Health assessment of perchlorate residues in foods

BfR Opinion No. 022/2013, 28 June 2013

The Federal Institute for Risk Assessment (BfR) has been provided with non-representative findings from official food surveillance as well as from industry quality control activities regarding perchlorate drawing on four independent data sources. Perchlorate residues above 0.01 milligrams per kilogram were found in 33% of tested food samples, while residues of over 0.05 milligrams per kilogram were also detected in 17% of samples.

The BfR has assessed the health risks resulting from these findings and discussed the possible pathways by which perchlorate enters foods. Levels were measured in one or more samples of citrus fruit, exotic fruit, root vegetables, fruiting vegetables, brassica vegetables and leaf vegetables which could potentially lead to undesirable effects if large portions are consumed on a one-time basis. This concerns in particular the inhibition of iodide uptake in the thyroid gland, which could possibly lead to changes in thyroid hormone levels in people with thyroid disease, people suffering from iodine deficiency, newborn babies and children. It is, however, improbable that chronic health impairment will result from the lifelong consumption of medium-sized portions of fruit or vegetables with average perchlorate concentrations.

There are many possible routes via which perchlorate can enter foods. It can, for example migrate from fertilisers to plants and therefore also to plant-based foods. Migration from contaminated overhead irrigation or standard irrigation water is also possible. Perchlorate might, for example, enter the water together with industrial waste water or occur as a by-product of the chlorination of drinking water. Chlorination of drinking water and irrigation using drinking water are not customary in Germany, however. A further potential entry route for perchlorate is the direct chlorination of foods in order to kill germs, for example; this practice is, however, prohibited in Europe.

Against this backdrop, the BfR recommends that efforts be undertaken to reduce the entry of perchlorate into the food chain and therefore to minimise the burden for consumers. As the illegal use of perchlorate for purposes such as the disinfection of foods cannot be ruled out, this potential entry pathway should be investigated on both national and European level and, if necessary, suitable measures taken to prevent this happening. Consumers should not make any major changes to their normal diets, as the health benefits of fruit and vegetables remain undisputed.

1 Subject of the assessment

The BfR has summarised its previous health assessments on perchlorate in an overall assessment and discussed possible routes by which perchlorate enters foods. The health assessment also incorporated the perchlorate findings reported in recent weeks. The investigation of potential entry pathways also took account of the information provided by the Federal Environment Agency (UBA), the Federal Office of Consumer Protection and Food Safety (BVL) and the Federal Institute for Occupational Safety and Health (BAuA). On 24 June 2013, the EU Commission commissioned the European Food Safety Authority (EFSA) to conduct a comprehensive risk assessment.

	BfR Risk Profile: Perchlorate finds in foods Opinion no. 022/2013				
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. (for more detailed information, please refer to the text in BfR Opinion no. 022/2013 dated 28 June 2013).

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. 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)

2 Findings

Perchlorate residues were found in various foods from more than 15 different countries of origin. The highest number of perchlorate findings were reported for citrus fruit, berries and small fruit, root vegetables, fruiting vegetables, leaf vegetables and fresh herbs.

On the assessment of the acute risk: in citrus fruit, exotic fruit, root vegetables, fruiting vegetables, brassica vegetables and leaf vegetables (incl. fresh herbs), perchlorate was found in concentrations in one or more samples that, on current knowledge and based on a one-time intake of perchlorate, exceed the provisional maximum tolerable daily intake (PMTDI) derived by JECFA (Joint FAO/WHO Expert Committee on Food Additives). This means undesirable effects are possible, in particular inhibition of iodine intake into the thyroid gland, a phenomenon that can possibly lead to changes in thyroid hormone levels in people with thyroid disease, people with iodine deficiency, newborn babies and children.

Based on current knowledge, the information on possible entry pathways of perchlorate into foods are summarised as follows:

- Entry via atmospheric deposits can be viewed as being negligible in Germany.
- Perchlorate is not formed in plants and does not occur naturally in plants.
- Perchlorate can be absorbed by plants from fertiliser and migrate to plant-based foods.
- Perchlorate can migrate from contaminated overhead or standard irrigation water to plant-based foods if this water contains high perchlorate concentrations.
- Perchlorate could enter the water together with industrial waste water (region-based) or through chlorination if chlorinated drinking water is used for irrigation (not applicable to Germany).
- Direct chlorination of foods is prohibited in Europe. The possibility cannot be ruled out, however, that such practices have taken place - in order, for example, to kill germs. This would then be a possibly entry route for perchlorate into foods.
- Direct entry of perchlorate into foods via approved application of plant protection products is unlikely.
- Migration of perchlorate from packaging material to foods is unlikely.

As the illegal use of perchlorate for purposes such as the disinfection of foods cannot be ruled out, this potential entry route should be investigated on both national and European level and, if necessary, suitable measures taken to prevent this happening.

