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Health risk assessment of mineral water with very low mineral content[1]

BfR Opinion No 041/2020 issued 14 September 2020

Natural mineral water is water that, among other things, originates in underground water deposits protected from contamination, is of natural purity and is characterised by its content of minerals, trace elements as well as other constituents and, if applicable, by certain properties, in particular nutritional-physiological effects (see § 2 of the German Mineral and Table Water Ordinance). The type and quantity of minerals present in the water depends on the geological state of the locality from where it is taken. The composition therefore varies considerably. Mineral water is available with high contents of individual or several minerals up to mineral water with particularly low mineral contents. Mineral water that does not contain more than 50 mg of minerals per litre (calculated as total dissolved solids, TDS) may be labelled as '*With very low mineral content*' in accordance with the German Mineral and Table Water Ordinance.

The German Federal Institute for Risk Assessment (BfR) has assessed the potential health risks posed by low mineral content water. This was in response to a query received from one of the Federal State Offices for Consumer Protection and Food Safety (Landesuntersuchungsamt; LUA), which cited a research article published by the World Health Organisation (WHO) in 2005. It asked for an assessment of whether the consumption of low mineral content water could pose risks to human health, especially for certain groups of consumers.

Low mineral content water has long been consumed by the general population. To date only few scientific studies are available, thus there are knowledge gaps in the risk assessment of mineral waters with very low mineral content. According to the current state of scientific knowledge, however, it can be assumed that mineral, spring and table water with very low mineral content does not have any long-term adverse effects on health – assuming a balanced diet and normal drinking quantities. Ultimately, humans absorb minerals as part of all foods consumed on a daily basis, with water or mineral water being only one of several day-to-day sources of mineral intake.

Individual consumer groups – such as people with very unbalanced diets, people who consciously avoid certain foods (e. g. vegans, people with lactose intolerance) or people who engage in prolonged periods of fasting, as well as pregnant or breastfeeding women – should pay attention to their total daily intake of certain essential minerals if they use low mineral content water as their primary source of fluids over a longer period of time. In the case of individuals engaged in prolonged exercise or strenuous physical activity (longer than 1.5 hours), the use of mineral water with very low mineral content is not recommended as the sole or primary type of beverage to replenish fluids and maintain levels of athletic or physical performance.

[1] Mineral water whose mineral content, calculated as total dissolved solids (TDS), does not exceed 50 mg/l.

	BfR risk profile: Long-term consumption of low mineral content water (Opinion no 041/2020)					
A	Affected persons [1]	General population				
B	Likelihood of an impairment to health from the consumption of low mineral content water	**Practically impossible**	Unlikely	Possible	Probable	Certain
C	Severity of impairment to health from the consumption of low mineral content water	**No impairment**	Mild impairment [reversible/irreversible]	Moderate impairment [reversible/irreversible]	Severe impairment [reversible/irreversible]	
D	Validity of available data	High: The most important data are available and are internally consistent	**Medium: Some important data are missing or inconsistent**	Low: A large volume of important data is missing or inconsistent		
E	Controllability by the consumer	**Control not necessary**	Controllable with precautionary measures	Controllable by avoidance	Not controllable	

Fields highlighted in dark blue indicate the properties of the risks assessed in this Opinion (further information on this can be found in the text of the Opinion).

Explanations

The risk profile is intended to visualise the risk outlined in the BfR Opinion. It is not intended to be used to compare risks. The risk profile should only be read in conjunction with the corresponding Opinion.

[1] Row A – Affected persons:
This risk profile does not apply to pregnant or breastfeeding women, people with an unbalanced diet, people who avoid certain kinds of foods, or in the case of prolonged sporting or physically strenuous activity (longer than 1.5 hours).

GERMAN FEDERAL INSTITUTE FOR RISK ASSESSMENT (BfR)

1 Subject of the assessment

In 2006, the German Federal Institute for Risk Assessment (BfR) had conducted an assessment of the health risks of consuming mineral, spring or table water with very low mineral content. In response to an enquiry from one of the German Federal State Offices for Consumer Protection and Food Safety or the respective Ministry, the BfR has re-evaluated the current state of knowledge.

According to information from one of the federal state offices, mineral water *with a very low mineral content* is becoming increasingly popular due to its ‘neutral’ taste, and due to the fact that the consumption of low mineralised content water has been strongly promoted to the general public for many years. In its letter to the BfR, the federal state office refers to a scientific article by Kozisek (‘*Health Risks from Drinking Demineralised Water*’; 2005) that was included in a publication by the World Health Organisation (WHO) (‘*Nutrients in Drinking Water*’) in 2005, which reviewed the state of knowledge at that time on the health risks arising from long-term consumption of demineralised or low mineral content water. According to this it was believed that water with low mineral content would promote the excretion of certain minerals and that this or the lack of minerals in the water consumed was associated with a number of health disorders. Furthermore, this publication specifies minimum amounts for the total dissolved solids (TDS) as well as for magnesium and calcium for long-term consumption of such water. The federal state office was concerned that the loss of minerals caused by long-term consumption of water low in minerals cannot always be compensated for by other components of the diet, especially when large amounts of water are drunk in a short period of time after sporting activities during the hot summer months or in the case of diarrhoea.

Background: The German Mineral and Table Water Ordinance (MinTafWV) does not specify any minimum requirements for mineral, spring and table water with regard to the content of individual minerals or the total mineral content. Mineral water whose mineral content, calculated as TDS, does not exceed 50 mg/l, may be marketed with the claim '*With very low mineral content*' (Annex 6, MinTafWV).

2 Results

Mineral water with very low mineral content[1] has long been available on the German market. As part of a typical daily diet, mineral water is consumed together with a number of different foods that contribute in varying degrees to an individual's daily intake of nutrients.

At present, only a few studies are available for a risk assessment of low mineral content water and there are knowledge gaps in the risk assessment of such mineral water. However, according to the current state of knowledge, with a balanced diet and normal drinking quantities, no adverse effects are discernible that would suggest advising against the use of mineral, spring or table water with very low mineral content as food.

People with very unbalanced diets[2] and people who deliberately avoid certain foods (e. g. milk and dairy products due to lactose intolerance or because of a vegan diet), as well as pregnant and breastfeeding women, should ensure that they are getting adequate daily intakes of certain essential minerals, in particular calcium and magnesium[3], if they regularly use low mineral content water as their main source of fluids. During prolonged athletic, physically demanding activities (>1.5 hours), low mineral content water is not recommended as a beverage[4] for fluid replacement and maintenance of athletic performance.

3 Rationale

3.1 Agent

The term *'low mineral content water'* is not clearly defined. In the following, this term is used for mineral water or water with a mineral content of ≤50 mg/l (calculated as TDS), since according to Annex 6, MinTafWV mineral water with such a mineral content may be advertised as '*With very low mineral content'*. However, this delimitation is not based on nutritional-physiological or toxicological aspects, since it can be assumed that within a relatively wide range of values there are no significant nutritional differences with regard to the total mineral content of water.

