the different population groups are in Table A.1 in Annex A.

The mean chronic dietary exposure among the different population groups (age classes and special groups) is higher in general for infants, toddlers and other children while the other population groups are substantially aligned at lower values. The range across dietary surveys of mean chronic exposure (minimum LB–maximum UB) in infants is 0.04–0.61 μg/kg bw per day; in toddlers, the range is 0.08–0.54 μg/kg bw per day; in other children, it is 0.06–0.42 μg/kg bw per day. The range in adolescents and older population groups is overall 0.04–0.19 μg/kg bw per day.

The P95 of chronic dietary exposure is also higher for infants, toddlers and other children than for older population groups. The range across dietary surveys of P95 chronic exposure (minimum LB–maximum UB) in Infants is 0.09–0.81 μg/kg bw per day; in toddlers, the range is 0.15–1.0 μg/kg bw per day; in other children, it is 0.12–0.79 μg/kg bw per day. The range in the remaining population groups is overall 0.07–0.34 μg/kg bw per day.

In the LB scenario, the mean as well as the P95 of chronic dietary exposure related to all population groups are generally lower in the current assessment with respect to the one carried out in 2014 (EFSA CONTAM Panel, 2014); in the UB scenario, the chronic dietary exposure of the present assessment is lower than in the one of 2014 only for adolescents, adults, elderly and very elderly in the dietary survey with maximum exposure and for infants in the survey with minimum exposure. (see Table A.10 in Annex A).

As shown in Table A.1, in Annex A and in Section 2.1.2, the number of consumption surveys and subjects available for infants, lactating women and pregnant women is limited; therefore, the exposure ranges must be considered with caution.

The contribution of the different food groups to the chronic dietary exposure in the different population groups was evaluated and is summarised by aggregated food groups in Table A.5 and as raw percentages of contribution across population groups and national dietary surveys in Table A.9 in Annex A. The tables show the contribution to the chronic exposure in the LB, MB and UB approach, to allow calculating the impact of the left-censored data substitution approach on the ranking of the contributors to exposure.

In the MB scenario, for infants, the main contributor is 'Milk and dairy products', followed by 'Food for infants and small children'; 'Vegetable and vegetable products' and 'Fruit and fruit products' are also relevant contributors to the exposure of infants. A similar pattern of contribution is also observed in toddlers, but with decreasing importance of 'Food for infants and small children' and increasing for 'Fruit and vegetable juices'. For other children and adolescents, the major contributors are 'Milk and dairy products' and 'Vegetables and vegetable products', followed by 'Fruit and vegetable juices' and 'Fruit and fruit products'. For the older population groups, 'Vegetables and vegetable products' are the major contributor, but other food groups are also of relevance for the exposure, like 'Milk and milk products', 'Teas and herbal infusion (beverage)' and 'Fruit and fruit products'.

The LB and UB scenarios show similar ranking of contributors, with only minor differences, like a slight decrease of the importance of 'Food for infants and small children' and correspondingly a slight increase in the importance of 'Vegetable and vegetable products' in infants and toddlers in the LB scenario. Similarly, a small decrease of the importance of 'Milk and milk products' is observed when moving from the MB scenario to the LB scenario in the case of other children and adolescents. Other slight differences like these may be observed in Table A.5 in Annex A.

3.2.2. Assessment of short-term exposure to high levels of perchlorate

The short-term dietary exposure to perchlorate was calculated as explained in Section 2.2.4 using the values reported in Table A.6 in Annex A for the highest reliable percentiles. The analytical results originating from suspect sampling were included in the data set for estimating short-term human dietary exposure to perchlorate. For the FoodEx1 food groups thought to be potentially contaminated by perchlorate, but not represented in the data set, the same approach used in the case of chronic exposure (summarised in Table A.3) was adopted.

