National Institute for Public Health and the Environment
Ministry of Health, Welfare and Sport

FRONT OFFICE FOOD AND PRODUCT SAFETY

Dietary exposure to chlorate of children 1 and 2 years of age and monitoring activities of chlorate outside the EU

Risk assessment requested by:	Office for Risk Assessment & Research (BuRO)
Risk assessment performed by:	RIVM
Date of request:	02-04-2020
Date of risk assessment:	28-05-2020 (draft version)
	22-06-2020 (final version)
	20-10-2020 (final version, v2[1])
	03-11-2020 (final version, v3[1])
Project number:	V/093130

Nederlandse samenvatting

Voedingsmiddelen voor baby's en jonge kinderen kunnen hoge concentraties van chloraat hebben. Chloraat kan in voedsel terechtkomen door de desinfectie van het water dat wordt gebruikt bij de productie van voedsel en drinkwater. In deze beoordeling is berekend hoeveel chloraat Nederlandse kinderen van 1 en 2 jaar binnen kunnen krijgen via voedsel en drinkwater. Hiervoor zijn concentraties van chloraat in voedingsmiddelen en drinkwater gecombineerd met gegevens over hoeveel kinderen hiervan eten of drinken. De inname van chloraat is berekend met verschillende waarden die zijn gegeven aan concentraties die lager waren dan de detectielimiet of die tussen de detectielimiet en de kwantificatielimiet van de meetmethode lagen. Concentraties die gelijk waren aan de kwantificatielimiet of hoger zijn als zodanig meegenomen in de berekening. Verder is de inname berekend met verschillende concentraties van chloraat in drinkwater variërend van 0 mg/kg, dus het drinkwater bevat geen chloraat, tot een hoge waarde van 0.011 mg/kg. Het meeste drinkwater in Nederland bevat geen chloraat. Chloraat kan schadelijk zijn voor de gezondheid na inname over een lange periode en na een hoge inname op één dag (= kortdurende inname). Beide innamen zijn berekend.

De mediane (P50) inname van chloraat over een lange periode varieerde van 0,05 tot 0,52 µg/kg lichaamsgewicht (lg) per dag. Een hoge inname (P95) over een lange periode varieerde van 0,60 tot 1,3 µg/kg lg per dag. De hoge kortdurende inname (P99,9) varieerde van 5,5 tot 5,9 µg/kg lg per dag. Opvolgmelkpoeder en pap droegen het meeste bij aan de inname van chloraat door kinderen van 1 en 2 jaar. Wanneer drinkwater chloraat bevat, was ook drinkwater een belangrijke bron voor de inname. De berekende innamen waren lager dan de innamen waarboven chloraat schadelijk kan zijn voor de gezondheid, 3 µg/kg lg per dag voor de inname over een lange periode en 36 µg/kg lg per dag voor de kortdurende inname. Er is daarom geen reden tot zorg voor kinderen van 1 en 2 jaar op basis van de gebruikte concentraties van chloraat in voedingsmiddelen en drinkwater.

[1] These assessments include changes to improve the text and to further clarify the presence of chlorate in drinking water.

Daarnaast zijn verschillende organisaties in landen buiten de EU gevraagd of in hun land voedsel voor baby's en jonge kinderen worden gemeten op chloraat en of er maximale grenzen zijn voor hoeveel chloraat er in dit voedsel mag zitten. Vier organisaties uit de landen Amerika, Australië en Nieuw-Zeeland, Japan en Canada hebben gereageerd op deze vraag. Alle reageerden negatief op beide vragen. Ook de Codex Alimentarius bevat geen maximale grenzen voor chloraat in voedsel.

Subject

High concentrations of chlorate are frequently detected in foods, including those for infants and toddlers. The Office for Risk Assessment & Research (BuRO) has asked the Front Office (FO) to calculate the exposure to chlorate from the diet of children 1 and 2 years of age based on food consumption data from the Dutch National Food Consumption Survey (DNFCS) of 2012-2016. The Netherlands Food and Consumer Product Safety Authority (NVWA) provided chlorate concentrations in foods for use in the exposure calculations.

In addition, BuRO has made an inventory of running monitoring activities and limits for chlorate in foods for infants and toddlers in other countries of the European Union (EU). To supplement this inventory, BuRO has asked FO to provide an overview of (reviews of) monitoring programmes and product limits in several large countries outside the EU.

Questions

1. What is the chronic (median or 50th percentile (P50) and 95th percentile (P95)) and acute exposure (P50, P95, 99th percentile (P99) and 99.9th percentile (P99.9)) to chlorate of children 1 and 2 years of age from their total diet, based on food consumption data from the DNFCS 2012-2016 and concentrations in foods analysed by the NVWA?
2. What is the chronic (P50 and P95) and acute exposure (P50, P95, P99 and P99.9) to chlorate of children 1 and 2 years of age from their total diet when no chlorate is present in drinking water?
3. Which foods contribute at least 10% to the total chronic and acute exposure to chlorate of children 1 and 2 years of age?
4. What is the contribution of foods meant for children 1 and 2 years of age to the total chronic and acute exposure to chlorate? These foods include follow-on formula powder, children's food in jars and cereal-based foods for children (such as porridge, and children's biscuits and cookies).
5. What is the contribution of drinking water to the total chronic and acute exposure to chlorate of children 1 and 2 years of age?
6. Which information is available about monitoring programs focussed on chlorate in foods for infants and toddlers and about product limits for chlorate in these foods in several large countries outside the EU?