3.2 Risk assessment

Overall, only a few scientific studies are available for risk assessment of *low mineral content water*. Therefore, the risk assessment must take a broader-based approach and consider

[2] This may apply to adults, adolescents, children and infants.

[3] For people who follow a vegan diet, this may be less relevant in terms of magnesium intake.

[4] This refers to the sole or predominant consumption of mineral water with very low mineral content as a beverage for fluid replacement and maintenance of athletic or physical performance.

studies that look at effects of the hardness of drinking water (water hardness) on human health. The hardness of drinking water is essentially determined by the calcium and magnesium content of drinking water, i. e. the two mineral salts that are the focus of the scientific discussion on potential positive health effects of the total mineral content of water or mineral water. For the risk assessment, in many cases studies had to be included that also included water with higher mineral content than 50 mg/l.

The publication by Kozisek (WHO, 2005) cites various, mostly older animal and human studies written in Russian, we as well as findings from a report of the World Health Organisation (WHO, 1980), described only as an internal working document, from which according to the author, adverse effects of low mineral content water emerge. More recent reports from the WHO (WHO, 2009; 2011; 2017) on health aspects of water hardness as well as on the magnesium and/or calcium content of drinking water do no longer mention the results of these studies or of the WHO report from 1980. Accordingly, and also due to language barriers and questions about the exact implementation of the cited studies, which would be important for the interpretation of the study results, as well as due to scientific limitations of the cited studies, these studies will not be discussed in the current Opinion.

3.2.1 Available assessments by scientific bodies

Since the publication of its report '*Nutrients in drinking water*' (WHO, 2005), the WHO has addressed the health aspects of the magnesium and calcium content in water as well as water hardness on several occasions. In this respect, the statements in the publication by Kozisek (2005) are outdated. In 2006, the WHO hosted an expert meeting on the role of calcium and magnesium in drinking water[5] (WHO, 2009). Based on the findings of this symposium, the WHO published a background paper '*Hardness in drinking water*' (WHO, 2011), which served as the basis for the chapter '*Hardness*' in the now valid WHO '*Guidelines for Drinking-water Quality*' (WHO, 2017). In this chapter of the *Guidelines*, the WHO came to the following conclusion regarding the health effects of water hardness or the calcium and/or magnesium content in water:

"Natural and treated waters have a wide range of mineral content, from very low levels in rainwater and naturally soft and softened water to higher levels in naturally hard waters. Bottled and packaged waters can be naturally mineralised or naturally soft or demineralised. Thus, the mineral consumption from drinking-water and cooking water will vary widely, depending upon location, treatment and water source. (…)

Drinking-water can be a contributor to calcium and magnesium intake and could be important for those who are marginal for calcium and magnesium. (…)

Although there is evidence from epidemiological studies for a protective effect of magnesium or hardness on cardiovascular mortality, the evidence is being debated and does not prove causality. Further studies are being conducted. There are insufficient data to suggest either minimum or maximum concentrations of minerals at this time, as adequate intake will depend on a range of other factors. Therefore, no guideline values are proposed." (WHO, 2017)

[5] The expert meeting was conducted with the aim of elucidating the role of drinking water as a contributory source to the daily total intake of calcium and magnesium. This was specifically to address the question of whether the small contribution of drinking water-associated calcium and magnesium intakes to the total daily intake of these two nutrients provides a health benefit, particularly with respect to cardiovascular disease mortality, at least for individuals whose total daily intake is deficient in one of the two nutrients (WHO, 2009).

For further details and the previous WHO assessments on which these conclusions are based (WHO 2009, 2011) and their data basis, please refer to Section 3.2.3.1.

3.2.2 Available animal studies

In a study in rats looking at the acute toxicity of highly demineralised water (conductivity <0.1 µS/cm), the authors first withheld access to water and then monitored the animals as they subsequently drank large quantities of highly demineralised water (approx. 40 ml/12 h or approx. 4 % of body weight within the first 90 minutes, corresponding to approx. 2.8 l in humans). No macroscopic or microscopic changes were observed in the organs examined (oesophagus, stomach, duodenum, colon, pancreas, heart, lungs, spleen, brain) including inflammations or erosions in the oesophageal epithelium or the mucosa of the stomach and intestine. The activity of alkaline phosphatase in the small intestine—as a biochemical indicator of cell damage—was not significantly different compared to the control group which received normal tap water (Schumann et al., 1993). However, it is not clear from the study data at what time the animals were euthanised (i. e. exactly 12 hours after the previous water deprivation or later).

When the same highly demineralised water was administered to rats for 14 days, no significant differences in regard to body weight, feed and water intake or urine and faeces excretion were observed by Schuman et al. (1993), although no statistical analyses were available on this. In addition, no macroscopic or microscopic changes were observed in the organs examined, nor in the activity of alkaline phosphatase or in the uptake of a glucose derivative in the small intestine (as a parameter for functional testing of small intestinal activity).

In another study in rats lasting 21 days, slightly higher rates for the consumption of water (26.2 ml/day) and feed intake (36.1 g/day) were recorded when distilled water was administered, in comparison to the control group that received normal drinking water (24.8 ml/day and 28.3 g/day, respectively). However, these increased intakes were associated with a higher weight gain during the study period (108.4 g versus 103.3 g). In this respect, the increased intake quantities cannot be interpreted definitively. However, this study was primarily carried out to investigate the taste preferences of the test animals (Eberova et al., 2005).

In a UK study in pigs, animals of two different breeds given the same feed and with otherwise largely identical housing conditions were reared in two experimental stations with either ‘soft’ (42 mg/l carbonate) or ‘hard’ (275 mg/l carbonate) drinking water up to a slaughter weight of 90.9 kg (corresponding to an age of around 6 months). No marked differences were observed in the incidence and the extent of arteriosclerotic changes in the aorta between the two groups of animals who received soft or hard drinking water. However, differences between the breeds were registered. The authors concluded that pigs are an unsuitable animal model for investigating the influence of water hardness on arteriosclerotic vascular changes in humans, since normal pig feed contains considerable amounts of calcium and mineral supplements which could mask possible influences of the varying concentrations of minerals present in drinking water. The authors also point to potential genetic differences affecting the occurrence of arteriosclerotic changes (Howard et al., 1969). In the broadest sense, this study can be seen as an intervention study and it illustrates the importance of the kind of feed in the investigation of the question at issue here.

