Superior
Health Council

PFAS AND PERCHLORATE IN BOTTLED WATER AND WATER USED FOR MANUFACTURING FOODSTUFFS

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Superior Health Council

ADVISORY REPORT OF THE SUPERIOR HEALTH COUNCIL no. 9791

PFAS and perchlorate in bottled water and water used for manufacturing foodstuffs

In this scientific advisory report, which offers guidance to public health policy-makers, the Superior Health Council of Belgium provides advice concerning exposure and health risks regarding PFAS and perchlorate in bottled water and water used for manufacturing foodstuffs.

This version was validated by the Board on February 7, 2024[1]

I INTRODUCTION AND ISSUE

The Superior Health council (SHC) received a request for advice on the 22nd of August 2023 from the Belgian Minister of Social Affairs and Public Health, Frank Vandenbroucke, and the Belgian Minister of Climate, Environment, Sustainable Development and Green Deal, Zakia Khattabi, concerning the effect on the health risk for Belgian consumers and on the relevance for the protection of the health of Belgian consumers of the establishment of a target value for the sum of 4 PFAS and a maximum limit for perchlorate in bottled water and water used for the manufacturing of foodstuffs.
The 4 PFAS targeted are: perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA) and perfluorohexane sulfonic acid (PFHxS).

Ten questions were addressed to the Superior Health Council:

1. What is the effect on exposure and (chronic) health risk for the various Belgian consumer groups of setting a non-binding national target value of 4 ng/L for the sum of PFOA, PFOS, PFNA and PFHxS in water that is used in the processes of manufacturing, processing, preserving and marketing the various categories of foodstuffs?
2. What is the effect on exposure and (chronic) health risk for the various Belgian consumer groups of setting a national target value of 4 ng/L for the sum of PFOA, PFOS, PFNA and PFHxS in bottled water (spring water and drinking water)?
3. What is the effect on exposure and health risk (chronic and acute) for the various Belgian consumer groups of setting a maximum limit of 13 µg/L and 15 µg/L for perchlorate in water that is used in the processes of manufacturing, processing, preserving and marketing the various categories of foodstuffs?
4. What is the effect on exposure and health risk (chronic and acute) for the various Belgian consumer groups of setting a maximum limit of 13 µg/L and 15 µg/L for perchlorate in bottled water (spring water and drinking water)?

[1] The Council reserves the right to make minor typographical amendments to this document at any time. On the other hand, amendments that alter its content are automatically included in an erratum. In this case, a new version of the advisory report is issued.

5. On the basis of the answers to questions 1 and 2, what is the scientific relevance for the health protection of the various Belgian consumer groups of setting a national target value for the sum of PFOA, PFOS, PFNA and PFHxS in bottled water and in water that is used in the processes of manufacturing, processing, preserving and marketing the various categories of foodstuffs?
6. On the basis of the answers to questions 3 and 4, what is the scientific relevance for health protection of the various Belgian consumer groups of setting a maximum limit for perchlorate in bottled water and in water used in the manufacturing, processing, preservation and marketing of the various food categories?
7. Can the methodology used to set the target value of 4 ng/L for the sum of PFOA, PFOS, PFNA and PFHxS in drinking water from the distribution network be transposed as it stands to water used in the manufacturing, processing, preservation and marketing of the various food categories? If not, what methodology should be used and what would be the result?
8. Is the methodology used to set the target value of 4 ng/L for the sum of PFOA, PFOS, PFNA and PFHxS in drinking water from the distribution network transposable as it stands for bottled water (spring water and drinking water)? If not, what methodology should be used and what would be the result?
9. Is the methodology used to set the parametric value of 13 µg/L (Flanders) or 15 µg/L (Walloon and Brussels-Capital Regions) for perchlorate in drinking water from the distribution network transposable as it stands for water used in the manufacturing, processing, preservation and marketing of different categories of foodstuffs? If not, what methodology should be used and what would be the result?
10. Is the methodology used to set the parametric value of 13 µg/L (Flanders) or 15 µg/L (Walloon and Brussels-Capital Regions) for perchlorate in drinking water from the distribution network transposable as it stands for bottled water (spring water and drinking water)? If not, what methodology should be used and what would be the result?

The Federal Public Service for Health is responsible for measures relating to water used by food companies for the production, processing, preservation and/or commercialization of food, including bottled water (spring water and drinking water). According to Article 5, §1 of the Law of January 24, 1977 concerning the protection of consumer health regarding foodstuffs and other products, the national regulatory measures for contaminants in foodstuffs must be submitted for opinion to the SHC.

II CONCLUSION

The SHC supports the use of the proposed target value of 4 ng/L for the sum of 4 PFAS (PFOA, PFOS, PFNA and PFHxS), both for food preparation and bottled water. This target value is toxicologically sound and is in line with a proposal for drinking water guidelines based on the Tolerable Weekly Intake (TWI) as derived by EFSA (2020). The SHC stresses the need for the introduction of a target value, as measured concentrations in water that can be used as a source for preparations exceeds the proposed target value in some cases. As such the SHC is of the opinion that the exposure of the Belgian population may decrease if bottled water and water that is used for manufacturing, processing, preserving and marketing various categories of foodstuffs complies with a target value of 4 ng/L.

There remains uncertainty about the extent of transfer of contaminants from the preparation water to the food as PFAS components can bind to proteins.

It should be noted that the proposed target value of 4 ng/L for 4 PFAS is considered a positive measure as it is protective for the four mentioned substances. The SHC stresses the importance to quantify not only linear, but also branched isomers of these compounds to get accurate occurrence data.
However, the SHC also suggests setting an additional target value for the sum of 20 relevant PFAS substances that can be accurately measured in water as mentioned in the Drinking Water Directive (2020/2184/EU) which sets a limit of 100 ng/L for the sum of 20 PFAS . This is needed as more PFAS than the four mentioned substances are found both in drinking water and in other water sources.

The SHC recommends closely monitoring the knowledge database of the quantifiable PFAS to derive health-based guidance values applicable for risk assessment. This also applies to linear and branched isomers of PFAS.
The SHC recommends that more occurrence data of PFAS in processed food items should be obtained.
The SHC recommends that effective risk management measures should be implemented to comply with the proposed target value for the sum of the 4 PFAS (PFOA, PFOS, PFNA and PFHxS) in bottled water and water used for manufacturing foodstuffs.

It is the opinion of the SHC that a maximum limit of 13 µg/L and 15 µg/L of perchlorate in water used in the manufacturing, processing, preservation and commercialization of the different categories of food products or to prepare bottled water is an acceptable maximum limit for the general population. We suggest the use of the lowest value as a limit. Considering measurement uncertainties in analytical chemistry, these values (13 and 15 µg/L) are in fact quite similar. For sensitive subgroups, such as toddlers and children, the SHC recommends a lower maximum limit value. A maximum limit value of 2 µg/L would comply with the EFSA TDI of 0.3 µg/kg bw per day for babies and infants.

III METHODOLOGY

After analysing the request, the Board and the co-Chairs of the Chemical Environmental Factors group identified the necessary fields of expertise. An *ad hoc* working group was then set up which included experts in toxicology, oncology, cancer prevention, environmental health, neuroendocrinology and chemistry. The experts of this working group provided a general and an *ad hoc* declaration of interests and the Committee on Deontology assessed the potential risk of conflicts of interest.

This advisory report is based on a review of the scientific literature published in both scientific journals and reports from national and international organisations competent in this field (peer-reviewed), as well as on the opinion of the working group members. The scientific literature was collected using search engines such as Google Scholar and databases such as PubMed, Web of Science and Scopus.

Once the advisory report was endorsed by the working group and experts from Sciensano, it was ultimately validated by the Board.

Keywords and MeSH *descriptor terms*[2]

MeSH terms*	Keywords	Sleutelwoorden	Mots clés	Schlüsselwörter
Drinking Water	Drinking Water	Drinkwater	Eau potable	Trinkwasser
Environment and Public Health	Environment and Public Health	Milieu en Volksgezondheid	Environnement et santé publique	Umwelt und öffentliche Gesundheit
Environmental pollutants	Environmental pollutants	Milieuverontreinigende stoffen	Contaminants de l'environnement	Umweltkontaminanten
Fluorocarbons	Per-and polyfluoroalkyl substances	Per- en polyfluoralkylstoffen	Substances per- et polyfluoroalkylées	Per- und polyfluorierte Alkylverbindungen
Perchlorates	Perchlorates	Perchloraten	Perchlorates	Perchlorate

MeSH (Medical Subject Headings) is the NLM (National Library of Medicine) controlled vocabulary thesaurus used for indexing articles for PubMed http://www.ncbi.nlm.nih.gov/mesh.