Conclusion

1) The P50 (median) **chronic** exposure to chlorate of children 1 and 2 years of age from food and drinking water ranged from 0.08 to 0.52 µg/kg body weight (bw) per day, depending on the concentration of chlorate assigned to concentrations reported below the limit of detection (LOD) and between the LOD and the limit of quantification. The P95 chronic exposure ranged from 0.65 to 1.3 µg/kg bw per day. **Acute** exposure to chlorate from food and drinking water ranged from 0.05 to 0.49 µg/kg bw per day for the P50 and from 0.91 to 1.5 µg/kg bw per day for the P95. Ranges for the P99 and P99.9 acute dietary exposure were 2.4-2.8 µg/kg bw per day and 5.7-5.9 µg/kg bw per day, respectively.

2) When no chlorate is present in drinking water, which is relevant for most of the children living in the Netherlands, the P50 **chronic** exposure to chlorate of children 1 and 2 years of age from food ranged from 0.05 to 0.13 µg/kg bw per day and the P95 from 0.60 to 0.68 µg/kg bw per day. **Acute** exposure from food ranged from 0.007 to 0.09 µg/kg bw per day for the P50 and from 0.85 to 0.90 µg/kg bw per day for the P95. Ranges for the P99 and P99.9 acute dietary exposure were 2.2-2.3 µg/kg bw per day and 5.5-5.7 µg/kg bw per day, respectively.
3) To assess the exposure to chlorate of children 1 and 2 years of age, foods that were analysed for chlorate, including drinking water, were grouped in ten groups. Groups contributing at least 10% to the total chronic and acute dietary exposure to chlorate were follow-on formula powder, drinking water and porridge, when chlorate is present in drinking water.
4) Groups that consisted of foods specifically meant for children, such as follow-on formula (including drinking water), children's meals in jars, children's fruit in jars, children's biscuits and porridge, contributed 31% to 72% to the total chronic and acute exposure distribution of chlorate. When no chlorate is present in drinking water, percentages ranged from 58% to 79%.
5) When chlorate is present in drinking water, the contribution of drinking water to the chronic and acute dietary exposure to chlorate ranged from 22% to 65%. Of these contributions, 10% was from drinking water used in follow-on formula.
6) Information obtained from four major countries outside the EU shows that these countries do not perform specific monitoring programs focussed on chlorate in foods for infants and toddlers and do not have product limits for chlorate in these foods. In addition, no product limits for chlorate in foods for infants and toddlers have been established in the Codex Alimentarius.

1. Background

Chlorate (ClO_3^-) is a chemical that can be present in food and drinking water as a by-product of chlorine, chlorine dioxide or hypochlorite. These compounds may be used as disinfectants in food and drinking water processing. Chlorate was also used as a pesticide up to 2007. Since 2008, it can no longer be used according to Commission Decision No 2008/865/EC, and the default maximum residue limit (MRL) of 0.01 mg/kg is applicable to all foods.

Chlorate is frequently detected at higher concentrations in foods, including foods for infants and toddlers, than this default MRL. Currently, an amending Regulation is being developed in which temporary MRLs for chlorate are set based on the ALARA ('as low as reasonably possible') principle. The default level of 0.01 mg/kg cannot be achieved even with current best practices.[2] This amendment does not include MRLs for foods for infants and young children.

In 2015, the European Food Safety Authority (EFSA) Panel on Contaminants in the Food Chain (CONTAM) determined that chlorate may be adverse after both chronic and acute dietary exposure (EFSA, 2015). This Panel derived a tolerable daily intake (TDI) of 3 µg/kg body weight (bw) and an acute reference dose (ARfD) of 36 µg/kg bw. Critical effect of chlorate for the TDI is inhibition of iodine uptake, and the ARfD is based on formation of methaemoglobin.

BuRO has asked the FO to assess the dietary exposure to chlorate of children 1 and 2 years of age using consumption data from the most recent Dutch National Food Consumption

[2] eur-lex.europa.eu/legal-content/EN/ALL/?uri=PI_COM:Ares(2019)334046

Survey (DNFCS) of 2012-2016. Furthermore, BuRO has made an inventory of the ongoing monitoring activities and product limits for chlorate in foods for infants and young children in EU countries. In addition to this information, BuRO has asked the FO to provide information on monitoring programs for chlorate in foods for infants and young children and on product limits for chlorate in these foods in major countries outside the EU.

2. Dietary exposure assessment

2.1 Input data and exposure calculation

Consumption and concentration data

Chronic and acute dietary exposure to chlorate was calculated for children 1 and 2 years of age. DNFCS of 2012-2016 contains food consumption data of 440 children in this age group, recorded on two non-consecutive days. Concentration data of chlorate in foods measured in 2016-2019 were obtained from the Netherlands Food and Consumer Product Safety Authority (NVWA).

Chlorate may also be present in drinking water. To include this source of exposure in the calculations, concentrations measured in 2015-2019 were obtained from the REWAB (Registration Tool Water Quality Data) database. This database contains analytical results of numerous substances analysed in Dutch drinking water. These results are generated as part of the Dutch Drinking Water Act. Based on this act, Dutch drinking water companies routinely monitor sources of drinking water and drinking water derived from these sources. Results of these routine activities are collected in the REWAB database. REWAB data are used to compile annual reports on the quality of drinking water in the Netherlands, which are published by the Dutch Human Environment and Transport Inspectorate (e.g. ILT, 2018).

Mapping concentration and consumption data

Only concentrations of chlorate in foods consumed by children 1 and 2 years of age were included in the exposure assessment. For example, concentrations analysed in infant formula powder were not considered. Concentrations were grouped in ten groups:

1. Children’s meals in jars;
2. Children’s fruit in jars;
3. Children’s biscuits;
4. Drinking water;
5. Follow-on formula powder;
6. Fruit;
7. Leafy vegetables;
8. Other vegetables (including legumes, but excluding leafy vegetables);
9. Porridge;
10. Potatoes.