In a long-term study in rabbits, no statistically significant differences were observed with regard to water and feed intake, body weight or lipid levels when either tap water (TDS: 229 mg/l), bottled natural water (TDS: 87.2 mg/l), bottled mineralised water (TDS: 10.9 mg/l) or bottled purified water (TDS: 1.2 mg/l) was administered over a period of 12 months. (Note:

Here and in the following, the designations chosen by the respective authors for the water types investigated were adopted.). According to the authors, more severe changes were observed in the heart (interstitial oedema with focal fibre dissolution and fracture) and in the aortic arch intima (mucoid degeneration, localised exfoliation of endothelial cells, scattered foam cells) when the bottled mineralised water (TDS: 10.9 mg/l) and the bottled purified water (TDS: 1.2 mg/l) were administered than when the other two types of water with higher mineral contents were administered. Focal mucoid degeneration of the aortic intima was also observed in animals given the bottled natural water (TDS: 87.2 mg/l). It should be noted that this study was conducted to investigate cardiovascular effects of low mineral content water, but the authors do not provide any information on the diet of the animals, despite the importance of diet in the development of cardiovascular disease. Furthermore, no information is available on how many animals in each study group exhibiting such findings, nor on the distribution of the severity of the findings or the respective incidence of the individual pathological changes listed above. In addition, a statistical analysis of these findings is not provided. Furthermore, no information is available on the health status of the animals, e. g. whether animals became ill or died during the study. The scientific relevance of this study is therefore to be classified as low. In addition, this publication also reports results of a human study conducted by the authors (see below), which give rise to criticism and appear to be over-interpreted (Luo et al., 2013).

In a multigenerational study in rats conducted by the same research group, the animals were given tap water (Ca: 52.9 mg/l, Mg: 12.7 mg/l), bottled natural water (Ca: 10.6 mg/l, Mg: 9.4 mg/l), bottled mineralised water (Ca: 0.02 mg/l, Mg: 0.4 mg/l) and bottled purified water (Ca: 0.04 mg/l, Mg: 0.02 mg/l). These waters are likely to be the same types of water as used in the animal study conducted by Luo et al. (2013). In the F0 and F1 generation, the animals received the respective type of water in the period before mating (17^{th} week of life) and during pregnancy. In the F2 generation, which comprised only females, the animals received the water until 10 months of age. In the F2 generation (female animals only), a reduced maximum and elastic deflection and ultimate strain of the femoral diaphysis was observed in the groups receiving the three bottled water types compared to the tap water. The calcium content of the tibia was statistically significantly reduced only in the group receiving bottled purified water but not in the group receiving bottled mineralised water—although both of these waters had similarly low levels of calcium. The magnesium content of the tibia was reduced in all three types of water compared to tap water, although this was only statistically significant for bottled natural water and bottled purified water. It should be noted, however, that the magnesium content of the tap water and the bottled natural water differed only slightly (12.7 mg/l versus 9.4 mg/l) and therefore the differing magnesium levels of the tibia (see above) are difficult to understand. Reduced vitamin D serum levels were observed in all three types of bottled water compared to tap water. Due to the lack of information on the mineral content of the feed given and its composition in general, the animals' feed intake, the health status of the animals during the study and also due to missing information on normal ranges of the parameters measured, it is difficult to interpret this study's findings (Qiu et al., 2015).

In an older study in rats, Robbins and Sly (1981) observed higher serum zinc levels when rats were given a semisynthetic diet together with tap water for 13 weeks, in comparison with the groups of rats that received the same semisynthetic diet together with deionised water and additional increasing amounts of zinc that, depending on the group of rats, ranged up to twice the amount of zinc contained in the semisynthetic diet. The article states, however, that the zinc levels decreased during the course of the study, but only the mean serum zinc levels measured at five intervals during the 13-week study are listed for the individual groups, but not the initial serum levels. Therefore, the actual decrease in each level remains unclear. In this respect, the scientific validity of this study is considerably limited. The authors state that similar results were obtained with magnesium in the same experimental set-up without giving further details. Accordingly, and due to the above-mentioned limitations, these findings are of no further value for the present risk assessment. The results of this study were also cited in the Kozisek publication (2005), without the author addressing the serious limitations mentioned above.

In an animal study with rats, a 20 % increase in fluid intake, increased serum electrolyte levels (chloride, potassium, sodium), increased renal electrolyte excretion, decreased levels of serum aldosterone and triiodothyronine as well as increased cortisol levels and histomorphological changes in renal tissue were observed when distilled water was administered over 12 months compared to tap water. In an animal study investigating reprotoxicity, according to the authors a slowed ossification of embryonal skeletons was registered. The publication does not provide any detailed information on the extent of the changes in the above-mentioned serum levels or renal excretions, nor does it provide data on the incidence and severity of the stated histopathological changes. Basic information on the number of animals, their sex (caveat: age-related kidney damage in male rats), the diet of the animals (e. g. mineral content in the feed), the quantities of feed consumed, the animals' state of health during the study, as well as basic data about the reproductive toxicological tests conducted are also missing (Rachmanin et al., 1989). This study was included in the publication by Kozisek (2005) and illustrates the limitations of such older studies on this topic.

Compared with the findings of Luo et al. (2013), Qiu et al. (2015), Robbins and Sly (1981) or the statements made by Kozisek (2005), the Working Group on Laboratory Animal Nutrition of the Society of Laboratory Animal Science (GV-SOLAS) comes to very different conclusions in its technical information sheet '*Drinking water supply for laboratory animals*': *"Even with lifelong administration of distilled water, no adverse effects or deficiencies were observed in the animals, including their offspring. The mineral requirement is apparently sufficiently covered by the feed, just as with tap water that is very low in minerals."* (Hagelschuer et al., 2016). It should be noted, however, that this statement is substantiated solely by citing a personal opinion given by a single researcher and that no further scientific evidence is presented in its support.

In summary, in an older animal study, no adverse effects were observed with acute and subacute administration of distilled water when analysing a limited number of parameters studied. In two more recent and longer-lasting animal studies by one research group (Luo et al., 2013, Qiu et al., 2015), negative health effects from the consumption of water with low total mineral content or low calcium and magnesium contents were registered (initial adverse effects on cardiac muscle and aortic intima, plus reduced bone deflection). However, both studies have considerable limitations that severely restrict their scientific validity and do not allow a conclusive health assessment of these study results. In addition to the limitations mentioned, the study findings are also difficult to explain. Minerals are supplied through the consumption of solid feed and fluids. Apart from a potentially better bioavailability, no special quality is attributed to the intake of nutrients from water or other fluids compared to nutrient intake from solid feed. As regards water and mineral homeostasis in the body, it is irrelevant from which source (fluid or solid feed) the minerals originate. When water with very low mineral content is used, water is no longer a source of minerals that helps to meet daily mineral requirements and the intake of these minerals may therefore be reduced. However, this can be compensated by mineral intake from solid feed.
The findings of the two studies are also contradicted by the statement of the Working Group of the Society of Laboratory Animal Science, according to which no adverse effects or deficiencies were observed when distilled water was administered, as the mineral requirement was apparently sufficiently covered by the feed (Hagelschuer et al., 2016).