3 Statement of reasons/Risk assessment

3.1 Introduction

Perchlorates are the salts of perchloric acid. They are generally easily soluble in water and stable at room temperature. They only decompose at high temperatures while giving off oxygen. Their occurrence in the environment is mainly due to anthropogenic, i.e. man-made, sources, but they may also occur naturally. Low quantities of perchlorates are also formed in the atmosphere by oxidation processes. They occur naturally in the mineral deposits of some countries such as in the Atacama Desert in Chile. The Chile saltpetre mined there is used as fertiliser and contains perchlorate. Perchlorates are currently neither approved as active ingredients in plant protection products nor in biocides, but they may be used as industrial chemicals and medications and may be released from rocket fuels and fireworks. Due to disproportionation, perchlorates can also be formed from hypochlorites, chlorites and chlorates, which in turn are used as disinfecting agents. Residues of perchlorate were detected in numerous fruit and vegetable products during quality controls in the food industry and during official food surveillance. At the current point in time, it is not definitively known how perchlorate has found its way into foods, in some cases in high concentrations. The discussion of potential pathways incorporated the insights gained by the Federal Environment Agency (U-BA), the Federal Office of Consumer Protection and Food Safety (BVL) and the Federal Institute for Occupational Safety and Health (BAuA).

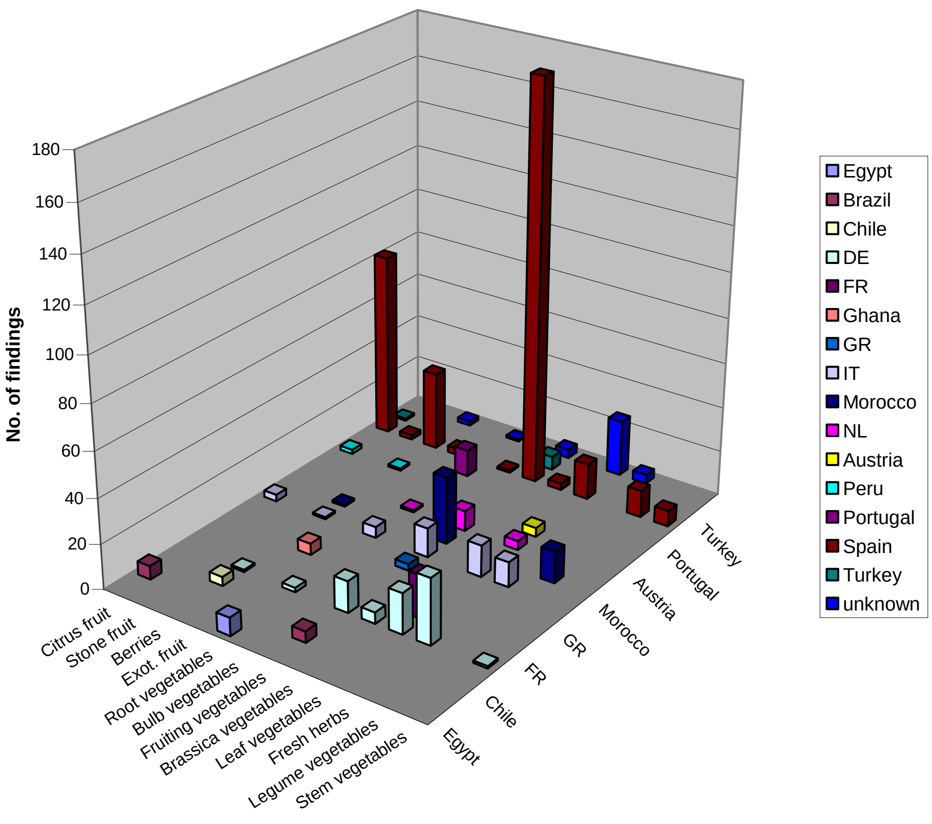
When "perchlorate" is mentioned in the following, we are referring to the perchlorate anion (chemical formula ClO_4^-), which was the subject of analytical detection in foods. It is not known which perchlorate compounds were contained in the foods.

3.2 Overview of perchlorate findings in foods to date

The Federal Institute for Risk Assessment (BfR) has meanwhile examined findings from official food surveillance as well as from industry quality control activities (a total of four different data sources, anonymised, correct as of 3 June 2013). This data is non-representative.

There follows a brief overview of the available data. The foods with measurable perchlorate residues came from over 15 different countries of origin. Some of the samples with perchlorate residues were labelled as organic products. A relatively high number of positive findings were reported for Spanish products, in particular citrus fruit, berries and small fruit and fruiting vegetables. It must be said, however, that a particularly high volume of Spanish products were imported in these product groups (and tested for perchlorate) during the period in question. German products were also tested positive for perchlorate, above all leaf vegetables, in particular fresh herbs, and fruiting vegetables. No perchlorate has been found in cereals, pulses, pome fruit, oilseeds, mushrooms and tree nuts to date, and perchlorate residues have been detected only very seldom in stone fruit and bulb vegetables.

