Bundesinstitut für Risikobewertung

EU proposal for maximum perchlorate concentrations in foods is inadequate

Updated BfR Opinion No. 027/2013, 9 July 2013

The Federal Institute for Risk Assessment (BfR) has been provided with non-representative monitoring data based on four independent data sources in which perchlorate residues were found in various foods from more than 15 different countries of origin. Some samples of citrus fruit, exotic fruit, root vegetables, fruiting vegetables, brassica vegetables and leaf vegetables contained perchlorate concentrations that can have undesirable effects on health if large portions are consumed on a one-time basis (see BfR Opinion no. 022/2013, dated 28 June 2013).

The EU Commission has commissioned the European Food Safety Authority (EFSA) to conduct a comprehensive risk assessment. As a provisional enforcement approach until this assessment is completed, the EU Commission has initially proposed a general reference value of 0.5 milligrams (mg) per kilogram (kg) of food for perchlorate concentrations in fruit and vegetables. The proposal was adapted following discussions with the member states, and the following provisional enforcement approach was adopted on 16 July 2013: the reference value is 0.2 mg per kg for citrus fruit, pome fruit, root and tuber vegetables, table grapes, spinach, melons and water melons, 1.0 mg per kg for leaf vegetables (apart from spinach), fresh herbs and celery grown in glasshouses/under cover, and 0.5 mg per kg for all other fruit and vegetable products.

The BfR welcomes the partial lowering of reference values to 0.2 mg per kg. However, the BfR does not consider the adopted values to be suitable to adequately protect consumers against potential health risks due to the consumption of large portions of fruit and vegetable products with perchlorate residues. The BfR believes that only a concentration of 0.05 mg per kg would be acceptable for all fruit and vegetable products based on the assessment methodology used for pesticides.

As it is still not ultimately clear how perchlorate finds its way into foods, it is also unclear whether the presence of perchlorate in foods should be considered a "contaminant" or a "residue". The BfR recommends EFSA consults groups of experts for both assessment areas in its assessment of perchlorate.

1 Subject of the assessment

The BfR has assessed the reference values for perchlorate for fruit and vegetables proposed by the EU Commission.

2 Findings

With regard to the repeated consumption of average amounts of foods with perchlorate residues, the reference values for perchlorate defined by the EU Commission of 0.2 mg per kg for citrus fruit, pome fruit, root and tuber vegetables, table grapes, spinach, melons and water melons, 1.0 mg per kg for leaf vegetables (apart from spinach), fresh herbs and celery grown in glasshouses/under cover, and 0.5 mg per kg for all other fruit and vegetable products are suitable to adequately protect consumers against potential health impairments.

BfR Risk Profile:
Maximum level of perchlorate in foods
Opinion no. 027/2013

A	**Affected group**	**General population, children, people with thyroid disease or iodine deficiency**				
B	**Probability of health impairment due to one-time consumption of large portions of products with high concentrations**	Practically impossible	Improbable	**Possible**	Probable	Certain
C	**Severity of health impairment due to one-time consumption of large portions of products with high concentrations**	No impairment	**Slight impairment [reversible]**	Moderate impairment [reversible/irreversible]	Serious impairment [reversible/irreversible]	
D	**Validity of available data**	High: the most important data is available and there are no contradictions	**Medium: some important data is missing**	Low: much important data is missing or contradictory		
E	**Controllability by the consumer [1]**	Control not necessary	Controllable through precautionary measures	Controllable through avoidance	**Not controllable**	

Text fields with dark blue background highlighting characterise the properties of the risk assessed in this Opinion (see the text of the Opinion for more details)

Notes

The Risk Profile is designed to visualise the risk described in the BfR Opinion. It is not designed to permit risk comparisons. The Risk Profile should only be read together with the Opinion.