3.2.3 Available human studies

3.2.3.1 Epidemiological studies

The scientific basis for the chapter '*Hardness*' in the now valid WHO '*Guidelines for Drinking-water Quality*' (WHO, 2017) was the background document '*Hardness in Drinking-water*' (WHO, 2011), which was essentially based on the results of a symposium on the health aspects of calcium and magnesium in drinking water published in 2009 ('*Calcium and magnesium in Drinking-water*', WHO, 2009).

In the background paper (WHO, 2011), the epidemiological studies available until then were evaluated. The limited significance of ecological epidemiological studies was pointed out. With regard to further epidemiological studies, it was stated[6]:
"Seven case–control studies and two cohort studies of acceptable quality investigating the relationship between calcium or magnesium and cardiovascular disease or mortality were identified in the literature. Of the case–control studies, one addressed the association between calcium and acute myocardial infarction and three the association between calcium and death from cardiovascular disease. None found a positive or inverse correlation between calcium and either morbidity or mortality. Two examined the relationship between magnesium and acute myocardial infarction, finding no association. Five examined the relationship between magnesium and cardiovascular mortality; while some failed to yield statistically significant results, collectively they showed similar trends of reduced cardiovascular mortality as magnesium concentrations in water increased. Statistically significant benefits (where observed) generally occurred at magnesium concentrations of about 10 mg/l and greater. The cohort studies examined the relationship between water hardness (rather than calcium or magnesium content) and cardiovascular disease or mortality and found no association." (WHO, 2011).

Overall, the background paper came to almost the same conclusion as the chapter '*Hardness'* of the WHO Guideline: "*Although there is some evidence from epidemiological studies for a protective effect of magnesium or hardness on cardiovascular mortality, the evidence is being debated and does not prove causality. Further studies are being conducted. There are insufficient data to suggest either minimum or maximum concentrations of minerals at this time, and so no guideline values are proposed." (WHO, 2011).*

For a better understanding, the following section briefly summarises the results of the case-control studies and cohort studies cited in the WHO background paper.
This is followed by a discussion of the results of epidemiological studies published in the meantime after the preparation of the WHO background paper.

3.2.3.1.1 Studies considered by the WHO

The WHO background paper (WHO, 2011) reviewed seven case-control studies (Luoma et al., 1983; Rosenlund et al., 2005; Rubenowitz et al., 1996; 1999; Rubenowitz et al., 2000; Yang and Chiu, 1999; Yang and Hung, 1998) and two cohort studies (Comstock et al., 1980; Punsar and Karvonen, 1979), which investigated the association between calcium and magnesium concentrations in drinking water and the risk of cardiovascular disease. Furthermore, reference was made to another cohort study by Leurs et al. (2010).

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[6] The background paper also referred to another cohort study by Leurs et al. (2010) (see below).

- Case-control studies

In their three studies, Rubenowitz et al. analysed population data from the same geographical regions in the southern part of Sweden, which had different magnesium levels in the drinking water (16–18 municipalities depending on the study) at different study periods (Rubenowitz, 1996; 1999; 2000). Therefore, they cannot be regarded as three independent publications. In the Rubenowitz et al. publications (1996; 1999), the influence of magnesium concentration in drinking water on the risk of suffering a fatal myocardial infarction (MI) in men (Rubenowitz et al., 1996) and women (Rubenowitz et al., 1999) was investigated in comparison to mortality from cases of cancer in the same region. The authors observed a negative association (i. e. a protective effect) between the magnesium concentration in drinking water and the risk of suffering a fatal MI in both men and women. Neither study made adjustments for the various parameters that are recognised as confounders for cardiovascular disease (such as nutrition, physical activity, smoking habits and alcohol consumption). Nor was drinking water consumption recorded individually. An allocation of individuals with regard to the stratification of magnesium levels in drinking water was only carried out on the basis of information on the last place of residence and the magnesium levels in drinking water stated by local water utilities for this purpose (i. e. the drinking water exposure value assigned to study participants did not necessarily reflect actual, individual exposure). These points constitute significant limitations of the studies. The results of the third study by the authors (Rubenowitz et al., 2000) showed that the magnesium content in drinking water had no influence on the risk of suffering an acute MI. However, the proportion of survivors of an acute MI was greater in the group with a higher magnesium content compared to the group with a lower magnesium content in their drinking water[7]. Although the authors adjusted for a variety of sociodemographic and behavioural factors in their study (smoking, alcohol, stress, physical activity, education and diet) and also recorded drinking water consumption, this data was not available in cases where participants had died of a heart attack or for previously deceased control-group subjects (i. e. for the specific sub-population in which the authors' analysis had revealed an effect for magnesium concentrations). These issues substantially limit the significance of this study.

The two Taiwanese case-control studies by Yang (1998) and Yang and Chiu (1999) investigated the effects of magnesium levels in drinking water on mortality due to stroke (Yang, 1998) or hypertension (Yang and Chiu, 1999), respectively, compared to general mortality (excluding cardiovascular disease) in the population aged 50-69 years in 252 municipalities. Although the results for both endpoints showed a protective effect of higher compared to lower magnesium concentrations in drinking water[8], the above-mentioned factors influencing the development of cardiovascular disease were not taken into account in these two studies either. In addition, the stratification in terms of magnesium content in the drinking water was only based on information on the place of residence.

Luoma et al. (1983) also observed that a higher rather than a lower magnesium content in drinking water constituted a protective factor for the risk of suffering an acute MI. However, the study has considerable limitations as only a small number of male participants were included in the study and no adjustments were made for a variety of sociodemographic and behavioural factors. Moreover, no records of the daily consumption of drinking water and the associated magnesium and calcium intake as well as the magnesium and calcium intake via food were kept.

[7] The cut-off in this study was drinking water magnesium intakes exceeding 13 mg/day (not the magnesium concentration in the drinking water); adjusted odds ratio (OR) of 1.39; 95 % CI: 1.07–1.80.

[8] OR for category with highest vs lowest Mg concentration (16.4–41.3 vs 1.5–3.8 mg/l): 0.63 (95 % CI: 0.47–0.84).

In the study by Rosenlund et al. (2005), no protective effect of the magnesium concentration in drinking water on the incidence of an acute MI was observed, although this study was conducted in a region with generally low magnesium levels in drinking water (4–6 mg/l) and resulting small differences in magnesium levels in drinking water, which may limit the significance of the results.

– Cohort studies

The methodologically well-designed cohort study from the Netherlands by Leurs et al. (2010), in which 4,114 individuals aged 55-69 years were observed over a period of 10 years, showed no association between the calcium and magnesium concentrations in drinking water and mortality due to ischaemic heart disease (IHD) or stroke. In this study, a large number of factors influencing the development and progression of cardiovascular disease were taken into account (Leurs et al., 2010).

Comstock et al. (1980) analysed data from 30,534 participants (> 25 years). The research team found no evidence of a consistent association between water hardness and mortality from cardiovascular disease (CVD); in male participants, low water hardness (0 vs 200 ppm $CaCO_3$) was associated with a lower risk of suffering fatal cardiovascular disease; in female participants, low water hardness was associated with a slightly higher risk, which varied depending on the individual's length of residence in the drinking water regions. This study did not control for important influencing factors (drinking water consumption) and factors influencing the development of cardiovascular disease (diet, physical activity and sociodemographic parameters).