Figure 1: Perchlorate findings > 0.01 mg/kg by country of origin *



*Only countries with more than two samples > 0.01 mg/kg are taken into account.

Figure 2: Residue concentrations of perchlorate in analysed foods

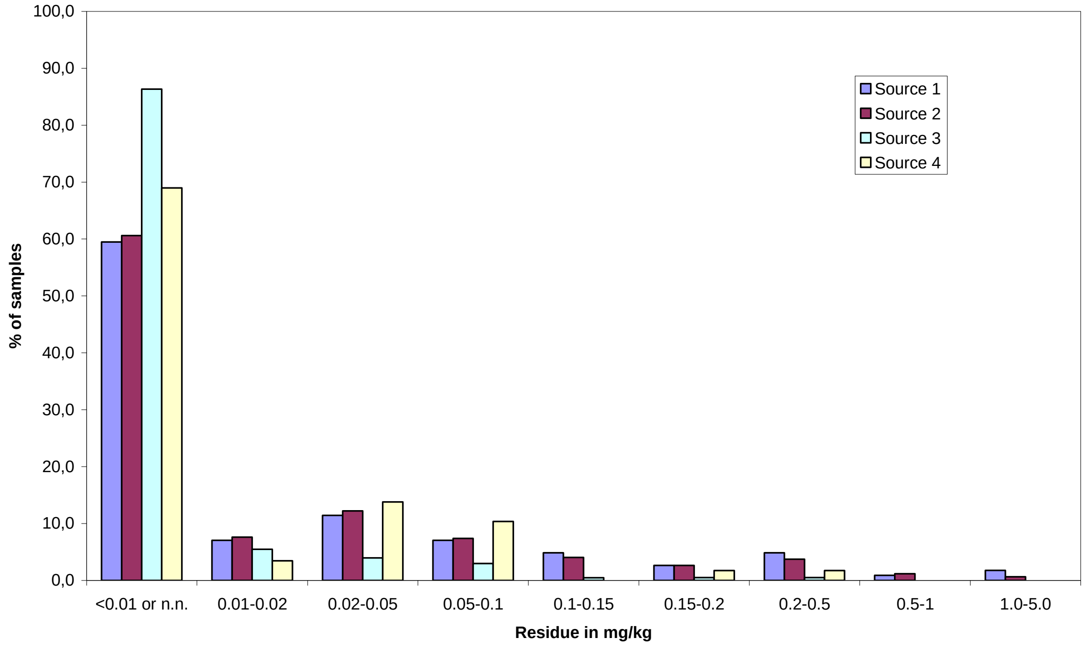
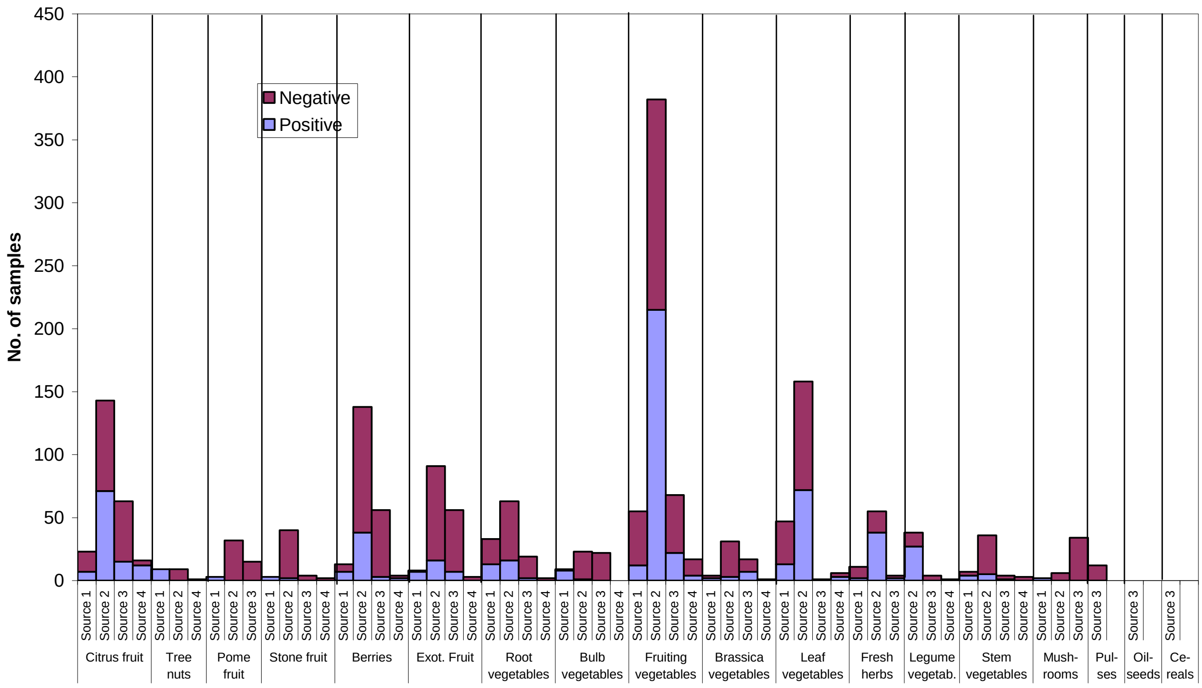