Line E - Controllability by the consumer
[1] – Efforts are needed on all levels to reduce the entry of perchlorate into the food chain and therefore to minimise the burden for consumers. In particular, it is necessary to investigate how perchlorate enters foods. The details in the line "Controllability by the consumer" are not designed to serve as a recommendation by the BfR but are of descriptive character.

FEDERAL INSTITUTE FOR RISK ASSESSMENT (BfR)

This does not apply, however, with regard to the short-term consumption of large portions of the foods in question. The short-term intake of perchlorate of the German population and European consumer groups exceeds the PMTDI (*provisional maximum tolerable daily intake*) of 0.01 mg per kg bodyweight used for assessment purposes based on current knowledge. The calculations were performed using the German Consumption Model (NVS II Model) and EFSA's Pesticide Residue Intake Model (PRIMo).

The BfR therefore considers the reference values defined by the EU Commission not to be suitable to adequately protect consumers against potential health impairments in the case of consumption of large portions of fruit and vegetables with perchlorate residues. The BfR believes that only a concentration of 0.05 mg per kg would be acceptable for all fruit and vegetable products based on the assessment methodology used for pesticides. Raising this limit to just 0.1 mg per kg would result in the PMTDI being exceeded in the case of oranges, pineapples, potatoes, melons and water melons. Any further increase in the admissible perchlorate residues would also increase the number of foods for which intake would exceed the PMTDI if one large portion was consumed.

As analysis of composite samples does not measure the individual concentrations of single food items, the consumption of a single piece of fruit of vegetable can lead to far higher

short-term intake than might be assumed based on the test result. The BfR therefore believes it is necessary to use so-called variability factors of the kind used in the assessment methodology for pesticides (see BfR Opinion No. 015/2013 dated 6 June 2013[1]) in order to avoid the problem of significantly underestimating the short-term intake of residues.

If there is evidence that there is no difference in perchlorate residues between individual units of foods, a variability factor would not be necessary, and a perchlorate residue of up to 0.2 mg per kg for fruit and vegetables would be safe from a health perspective. No such evidence is available at the current point in time, however.

It is still not ultimately clear how perchlorate finds its way into foods and whether the concentrations found should be considered contaminations or residues. As there are differences in the standard assessment approaches between contaminant law on the one hand and plant protection and biocide law on the other, the BfR recommends that EFSA consults experts from both assessment areas.

3 Assessment

3.1 Introduction

The EU Commission has initially proposed a general reference value of 0.5 milligrams (mg) per kilogram (kg) of food for perchlorate concentrations in fruit and vegetables. The proposal was adapted following discussions with the member states, and the following provisional enforcement approach was adopted on 16 July 2013: the reference value is 0.2 mg per kg for citrus fruit, pome fruit, root and tuber vegetables, table grapes, spinach, melons and water melons, 1.0 mg per kg for leaf vegetables (apart from spinach), fresh herbs and celery grown in glasshouses/under cover, and 0.5 mg per kg for all other fruit and vegetable products.

The BfR has analysed these values with regard to potential acute and chronic health impairments for consumers.

Since perchlorate has not been assessed in the framework of the EU active substances programme and currently no toxicological studies on perchlorate are available to BfR, use was made of assessments conducted by the National Academy of Sciences (NAS), the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the United States Environmental Protection Agency (US EPA). The BfR recommends basing the acute and chronic risk assessment for consumers on the PMTDI of 0.01 mg/kg body weight derived by JECFA.

Consumer exposure was calculated using EFSA's PRIMo Model, which EFSA has published on its website[2] and which contains consumption data for numerous European consumer groups (children and adults, including the consumption data for German children). Additional calculations were performed using the German model (NVS II), which is available on the BfR website[3] and contains consumption data for German children between the ages of 2 and 4 as well as for the overall German population between the ages of 14 and 80.