Tables 6 and 7 show the statistics for the mean and P95 of exposure, respectively. For the different population groups, the minimum, median and maximum across dietary surveys of the estimated mean and P95 of exposure are reported, expressed in μg/kg bw per day. The dietary surveys where the number of subjects was less than 60 were excluded from the evaluation of the P95 of exposure. The median in Tables 6 and 7 is not shown for those population groups where the number of available surveys is less than 6. Taking into account the LB, MB and UB values for the occurrence, each exposure statistic is given as MB, followed in brackets by the range LB–UB.

Additionally, Table A.8 in Annex A provides the details of the mean and P95 of short-term dietary exposure (μg/kg bw per day) to perchlorate by population groups and national dietary surveys.

The mean short-term dietary exposure to perchlorate among the different population groups (age classes and special groups) is higher for infants, toddlers and other children than for the older population groups. The range across dietary surveys of mean short-term exposure (minimum LB–maximum UB) in infants is 0.40–2.1 μg/kg bw per day; in toddlers, the range is 0.62–2.3 μg/kg bw per day, and in other children, it is 0.41–1.7 μg/kg bw per day. The range in adolescents and adult classes is overall 0.26–1.3 μg/kg bw per day.

The P95 of short-term dietary exposure to perchlorate is higher for toddlers, followed by infants and other children, while older population groups show relatively lower levels. The range across dietary surveys of P95 short-term exposure (minimum LB–maximum UB) in infants is 1.0–6.0 μg/kg bw per day; in toddlers, the range is 1.5–6.5 μg/kg bw per day; in other children, it is 0.94–5.4 μg/kg bw per day. In the remaining older population groups, the overall range of P95 of short-term exposure to perchlorate is 0.67–3.6 μg/kg bw per day.

The mean as well as the P95 of short-term dietary exposure are lower in the current assessment with respect to the one carried out by the CONTAM Panel in 2014 (EFSA CONTAM Panel, 2014) for all scenarios (LB and UB) and all population groups (see Table A.11 in Annex A).

Table 6: Mean short-term dietary exposure (μg/kg bw per day) to perchlorate (including suspect samples) across national dietary surveys, using the highest reliable percentile of occurrence

Population group	N of surveys	Min MB (LB–UB) (μg/kg bw per day)	Median MB (LB–UB) (μg/kg bw per day)	Max MB (LB–UB) (μg/kg bw per day)
Infants	6	0.63 (0.40–0.95)	1.0 (0.80–1.4)	1.7 (1.4–2.1)
Toddlers	10	0.81 (0.62–1.2)	1.2 (0.90–1.6)	2.0 (1.8–2.3)
Other children	18	0.54 (0.41–0.74)	1.0 (0.80–1.1)	1.4 (1.3–1.7)
Adolescents	17	0.32 (0.26–0.41)	0.52 (0.46–0.64)	1.2 (1.1–1.2)
Adults	17	0.42 (0.39–0.46)	0.61 (0.53–0.71)	0.95 (0.89–1.0)
Elderly	14	0.44 (0.36–0.53)	0.68 (0.61–0.77)	1.0 (1.0–1.2)
Very elderly	12	0.46 (0.38–0.56)	0.75 (0.68–0.83)	1.2 (1.1–1.3)
Lactating women	1	0.54 (0.50–0.60)	–	0.54 (0.50–0.60)
Pregnant women	1	0.77 (0.70–0.86)	–	0.77 (0.70–0.86)

MB: middle-bound; LB: lower bound; UB: upper bound; bw: body weight.

Table 7: P95 of short-term dietary exposure (μg/kg bw per day) to perchlorate (including suspect samples) across national dietary surveys, using the highest reliable percentile of occurrence

Population group	N of surveys	Min MB (LB–UB) (μg/kg bw per day)	Median MB (LB–UB) (μg/kg bw per day)	Max MB (LB–UB) (μg/kg bw per day)
Infants	5	1.3 (1.0–1.8)	–	5.4 (4.9–6.0)
Toddlers	7	1.7 (1.5–2.1)	2.3 (2.1–2.8)	6.1 (5.6–6.5)
Other children	18	1.1 (0.94–1.5)	2.2 (2.0–2.5)	5.2 (5.1–5.4)
Adolescents	17	0.76 (0.67–0.91)	1.4 (1.3–1.6)	3.7
Adults	17	1.0 (0.92–1.0)	1.5 (1.3–1.6)	3.3 (3.2–3.3)
Elderly	14	0.88 (0.74–1.0)	1.5 (1.4–1.7)	3.4 (3.3–3.5)