Figure 3: Perchlorate findings by food *



*Source 1, 2 and 4: determination limit 0.01 mg/kg; source 3: determination limit 0.005 mg/kg

Perchlorate residues > 0.01 mg/kg were found in 33% of the tested food samples, while residues of over 0.05 mg/kg were also detected in 17% of samples.

Several statistical indicators have been derived (all residue levels in mg/kg) for the various product groups based on the total data pool currently available to the BfR with regard to perchlorate residues:

Table 1: Evaluation of findings by product group

Product group	No. of positive findings *	Total no. of values	Median	Mean	90th perc.	95th perc.	Max.
Citrus fruit	115 (50 %)	240	0.0100	0.0335	0.069	0.150	1.100
Tree nuts	0	19	0.0100	0.0100	0.010	0.010	0.010
Pome fruit	0	50	0.0100	0.0085	0.010	0.010	0.010
Stone fruit	2 (4 %)	49	0.0100	0.0099	0.010	0.010	0.018
Berries	56 (27 %)	211	0.0100	0.0142	0.024	0.049	0.111
Exotic fruit	31 (20 %)	158	0.0100	0.0203	0.034	0.075	0.450
Root vegetables	60 (51 %)	118	0.0100	0.0394	0.120	0.163	1.160
Bulb vegetables	2 (4 %)	54	0.0100	0.0083	0.010	0.010	0.030
Fruiting vegetables	306 (59 %)	522	0.0110	0.0519	0.140	0.200	0.813
Brassica vegetables	13 (25 %)	53	0.0100	0.0147	0.021	0.028	0.190
Leaf vegetables	133 (63 %)	212	0.0100	0.1102	0.128	0.224	4.228
Fresh herbs	52 (76 %)	68	0.2020	0.8269	0.904	1.410	26.000
Legume vegetables	29 (67 %)	43	0.0560	0.1079	0.278	0.307	0.670
Stem vegetables	11 (21 %)	52	0.0100	0.0177	0.031	0.054	0.120
Mushrooms	0	42	0.0050	0.0098	0.010	0.050	0.050
Pulses	0	12	0.0050	0.0050	0.005	0.005	0.005
Oilseeds	0	1	0.0050	0.0050	0.005	0.005	0.005
Cereals	0	24	0.0050	0.0050	0.005	0.005	0.005

* different LOQs

The limits of quantification (LOQs) achieved by the laboratories differed, and in some cases the labs measured residue levels that were still below the LOQs of the other data sources. The mean values for residues in each product group are used as a basis for assessing potential chronic effects. For the purpose of the preliminary assessment of potential acute effects, a calculation is performed on the basis of the 95th percentile of the measured data and a calculation performed based on the highest value determined for each product group. The same residue level is used for all foods belonging to a product group (exception: fresh herbs, which belong to the group of leaf vegetables).

3.3 Assessment of the acute risk to consumers

In June 2013, the BfR issued a preliminary recommendation on the health assessment of perchlorate residues on its website, providing detailed background information on the assessment (BfR, 2013). If necessary, this recommendation will be updated in light of further data on the toxicological properties of perchlorate and additional test results.

The BfR has not been able to evaluate any original studies to date and, based on summarised data and assessments of other bodies (EPA, JECFA), recommends the use of the PMTDI value (provisional maximum tolerable daily intake) derived by JECFA of 0.01 mg/kg body weight (JECFA, 2010) for the purposes of health risk assessment. In the absence of a

European harmonised short-term limit value, this limit value derived for long-term intake was also used for the assessment of acute effects.

In line with the recommendations of the BfR, calculation of international estimated short-term intake (IESTI) via the consumption of contaminated foods and the assessment of the acute risk is based on the Pesticide Residue Intake Model (PRIMo) of the European Authority for Food Safety (EFSA), which contains consumption data for children and adults from various EU member states including the consumption data for children in Germany (EFSA, 2008). Until such time as data becomes available that permits estimation of actual variability, the variability factors already implemented in the EFSA model PRIMo rev. 2_0 should be used for calculation purposes. Only in the case of head cabbage and head lettuce is the variability factor 3 used instead of the preset factor 5 in line with the procedure used for pesticide residues (BfR, 2010).