[1] BfR, 2013: BfR recommendations on how to perform the consumer risk assessment for perchlorate residues in foods, BfR Opinion No. 015/2013 dated 6 June 2013, http://www.bfr.bund.de/cm/349/bfr-recommendations-on-how-to-perform-the-consumer-risk-assessment-for-perchlorate-residues-in-food.pdf

[2] http://www.efsa.europa.eu/en/mrls/docs/calculationacutechronic_2.xls

[3] http://www.bfr.bund.de/cm/349/bfr-model-for-pesticide-residue-intake-calculations-nvs2.zip

3.2 Calculation of short-term intake and assessment of potential acute health impairments

The BfR chose a sequential procedure in order to investigate the reference values defined by the EU Commission with regard to potential acute health impairments for consumers based on these concentrations as well as to pave the way for future decisions: in the first step, a perchlorate concentration of 0.5 mg per kg was assumed for all fruit and vegetable products, in the second step a concentration of 0.2 mg per kg, and in the third step a concentration of 0.1 mg pro kg.

With regard to short-term intake, it is first generally necessary to determine the extent to which the variability of residue concentrations in individual units of raw foods should be included in exposure calculations. The standard analysis of composite samples (normally consisting of 5 to 10 individual units) neglects the individual concentrations of single units in favour of a robust estimate of average residues in the overall "lot". Even though this proven method is highly suitable for the legal assessment of a large lot (e.g. the yield of an entire field or an entire container) when determining compliance with maximum residue concentrations, for example, it can also result in significant underestimation of the de facto exposure of consumers.

Only one or a small number of units of the product in question are normally consumed, so that the residues with which consumers come into contact are sometimes higher, sometimes lower than the average. This unequal distribution of residues is due to natural fluctuations and a result of numerous factors such as plant morphology, the contamination pathway, the properties of the product and the way the foods are stored and packaged. Variability does not depend on the type of residue. For all foods whose properties make it likely that residues are unevenly distributed, therefore the so-called "variability factor" was introduced, which is currently chiefly used for pesticide assessment but which is also suitable for use in the assessment of residues of other chemicals such as perchlorate. Statistical evaluations of residue data showed that the 2.5% of the individual units with the highest contamination had residue concentrations that were 3 to 7 times higher than the average value based on all individual values. The consumption of a single piece of fruit or vegetable can therefore lead to a far higher short-term intake than would be assumed based on the analytical result.

Variabilities can be neglected in the following cases:

- The consumed quantity of the raw product consists of many small individual units (e.g. blueberries or strawberries). In this case, an individual high residue would have no effect, as many units with lower residues would be consumed at the same time and this would result in a moderate overall residue level.
- The product has been industrially processed and blended during this process (e.g. juices).
- The sample corresponds to the total consumed portion (e.g. finished products).

As these criteria do not apply to many fresh fruit and vegetable products, the BfR believes that it is necessary to use variability factors to calculate the intake of perchlorates in order to ensure that the short-term intake of residues is not significantly underestimated.

The standard variability factors of up to 7 used in the field of pesticides were therefore used to estimate acute perchlorate intake due to the consumption of fruit and vegetables. An additional calculation was performed using a variability factor of 1 (which equates to even distribution of residues) in order to prepare recommendations for action for the risk management authorities. Table 1 lists all products for which levels above the PMTDI were calculated using at least one of the assessment methods (i.e. using the variability factors of up to 7 as out-

lined in the EFSA PRIMo, or using a variability factor of 1). The calculated intake is below the PMTDI for all non-listed products (fruit and vegetables according to Annex I of Regulation (EC) No. 396/2005).