Also in the cohort study by Punsar and Karvonen (1979), in which an increased mortality of men (14.7 % vs. 8.7 %) due to coronary heart disease was observed in the region with low compared to the region with higher magnesium levels in the drinking water, no adjustment for individual risk factors was made.

The limitations of the epidemiological studies cited here underline the fact that the association between the magnesium (and calcium) content in drinking water or the water hardness and the risk of suffering a fatal cardiovascular disease or potentially promoting the occurrence of such a disease, as discussed in the literature, cannot be sufficiently proven with epidemiological data. These same conclusions were drawn previously by the WHO background paper and in the '*Hardness'* chapter in the WHO Guideline (2017) on water quality.

3.2.3.1.2 Studies from 2010 onwards

– Influence of low calcium and magnesium levels in drinking water on the risk of cardiovascular diseases

The BfR identified three smaller-scale prevalence studies (Knezovic et al., 2014; Rapant et al., 2019; Rasic-Milutinovic et al., 2012) and one ecological study from the UK (Lake et al., 2010) that were published in the period since the preparation of the WHO background paper (WHO, 2011) and investigated an association between the concentrations of magnesium and calcium in drinking water and the risk for the occurrence of cardiovascular diseases.

Rasic-Milutinovic et al. (2012) examined blood pressure at a single measurement in healthy individuals living in three different municipalities whose drinking water had different calcium and magnesium contents. Contrary to the authors' claims, the study did not show any consistent results with regard to a correlation between (diastolic) blood pressure and the magnesium content in drinking water.

The study by Knezovic (2014) also showed inconsistent results: Although the authors observed a higher prevalence of CVD (21.3 % vs 13.7 %) in individuals aged between 45 and 60 in the study region with lower rather than higher magnesium levels in drinking water, the CVD prevalence was lower in the 61 to 75 age group (39.5 % to 46.7 %); no difference was observed in the 76 to 90 age group.

Rapant et al. (2019) observed higher arterial stiffness and arterial age in residents supplied with drinking water with low concentrations of calcium and magnesium (Ca: 20–25 mg/l, Mg: 5–10 mg/l) compared to residents whose drinking water supply contained a higher mineral content (Ca: 80–90 mg/l, Mg: 25–30 mg/l).

None of these studies took into account known confounders (diet, alcohol consumption, physical activity) for the development of cardiovascular diseases or determined how much drinking water was consumed daily and to what extent it contributed to magnesium and/or calcium intake. These factors severely limit the scientific validity of these studies.

The scientific reliability of ecological studies, as conducted by Lake et al. (2010), is severely limited due to the limitations of the descriptive study design and therefore unsuitable for a risk assessment, which was also pointed out by the WHO in its background document of 2011.

The findings of these studies do not reveal any new aspects beyond the WHO background paper that would strengthen the empirical evidence for a protective effect of higher compared to lower magnesium and calcium content in drinking water against the risk for occurrence of cardiovascular diseases.

– Influence of low calcium and magnesium levels in drinking water on bone health

Three further epidemiological studies were identified that were published after the preparation of the WHO background paper, and which investigated the correlation between low concentrations of calcium and magnesium in drinking water and potential adverse health effects concerning parameters relating to bone health.

Two retrospective cohort studies investigated the influence of very low mineral content water on height gains in schoolchildren and biomarkers of bone remodelling in China (Huang et al., 2019; Huang et al., 2018). In the study by Huang et al. (2019), a group of 229 schoolchildren that consumed water with a 'normal' mineral content (Ca: 53 mg/l, Mg: 10 mg/l) exhibited greater height increase, a higher bone mineral content, higher osteoblast activity and a lower bone resorption than a group of 431 schoolchildren that consumed drinking water with very low mineral content (Ca: 2.3 mg/l, Mg: 0.7 mg/l). However, when considering total daily intake, the two groups investigated showed insufficient calcium and magnesium intakes (Ca and Mg: about 36–41 % and 82–86 % of recommended daily intake, respectively). This significantly limits the generalisability and scientific relevance of this study. The same situation (insufficient total daily intake of calcium and magnesium) also applies to the previously conducted study by Huang et al. (2018). This study, which investigated a larger cohort of 29,844 schoolchildren, observed reduced height gain as well as a greater incidence and prevalence of caries in children consuming drinking water with low calcium and magnesium levels compared to children consuming drinking water with about 12 times higher magnesium and calcium levels.

A prospective study from Norway conducted as part of the *Norwegian Epidemiologic Osteoporosis Study* (NOREPOS) investigated the relationship between the concentration of calcium and other minerals in drinking water and the risk of suffering a hip fracture in the population aged 50-85 years (Dahl et al., 2015). When comparing high calcium concentrations in drinking water with low concentrations, a 15 % reduction in the incident rate ratio (IRR) was observed for hip fractures in men. No reduction was observed in women. An IRR reduction of 10 % was recorded for both sexes at high magnesium intakes. However, this study did not record daily drinking water consumption or the total daily intake of calcium, vitamin D and magnesium as well as of other minerals. Therefore, this limits the relevance of this study.

Overall, these studies do not provide robust evidence that calcium and magnesium intake via drinking water has a different nutritional-physiological relevance than that via other dietary intake.

3.2.3.2 Intervention studies

After intragastric administration of 22 ml/min of demineralised water[9] to healthy subjects, water absorption in the gastroduodenal segment (50 cm) was associated with net secretion of sodium and chloride into the intestinal lumen. Water absorption was highest in the following jejunal segment, with almost no electrolyte imbalance. In the ileum, with a near isotonic solution in the intestinal lumen, water absorption was accompanied by net absorption of sodium and potassium. With demineralised water, a higher rate of water absorption was observed in these intestinal segments than with a plasma-like solution. At the end of the seven-hour study, during which 9.2 l of demineralised water was administered to each subject (and during which time most likely no other food was consumed), all test subjects showed hyponatremia. When 15 l of demineralised water/day was given for three days in combination with a normal diet, hyponatremia was also observed (Santangelo & Krejs, 1986). Due to the high intake quantities of demineralised water, this study has only limited relevance for the present risk assessment.