List of abbreviations used

ALARA	As Low As Reasonably Achievable
ANSES	*Agence Nationale de Sécurité Sanitaire de l'Alimentation, de l'environnement et du travail*
ATSDR	Agency for Toxic Substances and Disease Registry
BBDR	Biologically based dose–response
BMD	Benchmark dose
BMDL	Lower confidence limit of the benchmark dose
bw	Body weight
C	Daily drinking water consumption
CAR	Constitutive androstane receptor
CONTAM	Panel on Contaminants in the Food Chain

[2] The Council wishes to clarify that the MeSH terms and keywords are used for referencing purposes as well as to provide an easy definition of the scope of the advisory report. For more information, see the section entitled "methodology".

DWD	Drinking Water Directive
EFSA	European Food Safety Authority
EPA	U.S. Environmental Protection Agency
EU	European Union
fT4	Free thyroxine
GV	Guidance value
HBM	Human Biomonitoring
Hib	Haemophilus influenzae type b
IARC	International Agency for research on Cancer
IQ	Intelligence quotient
ISSeP	*Institut Scientifique de Service Public*
LB	Lower Bound
LOAEL	Lowest-Observed-Adverse-Effect-Level
LOQ	Limit of quantification
MB	Middle Bound
ML	Maximum Limit
NIS	Sodium-Iodide symporter protein
NOEL	No Observed Effect Level
P	Allocation factor
PFAS	Per- and polyfluoroalkyl substances
PFBS	Perfluorobutanesulfonic acid
PFDA	Perfluorodecanoic acid
PFHxA	Perfluorohexanoic acid
PFHxS	Perfluorohexanesulfonic acid
PFNA	Perfluorononanoic acid
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctanesulfonic acid
PFPeA	Perfluoropentanoic acid
PPARα	Peroxisome proliferator-activated receptor α
PPARγ	Peroxisome proliferator-activated receptor γ
PXR	Pregnane X receptor
RfD	Reference dose
SHC	Superior Health Council
SWDE	*Société Wallonne des Eaux*
TDI	Tolerable Daily Intake
TRV	Toxicological Reference Value
TWI	Tolerable Weekly Intake
UB	Upper Bound
US	United States
VITO	*Vlaams Instituut voor Technologisch Onderzoek*
VMM	*Vlaamse Milieu Maatschappij*

IV ELABORATION AND ARGUMENTATION

1 Introduction

Per- and polyfluoroalkyl substances (PFAS)

Per- and polyfluoroalkyl substances (PFAS) are a large, complex group of synthetic chemicals that have been used in a wide range of consumer products around the world since about the 1950s. As these molecules are water, oil and grease repellent, they are used as ingredients in various everyday products, such as food packaging, cookware, outdoor gear and firefighting foam (Glüge et al., 2020). Emissions during production, manufacturing, usage and disposal, resulted in widespread contamination of the environment (Evich et al., 2022). PFAS molecules have a chain of linked carbon and fluorine atoms, and because the carbon-fluorine bond is one of the strongest, these chemicals do not degrade easily in the environment and are therefore known as “forever chemicals”. Additionally, many of these polyfluorinated compounds are known to bioaccumulate and biomagnify (George et al., 2023).
From a regulatory and toxicological perspective, two substances have received a lot of attention in the past, namely perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS). They are widely used, ubiquitous and characterised by a chain of eight carbon atoms (C8 molecules). More recently, other PFAS compounds such as PFHxS , PFNA and also some shorter chain PFAS molecules are studied as well, but many PFAS compounds remain poorly characterised (Fenton et al., 2021).
PFAS are primarily manufactured through electrochemical fluorination or telomerization reactions. The telomerization process produces substances consisting of only linear alkyl chains, whereas electrochemical fluorination (ECF) produces a mixture of branched and linear isomers (Buck et al., 2011). Only rather recently, branched PFAS isomers can be measured and the PFAS branched to linear isomer ratio is used as a source characterization tool.
Analyzing PFAS presents significant challenges due to the necessity of achieving low limits of detection. Ensuring blank measurements can be difficult, as potential contaminations may arise from various sources, including the materials used (such as solvents and pipets), the equipment employed, or even the operator themselves (such as through personal care products). As PFAS also exist in multiple branched isomeric forms, each with its own distinct properties, considerable research attention has been devoted to developing analytical methods capable of addressing these branched isomers. However, the scarcity of pure and unique branched PFAS certified reference materials severely hampers the ability to quantify these substances accurately. Additionally, achieving chromatographic separation of all unique branched isomers, which is essential for reliable quantification, is not always feasible.
The physical-chemical and toxicological properties of linear and branched isomers differ slightly which leads to differences in their relative distribution and fate in environmental compartments (Sadia et al., 2023) as well as in the human body (Varsi et al., 2022). The current risk assessments do not yet distinguish between linear and branched forms but this may be needed if more information is obtained.
In the human body, PFAS bind to blood proteins and transporter molecules. They accumulate in liver, blood and kidneys, they cross the placenta and are transferred from mother to the baby by breast milk (Loccisano et al., 2013). The accumulation levels vary based on PFAS types, human tissues, life stages, and genders (Perez et al., 2013).
Environmental concentrations of PFOA and PFOS show an increase from the 1970s to the 2000s, followed by a decrease from the 2000s to the 2010s (Calafat et al., 2007; Sundstrom et al., 2011). Serum levels are influenced by age, demographics and manufacturing processes (Colles et al., 2020; Sunderland et al., 2019).
Humans are exposed to PFAS mainly by ingestion (food, drinking water, dust). Inhalation and dermal contact contribute to a lesser extent (Trudel et al., 2008). Consumption of crops grown in contaminated areas may result in an elevated body burden (Liu et al., 2019) . Dust in the occupational or living environment may contribute significantly to the daily intake (Fu et al.,

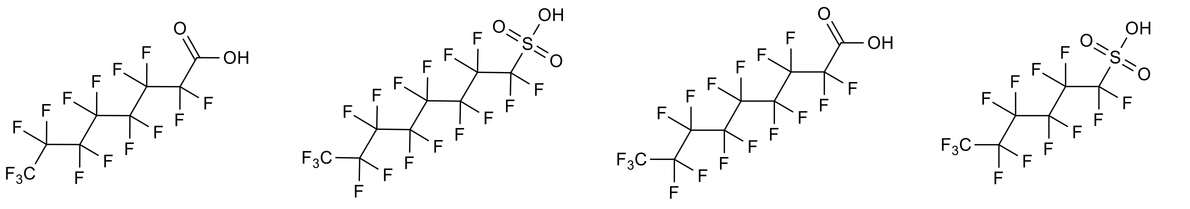
2015). A Norvegian study showed that for some study participants, house dust ingestion and indoor air inhalation contributed most to the total intakes (Poothong et al., 2020).
Expert panels from EFSA, and US ATSDR have recently reviewed and summarized current knowledge from experimental and epidemiological studies on PFAS substances (Agency for Toxic Substances and Disease Registry, 2021; Schrenk et al., 2020). Of the relatively few well-studied PFAS, most are considered moderately to highly toxic. A variety of adverse health outcomes are observed depending on age, sex and type of PFAS substance. This has to do with the endocrine disrupting properties of PFAS substances, the induction of oxidative stress and/or epigenetic alterations caused by PFAS substances (Boyd et al., 2022; Kim et al., 2021). Interference with PPARα (Peroxisome proliferator-activated receptor α), PPARγ (Peroxisome proliferator-activated receptor γ), CAR (constitutive androstane receptor) and PXR (pregnane X receptor) have been observed in experimental animals which may be a mechanism related to the liver damage seen in experimental animals (Gundacker et al., 2022). Also in humans changes in liver enzymes, increases in cholesterol, liver damage, increased risks for diabetes type 2 and cardiovascular diseases are associated with exposure to elevated PFAS concentrations at the workplace or in the living environment around contaminated sites (Costello et al., 2022; Wang et al., 2022; Wen et al., 2023; Yan et al., 2022).
Several studies in mother child cohorts have shown associations of elevated maternal exposure to certain PFAS with reduced birth weight and with increased risk for pre- term birth risk (PFOS, PFNA, PFOA), miscarriage (PFDA), preeclampsia (PFOS), being born small for gestational age (PFDA) and intra uterine growth retardation (PFOS, PFOA) (Cao et al., 2021; Gao et al., 2021; Govarts et al., 2018; Gui et al., 2022). In experimental animals PFAS exposure caused low birth weight, birth defects, delayed development, and newborn deaths. Changes in levels of thyroid hormones and of sex hormones have been observed in experimental animals and in human studies (Gundacker et al., 2022; Rodríguez-Carrillo et al., 2023), as well as changes in male fertility (sperm motility and sperm concentration) (Hærvig et al., 2022; Wang et al., 2023) and female fertility (Polycystic Ovarian syndrome, delayed menarche)(Hammarstrand et al., 2021; Wang et al., 2023). Very recently an IARC working group conducted a cancer hazard evaluation of PFOA and PFOS and classified PFOA as *carcinogenic to humans* (Group 1) (renal cell carcinoma and testicular cancer) and PFOS as *possibly carcinogenic to humans* (Group 2B)(Zahm et al., 2023).
Immune suppression is considered as the most sensitive endpoint after exposure to PFAS. Multiple well conducted studies in different populations of exposed humans, including children and adults, have shown that exposure to PFOA is associated with increased risk of infectious diseases and decreased vaccine response to diverse antigens (Dalsager et al., 2021; Grandjean et al., 2012). These findings are corroborated by evidence of decreased production of cytokines and reduced lymphoproliferation in human primary cells and by altered antibody responses to T-cell-dependent antigens and leukocytes in rodents (Corsini et al., 2014; Peden-Adams et al., 2008).
Biomonitoring studies have shown that humans are exposed to PFAS mixtures (Bil et al., 2023). The health effects of mixtures are largely unknown. Evaluating PFAS toxicity is challenging due to complexity of this class of contaminants, lack of an unexposed population, a broad variety of exposure factors, and the human body's complexity (Wee and Aris, 2023).