To calculate the exposure to chlorate, foods and beverages recorded in the DNFCS were mapped to these groups.

Concentrations of chlorate in herbs (n=4) and raw cereals (n=14) were not included in the exposure assessment. No consumption of herbs is recorded in the DNFCS. Concentrations in raw cereals referred to wheat (n=8), barley (n=4) and rye (n=1). For these cereals, no consumptions are recorded in the DNFCS for children 1 and 2 years of age, except for one child that had consumed boiled wheat.

Consumed amounts for follow-on formula are recorded as prepared formula in the DNFCS, whereas chlorate was analysed in powdered follow-on formula and drinking water. Hence, to include exposure to chlorate via the consumption of prepared formula in the assessment, consumed amounts of prepared formula were converted to consumed amounts of powdered formula and of drinking water. For this, it was considered that 13% of prepared formula was powdered formula and 87% drinking water. These percentages were based on the use of three scoops (each weighing 4.5 gram) of powdered formula per 90 ml drinking water.

For porridge, chlorate was analysed in cereals that are used to prepare porridge (n=21) and in ready-to-eat porridge (n=6). Concentrations in these two types of porridge were mapped to corresponding consumptions recorded in the DNFCS. For porridge that is prepared at home, it was considered that 10% of the consumed amounts were cereals.[3]

Concentrations analysed in potatoes were mapped to the consumption of potatoes and potato products, such as French fries, potato croquettes and pommes duchesses.

Lemonade, tea and bouillon are frequently consumed by children 1 and 2 years of age. These beverages are prepared at home and consist mainly of drinking water, and are therefore a potential source of chlorate exposure via drinking water in this age group. As consumed amounts of these beverages are reported as prepared in the DNFCS, these amounts were converted to consumed amounts of drinking water based on the following percentages of water for inclusion in the exposure assessment:

- Lemonade: 90%;[4]
- Tea: 100%
- Bouillon: 99%.[5]

Consumption of lemonade is also reported as a separate consumption of lemonade syrup and drinking water. For these entries, drinking water was included as such in the exposure assessment.

Lower bound, medium bound and upper bound scenario's

Concentrations of chlorate were reported as a numerical value at or above the limit of quantification (LOQ), as a value between the limit of detection (LOD) and the LOQ, or as undetectable (below the LOD). A lower bound (LB), medium bound (MB) and upper bound scenario (UB) were considered in the exposure assessment to quantify the uncertainty regarding the undetectable results and those reported between the LOD and the LOQ. In the LB scenario, all samples with an undetectable result were assumed to contain no chlorate, and samples with a reported value between the LOD and the LOQ were assumed to contain chlorate at the level of the LOD. Respective values were ½ LOD and ½ LOQ in the MB scenario, and LOD and LOQ in the UB scenario. Table 1 lists the concentrations assigned in the three scenarios. Concentrations reported as numerical values at or above the LOQ were used as such in the scenarios.

Chlorate concentrations in drinking water extracted from the REWAB database included only a minimum, maximum and mean concentration, and the total number of measurements per drinking water company. Based on these data, a mean LB concentration of 0.001 mg/L (half the lowest reported LOD) and a mean UB concentration of 0.011 mg/L were derived. Mean UB concentration was calculated as the average of the mean concentrations of the drinking water companies that reported chlorate concentrations above the LOD. Mean MB concentration was set at 0.006 mg/L, the average of the mean LB and mean UB

[3] Derived from the Dutch Food Composition Database (NEVO). Percentages cereals present in prepared porridge were 7-8%. A percentage of 10% was selected as a high value.
[4] Derived from the Dutch Food Composition Database (NEVO). Percentages drinking water mentioned differed per lemonade and ranged from 83-92%. A percentage of 90% was selected as a high value.
[5] Derived from the Dutch Food Composition Database (NEVO). Percentages of drinking water in bouillon were 98.1-98.6%.

Table 1. Concentrations assigned to results reported as below the LOD or below the LOQ[1] per exposure scenario

Period and scenario	Concentrations (mg/kg)	
	<LOD	<LOQ
2016 - 2018		
Lower bound	0	0.005
Medium bound	0.0025	0.005
Upper bound	0.005	0.01
2019		
Lower bound	0	0.0005
Medium bound	0.00025	0.0005
Upper bound	0.0005	0.001

LOD: limit of detection; LOQ: limit of quantification
[1] Results below the LOQ were reported as a value between the LOD and the LOQ.

concentration.[6]

Concentrations and consumed amounts for each group are listed in Appendices A and B, respectively.

Exposure calculation
Chronic exposure was calculated using the Observed Individual Mean (OIM) model as implemented in the Monte Carlo Risk Assessment (MCRA) calculation tool, version 8.3 (MCRA, 2019). Using the OIM model, the daily consumed amount of relevant foods and beverages by each child was multiplied by the relevant mean chlorate concentration and then summed, resulting in a total exposure per day for each child. Exposures were divided by the child's body weight, which was measured during a home visit. To obtain a measure for chronic exposure, exposures per day were averaged across the two consumption days present in the DNFCS for each child. Result was a distribution of two-day-average exposures for each child in the DNFCS.

This procedure was repeated 100 times using a bootstrap approach. For this, 100 food consumption and 100 concentration databases were generated by resampling the original databases and used to calculate exposure. This resulted in 100 distributions of two-day-average exposures for each child. For each distribution, the 50th (median; P50) and 95th (P95) percentiles of exposure were calculated, resulting in 100 P50s and 100 P95s. From these 100 P50s and P95s, the median value was calculated as the best estimate for the percentiles. The 95th uncertainty interval around the percentiles was also calculated. This uncertainty interval quantifies the uncertainty around the P50 and P95 due to the sample size of the food consumption and concentration databases (Efron, 1979; Efron & Tibshirani, 1993).