Population group	N of surveys	Min MB (LB–UB) (μg/kg bw per day)	Median MB (LB–UB) (μg/kg bw per day)	Max MB (LB–UB) (μg/kg bw per day)
Very elderly	9	0.93 (0.83–1.1)	1.8 (1.7–2.0)	3.5 (3.5–3.6)
Lactating women	1	1.8 (1.7–1.8)	–	1.8 (1.7–1.8)
Pregnant women	1	1.5 (1.4–1.6)	–	1.5 (1.4–1.6)

MB: middle-bound; LB: lower bound; UB: upper bound; bw: body weight.

3.3. Uncertainty analysis

3.3.1. Exposure model/exposure scenario

EFSA received 18,217 analytical results on perchlorate submitted by 16 countries and some European food business associations, but 80% of the data were from two countries only. The majority of the samples belonged to the food groups 'Vegetables and vegetable products' and 'Fruits and fruit products'. 'Grains and grain-based products' were excluded from the dietary exposure assessment considering that all available analytical results were not quantified. Data from the EFSA CONTAM opinion were used for perchlorate occurrence in beer; for several FoodEx1 food groups where analytical results were not available, values from other similar or related food groups in the same categories, represented in the data set, were used.

The limited occurrence data of perchlorate in several food groups in Europe increases the uncertainty of the estimated exposure. Assumptions were done in relation to soft drinks (assumed to contain the same levels as water) and beer (using default value from the literature). Additional uncertainty comes from possible differences in perchlorate contamination of food commodities due to regional, seasonal and technological differences and it is reasonably assumed that the data set is not fully representing the food on the EU market. The relatively high number of left-censored data, which are treated with the LB, MB and UB approaches also influences the uncertainty of the assessment because the LB scenario potentially underestimates the occurrence and exposure calculation while the UB scenario potentially overestimates them; the uncertainty of the MB scenario could potentially go in either direction.

Perchlorate can contaminate food and drinking water via different sources: fertilisers, irrigation with perchlorate-contaminated water and water disinfection with chlorinated substances that potentially degrade to perchlorate are some sources. The representativeness of the data with respect to the heterogeneity of the sources cannot be inferred from the data set. Overall, there is still considerable uncertainty regarding the dietary exposure to perchlorate.

3.3.2. Summary of uncertainties

In Table 8, a summary of the uncertainty evaluation is presented for perchlorate highlighting the main sources of uncertainty related to occurrence and exposure calculations; the table also reports an estimate of whether the respective source of uncertainty might have led to an over- or under-estimation of the exposure.

Table 8: Summary of qualitative evaluation of the impact of uncertainties on the evaluation of occurrence and dietary exposure of perchlorate

Sources of uncertainty	Direction[(a)]
Extrapolation of occurrence data to whole Europe while data are in large majority from two countries plus few data from many other countries/providers	+/–
Occurrence data available for a limited number of food commodities; values attributed from other similar commodities	+/–
Possible insufficiency of the data set to represent the heterogeneity related to regions, seasons and agricultural practices.	+/–
Limited consumption data for infants and lactating/pregnant women	+/–
Relatively high number of left-censored data	– (LB scenario) +/– (MB scenario) + (UB scenario)

(a): + = uncertainty with potential to cause overestimation of exposure/risk; – = uncertainty with potential to cause under-estimation of exposure/risk.

Considering that the identified uncertainties may lead to over- or under-estimation of exposure the impact of the uncertainties on the assessment of human chronic exposure to perchlorate is considered moderate, and is greater for the short-term exposure.