At the request of the European Commission, the European Food Safety Authority (EFSA) assessed the risks of PFAS to human health arising from the presence of these substances in food (Schrenk et al., 2020).

EFSA scientists identified toddlers and other children as the most exposed population groups, and exposure during pregnancy and breastfeeding as the main contributor to PFAS levels in infants. They selected as the critical study the decreased vaccination response against tetanus, diphtery, and haemophilus influenzae type b (Hib) in one year old children (Abraham et al., 2020). They identified as a safety threshold the serum level of the mother (sum of PFOA, PFNA, PFHxS and PFOS), that corresponds with 10% reduction in vaccination response in the child at one year assuming one year of breastfeeding (Schrenk et al., 2020).

This serum level has been converted by pharmacokinetic modelling to a Tolerable Weekly Intake (TWI)(Loccisano et al., 2013). As such, the EFSA opinion sets a group tolerable weekly intake (TWI) limit of 4.4 ng/kg body weight for the sum of four PFAS substances (PFOA, PFNA, PFOS and PFHxS) (Figure 1) (Schrenk et al., 2020).

These four substances co-occur in the body and contribute most to the PFAS levels currently observed in human serum. In adults, the four PFAS contributed approximately 46% to the sum for which the exposure was calculated. Other PFAS that contributed more than 5% to this sum were PFBA (16%) and PFHxA (15%), which have shorter half-lives in humans than PFOA (Schrenk et al., 2020).



PFOA	PFOS	PFNA	PFHxS
Perfluorooctanoic acid	Perfluorooctanesulphonic acid	Perfluorononanoic acid	Perfluorohexanesulphonic acid
CAS 335-67-1	CAS 1763-23-1	CAS 375-95-1	CAS 355-46-4

Figure 1*: Structure and name of the 4 PFAS compounds selected by EFSA. Only the linear variants are shown.*

Drinking water, fish, fruit, eggs and derived products are major contributors to dietary PFAS intake (Cornelis et al., 2012; Fabelova et al., 2023; PERFOOD, 2012; Schrenk et al., 2020; Sunderland et al., 2019).
Food can become contaminated with PFAS through contaminated soil and water used to grow the food (in particular in the vicinity of production facilities of industrial premises which uses PFAS in their products, e.g. textile, paper, metal industry, etc.), through the bioaccumulation of these substances in animals via feed and water, through leaching from food packaging containing PFAS, or from food processing equipment that contains PFAS.

Human biomonitoring (HBM) data from Flanders (Colles et al., 2020; Schoeters et al., 2022) and from Wallonia (Pirard et al., 2020) have shown that all participants of HBM studies have quantifiable serum levels of PFOS and PFOA, with PFOS the most abundant compound, while levels of PFNA and PFHxS were lower. HBM-data may be compared with internal concentrations that correspond with the intake limits recently proposed by EFSA based on the reduced vaccination response in one year old children as critical effect. In the Flemish study (FLEHS IV) with sampling in 2017, 15.7 % out of the 428 participating adolescents exceeded the health based human biomonitoring guidance values for the sum of PFOS, PFHxS, PFOA and PFNA (6.9 ng/ml) that corresponds to the TWI derived by EFSA based on reduced vaccination response in children.
In a Walloon study with 242 adults (>18 years) sampled in 2016, about 50% of the study participants had serum values that exceeded the health based HBM guidance values (HBM-I values) set by the German Human Biomonitoring Commission at respectively 5 and 2 ng/mL for PFOS and PFOA based on human epidemiological studies reporting association with PFOS and PFOA exposure and fertility impairments, reduced weight of newborns at birth, lipid metabolism disorders, and immunity impairments after vaccination (Hölzer et al., 2021; Pirard et al., 2020).

Perchlorate

Perchlorate is a monovalent inorganic anion with the formula ClO_4^- and has oxidizing properties. Naturally occurring in some minerals, perchlorate is also thought to be formed through certain atmospheric processes. Perchlorate is widely used in various industries, including the production of munitions, explosives, fireworks, and road flares. It is also used as an oxidizer in flares, pyrotechnics, and as a chemical sensitizing agent in detergent-based lab glassware cleaning agents. Due to its exceptional oxidizing capacity, perchlorate is used in numerous applications, ranging from medical treatments to consumer products (Nizinski et al., 2021). Perchlorate is relatively stable in the environment and very mobile as it is highly water soluble. Contamination of food and drinking water may originate from the presence of perchlorate in soil and water. It comes from natural or industrial sources close to water catching areas. Perchlorate is also a well-known component of fertilizers of natural origin, such as Chilean nitrate, mainly applied for growing vegetables. Disinfection of drinking water with chlorine or gaseous ClO_2, may be another source of drinking water contamination (Cao et al., 2019; FPS Health Food Chain Safety and Environment, 2023; Nizinski et al., 2021; Wu et al., 2010).
In its scientific opinion of 2017, the EFSA CONTAM Panel assessed the exposure levels to perchlorate, considering approximately 12,000 results on occurrence of perchlorate, mainly on fruit and vegetables submitted by eight European Union (EU) Member States, as well as literature occurrence data on infant formula, milk and dairy products, alcoholic beverages, fruit juices and breast milk. 'Vegetable and vegetable products', 'Milk and dairy products' and 'Fruit and fruit products' were found to be important contributors to the exposure across all population groups (Arcella et al., 2017).
The main health concern of human perchlorate exposure is related to the biochemical activity of perchlorate to competitively inhibit thyroid iodine uptake via the sodium-iodide symporter protein (NIS), hence causing possible disruption of the hypothalamic–pituitary–thyroid axis homoeostasis (Serrano-Nascimento and Nunes, 2022).
The choice of a health-based reference value is crucial in determining maximum limits. There are some relevant factors determining this choice. First, there is the consideration of iodine uptake inhibition as an effect, with or without health significance. Additionally, the perspective on whether to view the inhibition of iodide uptake in adults or the reduction of IQ in offspring as a primary health endpoint plays a role. The choice between using a NOEL (No Observed Effect Level) or a BMD (Benchmark Dose) value as a starting point for deriving a reference value is another factor. Furthermore, the decision to apply additional uncertainty factors to be protective also for sensitive groups, such as unborn children and infants, introduces variability in the health based reference values. The allocation of the largest contribution to total exposure, through drinking water or food, is also a consideration. Lastly, the decision to base drinking water intake calculations on either infants or adults contributes to the diversity in the derivation of these reference values.

The investigation conducted by Greer et al. (2002) and other human studies have not yet revealed a clear link between exposure to perchlorate through drinking water and discernible health effects. This lack of clarity might be due to limited research sample sizes, brief study durations, and the inclusion of exclusively healthy adults (Steinmaus, 2016; Zewdie et al., 2010). Consequently, it remains uncertain whether the level of iodide uptake inhibition related to drinking water exposure will actually result in impacts on thyroid hormones. If this is not the case, as argued by the World Health Organization (WHO), further reducing concentrations in drinking water may not yield health advantages. Guidelines for drinking water derived from a NOEL, LOAEL, or BMD based on iodide inhibition could potentially be overly cautious. However, these guidelines do offer additional safeguards for prolonged exposure and for individuals with low iodide intake or thyroid issues. The European Food Safety Authority (EFSA) goes as far as suggesting that sustained inhibition of iodine uptake may indeed be linked to compromised thyroid function. The US Environmental Protection Agency (EPA) acknowledged scientific evidence in 2019 supporting the inhibition of iodide uptake and, consequently, the production of thyroid hormones by perchlorate.

While it seems likely that perchlorate affects pregnant women, unborn, and newborn children more profoundly, supported by recent studies, there remains no unanimous stance on the health repercussions of perchlorate for these specific groups. Variables like age, thyroid conditions, iodine intake, and other contaminants could potentially impact the outcomes of studies and the methodologies used for analysing perchlorate exposure, thyroid hormone levels, and statistical analysis (Steinmaus, 2016). In instances of heightened sensitivity within a subpopulation, it is advisable to base the health-based reference value on dose-response data for that particular group (Strawson et al., 2005). Some drinking water reference values incorporated an additional uncertainty factor (beyond the 10-fold factor for interindividual differences) for these subpopulations, and/or the allocation to drinking water or drinking water intake was specifically tailored to pregnant women or children. In 2019, the US Environmental Protection Agency (EPA) did, in fact, derive a health-based toxicity reference value of 0.7 µg/kg bw per day for perchlorate based on the most sensitive subpopulation: the foetus of pregnant women with low iodine intake and impaired thyroid function (EPA, 2019).