After the administration of tap water (TDS: 59.0 mg/l, $CaCO_3$: 30.0 mg/l), bottled natural water (TDS: 87.2 mg/l; $CaCO_3$: 69.6 mg/l), bottled mineralised water (TDS 10.9 mg/l, $CaCO_3$: 2.3 mg/l) and bottled purified water (TDS: 1.2 mg/l, $CaCO_3$: 0.8 mg/l) to young men over 30 days, Luo et al. (2013) observed a decrease in total serum levels of cholesterol and low-density lipoprotein (LDL) in the groups given tap water and bottled natural water. In the two groups that received low mineral content water (i. e. bottled mineralised water and bottled purified water), this decline was less pronounced, or in the case of bottled mineralised water, there was an increase in both parameters. In the tap water group, the serum homocysteine level decreased, while it increased in the other three groups. The authors concluded that the consumption of bottled low mineral content water leads to a worsening of the serum lipid profile and an increase in the homocysteine serum level. In conjunction with the findings of an animal study cited above (Luo et al., 2013), the authors argue that their results provide evidence for low mineral content water increasing the risk of cardiovascular diseases. However, the authors do not provide any information on the diet of the subjects during the study, although diet strongly influences serum lipid levels. In addition, only the concentration changes of the lipid parameters were reported, but not the concentrations at the start of the study.

[9] This article describes the water used as ‘pure water’, which most likely means demineralised or distilled water.

Furthermore, the clinical relevance of the observed differences in these parameters is questionable, as is the relevance of serum homocysteine levels as a risk factor for cardiovascular disease. This strongly challenges the scientific validity of this human intervention study, as well as the results of the animal study (referred to above) that were also included in this article.

After 4 weeks of administration of water with low magnesium and high calcium content (Mg: 2 mg/l, Ca: 67.6 mg/l) (water ‘a’), water with high magnesium and low calcium content (Mg: 82.3 mg/l, Ca: 4 mg/l) (water ‘b’) and water with high magnesium and high calcium content (Mg: 84 mg/l, Ca: 486 mg/l) (water ‘c’) to individuals with borderline hypertension, who also exhibited low renal magnesium excretion (as well as calcium excretion), a significant reduction in blood pressure was observed following administration of the calcium- and magnesium-rich water (water ‘c’), whereas no significant changes to blood pressure occurred with the other two types of water. In the people studied, the administration of the magnesium-rich or the calcium-rich water led to an increase in the renal excretion of the mineral in question (elevated magnesium/creatinine or calcium/creatinine ratio) (Rylander and Arnaud, 2004).

In a study in athletes, test subjects received 4–4.5 l of water with high concentrations of calcium and magnesium (Ca: 177 mg/l, Mg: 151 mg/l), with medium concentrations (Ca: 89.6 mg/l; Mg: 11.4 mg/l) or, in the control group, with very low concentrations of calcium (1.2 mg/l), magnesium (0.4 mg/l) and other minerals daily over a period of 7 days. The authors state that no significant differences in total body water or intracellular or extracellular water were observed, either before or after a short period of physical-demanding activity. Comprehensive data supporting this conclusion were not provided, however (Chycki et al., 2017).

Overall, the human intervention studies currently available do not provide an adequate basis for the risk assessment of mineral water or drinking water with very low mineral content. On the other hand, mineral waters with very low mineral content have been available on the market for a long time without any known disturbances of the water and mineral homeostasis or other adverse health effects in people who otherwise follow a balanced diet (although no specific studies of this kind are available).

3.2.4 Individuals performing high-impact athletic activities and/or work in hot environments

During high-impact and prolonged sporting activities, and bouts of extreme physical exertion and/or work in high heat, fluid losses, depending on individual disposition and the degree of physical effort up to 0.3 to 2.4 l sweat/hour, and associated mineral losses can occur. At the forefront of mineral losses is sodium, whose average concentration in sweat is about 900–1150 mg/l and can rise to 1840 mg/l. Other salts include chloride (approx. 1065–2470 mg/l), potassium (approx. 156–312 mg/l) and magnesium (approx. 24–98 mg/l). Once the body has lost fluid equivalent to 2–4 % of body weight, drop in performance is to be expected in terms of physical strength and endurance (Mosler et al., 2019; Jeukendrup et al., 2015, Thomas et al., 2016).

According to recommendations of the working group on sports and nutrition of the German Nutrition Society (DGE), fluid intake is generally not necessary during sporting activities of less than 30–40 minutes. During prolonged sporting (physically strenuous) activities (> 1.5 h), the simultaneous intake of beverages containing carbohydrates (4–8 %) and sodium (400–1100 mg) is recommended to maintain athletic performance (Mosler et al., 2019).

In the case of sporting activities that involve considerable losses of sweat (e. g. long endurance sports), the risk of hyponatremia[10] resulting from excessive fluid intake is also pointed out (Mosler et al., 2019).

After exercise, fluid and electrolyte homeostasis must be restored. If body weight is reduced by less than 5 % and no further exertion is scheduled in the next 24 hours, athletes can replace fluids and electrolytes (particularly sodium) as they see fit. In this situation, the consumption of normal meals and snacks combined with an adequate intake of water is considered sufficient for the restoration of fluid and mineral homeostasis (Mosler et al., 2019). If fluid losses are greater or regeneration times are shorter, a more stringent approach is recommended (Mosler et al., 2019).

The facts presented illustrate the role of beverages in terms of fluid and carbohydrate replacement and as sources of minerals in the context of sporting activities. Mineral water can contribute as one of many sources of minerals as part of the general diet to replace sport-related mineral losses <u>after the sporting activity</u>. However, the low mineral content of very low-mineralised mineral water would then have to be compensated for by other foods, which does not seem to be an especially efficient strategy. <u>During prolonged (physically strenuous) sporting activities</u> (> 1.5 hours), the use of mineral water with very low mineral content is not recommended to replace fluids[11] in order to maintain athletic performance due to its low sodium and lack of carbohydrate content (whereby the recommended carbohydrate and sodium contents were based on the aspect of maintaining sporting performance). In terms of sodium content, however, this would also apply to a number of mineral waters that are not to be classified as mineral waters with very low mineral content.

3.2.5 Individuals with a diet-related marginal intake of minerals or with mineral deficiencies (very unbalanced diet) as well as people who deliberately avoid certain foods (e. g. milk and dairy products due to lactose intolerance or a vegan diet) [12]

The daily mineral intake may be low or even insufficient in individuals with a very unbalanced diet or for people on long-term fasting regimens, as well as for individuals who consciously avoid certain foods (e. g. milk and dairy products due to lactose intolerance or a vegan diet)[12]. Water or mineral water can be a significant source of minerals if the mineral content is appropriate. When using mineral, spring or table water with a very low mineral content to replace lost fluids, this water or mineral water can no longer be considered an appreciable source of minerals. In these groups of people[12], this can contribute to a deficiency or undersupply, especially of calcium and magnesium[13]. If people in this group switch from their usual mineral water type[14] to a water with very low mineral content, this can, depending on the mineral content of the water consumed previously, result in a more or less worsening of existing inadequacies in the daily intake of these minerals, especially of calcium and magnesium. However, the total daily intake of an individual mineral from the daily diet is important here, since water/mineral water constitutes only one of several daily sources of minerals.

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[10] Hyponatremia can be associated with severe health impairments.

[11] This refers to the sole or predominant consumption of mineral water with very low mineral content as a beverage of fluid replacement and maintenance of athletic/physical performance.