As no representative monitoring data is yet available for perchlorate and as the entry pathways are still not clear, it is also not clear which segment of the overall distribution of perchlorate residues has been documented to date. To be on the safe side, therefore, the worst case approach was chosen, in which the data on individual foods was summarised in product groups (based on the product groups defined in Annex I of Regulation (EC) No. 396/2005). In the assessment process, the residue value derived for the product group is transferred to all foods in this group.

Table 2: Results of the assessment of acute risk to consumers (based on EFSA-PRIMo)

Product group	Highest residue (mg/kg)	PMTDI* exhaustion	95th percentile of residues (mg/kg)	PMTDI* exhaustion	Threshold concentration (mg/kg)**	Findings above threshold concentration
Citrus fruit	1.100	**1459 %**	0.150	**199 %**	0.075	22 (9 %)
Tree nuts	0.010	0.4 %	0.010	0.4 %		
Pome fruit	0.010	9.8 %	0.010	9.8 %		
Stone fruit	0.018	11 %	0.010	5.9 %		
Berries	0.111	73 %	0.049	32 %		
Exotic fruits	0.450	**455 %**	0.075	76 %	0.099	6 (4 %)
Root vegetables	1.160	**1784 %**	0.163	**251 %**	0.065	19 (16 %)
Bulb vegetables	0.030	12 %	0.010	4.0 %		
Fruiting vegetables	0.813	**1233 %**	0.200	**303 %**	0.066	121 (23 %)
Brassica vegetables	0.190	**126 %**	0.028	19 %	0.151	1 (2 %)
Leaf vegetables	4.228	**3696 %**	0.224	**196 %**	0.114	23 (11 %)
Fresh herbs	26.000	**1491 %**	1.410	81 %	1.743	2 (3 %)
Legume vegetables	0.670	76 %	0.307	35 %		
Stem vegetables	0.120	55 %	0.054	32 %		
Mushrooms	0.050	6.3 %	0.050	6.3 %		
Pulses	0.005	0.9 %	0.005	0.9 %		
Oilseeds	0.005	0.3 %	0.005	0.3 %		
Cereals	0.005	0.7 %	0.005	0.7 %		

* Based on the consumer group with the highest exposure to the most frequently consumed commodity within the group
** Leads to 100% ARfD exhaustion, i.e. remains exactly below excessive levels, in all foods of this group and for all consumer groups.

Perchlorate was found in one or more samples of citrus fruit, exotic fruit, root vegetables, fruiting vegetables, brassica vegetables and leaf vegetables (incl. fresh herbs) in a concentration that leads to short-term intake of over 0.01 mg/kg body weight. On current knowledge and based on the described precautionary approach, undesirable effects are possible with a one-time intake of perchlorate at this level. This concerns in particular the inhibition of iodide uptake in the thyroid gland, which could possibly lead to changes in thyroid hormone levels in people with thyroid disease, people suffering from iodine deficiency, newborn babies and children (BfR, 2013).

The following general statements can be made with regard to a residue level that is acceptable for consumers:

- It is unlikely that European consumer groups will suffer any health impairment due to the one-time consumption of a large portion of fruit or vegetables with perchlorate residues of up to 0.05 mg/kg. At this level, the PMTDI is not exceeded for any consumer group.
- However, the findings reported here include samples with higher residue concentrations. In such cases, a risk assessment should be performed in line with the recommendations of the BfR.

3.4 Assessment of the chronic risk to consumers

The PMTDI value is also used for assessment of the chronic risk, as recommended by JECFA. When considering lifelong consumption, it is assumed that foods contain only average levels of perchlorate residues. The mean value of reported residues (see above) is therefore used for all product groups. In addition, average consumption quantities are also used for assessment purposes (in contrast to the high consumption amounts with one-time consumption used for the acute risk assessment). Calculations are performed using EFSA's PRIMo rev. 2_0 model. The calculated chronic intake of perchlorate via foods is not above the PMTDI value of 0.01 mg/kg body weight for any of the European consumer groups whose consumption habits are represented in EFSA PRIMo: the calculated levels are only as high as roughly 8% of this figure. The highest intake relative to body weight is calculated for Dutch, French and German children.

It is unlikely that European consumer groups will suffer any health impairment due to the lifelong consumption of medium-sized portions of fruit or vegetables with average perchlorate concentrations.