2 Elaborated answers to the questions

The questions posed to the SHC address the use of water in food production and the potential contamination of these water sources with PFAS and perchlorate.
In a very broad sense, there are four major uses of water in food production:

1) primary production,
2) cleaning and sanitation,
3) processing operations,
4) as food ingredient.

Water used for primary production refers to water used for watering crops, irrigation, maintenance of equipment, maintenance of the general hygiene of livestock, and livestock drinking. In food processing, water is used for boiling or steaming to prepare food such as pasta and rice, soups, tea and coffee. Water is used for transport of food products during processing, and for cleaning of food products and food processing equipment. There are also food items where water is an important component, such as soups, jams, or it is even the main ingredient, such as in fruit juices or beers. Aside from that, water may be used as a medium through which food can be preserved, stored, and consumed by humans.
Contaminants in the water used for food preparation can be concentrated or diluted in the final food product. This depends on the contaminant, the type of food and the preparation method. In this way substances can further contaminate food items and contribute to human exposure (Bhagwat, 2019; Linderhof et al., 2021).

Answer to question 1 : *"What is the effect on exposure and (chronic) health risk for the various groups of Belgian consumers of setting a non-binding national target value of 4 ng/L for the sum of PFOA, PFOS, PFNA and PFHxS in water used in the manufacturing, processing, preservation and marketing of the various categories of foodstuffs?"*

Effect on exposure

Based on the most recent food occurrence data and consumption data, EFSA concluded in its opinion of 2020 that PFAS contaminant intake by food contributes significantly to PFAS exposure of the general public (Schrenk et al., 2020).
For the group of adolescents, adults, elderly and very elderly, mean Lower Bound (LB) exposure to the 4 EFSA PFAS varied among surveys between 3 and 22 ng/kg bw per week or 0.4 and 3.1 ng/kg bw per day. P95 (LB) ranged between 9.1 and 70 ng/kg bw per week. For toddlers and children mean LB exposure varied between 6 and 46 ng/kg bw per week (0.9 and 6.6 ng/kg bw per day) P95 (LB) ranged between 18.9 and 95.9 ng/kg bw per week (Schrenk et al., 2020). Table 1 shows the specific data from the surveys that took place in Belgium. However the EFSA panel acknowledges that considerably higher concentrations have been observed for some individuals, including both occupationally exposed adults, and children and adults, which have experienced elevated exposure from e.g. contaminated drinking water. In these cases, the relative abundance of the various PFASs may deviate considerably from what is observed in general populations.

Table 1: Specific exposure data from Belgian surveys, extracted from Schrenk et al., 2020. The study, age group, number of subjects and exposure data is shown for the sum of PFOA, PFOS, PFHxS and PFNA. All data is reported in ng/kg bw per day.

Study	Age group	number	Mean LB		Mean UB		P95 LB		P95 UB	
			per day	*per week*	*per day*	*per week*	*per day*	*per week*	*per day*	*per week*
DIET NATIONAL 2004	Adolescents ≥10-<18	576	0.54	3.77	20.59	144.11	1.45	10.18	44.17	309.21
DIET NATIONAL 2004	Adults ≥18-<65	1292	0.72	5.07	15.91	111.39	2.29	16.01	33.41	233.87
DIET NATIONAL 2004	Elderly ≥65-<75	511	0.78	5.45	15.18	106.25	2.33	16.31	27.92	195.43
DIET NATIONAL 2004	Very elderly ≥ 75 yrs	704	0.78	5.45	15.41	107.89	1.98	13.83	31.09	217.61
REGIONAL FLANDERS	Toddlers ≥ 1-<3 yr	36	1.51	10.58	112.09	784.64	3.35	23.45	229.04	1603.3
REGIONAL FLANDERS	Other children ≥3-<10 yr	625	1.40	9.83	81.78	572.43	4.36	30.51	165.31	1157.2

Drinking water, fish, fruit, potatoes and eggs and derived products are major contributors to dietary PFAS intake as found in different European studies, including in Belgium (Colles et al., 2020; Fabelova et al., 2023; Schrenk et al., 2020; Sunderland et al., 2019). Based on the EFSA database (2020), it was estimated that the highest dietary contribution for PFOS in Belgian adults came from fish and seafood (63.4%) followed by meat including offal (12.6%), fruit and fruit products (10.3%), egg and egg products (9%), water (1.3%), vegetables and vegetable products (1.2%) (Touchant et al., 2022). Within the PERFOOD project (2008-2012) some additional food items commercially grown and produced in Flanders were collected and analysed. The highest PFOS levels were found in eel 72.8 ng/g wet weight (ww) (range: 10.5-166 ng/g ww), eggs 7.8 ng/g ww (<0.12-22 ng/g ww), potatoes 6.18 ng/g ww (<0.021-19 ng/g ww) and sea fish 0.32 ng/g ww (<0.12-0.55 ng/g ww). Four tap water samples and five beer samples were analysed and had much lower concentrations: the average (range) concentrations of the water samples were 0.005 ng/g (0.004-0.01 ng/g) for PFOS and 0.002 ng/g (0.001-0.005 ng/g) for PFOA. For the beer samples, the PFOS concentrations were 0.013 ng/g (<0.0013-0.04 ng/g) and PFOA concentrations 0.006 ng/g (<0.0008-0.02 ng/g) (Cornelis et al., 2012).

The PERFOOD study calculated that dietary exposure of children to PFOS was dominated by intake from potatoes (48%), followed by fish and seafood, dairy products, eggs and fruit (each contributing about 10%). In adults, intake was dominated by fish and seafood (57%), followed by potatoes (28%). The intake of PFOA in children resulted mainly from fruit (30%) and vegetables (20%), with fish and seafood constituting only a small fraction, whereas the exposure of adults results from fish and seafood, potatoes, fruit and vegetables with almost equal contributions of about 20%. Although concentrations of PFOS and PFOA were detected in drinking-water and beer, their contribution to exposure was less than 1%.

Contamination of food by PFAS occurs from the environment (contaminated soil, dust deposition, watering with contaminated water) and/or from using cookware that contains PFAS. Non-specific adhesion or other mechanisms could result in an accumulation of PFAS on specific materials, such as glass or polypropylene (Mancini et al. 2023).

Little information is available about the impact of PFAS contaminants in water used for food production. Specific transfer factors for PFAS from water to food are lacking but there is some concern that PFAS may bind to proteins present in the food (Li et al. 2021). The hydrophobic fluorinated carbon chains of PFAS may occupy the binding cavities of target proteins, and the acid groups of PFAS may form hydrogen bonds with amino acid residues (Zhao et al., 2023).

Few studies are available on the effects of cooking or steaming on the PFAS concentrations in food. They are summarized in EFSA CONTAM Panel opinion of 2018 and 2020. The limited number of studies gives an inconsistent view about whether or not losses or increases occur as a result of cooking and processing. The EU PERFOOD study (2009-2012) assessed the impact of some food processing techniques. They found that after cooking of carbohydrate rich food in PFAS-containing water 80 % of the PFOS was found in pasta, but only 7 % in potato dumplings. They reported that PFAS transfer from water to food increased with surface area of the food and with the amount of absorbed water during cooking. In most cases raw food items contained higher PFAS levels than the processed or cooked food products. One major reason could be the dilution effect due to the addition of a broad variety of ingredients to the respective composite product.
A recent study as part of the US total diet study analysed 167 national collected samples of processed foods and reported positive detections of PFAS in canned tuna (PFDA), fish sticks (PFOS and PFNA), and protein powder (PFOS), all below 0,15 µg/kg (Young et al. 2022). **Quantification or derivation of transfer factors of PFAS from water to food is however not yet possible due to lack of information. Even for the most studied compounds such as PFOS and PFOA, this information is lacking.**
Water used to prepare food can also become a fraction of the prepared food. Examples are canned soups and vegetables, pickles, jams, fruit jellies and juices. Results also showed that although different beverage preparation processes possibly affect the concentrations of PFAS encountered in the final consumed product, the water used for preparation remains the most important source of PFAS. This in turn has implications for areas where drinking water is contaminated.
Therefore, we compared the proposed target limit value of 4 ng/L with maximum levels (MLs) set for specific food items.