4. Conclusions

- The European Commission requested EFSA to perform an updated human exposure assessment to perchlorate taking into account the occurrence data available in the EFSA database from samples taken after 1 September 2013. Based on this mandate, 18,217 analytical results corresponding to the requested criteria were extracted from the EFSA database on 6 April 2017 and analysed to determine the occurrence levels in different food groups and consequently estimate the human dietary exposure to perchlorate.
- Almost 94% of the data were submitted by governmental organisations of 16 European countries and roughly 6% from food business operators. However, the distribution of the data among reporting countries was not balanced since 2 countries alone accounted for 80% of the data (one for 68%).
- Overall, almost 77% of the data were left-censored and these data were treated comparing the LB, UB and MB approaches.
- Relatively high mean MB occurrence values were found for vegetables in dried form, like 'Tea and herbs for infusion (solids)' (324 μg/kg) and 'Herbs, spices and condiments' (63 μg/kg); among the fresh vegetables, relatively high mean MB occurrence levels were found in 'Radishes' (117 μg/kg), 'Rocket salad, rucola' (75 μg/kg) and 'Spinach (fresh)' (132 μg/kg).
- The young population groups (infants, toddlers and other children) show higher chronic dietary exposure levels than the other groups: the range across dietary surveys of mean chronic exposure (minimum LB–maximum UB) is overall in these groups 0.04–0.61 μg/kg bw per day, while in the older population groups, the range is 0.04–0.19 μg/kg bw per day. Similarly, in the young population groups, the range of P95 of chronic dietary exposure is 0.09–1.0 μg/kg bw per day, while in the older population groups, it is 0.07–0.34 μg/kg bw per day.
- 'Vegetable and vegetable products', 'Milk and dairy products' and 'Fruit and fruit products' are important contributors to the exposure across all population groups. Other food groups are more relevant for specific population groups, like 'Food for infants and small children' among Infants and Toddlers, 'Fruit and vegetable juices' among toddlers, other children and adolescents or 'Teas and herbal infusion (beverage)' among adults.
- The range across dietary surveys of mean short-term dietary exposure (minimum LB–maximum UB) for young population groups (infants, toddlers and other children) is overall 0.40–2.3 μg/kg bw per day, while in the older population groups, the range is 0.26–1.3 μg/kg bw per day. Similarly, in the young population groups, the range of P95 of short-term dietary exposure is 0.94–6.5 μg/kg bw per day, while in the older population groups, it is 0.67–3.6 μg/kg bw per day.
- The uncertainty in the exposure assessment mainly depends on the limitations of the analytical data set in terms of balanced coverage of the European market, representation of all relevant food groups and representation of the potential variability in regions, seasons, contamination sources and agricultural practices. The relatively high number of left-censored data also influences the uncertainty in the exposure assessment. Another source of uncertainty is the availability of only few food consumption surveys for infants and only one survey for pregnant and lactating women.

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Abbreviations

bw	body weight
EFSA CONTAM opinion	Opinion of the EFSA CONTAM Panel on the risks to public health related to the presence of perchlorate in food, in particular fruit and vegetables, issued in 2014
FoodEx1	EFSA food classification adopted for the Comprehensive Food Consumption Database
ID	Identifier
LB	lower bound
LC	left-censored values. i.e. analytical values reported as <LOD or <LOQ
LOD	limit of detection
LOQ	limit of quantification
MB	middle bound
NIS	sodium-iodide symporter protein
RESVAL	Field of the EFSA standard sample description used to record the measured concentration value for a particular analysis
SDWH	Scientific Data Warehouse
SSD	Standard Sample Description (SSD1 = version 1; SSD2 = version 2)
TDI	tolerable daily intake
UB	upper bound

Annex A – Support tables for the occurrence and exposure sections

The file 'Annex A to perchlorate report with support tables.xlsx' collects the detailed support tables to which a reference is done in the main text of the opinion.

Annex A can be found in the online version of this output, under the section 'Supporting information', at: http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2017.5043/full