3.5 Possible entry pathways of perchlorate into foods

3.5.1 *Entry via the atmosphere*

Perchlorate has also been found in regions of the USA where anthropogenic pathways are seen as improbable. It is assumed that small amounts of perchlorate can also be formed in the atmosphere from marine (chloride) aerosols, due to electrical discharge for example, and find their way to the earth's surface in rain/snow or via dust deposits (Dasgupta, 2005) and could then be absorbed by plants. However, this pathway would only explain low background concentrations and not the sometimes high-level residues observed in foods.

3.5.2 Formation of perchlorate in plants

To date, the BfR is not aware of any information that indicates that perchlorate might be formed from precursor substances in plants. There is also no evidence of natural perchlorate concentrations in plants.

3.5.3 Migration to plants via fertilisers, irrigation water or soil

Chile saltpetre is used in fertilisers and is known to have high perchlorate concentrations of between 0.5 and 2 g/kg (Urbansky, 2001). Perchlorate has been detected in tobacco plants fertilised using Chile saltpetre (max. 64 kg/ha; Ellington, 2001).

During the investigation of the causes of some of the perchlorate findings in food in Germany, perchlorate was also detected in the fertilisers used in the production process, including in liquid and solid NPK and monopotassium fertilisers as well as vinasse fertilisers. NPK fertilisers are fertilisers that contain nitrogen (N), phosphate (P) and potassium (K). Perchlorate was also found in soil and water samples as well as fertilised substrate. The perchlorate concentrations in the analysed fertilisers ranged from 0.035 to 408 mg/kg. The identity of the highly contaminated fertilisers was not always known, as they were not marketed and used in Germany. In some cases, these fertilisers were Chile saltpetre-based.

The BfR is also in possession of information that proves a causality between the perchlorate concentration in the soil (based on the quantity of added fertiliser) and the perchlorate concentration in the lettuce grown in this soil.

The French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has also reported contamination of drinking water with perchlorate due to industrial discharges in certain regions of France.

Perchlorates are also used as industrial chemicals and medications in Germany and are released from rocket fuels and fireworks. Perchlorate migration from industrial point sources in sewage sludge, ground water and surface water has been reported in other parts of the world (USA, China; Sanchez, 2005a; Cai, 2007), but no corresponding information is available for Germany/Europe. It is, however, conceivable that perchlorate migrates from industrial waste water or sewage sludge in certain regions.

Perchlorates were not identified or notified as biocidal active substances in Regulation (EC) No. 1451/2007 in the context of the existing active substances programme of the EU. As perchlorates have also not been approved as new active substances, the marketing of biocidal products that contain perchlorates as active substances is not permitted in the EU. No biocidal product containing perchlorates is registered in Germany under the German ordinance on the notification of biocidal products. Under certain circumstances, perchlorate can occur as a technical by-product of hypochlorite solutions used as biocidal products for the purpose of disinfection. The extent to which they are formed during such processes primarily depends on the concentration, the duration of storage, the temperature and the pH level. High concentrations, high temperatures and long storage times promote the formation of perchlorate, as do pH levels below 11 and above 13 (Stanford, 2011). Perchlorates can also occur as by-products of chlorine electrolysis: hypochlorous acid or sodium hypochlorite and other reactive substances containing chlorine with germ-inhibiting effects are created from sodium chloride solutions by means of electrolysis. In the high dilutions in which hypochlorite is used in biocidal products for disinfection (normally 0.05 %-0.2 %), it appears unlikely that these applications can lead to any noteworthy perchlorate residues on foods via the waste water – water treatment – overhead irrigation pathway. Substances containing chlorine in waste water could generally also form perchlorate in small amounts in the event of ozone treatment during processing. Even if this water were to be used for irrigation purposes, it is unlikely that any relevant perchlorate residues would migrate to foods. Irrigation tends to be the exception in German agriculture and is mainly used in greenhouses.

A further conceivable entry pathway in other European countries is the chlorination of drinking water and the subsequent direct use of this drinking water for the irrigation of crops. Drinking water is not normally chlorinated in Germany and also not used for irrigation, but drinking water chlorination and the use of drinking water for irrigation is common practice in some EU member states. As chlorination - as explained in the previous section - can create perchlorate as a by-product, this could be one pathway for exposure of crops to perchlorate.

The BfR is currently not in possession of any data on perchlorate concentrations in soil or in surface, drinking and ground water in Germany. According to the Federal Environment Agency (UBA), perchlorate is not included in the monitoring programmes of the federal states in Germany. Environmental quality standards have not been defined in Germany for perchlorate to date, and perchlorate is also not regulated in the sewage sludge regulations.