The EFSA scientific opinion (Schrenk et al. 2020) concluded that the exposure of parts of the European population to the 4 PFAS exceeds the Tolerable Weekly intake (TWI) of 4.4 ng/kg bw (sum 4 PFAS) (or 0.63 ng/kg bw if expressed as Tolerable Daily Intake).
The exceedances of the TWI are reasons for concern and require setting of maximum levels for food items. As a consequence, the EU commission has set MLs targeting primarily the food groups that are the most significant contributors to the exposure, according to the available scientific evidence as identified by the EFSA panel. These MLs are not primarily risk based but are set according to the ALARA principle (i.e. As Low As Reasonably Achievable, taking into account options of prevention and reduction and excluding exceptional hot spots of environmental contamination), with a view to reducing exposure.
Therefor we compared the MLs for the sum of 4 PFAS (ranging between 1.3 and 50 µg/kg wet weight for meat of bovine animals, pigs, poultry and for offal respectively) with the suggested sum parameter of 4 ng/L for water as proposed for preparation of food,
The MLs for PFOS, PFOA, PFNA and PFHxS and the sum of PFOS, PFOA, PFNA and PFHxS in eggs, fish meat, crustaceans, bivalve molluscs, meat and offal of farmed and wild animals were established by means of Regulation (EU) 2023/915 (European Commission, 2023) and are shown in Appendix I. The Commission also established indicative levels of concentrations of PFAS in fruits, vegetables, milk and baby food by Recommendation (EU) 2022/1431 that relate to the monitoring of PFAS in food (Appendix 2). Those levels should not affect the possibility to place on the market any food, but investigations of potential sources of contamination should be carried out when the concentration of PFAS in a foodstuff exceeds them. However, such levels do not exist for all food items.
Based on the comparison, **we consider that it is unlikely that the proposed 4 ng/L in water would raise the concentrations of those 4 PFAS in food items to a level that would exceed the MLs or indicative limits. For baby food there is an indicative level of 0.050 µg/kg for PFOS, 0.050 µg/kg for PFOA, 0.050 µg/kg for PFNA and 0.050 µg/kg for PFHxS. It is also unlikely that water with the proposed target value of 4 ng/L for the sum of 4 PFAS will significantly increase the concentration of these PFAS in baby food above the indicative level.** We have no arguments to assume that the proposed target value

will result in high concentrations in food above the current MLs or indicative values. Some uncertainty remains as to whether protein binding may translocate PFAS from water to food. But based on current scientific knowledge, the SHC cannot form a more detailed opinion on every possible technique and material used in the production, processing, preservation and commercialization of the different categories of food products. We conclude that in any case **the prepared food items should comply with the MLs as set by the Commission and that exceedance of the indicative levels should receive follow up of the causes of contamination (including the water used for production) as indicated by the European recommendation.**
Based on this, the SHC concludes that using water with a target value of 4 ng/L to prepare food will decrease current human exposure.

Effect on health risk

The SHC concludes also that using a target value of 4 ng/L to prepare food will not increase health risks. The 4 ng/L target value would be compatible with a drinking water limit in accordance with the health-based tolerable weekly intake (TWI) set by EFSA (see Q5).
The SHC also strongly supports the limit setting for water to be used for preparing food as there is a measurable presence of PFAS in environmental water sources. Emissions from industry and wastewater treatment plants are still contributing to the contamination (see Q5).

> **Answer to question 2:** ***"What is the effect on exposure and (chronic) health risk for the various groups of Belgian consumers of setting a national target value of 4 ng/L for the sum of PFOA, PFOS, PFNA and PFHxS in bottled water (spring water and drinking water)?"***

Effect on exposure

Assuming a limit value of 4 ng/L water for bottled water corresponds with an intake of 8 ng (sum of PFOA, PFOS, PFNA and PFHxS) if a volume of 2 L is consumed which is considered a standard liquid intake volume per day for a 60 kg adult. This corresponds to intake values for the sum of PFOA, PFOS, PFNA and PFHxS of 0.13 ng/kg bw per day. This is 18% of the mean daily dietary intake (LB exposure) estimated by the EFSA panel which was 0.72 ng/kg bw per day for Belgian adults. The recommended total fluid intake for infants, according to EFSA guidelines, decreases from 110 mL/kg bw per day at one year to 78 mL/kg bw per day at age 3, this would result in intake values for the sum of PFOA, PFOS, PFNA and PFHxS of 0.44 to 0.3 ng/ kg bw per day (EFSA Panel on Dietetic Products and Allergies, 2010). We can compare these values with the mean daily dietary intake (LB exposure) estimated by the EFSA panel which was 1.5 ng/kg bw per day for Belgian toddlers, shown in Table 1. This allows us to conclude that the proposed target value of 4 ng/L for bottled water will be a minor contribution to the mean daily intake. Moreover it is unlikely that bottled water will be the sole intake of liquids.

Effect on health risk

The proposed target value is in accordance with the health-based TWI of 4.4 ng/kg bw per week or a TDI of 0.63 ng/kg bw per day for the sum of PFOA, PFOS, PFNA and PFHxS set by EFSA. Thereby it is assumed that 20% of the TDI (0.13 ng/kg bw per day) can be attributed to drinking water (including bottled water).
The TWI protects mothers against cumulating a PFAS body burden which may lead to a reduced antibody response at vaccination in breastfed children when they are one year old. This is considered as the most critical endpoint (Abraham et al., 2020). Above the TWI adverse health effects cannot be excluded, below the TWI is considered as safe, based on current scientific knowledge. Note that the TWI or TDI is considered as an estimate of the amount of

a substance in air, food or drinking water that can be taken in weekly or daily, respectively, over a lifetime without appreciable health risk.

We also find the proposed target value protective for babies and small children who are considered as the most vulnerable group. Babies between 7 and 28 days consume between 100 and 190 ml of water/kg bw per day (EFSA Panel on Dietetic Products and Allergies, 2010). Using water with 4 ng/L (sum of 4 PFAS) to prepare the formula milk will result in a daily intake of 0.4-0.76 ng/kg bw per day which exceeds the TDI. However, the target value of 4 ng/L (sum of 4 PFAS) is well below the critical concentration for the sum of 4 PFAS in maternal milk which is 133 ng/L and which protects against a cumulating body burden in mothers at age 30 that may lead to reduced vaccination response in their children (Schrenk et al. 2020).

Answer to question 3: *"What is the effect on exposure and health risk (chronic and acute) for the various Belgian consumer groups of setting a maximum limit of 13 µg/L and 15 µg/L for perchlorate in water that is used in the processes of manufacturing, processing, preserving and marketing the various categories of foodstuffs?"*

In an adult population, it is the opinion of the SHC that a maximum limit of 13 µg/L and 15 µg/L for water used in the manufacture, processing, preservation and commercialization of the different categories of food products is likely to contribute significantly to exposure, depending on the percentage of transfer or mixing.
The proposed maximum limit is too high for sensitive groups (infants and toddlers).

Effect on exposure

The 2017 EFSA CONTAM panel reported on "*Dietary exposure assessment to perchlorate in the European population*". Chronic exposure of Belgian residents was estimated by EFSA (2017) based on food consumption data (food record study (2002) from Flanders and a national 24-hours dietary recall study from 2004) and occurrence data of perchlorate in food from 2015 (122 samples). Mean chronic exposure of toddlers (as µg/kg body weight (bw) per day) was estimated as 0.15 (LB) and 0.47 (UB), of other children 0.10 (LB) and 0.35 (UB), of adolescents 0.04 (LB) and 0.10 (UB), while in adults and elderly it was 0.04 (LB) and 0.11 (UB). The P95 of chronic exposure (µg/kg bw per day) of other children was 0.23 (LB) and 0.60 (UB) of adolescents and adults 0.10 (LB) and 0.20 (UB), of elderly 0.11 (LB) and 0.21 (UB). There are no data listed for infants in Belgium, but median exposure of infants across all the participating dietary surveys ranges from 0.09 (LB) to 0.47 (UB) µg/kg bw per day. It was noted that infants, toddlers and other children have on average higher exposures than other population groups (Arcella et al., 2017).

The main contributors to the exposure across all population groups are 'Vegetable and vegetable products', 'Milk and dairy products' and 'Fruit and fruit products'. In the middle bound (MB) scenario, for infants, the main contributor is 'Milk and dairy products', followed by 'Food for infants and small children'; 'Vegetable and vegetable products' and 'Fruit and fruit products' are also relevant contributors to the exposure of infants. A similar pattern of contribution is also observed in toddlers, but with decreasing importance of 'Food for infants and small children' and increasing for 'Fruit and vegetable juices'. For other children and adolescents, the major contributors are 'Milk and dairy products' and 'Vegetables and vegetable products', followed by 'Fruit and vegetable juices' and 'Fruit and fruit products'. For the older population groups, 'Vegetables and vegetable products' are the major contributor, but other food groups are also of relevance for the exposure, like 'Milk and milk products', 'Teas and herbal infusions (beverage)' and 'Fruit and fruit products' (Arcella et al., 2017).

In its scientific opinion, the CONTAM Panel assessed the exposure levels to perchlorate, considering approximately 12,000 results on occurrence of perchlorate, mainly on fruit and vegetables submitted by eight European Union (EU) Member States as well as literature occurrence data on infant formula, milk and dairy products, alcoholic beverages, fruit juices and breast milk. After the exclusion of suspect samples, the highest mean perchlorate concentrations were observed in turnips (350 µg/kg, upper bound (UB)) and in lettuce (120 µg/kg, UB) (Arcella et al., 2017; 2014).