Table 1: Foods from the "fruit and vegetables" groups for which consumption of a large portion (short-term intake) results in the PMTDI for perchlorate being exceeded if the food in question contains perchlorate in a concentration of 0.5 mg per kg

Food	Variability factor up to 7			Variability factor of 1		
	PRIMo	NVS II – children, 2–4 yrs of age	NVS II – adults, 14–80 yrs of age	PRIMo	NVS II – children, 2–4 yrs of age	NVS II – adults, 14–80 yrs of age
Citrus fruit						
Grapefruit	**446%**	**391%**	72%	**111%**	81%	14%
Oranges	**663%**	**434%**	81%	**111%**	72%	21%
Orange juice	no data	not applicable - no variability in juice		no data	**264%**	52%
Lemons	**172%**	**260%**	25%	14%	37%	4%
Mandarins	**278%**	**260%**	36%	71%	72%	13%
Pome fruit						
Apples	**490%**	**464%**	**123%**	**104%**	75%	39%
Apple juice	no data	not applicable - no variability in juice		no data	**271%**	74%
Pears	**455%**	**464%**	**111%**	72%	70%	22%
Stone fruit						
Apricots	**155%**	**174%**	51%	62%	69%	32%
Peaches	**297%**	**393%**	83%	60%	68%	24%
Plums	**165%**	**194%**	84%	71%	37%	43%
Berries and small fruit						
Table grapes	**327%**	**357%**	**149%**	66%	71%	30%
Grape juice	no data	not applicable - no variability in juice		no data	**161%**	33%
Other fruit						
Kakis	**199%**	**230%**	96%	29%	33%	27%
Kiwis	**201%**	**234%**	48%	62%	61%	12%
Avocados	**169%**	**253%**	74%	24%	36%	11%
Bananas	**418%**	**342%**	49%	73%	75%	11%
Mangos	**393%**	**236%**	98%	56%	34%	19%
Pomegranates	**151%**	**119%**	28%	17%	17%	4%
Pineapple	**506%**	**221%**	81%	**101%**	44%	16%
Root and tuber vegetables						
Potatoes	**769%**	**270%**	64%	**110%**	69%	28%
Sweet potatoes	**102%**	no data	12% (processed)	15%	no data	12% (processed)
Yams	**218%**	no data	no data	31%	no data	no data
Beetroot	**219%**	63%	72%	50%	9%	15%
Carrots	**317%**	**174%**	33%	45%	46%	9%
Carrot juice	no data	not applicable - no variability in juice		no data	**180%**	12%
Celeriac	**277%**	22%	49%	55%	4%	10%
Parsnips	**181%**	28% (processed)	15%	26%	28% (processed)	2%
Radishes	**110%**	86%	47%	16%	12%	7%
Salsify	**196%**	45% (processed)	33% (processed)	28%	45% (processed)	33% (processed)
Turnips	**180%**	63% (processed)	**171%** (processed)	26%	13% (processed)	37% (processed)
Swedes	**259%**	no data	20% (processed)	26%	no data	20% (processed)

Food	Variability factor up to 7			Variability factor of 1		
	PRIMo	NVS II – children, 2–4 yrs of age	NVS II – adults, 14–80 yrs of age	PRIMo	NVS II – children, 2–4 yrs of age	NVS II – adults, 14–80 yrs of age
Bulb vegetables						
Onions	**199%**	53%	20%	31%	8%	3%
Fruiting vegetables						
Tomatoes	**291%**	**245%**	64%	51%	48%	16%
Peppers	**315%**	**296%**	69%	45%	46%	12%
Aubergines	**125%**	78%	**111%**	25%	16%	22%
Cucumbers	**292%**	**235%**	56%	59%	47%	11%
Courgettes	232%	**136%**	61%	33%	19%	9%
Melons	**758%**	**382%**	**201%**	**152%**	76%	40%
Pumpkins	**171%**	**116%** (processed)	42% (processed)	34%	23% (processed)	8% (processed)
Water melons	**611%**	**580%**	**165%**	**122%**	83%	29%
Sweetcorn	**367%**	45% (processed)	54%	52%	45% (processed)	13%
Brassica vegetables						
Broccoli	**291%**	**200%** (processed)	87% (processed)	42%	40% (processed)	19% (processed)
Cauliflower	**330%**	**191%** (processed)	67% (processed)	66%	38% (processed)	13% (processed)
Head cabbage	**263%**	100% (processed)	78% (processed)	53%	100% (processed)	78% (processed)
Chinese cabbage	**186%**	**137%** (processed)	70% (processed)	37%	27% (processed)	14% (processed)
Curly kale	**338%**	44% (processed)	33% (processed)	49%	44% (processed)	33% (processed)
Kohlrabi	**251%**	**259%**	57%	50%	52%	11%
Leaf vegetables						
Lettuce	**135%**	72%	17%	27%	24%	6%
Endives	**437%**	27%	10%	87%	27%	10%
Spinach	**113%**	47% (processed)	16% (processed)	**113%**	47% (processed)	16% (processed)
Chicory	**232%**	82%	67%	66%	12%	13%
Shoot vegetables						
Celery	**230%**	13%	74%	46%	3%	15%
Fennel	**102%**	30%	99%	20%	6%	20%
Leek	**295%**	98% (processed)	26% (processed)	42%	14% (processed)	4% (processed)
Rhubarb	**186%**	44%	<1%	29%	44%	<1%