Acute exposure was calculated using Monte Carlo sampling as implemented in MCRA, version 8.3 (de Boer et al., 2019). In short, a consumption day was randomly drawn from the DNFCS database. Consumed amounts of relevant foods and beverages on that day were multiplied by randomly drawn single concentrations. Exposures per food and beverage were summed resulting in an exposure on one consumption day. This was repeated 10.000 times resulting in a distribution of exposures on 10.000 consumption days. This procedure was also performed 100 times using a bootstrap approach resulting in 100 distributions of 10.000 daily exposures. These distributions were used to calculate the P50, P95, and the 99th (P99) and 99.9th (P99.9) percentiles of exposure. As for chronic exposure, the median of these percentiles and the 95th uncertainty interval around the percentiles were calculated.

[6] (0.001 + 0.011)/2

Chronic and acute exposure distributions were weighed for small deviances in age, sex, region, level of education, level of urbanization, day of the week and season. This ensured that the exposures were representative for the Dutch population of 1- and 2-year-olds.

Contribution of each group to the total exposure distribution expressed as a percentage was calculated for each of the 100 exposure distributions, both chronic and acute. Mean contribution across these distributions is reported.

2.2 Results

Chronic exposure

The P50 and P95 chronic dietary exposure to chlorate is listed in Table 2, together with the mean contribution of the groups to the total exposure distribution. In all scenarios, drinking water and follow-on formula powder were important contributors to the total exposure distribution. In the LB scenario, porridge was also an important contributor to the exposure. For drinking water, 10% of the contribution was due to drinking water used in follow-on formula. Chlorate was not detected in fruit. Contribution of fruit to the MB and UB exposure distributions was due to substituting all undetectable results by ½ LOD (MB) or LOD (UB) (Table 1) and a high consumption level (mean=132 grams per day; Appendix B). Foods specifically meant for children, including follow-on formula (including drinking water), children's meals and fruit in jars, children's biscuits and porridge, contributed 72%, 39% and 31% in the LB, MB and UB scenarios, respectively, to the total exposure distribution.

Chronic dietary exposure to chlorate was also calculated when no chlorate is present in drinking water (Table 3). In that case, chronic exposure was especially reduced in the MB and UB scenario compared to the situation that chlorate is present in drinking water (Table 2). When there is no exposure to chlorate via the consumption of drinking water, follow-on formula powder, fruit and porridge were the most important contributors to the exposure (Table 3). Foods specifically meant for children contributed 79%, 65% and 58% in the LB, MB and UB scenarios, respectively, to the total exposure distribution.

LB and MB chronic exposures did not differ when no chlorate is present in drinking water; the LB exposure of 0.05 µg/kg bw per day was within the 95% confidence interval around the MB exposure (Table 3). Only difference between these two scenarios was the value assigned to undetectable results (Table 1). Due to this, difference in concentrations between these scenarios was small (Appendix A). The P95 exposure did not differ between the three scenarios when chlorate is not present in drinking water. Exposure in the upper 5% of the distribution was mainly due to the consumption of follow-on formula powder and porridge that both had chlorate at concentrations at or above the LOQ. When chlorate is present in drinking water, the P50 exposure differed between the three scenarios (Table 2). The P95 exposure was not different between the LB and MB scenario.

Acute exposure

LB, MB and UB percentiles of acute dietary exposure to chlorate are listed in Table 4. Calculations were performed considering that chlorate could either be present in drinking water or not. Difference in exposure to chlorate between the three scenarios decreased at higher percentiles, independent of whether chlorate is present in drinking water. Examining the exposure at the upper 0.1% of the total exposure distribution showed that the exposure was mainly due to the consumption of porridge that contained chlorate at concentrations at or above the LOQ.

Contribution of the groups to the total acute exposure distribution was the same as for the chronic exposure distribution (Tables 2 and 3).

Table 2. Chronic dietary exposure to chlorate of children 1 and 2 years of age and the mean contribution of the groups to the total chronic exposure distribution

Percentiles and contribution	Exposure in µg/kg body weight per day and contribution (%) per scenario		
	Lower bound[1]	Medium bound[2]	Upper bound[3]
P50	0.08 (0.06 - 0.13)[4]	0.30 (0.27 - 0.34)	0.52 (0.49 - 0.57)
P95	0.65 (0.29 - 1.0)	0.95 (0.64 - 1.4)	1.3 (1.1 - 1.8)
Contribution	Follow-on formula powder (34%)	Drinking water (57%)[5]	Drinking water (65%)[5]
	Drinking water (22%)[5]	Follow-on formula powder (15%)	Follow-on formula powder (10%)
	Porridge (17%)[6]	Porridge (8%)	Fruit (9%)
	Other vegetables (10%)[7]	Fruit (7%)	Porridge (6%)
	Children's meals in jars (10%)	Other vegetables (5%)	Other vegetables (4%)
	Leafy vegetables (6%)[8]	Children's meals in jars (4%)	Children's meals in jars (3%)
	Children's fruits in jars (1.2%)	Leafy vegetables (3%)	Leafy vegetables (2%)
	Children's biscuits (0.8%)	Children's fruit in jars (0.8%)	Children's fruit in jars (1.0%)
	Potato (0.7%)	Potato (0.6%)	Potato (0.7%)
	Fruit (-)	Children's biscuits (0.3%)	Children's biscuits (0.4%)

LOD: limit of detection; LOQ: limit of quantification; P50: median or 50th percentile; P95: 95th percentile

[1] Concentrations in food reported below the limit of detection (LOD) were substituted a value of zero, and those reported between the LOD and the limit of quantification (LOQ) were substituted a value equal to the LOD. Mean concentration in drinking water was equalled to the lowest reported LOD, 0.001 mg/L.