It is not anticipated that perchlorate, which is highly water soluble, will be translocated from water to food. There is no evidence of biomagnification. However, during food preparation, water can be integrated into the final product in various proportions.

To put the proposed maximum limits (13 and 15 µg/L) in perspective, we compare them with the MLs set by the European Commission for various food items (COMMISSION REGULATION (EU) 2023/915). MLs range from 10 µg/kg fresh weight for processed cereal based food and infant formula, follow-on formula, foods for special medical purposes intended for infants and young children and young child formula over 50 µg/kg for fresh fruits and vegetables up to 750 µg/kg for dried tea and dried herbal and fruit infusions (Appendix III). These MLs are not primarily risk based but are set according to the ALARA principle, with a view to reducing exposure.
Exposure to perchlorate for breast-fed infants was estimated to range between 0.76 and 6.5 µg/kg bw per day based on mean concentrations of perchlorate in breast milk measured in the USA. Using water to prepare infant formulae with a proposed ML of 15 µg/L will result in 2.25 µg/kg bw per day (assuming consumption of 0.15 L per kg bw per day).

The SHC expresses its concern that using water with the proposed maximum limit for preparing infant food and baby food may increase concentrations near or above the MLs set by the European Commission for specific food items.

Effect on health risk

The EFSA Panel on Contaminants in the Food Chain (CONTAM) published a scientific opinion in 2014 (CONTAM, 2014) on the public health related risks to the presence of perchlorate in food, in particular fruits and vegetables. In this study, they established a tolerable daily intake of 0.3 µg/kg bw per day. The EFSA CONTAM panel selected the lowest 95 % lower confidence limit for the BMD response of 5 % extra risk (BMDL05) for a reduced thyroid iodine uptake as the reference point. The BMDL05 of 0.0012 mg/kg bw per day was based on the study of Greer et al. (2002), a safety assessment factor of 4 was used to derive the TDI of 0.3 µg/kg bw per day. The panel assumed that prolonged reduced iodine uptake may lead to changes in thyroid hormone levels that may be harmful in sensitive subpopulations, based on the inhibition of thyroid iodine uptake in healthy adults. The SHC prefers this health-based daily intake limit value as it is more conservative compared to limit values from the US EPA and by ANSES (see Q10).
As the exposure of adolescents, adults, elderly and very elderly to perchlorate is well below the TDI of 0.3 µg/kg per day, determined by EFSA, no health risk is to be expected. The Upper Bound scenario for Belgian toddlers, and European infants is already above the TDI, more exposure should be avoided.
For these sensitive groups, a lower maximum limit should be utilised.

Answer to question 4: ***"What is the effect on exposure and health risk (chronic and acute) for the various Belgian consumer groups of setting a maximum limit of 13 µg/L and 15 µg/L for perchlorate in bottled water (spring water and drinking water)?"***

The SHC estimates that setting a national limit value of 13 and 15 µg/L of perchlorate for bottled water is necessary. The data for perchlorate concentrations in drinking water in Belgium shows that exceedances may occur. For sensitive groups, water with a value of 13 or 15 µg/L could lead to potential health effects, thus a lower limit value should be adopted for these groups.

Effect on exposure

Assuming an intake of 2L of water with a concentration of 13 µg/L of perchlorate, for an adult of 60 kg, this would result in an exposure of 0.43 µg/kg bw per day.
For a baby between 7 and 28 days, consuming 150 mL water/kg bw per day, this would result in an exposure of 1.95 µg perchlorate /kg bw per day. These calculated intake values from water are relatively high compared to the by EFSA 2017 estimated daily dietary intake values for Belgian populations (mean chronic exposure of toddlers of 0.15 (LB) and 0.47 (UB) µg/kg bw per day, of other children 0.1 (LB) and 0.35 (UB) µg/kg bw per day, of adolescents 0.04 (LB) and 0.10 (UB) µg/kg bw per day, of adults and elderly 0.04 (LB) and 0.11 (UB) µg/kg bw per day.

Effect on health risk

For adults, the exposure is slightly higher than the TDI of 0.3 µg/kg bw per day, established by EFSA. No adverse health effects are to be expected if lifelong daily intake remains below this value. The US EPA however, determined a reference dose of 2.2 µg/kg bw per day and ANSES determined 0.7 µg/kg bw per day.
The exposure for babies to water with these proposed maximum limits is far too high and would pose a health risk as pregnancy and early child development are considered as the most critical window of exposure (see Q6).

Answer to question 5: ***"On the basis of the answers to questions 1 and 2, what is the scientific relevance for the protection of the health of the various groups of Belgian consumers of setting a national target value for the sum of PFOA, PFOS, PFNA and PFHxS in bottled water and in water used in the processes of manufacturing, processing, preserving and marketing the various categories of foodstuffs?"***

Concern for health risk

While research on the health effects of PFAS is an evolving area of science, there is enough scientific evidence that current exposure of the population to certain PFAS may lead to adverse health outcomes (Fenton et al., 2021). This information comes both from experimental studies and human observational studies. The results are extensively reviewed and summarized in a recent document of ATSDR (2021) and in the EFSA 2020 opinion (Schrenk et al., 2020), among other literature sources.

In Belgium, studies have shown that the currently measured human serum concentrations of PFAS are associated with adverse health outcomes. such as increased risk for being born small for gestational age, changes in sex hormones and behavioral changes in adolescents. Somewhat contrasting with the observations in adolescents, were the observations in older adults, where an increase in the capacity to give or sustain attention was observed (Govarts et al., 2016; van Larebeke et al., 2022).
Consumption of food has been shown to influence the body burden: consumption of fish, seafood and rice in the Walloon study in adults (Pirard et al., 2020) and consumption of fish, offal and locally grown food in the Flemish studies (Colles et al., 2020; Schoeters et al., 2022).

Concern for contamination of water supplies

The current exposure to PFAS from drinking water can be assessed based on concentrations found in drinking water. The VMM conducted a study related to PFAS contamination in distributed tap water in Flanders in 2021 (VMM, 2021). At that time, 13.3 % of the measurements of the four EFSA PFAS were higher than the proposed 4 ng/L as a sum parameter. The average EFSA 4 PFAS concentration was 1.9 ng/L, and the maximum value was 26 ng/L. More substances than only these 4 previously mentioned EFSA PFAS were analyzed in the entire Flemish drinking water distribution network. While more and more PFAS components get discovered, the VMM study focused on a group of 20 PFAS that are relevant and can be accurately measured. Most notably, of all the results above the limit of quantification (LOQ), the most occurring PFAS in the Flemish drinking water infrastructure are PFPeA, PFHxA and PFBS, with 51.9 %, 48.3 % and 47.8 %, respectively. Other, more exotic PFAS than the PFAS-20 group, were also detected above the LOQ. Although deemed relevant according to EFSA, only very few positive measurements were reported for PFNA. This VMM report only deals with data from Flanders, although it is mentioned that in some Flemish drinking water infrastructure with a positive result for the 4 EFSA PFAS, the water originates from a drinking water supplier in Brussels. It should be noted that the VMM study is from 2021, the current situation might be different due to technological advancements in water purification techniques.
In June of 2022, a communication between *Wallonie environnement* and the *Société Wallonne des Eaux* mentioned values in drinking water exceeding 300 ng/L for the sum of PFAS 20 (RTBF, 2023).
The ODISUPER project from ISSeP will analyze drinking water and surface water in Wallonia for the 20 PFAS. Once published, this study will provide more relevant information on the composition and concentrations of different PFAS in Wallonia. As a response to populations being exposed to drinking water with concentration well above the PFAS-20 100 ng/L limit, ISSeP has started with a blood analysis program for the inhabitants of Chièvres and Ronquières (ISSEP, 2024).

The BIODIEN project (2018) by ISSeP (Frippiat et al., 2018) reported results for PFAS in Wallonia and Brussels. They measured 5 PFAS: PFOS, PFOA, PFHxS, PFHpA and PFHxA, so there are no results for PFNA. Fifteen samples of bottled water were also measured for PFOA content, with 2 samples in which PFAS were detected, but below the LOQ of 0.5 ng/L, while PFAS were not detected in the other samples. The report also shares measurements on 9 samples of distributed tap water in the Brussels region. As they did not measure PFNA, we cannot determine the sum of the 4 EFSA PFAS; however, some samples contained more than 4 ng/L of PFOA, meaning that the sum parameter would certainly exceed 4 ng/L.
In surface water, average values of more than 200 ng/L (as a sum of the 5 compounds) were found. For groundwater, the results are lower, with maximal values reaching just over 50 ng/L for some points.

To summarize, the data in Belgium show that PFAS certainly need to be monitored, as they are ubiquitously present in our environment. As higher values than the suggested target value of 4 ng/L as a sum parameter for the 4 EFSA PFAS are currently measured in Belgium, it is reasonable to assume that a national target value of 4 ng/L for bottled water is advisable to keep human exposure by food and liquid intake within safe limits.
The SHC wants to emphasize that more PFAS than only those 4 EFSA PFAS are present in water samples, and those should be monitored and regulated as well. At EU level a maximum limit of 100 ng/L for the PFAS-20 group in drinking water will enter in force in January 2026 (European Parliament and Council, 2020). Although this limit value might not be fully toxicologically based, it is analytically achievable, and these PFAS are known to be present.