Based on consumption of a large portion of the food in question and taking account of the variability of individual units, the calculated perchlorate intake for numerous foods exceeded the PMTDI. With this scenario, there is the possibility that consumers may suffer undesirable health effects due to the consumption of these foods. Even if it is assumed that the residues are evenly distributed (variability factor 1), levels exceeding the PMTDI were still calculated in the case of oranges, grapefruit, orange juice, apples, apple juice, grape juice, pineapples, potatoes, carrot juice, melons and water melons, which means that consumers might suffer undesirable health effects due to the consumption of these foods. With regard to the short-term intake of a large portion of foods with high perchlorate concentrations, therefore, a general perchlorate residue of 0.5 mg per kg in fruit and vegetables is not acceptable from a health perspective.

In a second step, therefore, the short-term intake of perchlorate due to the consumption of fruit and vegetables was calculated based on a perchlorate residue of just 0.2 mg per kg.

Table 2 lists all products for which levels above the PMTDI were calculated using at least one of the methods in question (i.e. using the variability factors of EFSA PRIMo, or using a variability factor of 1). The calculated intake is below the PMTDI for all non-listed products (fruit and vegetables according to Annex I of Regulation (EC) No. 396/2005).

Table 2: Foods from the "fruit and vegetables" groups for which consumption of a large portion (short-term intake) results in the PMTDI for perchlorate being exceeded if the food in question contains perchlorate in a concentration of 0.2 mg per kg

Food	Variability factor up to 7			Variability factor of 1		
	PRIMo	NVS II – children, 2–4 yrs of age	NVS II – adults, 14–80 yrs of age	PRIMo	NVS II – children, 2–4 yrs of age	NVS II – adults, 14–80 yrs of age
Citrus fruit						
Grapefruit	178%	157%	29%	44%	32%	6%
Oranges	265%	174%	32%	45%	29%	9%
Orange juice	no data	not applicable - no variability in juice		no data	105%	21%
Lemons		104%	10%		15%	1%
Mandarins	111%	104%	15%	29%	29%	5%
Pome fruit						
Apples	196%	186%	49%	41%	30%	16%
Apple juice	no data	not applicable - no variability in juice		no data	108%	30%
Pears	182%	186%	44%	29%	28%	9%
Stone fruit						
Peaches	119%	157%	33%	24%	27%	10%
Berries and small fruit						
Table grapes	131%	143%	60%	26%	29%	12%
Grape juice	no data	not applicable - no variability in juice		no data	64%	13%
Other fruit						
Bananas	167%	137%	20%	29%	30%	5%
Mangos	157%	95%	39%	23%	14%	8%
Pineapples	202%	88%	32%	41%	18%	6%
Root and tuber vegetables						
Potatoes	308%	108%	26%	44%	27%	11%
Carrots	127%	70%	13%	18%	18%	4%
Carrot juice	no data	not applicable - no variability in juice		no data	72%	5%
Celeriac	111%	9% (processed)	20%	22%	2% (processed)	4%
Swedes	103%	25% (processed)	68% (processed)	21%	5% (processed)	15% (processed)
Fruiting vegetables						
Tomatoes	116%	98%	26%	20%	19%	6%
Peppers	126%	118%	28%	18%	18%	5%
Cucumbers	117%	94%	22%	23%	19%	4%
Melons	303%	153%	80%	61%	31%	16%
Water melons	245%	166%	48%	49%	33%	11%
Sweetcorn	147%	18% (processed)	22%	21%	18% (processed)	5%
Brassica vegetables						
Broccoli	117%	80% (processed)	35% (processed)	17%	16% (processed)	8% (processed)
Cauliflower	132%	76% (processed)	27% (processed)	26%	15% (processed)	5% (processed)
Head cabbage	105%	40% (processed)	31% (processed)	21%	13% (processed)	10% (processed)