In many places, the ground water and surface water in the USA contain perchlorate residues, mostly from industrial sources. Several studies have investigated whether plants irrigated with water containing perchlorate (in the catchment area of the Colorado River, for example), accumulate perchlorate (Jackson, 2005; Sanchez, 2005a; Sanchez, 2005b; Sanchez, 2006), and this kind of accumulation was observed above all in leaves. Citrus trees accumulate perchlorate residues that are ten times higher in the leaves than in the fruit. With perchlorate concentrations of 4-9 µg/L in the irrigation water, residues of approx. 1.8 mg/kg dry matter were measured in lemon leaves and levels of approx. 0.13 mg/kg dry matter in the lemons themselves (Sanchez, 2006). In leaf vegetables like lettuce, higher residues are found in open than in closed varieties, and in the latter the residues in the outer leaves are higher than in the inner leaves (Sanchez, 2005a). This points to displacement with the transpiration flow within the plants, leading to enrichment at the points within the plant that have the most intensive water release. In an American study, organically grown leaf vegetables had double the perchlorate contamination levels of conventionally grown leaf vegetables (Sanchez, 2005b). There is possibly a connection between these findings and the fact that, at the time of the survey, it was permitted to supply up to 20% of the nitrogen via Chile saltpetre in the organic production segment in the USA. Perchlorate could, however, also have migrated from other fertilisers that are frequently used in organic agriculture - via seaweed or fish meal products, for example.

In a trial in the USA with tomatoes, soybeans and alfalfa grown on sand in a greenhouse and irrigated with a solution containing liquid fertiliser with a perchlorate concentration of 50 µg/L, the following average perchlorate concentrations were found (Jackson, 2005): 31 mg/kg in soybean leaves, 0.6 mg/kg in soybeans, 11 mg/kg in tomato leaves, 0.18 mg/kg in tomatoes and 8.7 mg/kg in alfalfa (all figures refer to fresh mass). Perchlorate is mainly transported in soil with the water flow and is not bound either physically or chemically by soil particles to any relevant degree.

Conclusion: perchlorate can migrate from fertilisers and contaminated irrigation water to plant-based foods. While it is unlikely in Germany that irrigation water – where used at all – contains any perchlorate concentrations worthy of note (except in the case of contamination via industrial point sources), this possibility cannot be ruled out in other countries due to the direct use of chlorinated drinking water for irrigation purposes. These assumptions cannot currently be verified, however, as no information is available on perchlorate concentrations of water samples in Germany and other European countries.

3.5.4 Entry via the direct treatment of plants/food

Perchlorates themselves are not pesticidal active substances. In the past, potassium perchlorate was specified as a contaminant in a technical active substance (sodium chlorate) with a maximum concentration of 0.2 g/kg. The pesticide in question has not been authorised in Germany for 20 years, however. In the EU, a decision was made on the non-inclusion of the herbicide chlorate in Annex I, which means that the corresponding applications are today also no longer admissible in the EU (EU, 2008). Potassium chlorate (100 % purity, no perchlorate) and perchloric acid were used as co-formulants in approved pesticides until 2005 and 2002, respectively, but this is no longer the case. At the current point in time, it is possible to rule out relevant perchlorate residues resulting from contamination of pesticide ingredients, co-formulants or contaminants in pesticides or plant strengtheners in Germany within the framework of legally permitted applications. Direct entry via pesticide applications is therefore unlikely.

Direct chlorination of foods is prohibited in Europe, but it is permitted in the USA, for example. The possibility cannot be fully ruled out, however, that these or similar applications have nevertheless (illegally) been performed on foods in Europe for the purpose of killing germs. One conceivable pathway would be chlorine electrolysis, in which an electrochemical technique is used to make chlorine and chlorine compounds *in situ*, which can in turn kill germs, from sodium chloride solutions. It is possible that perchlorate is created as a by-product during this process. The BfR is currently not in possession of any information to the effect that this type of treatment has actually taken place. If this kind of treatment has taken place, however, it could point to a possible entry pathway of perchlorate into foods. To date, the BfR is also not aware whether perchlorate and other chlorine compounds like chlorate and hypochlorite have been simultaneously found in food samples. If this were the case, it would indicate that the foods might have been treated accordingly.

Conclusion: relevant perchlorate residues are not to be expected as a result of the legal use of approved plant protection products, plant strengtheners or biocidal products. However, it is not possible to rule out the illegal application of perchlorate-forming substances for the disinfection of foods.

3.5.5 Entry via food packaging

Perchlorates can be used as heat stabilisers in PVC. In line with Regulation (EU) 10/2011, perchlorates are approved as additives in the production of plastics that come into contact with foods. A specific migration limit value of 0.05 mg/kg food is stipulated for their use in this area. Inclusion in the EU positive list is based on an assessment by the Scientific Committee on Food of the EU Commission published in 2002 (SCF, 2002). Under consideration of the contact conditions during the transport and storage of fruit and vegetables and the migration behaviour of ionic species in plastics (Hampe, 1998), however, migration of perchlorate from PVC packaging materials is not to be expected.