The SHC concludes that it is important to reduce exposure to PFAS in the Belgian population. Based on experimental animal studies and on epidemiological observational studies, there is enough evidence that current human exposure to the 4 EFSA PFAS causes adverse health effects. The currently measured human serum concentrations of PFAS in a fraction of the Belgian population exceed the levels that are considered as safe based on current scientific knowledge (Colles et al., 2020; Pirard et al., 2020; Schoeters et al., 2022). Moreover, consumption of food has been shown to contribute to the body burden of PFAS.
While research is still ongoing to determine how different levels of exposure to different PFAS can lead to a variety of health effects, reducing exposure is an important part of reducing risk.

Answer to question 6: "*On the basis of the answers to questions 3 and 4, what is the scientific relevance for health protection of the various Belgian consumer groups of setting a maximum limit for perchlorate in bottled water and in water used in the manufacturing, processing, preservation and marketing of the various food categories?"*

Concern for health risk

Perchlorate exposure can have various health effects on humans, depending on the dose, duration, and route of exposure. The most well-known and well-studied health effect of perchlorate exposure is the interference with the thyroid function. Perchlorate exposure can interfere with the normal functioning of the thyroid gland by inhibiting the transport of iodide into the thyroid gland, which can lead to decreased production of thyroid hormones. Thyroid hormones are critical for normal growth and development of the central nervous system in fetuses and infants (Nizinski et al., 2021).
In this context, we refer to previous SHC advices 3933 and 8913. In SHC 3933, an iodide supply slightly below average was described for the Belgian population, more specifically for pregnant woman, fetuses, and children below the age of 3. According to SHC 8913, the situation has improved, but as perchlorate is known to inhibit the uptake of iodide, this remains a relevant concern (SHC - Superior Health Council, 1998; SHC - Superior Health Council, 2014). As explained earlier (Q3 & Q4), the estimated daily exposure of some toddlers and children in Belgium is above the TDI of 0.3 µg/kg bw per day as derived by EFSA. Usage of water with the proposed maximum levels for perchlorate for preparing infant formula and baby food may easily result in exceedance of the daily intake above the safe value set by EFSA. We should note however that other organizations have derived higher health-based guidance values for daily intake and that guidance values are conservative as they estimate the amount of a substance that people can consume on a daily base during their whole life without any appreciable risk to health.

Concern for contamination of water supplies

Perchlorate is not removed adequately from water by most standard physical and chemical water treatment processes (Srinivasan and Sorial, 2009).
According to a VMM study in 2021 on drinking water quality, there are regions in Flanders where maximum concentrations of perchlorate are relatively high. This holds for 3 out of 51 distribution areas:

- *De Watergroep* O11 (SWDE Herstappe – 12 µg/L / WPC Diets-Heur – 9.7 µg/L)
- *De Watergroep* O12 (WPC Roclenge – 9.4 µg/L)
- *De Watergroep* O14 (WPC Tongeren - 11 µg/L)

The median concentrations reported for perchlorate in each distributing area are less than or equal to 1.5 µg/L (with the exception of 2 areas on the 51 area's reported) (VMM, 2021).

ISSeP published the SEMTEP study in 2019, which included measurements on perchlorate. They measured bottled water for perchlorate content, with no results above their limit of quantitation (0.2 µg/L). For reference, they measured the following brands: Boni Mont Blanc, Chaudfontaine (sparkling water), Boni Oiselle Saint Amand, Chaudfontaine, Delhaize Montcalm, Evian, Delhaize Montille, San Pellegrino (sparkling water), Delhaize Orée du Bois, Spa Reine, Delhaize Romy, Valvert, Vittel (Nott et al., 2019).

As water from different sources can be used in food manufacturing processes, environmental presence should be considered in assessing the exposure. The SEMTEP study of ISSeP (Nott et al., 2019) included measurements of perchlorate in groundwater. A maximum value of 25.8 µg/L was measured in water from "Sable du Thanétien des Flandres", but also maximum values of 20.2 µg/L (Calcaires du bassin de la Meuse bord Nord) and 18.7 µg/L (Crétacé du bassin du Geer). Multiple measurements were performed on these sites, and average values remain under the proposed 13 and 15 µg/L limits. Concerning surface water, 21 samples were analyzed in this study, with a median concentration of 0.75 µg/L and a maximum of 17.0 µg/L perchlorate.

Answer to question 7: ***"Is the methodology used to set the target value of 4 ng/L for the sum of PFOA, PFOS, PFNA and PFHxS in drinking water in the distribution network transposable as it stands for water used in the processes of manufacturing, processing, preserving and marketing the various categories of foodstuffs? If not, what methodology should be used and what would be the result?"***

The method used to set the target value for the sum of PFOA, PFOS, PFNA and PFHxS in drinking water is not predictive for the final concentrations of these compounds in food stuffs. PFAS are water soluble and may also bind to proteins (Li et al., 2021). However there is not enough scientific knowledge on transfer factors of PFAS from water to food items during food processing. Water may be integrated in the final food product at different percentages. In a risk based approach, the transfer of PFAS from source water to food should be modelled based on data from empirical studies and physicochemical properties of the investigated PFAS. This information is not yet available. We recommend that more occurrence data of PFAS in processed food items should be obtained.The recent FLUOREX project carried out by Sciensano will provide more useful data on concentrations of PFAS compounds in 350 agricultural food samples collected in the Flemish and Walloon region in 2022 and 2023. This will also allow to update the estimation of daily intake of PFAS substances by food for the Belgian population, but it should be noted that sampling in the FLUOREX project was performed in supermarkets, own-grown food from private gardens or local shops were not included (Sciensano, 2021).
In Europe, according to good practice, the food industry is required to use potable water (water with drinking water quality) for use in food production to ensure foods are not contaminated (European Parliament and Council, 2004). As argued in answering the previous questions, using water for food processing with a target value of 4 ng/L for the sum of PFOA, PFOS, PFNA and PFHxS is expected to be protective against adverse health effects of these substances.

Answer to question 8: ***"Can the methodology used to set the target value of 4 ng/L for the sum of PFOA, PFOS, PFNA and PFHxS in drinking water from the distribution network be transposed as it stands for bottled water (spring water and drinking water)? If not, what methodology should be used and what would be the result?"***

The methodology to determine the target value originates from the TWI of 4.4 ng/kg body weight per week, with an 'allocation factor' for drinking water denoted as 'P' (a fraction of the TWI allocated to drinking water; 20%). This factor ensures that exposure through drinking water, which adheres to the standard, remains at a maximum of 20% of the TWI. The remaining 80% of the TWI derived by EFSA for the sum of the 4 PFAS accounts for exposure from sources other than drinking water such as food, air, household dust, and exposure through consumer products. This formula is widely accepted and used by international risk assessment expert groups (WHO, 2022).
The guidance value (GV) is derived from the TDI as follows:

$$GV = \frac{TDI \ x \ bw \ x \ P}{C}$$

Where:
bw = body weight
P = fraction of the TDI allocated to drinking water
C = daily drinking-water consumption
TDI = Tolerable daily intake

The TDI is an estimate of the amount of a substance in food and drinking-water, expressed on a body weight basis (milligram or microgram per kilogram of body weight), that can be ingested over a lifetime without appreciable health risk, and with a margin of safety.
Wherever possible or in an ideal situation, derivation of guideline values uses data on the proportion of total daily intake based on mean levels in food, drinking-water, consumer products, soil and air, or data on intakes estimated on the basis of physical and chemical properties of the substances of concern. As the primary sources of exposure to chemicals are generally food (e.g. for pesticide residues) and water, it is important to quantify, whenever possible, the exposures from both sources. To inform this process, it is desirable to collect as much high-quality data as possible on food intake in different parts of the world as possible. The data collected can then be used to estimate the proportion of the intake that comes from food and the proportion that comes from drinking-water. However, in the absence of adequate exposure data or where documented evidence is available regarding widespread presence in one or more of the other media (i.e. air, food, soil or consumer products), the normal allocation of the total daily intake to drinking-water is 20% (floor value), which reflects a reasonable level of exposure based on broad experience, while still being protective (Krishnan and Carrier, 2013).
According to the SHC, this same method is applicable to set a national target level for bottled water. This is considered as conservative as it is unlikely that the bottled water will be the only source for liquid intake over a lifetime.

Answer to question 9: Is the methodology used to set the parametric value of 13 µg/L (Flanders) or 15 µg/L (Walloon and Brussels-Capital Regions) for perchlorate in drinking water from the distribution network transposable as it stands for water used in the manufacturing, processing, preservation and marketing of different categories of foodstuffs? If not, what methodology should be used and what would be the result?