[12] This may affect adults, adolescents, children and infants.

[13] For people who follow a vegan diet, this is presumably less relevant in terms of magnesium intake.

[14] The use of 'mineral water type' here refers to mineral waters with significantly different mineral contents.

These groups of people[12] should pay attention to their total daily intake of certain essential minerals, especially calcium and magnesium, when using very low mineralised mineral water as an essential source of fluid. Essentially, this seems to be primarily a matter of raising awareness of the situation.

3.2.6 Pregnant and breastfeeding women

While women require a greater daily intake of minerals when they are pregnant or breastfeeding, this is typically met by a balanced and nutritious diet.

With regard to daily fluid intake, the German Nutrition Society recommends an intake of around 1.5 litres for adults in the form of beverages (DGE, 2019). Pregnant women do not have an increased fluid requirement compared to women of the same age who are not pregnant. In contrast, breastfeeding women are recommended to increase their fluid intake by about 250 ml/day (DGE, 2019). The intake reference values of the DGE take into account the amount of water that is necessary to ensure fluid homeostasis within the human body; the material composition of the water is largely irrelevant.

When using mineral, spring or table water with very low mineral content to replace lost fluids, this water or mineral water can no longer be considered as a source of minerals. As already discussed in section 3.2.5, together with other dietary factors this can contribute to an undersupply of certain essential minerals, especially calcium and magnesium. If a person switches from their usual mineral water type to a water with very low mineral content, this individual may no longer achieve an adequate intake of certain minerals (magnesium/calcium), depending on other sources of mineral intake and the mineral content of the water consumed previously. However, the total daily intake of an individual mineral from the daily diet is also important here, since drinking water/mineral water constitutes only one of several daily mineral sources.

If pregnant and breastfeeding women consume mineral waters with very low mineral content as their main source of fluids, they should pay attention to their total daily intake of certain essential minerals, especially calcium and magnesium. Ensuring an adequate intake of all essential nutrients is especially important for these two groups of people.

3.2.7 Infants

In the first six months of life, infants are either breastfed or fed using an industrially manufactured infant formula product. Exclusively breastfed infants do not require any further fluid intake. Infants who are not breastfed receive all essential nutrients from commercially available infant formulas. In the EU, the composition of these formula products must meet certain regulatory requirements. When prepared according to the manufacturer’s instructions, an adequate intake of minerals (and other nutrients) is ensured. Even the use of mineral water with very low mineral content to prepare infant formula would not result in unphysiological intakes of calcium or magnesium from the ready-to-use infant formula product (see also: WHO, 2009).

If, contrary to official recommendations, other foods are used to feed infants, such as purely plant-based products including almond milk, rice milk or plain soy-based drinks that do not have the mineral content of infant formula or follow-on formula, the use of mineral water with very low mineral content will further increase the risk of inadequate mineral intakes.

Mineral waters advertised as '*Suitable for the preparation of infant formula*' must comply with upper limits for certain mineral salts[15] and activity concentrations for two specific radionuclides, in accordance with the German MinTafWV, Annex 6. It cannot be ruled out that very low-mineralised mineral waters comply with these upper limits and may therefore be advertised accordingly. As stated above, the use of such low-mineralised water for the preparation of industrially produced infant formula does not pose a health risk. The possibility to label mineral water '*Suitable for the preparation of infant formula*' should therefore remain.

Even for infants of complementary feeding age, no adverse effects on health are to be expected from the use of mineral, spring or table waters with very low mineral content, either as a beverage or for the preparation of complementary food, provided their diet is balanced. The intake recommendations for calcium and magnesium are normally met by (continued) consumption of breastmilk or commercial infant formula or follow-on formula in combination with solid foods.

3.2.8 Persons suffering from diarrhoea

Unlike medicines, foodstuffs are not intended to cure or alleviate diseases. In this respect, a risk assessment of a foodstuff is not the right place to answer the medical question posed by a Federal State Office for Consumer Protection and Food Safety regarding the suitability of water with very low mineral content to replace fluids in cases of diarrhoea.

3.3 Exposure

3.3.1 Exposure assessment

The BfR evaluations on the consumption of bottled mineral water, table water and spring water (hereinafter: 'bottled mineral water') are based on data from the diet history interviews conducted during the German National Nutrition Survey II (NVS II) by the Max Rubner Institute (MRI) for adolescents and adults aged 14 to 80 years. The diet history method was used to interview 15,371 people between 2005 and 2006, who retrospectively recorded their typical consumption over the last four weeks (Krems et al. 2006; MRI 2008).

According to the BfR exposure assessment of the consumption of bottled mineral water, the median daily consumption (P50) of bottled mineral water in the adult German population is 1 litre (women: 1.0 l/day, men 1.06 l/day). In the 95th percentile, the intake in the total population is 2.6 l/day and in 19-24 year olds, who have the highest age-stratified consumption in the 95th percentile, it is 3.04 l/day.

Based on an assumed magnesium content of 30 mg/l[16], the median magnesium intake (P50) for the total population is 30 mg solely from the consumption of mineral water or 78 mg/day for frequent consumers (P95).

[15] Sodium (20 mg/l), nitrate (10 mg/l), nitrite (0.02 mg/l), sulphate (240 mg/l), fluoride (0.7 mg/l), manganese (0.05 mg/l), arsenic (5 µg/l), uranium (0.005 mg/l).

[16] In the German Nutrient Database (BLS, version 3.02), the magnesium content of carbonated and non-carbonated mineral water is specified as 30 mg/l. For all other waters/mineral waters listed there, concentrations of 10 mg/l are given. In the BfR MEAL Study, mineral water was also tested for magnesium as a pool sample. Initial evaluations of mineral waters relevant for the German market indicate that the average content lies between the values listed in the BLS for natural mineral waters and all other bottled mineral, table and spring waters.

According to the evaluation of the MRI of the NVS II, the median total intake of magnesium (P50) is 361 mg per day for women and 432 mg per day for men. Non-alcoholic beverages are the main source of magnesium intake with about 25–28 % (MRI, 2008).
The present exposure assessment shows a median magnesium intake from bottled mineral water of 30.0 mg/day for women and 31.5 mg/day for men. Based on the median intakes from the MRI report, this is equivalent to a daily proportion of 8.3 % for women and 7.3 % for men.

3.3.2 Bioavailability of magnesium and calcium from mineral water

In healthy female subjects, the average bioavailability of magnesium from mineral water (Mg concentration: 110 mg/l) was around 46 % (range: 40–56 %) when consumed on its own. When consumed together with a meal, absorption increased to 52 % (range: 46–60 %) (Sabatier et al., 2002). A further study involving 10 male subjects (aged 25–42) revealed that the average bioavailability of magnesium from mineral water was around 59 % (range: 36–85 %); the age of the subjects showed an inverse correlation with the bioavailability of magnesium (Verhas et al., 2002).
In comparison, the European Food Safety Authority (EFSA) generally states an absorption rate of 40-50 % for oral magnesium intake, although values of 10–70 % have also been reported. Here, the percentage rate of magnesium resorption is inversely correlated with the magnesium intake (EFSA, 2015b).