[2] Concentrations in food reported below the LOD were substituted a value equal to ½ LOD, and those reported between the LOD and the LOQ were substituted a value equal to ½ LOQ. Mean concentration in drinking water was the average of the mean lower bound and mean upper bound concentration in drinking water, 0.006 mg/L.

[3] Concentrations in food reported below the LOD were substituted a value equal to the LOD, and those reported between the LOD and the LOQ were substituted a value equal to the LOQ. Mean concentration in drinking water was the average of the mean concentrations reported by drinking water companies that reported chlorate concentrations above the LOD.

[4] Exposures in brackets are the lower and upper limit of the 95% confidence interval due to uncertainties caused by the sample size of the food consumption and concentration databases.

[5] Of this contribution, 10% was drinking water used in follow-on formula.

[6] This group includes cereals that are used to prepare porridge and ready-to-eat porridge.

[7] This group includes vegetables and legumes, excluding leafy vegetables (endive, lettuce and spinach).

[8] This group includes endive, lettuce and spinach.

Table 3. Chronic dietary exposure to chlorate of children 1 and 2 years of age and the contribution of the groups to the total chronic exposure distribution considering that drinking water does not contain chlorate

Percentiles and contribution	Exposure in µg/kg body weight per day and contribution (%) per scenario		
	Lower bound[1]	Medium bound[2]	Upper bound[3]
P50	0.05 (0.01 - 0.10)[4]	0.08 (0.05 - 0.13)	0.13 (0.10 - 0.17)
P95	0.60 (0.25 - 0.98)	0.60 (0.30 - 1.0)	0.68 (0.40 - 1.1)
Contribution	Follow-on formula powder (43%)	Follow-on formula powder (35%)	Follow-on formula powder (28%)
	Porridge (21%)[5]	Porridge (18%)	Fruit (25%)
	Other vegetables (13%)[6]	Fruit (16%)	Porridge (16%)
	Children's meals in jars (13%)	Other vegetables (11%)	Other vegetables (11%)
	Leafy vegetables (8%)[7]	Children's meals in jars (10%)	Children's meals in jars (10%)
	Children's fruits in jars (2%)	Leafy vegetables (6%)	Leafy vegetables (5%)
	Children's biscuits (1.0%)	Children's fruits in jars (2%)	Children's fruits in jars (3%)
	Potato (0.9%)	Potato (1.4%)	Potato (2%)
	Fruit (-)	Children's biscuits (0.8%)	Children's biscuits (1.2%)

LOD: limit of detection; LOQ: limit of quantification; P50: median or 50th percentile; P95: 95th percentile

[1] Concentrations in food reported below the limit of detection (LOD) were substituted a value of zero, and those reported between the LOD and the limit of quantification (LOQ) were substituted a value equal to the LOD.

[2] Concentrations in foods reported below the LOD were substituted a value equal to ½ LOD, and those reported between the LOD and the LOQ were substituted a value equal to ½ LOQ.

[3] Concentrations in food reported below the LOD were substituted a value equal to the LOD, and those reported between the LOD and the LOQ were substituted a value equal to the LOQ.

[4] Exposures in brackets are the lower and upper limit of the 95% confidence interval due to uncertainties caused by the sample size of the food consumption and concentration databases.

[5] This group includes cereals that are used to prepare porridge and ready-to-eat porridge.

[6] This group includes vegetables and legumes, excluding leafy vegetables (endive, lettuce and spinach).

[7] This group includes endive, lettuce and spinach.

Table 4. Acute dietary exposure to chlorate of children 1 and 2 years of age

Percentiles	Exposure per scenario in µg/kg body weight per day		
	Lower bound[1]	Medium bound[2]	Upper bound[3]
Chlorate in drinking water			
P50	0.05 (0.04 - 0.05)[4]	0.27 (0.25 - 0.29)	0.49 (0.47 - 0.53)
P95	0.91 (0.34 - 1.3)	1.2 (0.70 - 1.7)	1.5 (1.2 - 2.1)
P99	2.4 (1.2 - 3.4)	2.5 (1.5 - 4.0)	2.8 (2.0 - 4.4)
P99.9	5.7 (2.3 - 9.5)	5.7 (2.7 - 9.6)	5.9 (3.0 - 9.6)
No chlorate in drinking water			
P50	0.007 (0.006 - 0.010)	0.05 (0.04 - 0.05)	0.09 (0.09 - 0.10)
P95	0.85 (0.29 - 1.3)	0.85 (0.31 - 1.4)	0.90 (0.42 - 1.4)
P99	2.2 (1.2 - 3.5)	2.2 (1.1 - 3.5)	2.3 (1.2 - 3.6)
P99.9	5.5 (2.3 - 9.2)	5.6 (2.3 - 9.5)	5.7 (2.3 - 9.5)

LOD: limit of detection; LOQ: limit of quantification; P50: median or 50th percentile; P95: 95th percentile; P99: 99th percentile; P99.9: 99.9th percentile

[1] Concentrations in food reported below the limit of detection (LOD) were substituted a value of zero, and those reported between the LOD and the limit of quantification (LOQ) were substituted a value equal to the LOD. Concentration in drinking water was equalled to the lowest reported LOD, 0.001 mg/L.

[2] Concentrations in food reported below the LOD were substituted a value equal to ½ LOD, and those reported between the LOD and the LOQ were substituted a value equal to ½ LOQ. Concentration in drinking water was the average of the mean lower bound and mean upper bound concentration in drinking water, 0.006 mg/L.