In addition, paper packaging should be discussed as a potential source of perchlorate contamination. Chlorine dioxide or hypochlorite may be used in the production of paper for bleaching of cellulose and as a slimicide, and the formation of perchlorate and/or the contamination of hypochlorite formulations with perchlorate cannot be completely ruled out. No data is available on perchlorate residues in paper. Due to the high solubility of perchlorates in water, however, it can be assumed that any concentrations present in the paper production process are almost all discharged and that the finished paper only contains small traces of perchlorate. Migration to foods would - if at all - only be feasible under extraction conditions that do not exist with its use as a packaging material for fruit and vegetables.

Conclusion: relevant perchlorate residues are not to be expected due to the migration of perchlorate from food packaging.

4 References

BfR, 2010: Variability factors for the acute dietary risk assessment of pesticides, BfR Information No 014/2010, 5 March 2010, http://www.bfr.bund.de/cm/349/variability_factors_for_the_acute_dietary_risk_assessment_of_pesticides.pdf

BfR, 2013: BfR recommendations on how to perform the consumer risk assessment for perchlorate residues in food, BfR Opinion No. 015/2013, 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

Cai, 2007: Yali Shi, Ping Zhang, Yawei Wang, Jianbo Shi, Yaqi Cai, Shinfen Mou, Guibin Jiang, Perchlorate in sewage sludge, rice, bottled water and milk collected from different areas in China, Environ Int. 2007 Oct, 33(7),955-62

Dasgupta, 2005: Purnendu K. Dasgupta, P. Kalyani Martinelango, W. Andrew Jackson, Todd A. Anderson, Kang Tian, Richard W. Tock and Srinath Rajagopalan, The Origin of Naturally Occurring Perchlorate: The Role of Atmospheric Processes, *Environ. Sci. Technol*., 2005, *39* (6), 1569-1575

EFSA, 2008: PRIMo rev. 2_0, http://www.efsa.europa.eu/en/mrls/docs/calculationacutechronic_2.xls

Ellington, 2001:J. J. Ellington, N. L. Wolfe, A. W. Garrison, J. J. Evans, J. K. Avants, Q. Teng, Determination of Perchlorate in Tobacco Plants and Tobacco Products. *Environ. Sci. Technol*., 2001, *35*, 3213-3218.

EU, 2008: COMMISSION DECISION of 10 November 2008 concerning the non-inclusion of chlorate in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (2008/865/EC), Official Journal of the European Union, L 307/7, 18.11.2008

Hampe, 1998: D. Hampe, O. Piringer, Studies on the permeation of inorganic salts through plastic films, Food Additives and Contaminants 15, No. 2, 209-216, 1998

Jackson, 2005: W. Andrew Jackson, Preethi Joseph, Patil Laxman, Kui Tan, Philip N. Smith, Lu Yu and Todd A. Anderson, Perchlorate Accumulation in Forage and Edible Vegetation, J. Agric. Food Chem. 2005,*53*, 369-373

JECFA, 2010: Safety evaluation of certain contaminants in food, prepared by the Seventy-second meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), WHO food additives series; 63. FAO JECFA monographs; 8. FAO & WHO, 685-762, 2011

Sanchez, 2005a: C. A. Sanchez, R. I. Krieger, N. Khandaker, R. C. Moore, K. C. Holts and L. L. Neidel, Accumulation and Perchlorate Exposure Potential of Lettuce Produced in the Lower Colorado River Region, J. Agric. Food Chem. 2005,*53*, 5479-5486

Sanchez, 2005b: C. A. Sanchez, K. S. Crump, R. I. Krieger, N. R. Khandaker and J. P. Gibbs, Perchlorate and Nitrate in Leafy Vegetables of North America, *Environ. Sci. Technol.*, 2005, *39* (24), 9391-9397

Sanchez, 2006: C. A. Sanchez, R. I. Krieger, N. R. Khandaker, L. Valentin-Blasini, B. C. Blount, Potential perchlorate exposure from *Citrus sp*. irrigated with contaminated water, Analytica Chimica Acta 567 (2006) 33-38

SCF, 2002: Opinion of the Scientific Committee on Food on the 20th additional list of monomers and additives for food contact materials, expressed on 25 September 2002, http://ec.europa.eu/food/fs/sc/scf/out142_en.pdf

Stanford, 2011: Benjamin D. Stanford, Aleksey N. Pisarenko, Shane A. Snyder and Gilbert Gordon, Perchlorate, bromate, and chlorate in hypochlorite solutions: Guidelines for utilities, Journal American Water Works Association (AWWA), 103:6, 1-13, June 2011

Urbansky, 2001: E. T. Urbansky, S. K. Brown, M. L. Magnuson, C. A. Kelty, Perchlorate levels in samples of sodium nitrate fertilizer derived from Chilean caliche. *Environ. Pollut.* 2001, *112*, 299-302