Two comprehensive reviews are available on the absorption of calcium from mineral water (Bohmer et al., 2000; Heaney, 2006). The bioavailability of calcium from mineral water is comparable to that from milk and ranged from around 24 % (for an intake of 248 mg calcium) to 48 % (for an intake of 100 mg calcium), depending on the amount of calcium available and whether the mineral water was consumed together with a meal or in the absence of an additional, solid foodstuff.
In comparison, EFSA states a general intestinal absorption rate of about 25 % for the oral intake of calcium in adults (EFSA, 2015a).

3.4 Risk characterisation

Mineral water can have a wide range of mineral contents, ranging from low total mineral contents in very low-mineralised mineral water to mineral water with very high contents. Mineral water with a mineral content of ≤ 50 mg/l, which can be claimed as '*with very low mineral content*' in accordance with the German legislation (MinTafWV, Annex 6) has long been available on the German market. Due to the prescribed indication of the analytical composition, as required by regulation or the above mentioned claim, very low-mineralised mineral water is recognisable as such for the consumer.

Water with very low mineral content is also used as drinking water. In preparing a risk assessment of the use of this kind of drinking water, the primary question of interest concerns the correlation between low concentrations of magnesium and calcium in drinking water or low water hardness and an increased risk of the occurrence of cardiovascular disease, which is essentially based on the findings of epidemiological studies in humans.

Overall, even taking into account the studies conducted with drinking water, there are currently only a few studies available for a risk assessment of very low-mineralised mineral water or water and there are gaps in knowledge regarding their health assessment. The identified intervention studies in animals and humans involving the administration of distilled water or water/mineral water with low or very low mineral contents, do not provide an adequate basis for a risk assessment of very low-mineralised mineral water/water due to various limitations.

However, the following additional points are important for the risk assessment of very low-mineralised water:

- The scientific validity of several more recent animal and human intervention studies describing negative health effects caused by water with very low mineral content (Luo et al., 2013; Qiu et al., 2015) is questionable.

- With regard to existing epidemiological studies with drinking water, the WHO stated that the results of these studies are not sufficient to prove a causal relationship between low magnesium and calcium contents of drinking water or low water hardness and an increased risk for the occurrence of cardiovascular disease (WHO, 2011; 2017). These conclusions have remained unchanged by the appearance of other epidemiological studies following the publication of the assessments made by the WHO.

  With regard to recommended limits for water hardness, the WHO has drawn on its previous assessments and concluded that the data as currently available are inadequate for recommending minimum or maximum levels for the mineral content of water (with magnesium and calcium being the most important minerals here), since an adequate mineral intake that meets an individual's daily needs depends on a number of other factors. Therefore, no minimum or maximum values for water hardness of drinking water were proposed, especially since, according to the WHO, there are no health concerns with the water hardness values typically found in drinking water (WHO, 2017). In the BfR's view, this assessment is also transferable to mineral water. As a result, no scientific justification can be derived from the above-mentioned epidemiological studies, according to which a minimum mineral content of mineral water appears to be necessary for health reasons.

- Mineral water can make a significant contribution to the daily intake of essential minerals, especially calcium and magnesium, if the mineral content is appropriate. This applies in particular to individuals with low intakes of calcium and magnesium. However, mineral water is only one of several sources of minerals in the human diet, and nutrient intake via water or beverages is not considered to be of any particular quality compared to nutrient intake via solid food, apart from possibly slightly better bioavailability. As regards water and mineral homeostasis in the body, research to date has not shown that the actual source (fluid or solid food) of the mineral is important. A lower mineral intake due to the consumption of water with very low mineral content can be compensated by the intake of minerals from other types of food. In this respect, no adequate scientific justification can be derived from considerations of the relevance of mineral water as a source of minerals for human nutrition that would argue for the establishment of minimum total mineral concentrations in mineral water—at least for magnesium and calcium—on health grounds.

- For individuals who achieve only a low dietary intake of minerals from the foods they typically consume, the use of mineral water with very low mineral content can <u>be a contributory factor</u> to a low or deficient intake of minerals (just as is possible with other foods containing low concentrations of minerals that make up a significant part of the liquid or total dietary intake). This applies in particular to individuals with a very unbalanced diet, for people on prolonged fasting regimens or for people who consciously avoid certain

foods (e.g. milk and dairy products due to lactose intolerance or a vegan diet). If these individuals consume mineral waters with very low mineral content as their main source of fluids, they should be mindful of their total daily intake of certain essential minerals, especially calcium and magnesium[17]. Similarly, pregnant and breastfeeding women should pay attention to their daily intake of certain minerals, especially calcium and magnesium, when using very low-mineralised mineral water as their main source of fluids. Ensuring an adequate intake of all essential nutrients is especially important for these individuals.
During prolonged periods of strenuous physical activity (>1.5 hours), very low-mineralised mineral water is not recommend as a beverage[18] to replenish fluids and maintain athletic performance.

In summary, there are currently only few studies available for a risk assessment of very low-mineralised mineral water and there are knowledge gaps in its risk assessment. However, according to the current state of knowledge, with a balanced diet and normal drinking quantities, no adverse effects can be identified that would suggest advising against the use of mineral, spring and table waters with very low mineral content.

People with a very unbalanced diet and those who deliberately avoid certain foods (e. g. milk and dairy products due to lactose intolerance or a vegan diet)[19] as well as pregnant and breastfeeding women should ensure that they are getting adequate daily quantities of certain essential minerals, especially calcium and magnesium, when using very low-mineralised mineral water as a primary source of fluid[20]. For individuals engaging in prolonged sporting or physically demanding activities (>1.5 hours), the use of mineral water with very low mineral content is not recommended as a fluid replacement[21] to maintain athletic performance.

Further information on mineral water is available on the BfR website:

List of all BfR publications on mineral water:
https://www.bfr.bund.de/en/a-z_index/mineral_water-129970.html

FAQ on uranium in mineral water (28 January 2009):
https://www.bfr.bund.de/cm/349/frequently_asked_questions_about_uranium_in_mineral_water.pdf

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[17] For people who follow a vegan diet, this is presumably less relevant in terms of daily magnesium intake.

[18] This refers to the sole or primary consumption of very low-mineralised mineral water as a beverage for fluid replacement and to maintain athletic or physical performance.

[19] This may affect adults, adolescents, children and infants.

[20] For people who follow a vegan diet, this is presumably less relevant in terms of daily magnesium intake.

[21] This refers to the sole or primary use of mineral water with very low mineral content as a beverage to replenish fluids and to maintain athletic/physical performance.

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2About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. The BfR advises the Federal Government and the federal states ('Länder') on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

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