[3] Concentrations in food reported below the LOD were substituted a value equal to the LOD, and those reported between the LOD and the LOQ were substituted a value equal to the LOQ. Concentration in drinking water was the average of the mean concentrations reported by the drinking water companies that reported chlorate concentrations above the LOD.

[4] Exposures in brackets are the lower and upper limit of the 95% confidence interval due to the sample size of the food consumption and concentration databases.

Same concentrations for chlorate in drinking water were used in the acute and chronic exposure assessment, whereas the variation in concentrations is of interest for the acute assessment. One company reported maximum chlorate concentrations of 0.012-0.066 mg/L during 2015-2019. These concentrations were higher than the mean UB concentration of 0.011 mg/L. Assuming that chlorate is present in drinking water at a high concentration of 0.050 mg/L resulted in a P99.9 UB acute exposure of 9.7 µg/kg bw per day and a contribution of drinking water to the total acute exposure distribution of 89%.

2.3 Exposure compared with HBGVs

Chronic and acute exposure to chlorate of children 1 and 2 years of age were well below the TDI of 3 µg/kg bw per day and the ARfD of 36 µg/kg bw per day, respectively. This was also true for the upper limits of the 95% confidence intervals (Tables 2, 3 and 4). Based on the available data, chronic and acute exposure to chlorate of children 1 and 2 years of age do not pose a safety concern.

2.4 Discussion

An important uncertainty in the chronic and acute exposure calculations was the chlorate concentration in drinking water. Concentrations used in the assessment were based on measurements reported in the REWAB database. This database contains chlorate concentrations analysed by a limited number of Dutch drinking water companies. Chlorate is only analysed if its presence is anticipated, due to disinfection of drinking water or because of its presence in surface water. It is therefore likely that chlorate is not present in drinking water available at most households in the Netherlands. However, when chlorate is present, the concentrations in drinking water used in the LB, MB and UB scenarios for the chronic exposure are expected to cover the range of values to which people may be exposed over a longer period. For the acute dietary exposure assessment, the same concentrations as in the chronic exposure assessment were used. However, for this type of assessment the variation in concentrations is of interest. When chlorate is present in drinking water, single concentrations of chlorate are needed to assess acute exposure, instead of minimum, mean and maximum values. The calculated acute exposure for the situation that chlorate is present in drinking water should therefore be considered as indicative.

Three beverages that are prepared at home and that consist for at least 90% of water were included in the exposure assessment. Other foods that contain water and can be prepared at home were not considered, such as soups, sauces and gravy, as well as foods that contain water and are industrially produced, such as soft drinks, low-fat margarine, fruit juices and water-based ice. Due to this, the exposure may have been underestimated.

Chlorate was also analysed in raw cereals, including wheat, barley and rye. Wheat is an important ingredient of foods that are consumed by children. Part of these foods were included in the exposure assessment, i.e. children's biscuits and porridge. However, other relevant foods were not covered, such as bread, biscuits, rusk, pasta and pancakes. These foods could have been included in the assessment by using a food conversion model. Such a model converts foods as consumed to their raw ingredients, including percentages. Considering the limited number of concentrations available for cereals and the uncertainty whether the analysed concentrations are representative for those in the ingredients used in foods, a food conversion model was not applied. This uncertainty can be addressed by measuring also other wheat-containing foods for chlorate.

3. Monitoring programmes and product limits in countries outside the EU

The FO asked five agencies in major countries outside the EU and the World Health Organization (WHO) for information on monitoring programs of chlorate and product limits for chlorate in foods for infants and young children in their countries. Information was received from four agencies and the WHO, which is reported below. A limited search on the internet did not yield additional information.

Codex Committee on Contaminants in Foods (WHO/FAO)
The Codex Committee on Contaminants in Foods (CCCF) of the Food and Agricultural Organization (FAO) and WHO has not set out recommendations for monitoring of chlorate in food. In the Codex Alimentarius, no product limits for chlorate in food have been established.

US Food and Drug Administration (FDA)
Currently, the US Food and Drug Administration (FDA) does not monitor chlorate in food or drinking water. The US Environmental Protection Agency (EPA) monitored concentrations of chlorate in drinking water from 2013 up to 2016 as part of its Unregulated Contaminant Monitoring Rule Three (UCMR3) program under the Safe Drinking Water Act. The data and information regarding this monitoring are available at:

- www.epa.gov/sites/production/files/2016-12/documents/810r16013.pdf;
- www.epa.gov/dwucmr/data-summary-third-unregulated-contaminant-monitoring-rule.

The FDA has not established product limits for chlorate in food. The US EPA calculated a health risk level (HRL) for chlorate of 210 µg/L in drinking water, using a reference dose of 0.03 mg/kg bw per day for a 70 kg adult ingesting 2 L of drinking water per day and a default relative source contribution of 20%.[7] However, this HRL was not a final concentration of chlorate in drinking water that is necessary to protect a particular population.

[7] www.federalregister.gov/documents/2014/10/20/2014-24582/announcement-of-preliminary-regulatory-determinations-for-contaminants-on-the-third-drinking-water

Food Standards Australia New Zealand (FSANZ)
Australia and New Zealand do not have a monitoring program for chlorate in food. In terms of monitoring programs at the national level, the Australian Total Diet Study looked at perchlorate in 2014.[8] Both countries do also not have product limits for chlorate in food or foods for infants and young children. On this basis, the Food Standards Australia New Zealand (FSANZ) would officially say that chlorate would need to be kept 'as low as reasonably achievable'.