Food	Variability factor up to 7			Variability factor of 1		
	PRIMo	NVS II – children, 2–4 yrs of age	NVS II – adults, 14–80 yrs of age	PRIMo	NVS II – children, 2–4 yrs of age	NVS II – adults, 14–80 yrs of age
Curly kale	135%	18% (processed)	13% (processed)	19%	18% (processed)	13% (processed)
Kohlrabi	100%	259%	57%	20%	52%	11%
Leaf vegetables						
Endives	175%	11%	4%	35%	11%	4%
Shoot vegetables						
Leek	118%	39% (processed)	10%	17%	6% (processed)	1 %

Based on consumption of a large portion of the food in question and taking account of the variability of individual units, the calculated perchlorate intake for numerous foods still exceeded the PMTDI, which means that, under these conditions, there is the possibility that consumers may suffer undesirable health effects due to the consumption of these foods.

Based on the assumption that residues are evenly distributed (variability factor of 1), the only products for which intake levels slightly above the PMTDI were still calculated were orange juice and apple juice. Juices are usually less contaminated than the fruit from which they are made. It is not known whether this also applies for perchlorate, which is highly soluble in water. As it is, however, extremely unlikely that all fruit used in the industrial production of juice contains a perchlorate concentration of 0.2 mg per kg (and as blending tends to result in a lower average residue level), this "formal" exceeding of the PMTDI is seen as negligible. As a result, a perchlorate residue of 0.2 mg per kg in fruit and vegetables would be safe from a health perspective if it can be shown that the residues are evenly distributed among individual units.

As, however, no information is available to date that would justify application of "variability factor 1", and as inclusion of the variability of individual units still resulted in numerous intake levels exceeding the PMTDI, perchlorate intake based on the consumption of fruit and vegetables with a perchlorate residue of only 0.1 mg per kg was analysed in a third step. Table 3 lists all the products for which calculations (including use of the variability factors in EFSA's PRIMo Model) resulted in the PMTDI being exceeded. The calculated intake is below the PMTDI for all non-listed products (fruit and vegetables according to Annex I of Regulation (EC) No. 396/2005).

Table 3: Foods from the "fruit and vegetables" groups for which consumption of a large portion (short-term intake) results in the PMTDI for perchlorate being exceeded if the food in question contains perchlorate in a concentration of 0.1 mg per kg

Food	Variability factor up to 7		
	PRIMo	NVS II – children, 2–4 yrs of age	NVS II – adults, 14–80 yrs of age
Citrus fruit			
Oranges	**133%**	87%	16%
Other fruit			
Pineapples	**101%**	44%	16%
Root and tuber vegetables			
Potatoes	**154%**	54%	13%
Fruiting vegetables			
Melons	**152%**	76%	40%
Water melons	**122%**	**116%**	33%

Based on consumption of a large portion of the food in question and taking account of the variability of individual units, the calculated perchlorate intake for some foods still exceeded the PMTDI, which means that, under these conditions, there is the possibility that consumers may suffer undesirable health effects due to the consumption of these foods.