Sodium chlorite is permitted as a processing aid (disinfectant) in the production of meat, fish, fruit and vegetables, in which chlorate (and chlorite, chlorous acid and chlorine dioxide) is permitted at the LOD. The only other 'limit' of chlorate is for drinking water in which chlorate (as a by-product of chlorination) may be present at a provisional guideline value of 0.7 mg/L, which is the same as the value of the WHO. On this basis, if drinking water, meat, fish, fruit or vegetables were to be used in foods for infants and young children, chlorate present in these foods should be consistent with these values.

Health Canada
Health Canada does not have a monitoring program for chlorate in food.

Canadian product limits (maximum levels, MLs) for chemical contaminants in food are set out in two separate lists. Part 2 of the 'List of Contaminants and Other Adulterating Substances in Foods' [9] includes regulatory MLs and this list is incorporated by reference into 'Division 15 of the Food and Drug Regulations (FDR)'.[10] The 'List of Maximum Levels for Various Chemical Contaminants in Foods' [11] includes additional MLs for chemical contaminants in foods. All MLs are established by Health Canada and are enforceable by the Canadian Food Inspection Agency (CFIA).

Health Canada does not have MLs for chlorate in foods for infants and young children. However, all foods sold in Canada are subject to 'Part I, Section 4 of the Food and Drugs Act' [12], which, in part, states that "no person shall sell an article of food that has in or on it any poisonous or harmful substances." Health Canada and the Canadian Food Inspection Agency (CFIA) conduct routine surveillance of a wide variety of contaminants in food. If elevated concentrations of contaminants are found in the absence of MLs, Health Canada will conduct health risk assessments on a case-by-case basis. If a potential safety concern is identified, appropriate risk management measures are taken to mitigate the health risk to Canadian consumers.

In terms of food additive use, there are no chlorates used directly as food additives. According to the 'List of Permitted Bleaching, Maturing or Dough Conditioning Agents' [13], chloride and chlorine dioxide are permitted for use in flour at a maximum level consistent with Good Manufacturing Practice.

Chlorine, chlorine dioxide and sodium hypochlorite may also be used in food processing in accordance with the Canadian food processing aid definition. However, as a food processing aid, there should be no or negligible residues of the food processing aid or its by-products

[8] www.foodstandards.gov.au/publications/Documents/1778-FSANZ_AustDietStudy-web.pdf
[9] www.canada.ca/en/health-canada/services/food-nutrition/food-safety/chemical-contaminants/contaminants-adulterating-substances-foods.html
[10] laws-lois.justice.gc.ca/eng/regulations/C.R.C.%2C_c._870/page-74.html#docCont
[11] www.canada.ca/en/health-canada/services/food-nutrition/food-safety/chemical-contaminants/maximum-levels-chemical-contaminants-foods.html
[12] laws-lois.justice.gc.ca/eng/acts/f-27/page-2.html#h-234067
[13] www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/2-bleaching-maturing-dough-conditioning-agents.html

remaining in the food. Health Canada is unaware of chlorates being used as a food processing aid.

Ministry of Health, Labour and Welfare of Japan
The Ministry of Health, Labour and Welfare (MHLW) does not have a monitoring program for chlorate in food.

There is a product limit (maximum level, ML) for chlorate in drinking water (more precisely, tap water or municipal water) established by the MHLW. In addition, there is an ML for pasteurized or disinfected "mineral water" (according to the definition of MHLW) of 0.6 mg/L. This level was calculated assuming a daily consumption of 2 L of water by a 50 kg individual and that the intake of chlorate from water occupies 80% of a TDI of 30 µg/kg bw.

No product limits are established for foods for infants or young children in Japan.

4. Conclusion

- The P50 (median) chronic exposure to chlorate of children 1 and 2 years of age from food and drinking water ranged from 0.08 to 0.52 µg/kg body weight (bw) per day, depending on the concentration of chlorate assigned to concentrations reported below the limit of detection (LOD) and between the LOD and the limit of quantification. The P95 chronic exposure ranged from 0.65 to 1.3 µg/kg bw per day. Acute exposure to chlorate from food and drinking water ranged from 0.05 to 0.49 µg/kg bw per day for the P50 and from 0.91 to 1.5 µg/kg bw per day for the P95. Ranges for the P99 and P99.9 acute dietary exposure were 2.4-2.8 µg/kg bw per day and 5.7-5.9 µg/kg bw per day, respectively.
- When no chlorate is present in drinking water, which is relevant for most of the children living in the Netherlands, the P50 chronic exposure to chlorate of children 1 and 2 years of age from food ranged from 0.05 to 0.13 µg/kg bw per day and the P95 from 0.60 to 0.68 µg/kg bw per day. Acute exposure from food ranged from 0.007 to 0.09 µg/kg bw per day for the P50 and from 0.85 to 0.90 µg/kg bw per day for the P95. Ranges for the P99 and P99.9 acute dietary exposure were 2.2-2.3 µg/kg bw per day and 5.5-5.7 µg/kg bw per day, respectively.
- To assess the exposure to chlorate of children 1 and 2 years of age, foods that were analysed for chlorate, including drinking water, were grouped in ten groups. Groups contributing at least 10% to the total chronic and acute dietary exposure to chlorate were follow-on formula powder, drinking water and porridge, when chlorate is present in drinking water.
- Groups that consisted of foods specifically meant for children, such as follow-on formula (including drinking water), children's meals in jars, children's fruit in jars, children's biscuits and porridge, contributed 31% to 72% to the total chronic and acute exposure distribution of chlorate. When no chlorate is present in drinking water, percentages ranged from 58% to 79%.
- When chlorate is present in drinking water, the contribution of drinking water to the chronic and acute dietary exposure to chlorate ranged from 22% to 65%. Of these contributions, 10% was from drinking water used in follow-on formula.
- Information obtained from four major countries outside the EU shows that these countries do not perform specific monitoring programs focussed on chlorate in foods for infants and toddlers and do not have product limits for chlorate in these foods. In addition, no product limits for chlorate in foods for infants and toddlers have been established in the Codex Alimentarius.

Acknowledgements

Harald Dik and Monique van der Aa of the Centre for Sustainability, Environment and Health (part of RIVM) are kindly acknowledged for providing chlorate concentrations in drinking water from the REWAB database, and for their input for the interpretation of these data.

References

Efron B (1979). Bootstrap methods: another look at the jackknife. Annals of Statistics 7: 1-26.

Efron B, Tibshirani R (1993). An introduction to the bootstrap. New York, Chapman & Hall.

EFSA (2015). Scientific Opinion on risks for public health related to the presence of chlorate in food. EFSA Journal;13(6):4135, 103 pp., doi:10.2903/j.efsa.2015.4135. Available from www.efsa.europa.eu.

ILT (2018). Drinkwaterkwaliteit 2018. Inspectie Leefomgeving en Transport, Den Haag. Available from www.rijksoverheid.nl/documenten/rapporten/2019/12/18/bijlage-rapport-drinkwaterkwaliteit-2018.

MCRA (2019). MCRA 8.3 a web-based program for Monte Carlo Risk Assessment. Reference Manual. February 2019. Bilthoven, Wageningen, The Netherlands and York, UK: Biometris, National Institute for Public Health and the Environment (RIVM), Wageningen UR, Food and Environmental Research Agency (Fera).

Appendix A. Concentrations of chlorate per group

Group	Number of samples[1]				Concentration (mg/kg)			
	Total	Below LOD	Between LOD and LOQ	At or above LOQ	Mean LB[2]	Mean MB[3]	Mean UB[4]	Range values at or above LOQ
Children's biscuits	4	0 (0)	4 (100)	0 (0)	0.005	0.005	0.01	Not applicable
Children's meals in jars	45	3 (7)	34 (76)	8 (18)	0.012	0.013	0.016	0.011 - 0.106
Children's fruits in jars	4	2 (50)	2 (50)	0 (0)	0.0025	0.0038	0.0075	Not applicable
Drinking water[5,6]	569	-	-	-	0.001	0.006	0.011	-
Follow-on formula powder	10	0 (0)	0 (0)	10 (100)	0.105	0.105	0.105	0.005 - 0.291
Fruit	25	25 (100)	0 (0)	0 (0)	0	0.0025	0.005	Not applicable
Leafy vegetables[7]	39	8 (21)	18 (46)	13 (33)	0.033	0.033	0.034	0.015 - 0.32
Other vegetables[8]	39	16 (41)	21 (54)	2 (5)	0.006	0.007	0.009	
Porridge[9]	27	1 (4)	24 (88)	2 (7)	0.009	0.009	0.012	0.025 - 0.152
Potatoes	6	1 (17)	5 (83)	0 (0)	0.0004	0.0008	0.0017	Not applicable

LB: lower bound; LOD: limit of detection; LOQ: limit of quantification; MB: medium bound; UB: upper bound
[1] Figure in brackets is the percentage of samples below the limit of detection (LOD).
[2] Concentrations in foods reported below the LOD were substituted a value of zero, and those reported between the LOD and the limit of quantification (LOQ) were substituted a value equal to the LOD.
[3] Concentrations in foods reported below the LOD were substituted a value equal to ½ LOD, and those reported between the LOD and the LOQ were substituted a value equal to ½ LOQ.
[4] Concentrations in foods reported below the LOD were substituted a value equal to the LOD, and those reported between the LOD and the LOQ were substituted a value equal to the LOQ.
[5] Number of samples below the LOD, between the LOD and the LOQ and at or above the LOQ could not be determined from the available data.
[6] Reported concentrations for drinking water included only minimum, maximum and mean concentrations of chlorate for each drinking water production station that analysed chlorate in drinking water. Based on these data, mean LB concentration was equalled to the lowest reported LOD. Mean MB concentration was calculated as the average of the mean LB and mean UB concentration. Mean UB concentration was the average of the mean concentrations reported by drinking water companies that reported chlorate concentrations above the LOD. Range of values at or above the LOQ was not available.
[7] This group includes endive, lettuce and spinach.
[8] This group includes vegetables and legumes, excluding leafy vegetables.
[9] This group included cereals that are used to prepare porridge and ready-to-eat porridge.

Appendix B. Consumed amounts per group

Group	Consumed amount (grams)		Number of consumption days[1,2]
	Mean	P95	
Children's biscuits	3.2	20	154 (18)
Children's fruit in jars[3]	9.5	90	71 (8)
Children's meals in jars	15	200	72 (8)
Drinking water	462	481	845 (96)
Follow-on formula powder	6.9	44	162 (18)
Fruit	132	300	743 (84)
Leafy vegetables[4]	4.0	27	76 (9)
Other vegetables[5]	34	136	489 (56)
Porridge[6]	29	206	280 (32)
Potatoes	35	134	441 (50)

P95: 95th percentile
[1] Total number of consumption days equals 880.
[2] Figure in brackets is the percentage of consumption days.
[3] This group includes 'knijpfruit'.
[4] This group includes endive, lettuce and spinach.
[5] This group includes vegetables and legumes, excluding leafy vegetables.
[6] This group includes cereals that are used to prepare porridge, ready-to-eat porridge and porridge that is prepared with cereals at home. In the exposure assessment, consumed amounts of porridge that is prepared with cereals at home were converted to consumed amounts of cereals that are used to prepare porridge assuming that prepared porridge contains 10% cereals.