To ensure that no foods and no consumer group in Europe exceed the PMTDI even if the variability of individual units is taken into account, the admissible perchlorate residue in fruit and vegetables needs to be lowered to 0.05 mg per kg. Health impairment of consumers due to the consumption of even large portions of these foods would then be unlikely. The BfR therefore considers the reference values defined by the EU Commission not to be suitable to adequately protect consumers against potential health impairments in the case of consumption of large portions of fruit and vegetables with perchlorate residues.

3.3 Calculation of long-term intake and assessment of potential chronic health impairments

Calculation of long-term intake takes account of all foods, and it is assumed that all foods are contaminated with the chemical in question - in other words, that they contain perchlorate in the case at hand. However, these assumptions are based on the consumption of average portions (in contrast to the large portions used as the basis for the calculation of short-term intake).

The BfR chose a sequential procedure in order to investigate the reference values defined by the EU Commission with regard to potential chronic health impairments for consumers based on these concentrations as well as to pave the way for recommendations for risk management: in the first step, a perchlorate concentration of 0.5 mg per kg was assumed for all fruit and vegetable products; in a second step, the concentration was reduced to 0.2 mg per kg for the sub-group of "fruit" and "vegetables" that has the biggest share in the overall intake quantity. Where necessary, the concentration of a further sub-group was reduced to 0.2 mg per kg in a third step.

The last line in Table 4 supplies the most important result (all consumer groups from the EFSA PRIMo in which chronic intake exceeds the PMTDI are listed), while the two lines above it ("Fruit" and "Vegetables") provide information on the shares of these two sub-groups.

Table 4: Consumer groups for whom long-term consumption of average quantities of fruit and vegetables with perchlorate residues of 0.5 mg per kg (chronic intake) results in the PMTDI being exceeded

Commodity group	Exhaustion of the PMTDI		
	EFSA PRIMo	NVS II – children, 2–4 yrs of age	NVS II – adults, 14–80 yrs of age
Fruit	(DE child) **115.2%**	**120.2%**	34.0%
Vegetables	(FR infant) **104.7%**	37.6%	18.9%
Fruit and vegetables overall	(FR infant) **180.7**% (DE child) **152.2**% (FR toddler) **145.4**% (NL child) **131.7%** (WHO Cluster B) **108.3**%	**157.8**%	52.9%

If the perchlorate concentration in consumed fruit and vegetables is 0.5 mg per kg, the computed long-term intake based on average consumption quantities is higher than the PMTDI for 5 European consumer groups including German children, and undesirable health effects for these consumer groups due to the consumption of foods containing perchlorate are possible.

A lower residue of just 0.2 mg per kg was used instead of a level of 0.5 mg per kg for the sub-groups in the product groups "fruit" and "vegetables" (product groups in acc. with Annex I of Regulation (EC) No. 396/2005) that make the biggest contribution. In the case of fruit, the highest share comes from the sub-group "pome fruit"; with vegetables from the sub-group "root and tuber vegetables". If the residue for these two sub-groups is set at just 0.2 mg per kg, this alone reduces chronic overall intake to a value equivalent to a maximum of 106.9% of the PMTDI (see Table 5). The minor differences in the results for German children in the PRIMo and NVS II models are due to the fact that the PRIMo results are based on the average body weight of the entire group, whereas the results from the NVS II Model are based on individual ratios of consumption quantity and body weight.

Table 5: Refinement of the computed results shown in Table 4: perchlorate residue is limited to 0.2 mg per kg for each of the two sub-groups with the highest contribution to total intake

Commodity group	Exhaustion of the PMTDI		
	PRIMo	NVS II – children, 2–4 yrs of age	NVS II – adults, 14–80 yrs of age
Fruit without pome fruit (0.5 mg per kg) Pome fruit (0.2 mg per kg)	(DE child) 77.1%	80.6%	26.3%
Vegetables without root and tuber vegetables (0.5 mg per kg) Root and tuber vegetables (0.2 mg per kg)	(DE child)[a] 25.9%	26.3%	14.0%
Fruit and vegetables overall	(DE child) **103.0**%	**106.9**%	40.3%

[a] No refinement for the critical population group "FR infant" is possible for the group of "vegetables" in EFSA's PRIMo model. The chronic consumption data from France are contradictory, as the overall consumption amount for vegetables is far bigger than the sum of the consumption amounts for the vegetable sub-groups. The refinement for "vegetables" is therefore performed for the second most critical group of consumers (German children).

In order to ensure intake levels are below the PMTDI, the maximum residue must be reduced to 0.2 mg per kg for at least one other food sub-group. After pome fruit, citrus fruit account for the highest share of fruit eaten by German children. The results of the calculations in which perchlorate residue is limited to 0.2 mg per kg for pome fruit, citrus fruit, and root and tuber vegetables, and 0.5 mg per kg for all other fruit and vegetable groups, are shown in Table 6.

Table 6: Refinement of the computed results shown in Tables 4 and 5: perchlorate residue is limited to 0.2 mg per kg for each of the three sub-groups with the highest contribution to total intake

Commodity group	Exhaustion of the PMTDI		
	PRIMo	NVS II – children, 2–4 yrs of age	NVS II – adults, 14–80 yrs of age
Fruit without pome fruit and citrus fruit (0.5 mg per kg) Pome fruit and citrus fruit (0.2 mg per kg)	(DE child) 63.3%	66.0%	20.5%
Vegetables without root and tuber vegetables (0.5 mg per kg) Root and tuber vegetables (0.2 mg per kg)	(DE child)[a] 25.9%	26.3%	14.0%
Fruit and vegetables overall	(DE child) 89.2%	92.3%	34.5%

[a] See Table 5 for explanation

The basis for calculation is the repeated consumption of average quantities. If the residue level was limited to 0.2 mg per kg instead of 0.5 per kg for at least the three sub-groups which have the biggest share in long-term consumption (pome fruit, citrus fruit, root and tuber vegetables), this would result in a maximum intake below the PMTDI (highest exhaustion:

92.3%) for all European consumer groups. Undesirable health effects on consumers due to perchlorate residues would then be unlikely.

With regard to the repeated consumption of average amounts of fruit and vegetable products with perchlorate residues, the BfR therefore considers the reference values defined by the EU Commission to be suitable to adequately protect consumers against potential health impairments. A reference value of 0.2 mg per kg was defined in the sub-categories with the highest share in overall exposure (citrus fruit, pome fruit, and root and tuber vegetables), and a value of 0.5 mg per kg for most other fruit and vegetable products.

The special provision for leaf vegetables (apart from spinach), fresh herbs and celery grown in glasshouses/under cover (1.0 mg per kg) has no influence, as the consumed average amounts of these foods have no significant effect on the total average intake of fruit and vegetables.

4 Recommendations for action

Although the reference values for perchlorate defined by the EU Commission of 0.2 mg per kg for citrus fruit, pome fruit, root and tuber vegetables, table grapes, spinach, melons and water melons, 1.0 mg per kg for leaf vegetables (apart from spinach), fresh herbs and celery grown in glasshouses/under cover, and 0.5 mg per kg for all other fruit and vegetable products are suitable to adequately protect consumers against potential health impairments in the case of repeated consumption of average quantities of foods with perchlorate residues, this is not the case with short-term consumption of large portions of the foods in question. The short-term intake of perchlorate of the German population and European consumer groups exceeds the PMTDI of 0.01 mg per kg bodyweight used for assessment purposes based on current knowledge. The BfR therefore considers the reference values defined by the EU Commission not to be suitable to adequately protect consumers against potential health impairments in the case of consumption of large portions of fruit and vegetables with perchlorate residues.