The method used to set the parametric value for perchlorate in drinking water from the distribution network is not predictive for the final concentrations of these compounds in food stuffs. Perchlorate is highly water soluble and is known as a poor complexing agent (Nizinski et al., 2021). There is not enough scientific knowledge on transferfactors of perchlorate from water to food items during food processing. Water may be integrated in the final foodproduct at different percentages. In a risk based approach the transfer of perchlorate from source water to food should be modelled based on data from empirical studies and fysicochemical properties of the contaminants. This information is not available.
In Europe, according to good practice, the food industry is required to use potable water (water with drinking water quality) for use in food production to ensure foods are not contaminated (Regulation (EC) 852/2004). As argued in answering the previous questions, using water for food processing with a target value of 13 and 15 µg/L for perchlorate is expected to be protective against adverse health effects of perchlorate, except for the sensitive population groups. The sensitive groups, infants and toddlers, will be protected to a greater extent when the maximum limit value for water will be lower. ANSES has proposed a limit of 4 µg/L for drinking water applicable for children between 0 and 6 months (see also Q10) (ANSES, 2012).

Answer to question 10: *"Is the methodology used to set the parametric value of 13 µg/L (Flanders) or 15 µg/L (Walloon and Brussels-Capital Regions) for perchlorate in drinking water from the distribution network transposable as it stands for bottled water (spring water and drinking water)? If not, what methodology should be used and what would be the result?"*

The same principle as in question 8 applies.
As already argued in answering the previous questions, using water for preparing bottled water with a target value of 13 and 15 µg/L for perchlorate is expected to be protective against adverse health effects of perchlorate, except for the sensitive population groups. The sensitive groups, infants and toddlers, will be protected to a greater extent when the maximum limit value for water will be lower. ANSES has proposed a limit of 4 µg/L for drinking water for children between 0 and 6 months. This would result in a daily intake of 0.6 µg/kg bw for a baby or child with a liquid intake of 150 mL/kg bw per day. If the EFSA TDI of 0.3 µg/kg bw per day is considered as a reference , the maximum limit should be 2 µg/L, as this will result in a daily intake of 0.3 µg/kg bw per day for babies and small children which is sufficiently protective according to the EFSA TDI guidance value of 0.3 µg/kg bw per day.

This TDI value of 0.3 µg/kg bw per day was derived from benchmark dose modelling. Based on a BMDL05 (dose where the change in response is likely to be smaller than 5%) for thyroid iodine uptake inhibition of 0.0012 mg/kg bw per day; the CONTAM panel applied an uncertainty factor of 4 to allow for intraspecies differences in toxicokinetics. This was deemed sufficient as a 5% inhibition of iodine uptake would not lead to adverse effects in any subgroup of the population (CONTAM, 2014).
Originating from the study of Greer *et al*. in 2002, a NOEL (No Observed Effect Level) was established of 7 µg/kg bw per day. This value was derived as the lowest concentration where no statistically significant inhibition of uptake of radioiodine was observed. Applying an intra-species uncertainty factor of 10, this brings us to a TRV (toxicity reference value) of 0.7 µg/kg bw per day, as adopted by ANSES (ANSES, 2012). Using this TRV, an allocation factor of 60%, body weight of 70 kg and a consumption of 2 L of water per day, one arrives at a limit of 15 µg/L.

In 2019, the US EPA (EPA, 2019) developed a Biologically Based Dose Response model (BBDR) describing the effect of perchlorate on thyroid hormones at each gestational week from conception to week 16. A study by Korevaar et al. (2016) revealed effects of maternal free thyroxine (fT4) levels during early pregnancy on the IQ of the child (measured at the age of 5). In the BBDR model, individuals were simulated with low iodine intake of 75 µg/day. Ultimately, this model describes a dose-response function that estimates changes in IQ, based on a given change in thyroid hormone concentration (fT4), which can be linked to a given dose of perchlorate. Based on a 2% decrease in the population standardized mean IQ, the EPA derived a value of 6.7 µg/kg per day. An uncertainty factor of 3 was further applied, as 6.7 µg/kg per day is already derived from data of the most sensitive group, to get a RfD (reference dose) of 2.2 µg/kg per day.
In a report by VITO on behalf of Agentschap Zorg & Gezondheid in 2020, the RfD of 2.2 µg/kg per day was used with an allocation factor of 20% for drinking water, average body weight of 60 kg and a drinking water consumption of 2 L to derive a health-based advisory value of 13 µg/L for perchlorate in drinking water (Baken, 2020).

It is the opinion of the SHC that both approaches are scientifically sound, but the SHC wants to emphasize that using two different limit values is far from ideal. We suggest the use of the lowest value of 13 µg/L as the limit value for the whole of Belgium. Considering measurement uncertainties in analytical chemistry, these values (13 and 15 µg/L) are in fact quite similar. Even more so, it is ultimately the average weight of 60 or 70 kg that determines the final limit.

In 2020, the US EPA withdrew its earlier recommendation (2019) for a limit value of perchlorate in drinking water, as perchlorate does not present a “meaningful opportunity for health risk reduction for persons served by public water systems” (EPA, 2020). Water with low concentrations of perchlorate might indeed not be one of the main contributors to the exposure to perchlorate. However, with concentrations of perchlorate in water close to the suggested parametric values, as in Belgium, the contribution of that water to the total exposure is very relevant.

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VI COMPOSITION OF THE WORKING GROUP

The composition of the Committee and that of the Board as well as the list of experts appointed by Royal Decree are available on the following website: About us.

All experts joined the working group ***in a private capacity***. Their general declarations of interests as well as those of the members of the Committee and the Board can be viewed on the SHC website (site: conflicts of interest).

The following experts were involved in drawing up and endorsing this advisory report. The working group was chaired by **Greet SCHOETERS**; the scientific secretary was Stijn BOODTS.

BOULAND Catherine	Environmental health	ULB
COVACI Adrian	Environmental health & toxicology	UAntwerpen
MOENS Jonas	Pharmacy	Poison centre
PARENT Anne Simon	Neuroendocrinology, paediatrics	ULiège
PAULUIS Jean	Environmental health	ULiège
PLUSQUIN Michelle	Environmental health	UHasselt
SCHOETERS Greet	Environmental health & toxicology	UAntwerpen
SCIPPO Marie-Louise	Chemicals in food	ULiège
SPANOGHE Pieter	Phytopharmacy & residue analysis	UGent
VAN LAREBEKE Nicolas	Cancerologie	UGent, VUB

The following experts were heard, but did not take part in endorsing the advisory report:

Debrouwere Katleen	Environmental Science	VITO

The following association and/or experts peer reviewed and endorse the advisory report:

Sciensano: Laure Joly and Els Van Hoeck

VII APPENDIXES

Appendix I:
Reproduced from Regulation (EU) 2023/915

4.2	Perfluoroalkyl substances	Maximum level (µg/kg)					Remarks
		PFOS	PFOA	PFNA	PFHxS	Sum of PFOS, PFOA, PFNA and PFHxS	**The maximum level applies to the wet weight.** **PFOS: perfluorooctane sulfonic acid** **PFOA: perfluorooctanoic acid** **PFNA: perfluorononanoic acid** **PFHxS: perfluorohexane sulfonic acid** **For PFOS, PFOA, PFNA, PFHxS and their sum, the maximum level refers to the sum of linear and branched stereoisomers, whether they are chromatographically separated or not.** **For the sum of PFOS, PFOA, PFNA and PFHxS, maximum levels refer to lower bound concentrations, which are calculated on the assumption that all the values below the limit of quantification are zero.**
4.2.1	Meat and edible offal (2)						
4.2.1.1	Meat of bovine animals, pig and poultry	0,30	0,80	0,20	0,20	1,3	
4.2.1.2	Meat of sheep	1,0	0,20	0,20	0,20	1,6	
4.2.1.3	Offal of bovine animals, sheep, pig and poultry	6,0	0,70	0,40	0,50	8,0	
4.2.1.4	Meat of game animals, with the exception of bear meat	5,0	3,5	1,5	0,60	9,0	
4.2.1.5	Offal of game animals, with the exception of bear offal	50	25	45	3,0	50	
4.2.2	Fishery products (2) and bivalve molluscs (2)						In case of dried, diluted, processed and/or compound food, Article 3(1) and (2) apply.
4.2.2.1	Fish meat						Where fish are intended to be eaten whole, the maximum level applies to the whole fish.
4.2.2.1.1	Muscle meat of fish, except products listed in 4.2.2.1.2 and 4.2.2.1.3 Muscle meat of fish listed in 4.2.2.1.2 and 4.2.2.1.3, in case it is intended for the production of food for infants and young children	2,0	0,20	0,50	0,20	2,0	
4.2.2.1.2	Muscle meat of the following fish, in case it is not intended for the production of food for infants and young children: Baltic herring (*Clupea harengus membras*) Bonito (*Sarda* and *Orcynopsis* species) Burbot (*Lota lota*)	7,0	1,0	2,5	0,20	8,0	

	European sprat (*Sprattus sprattus*) Flounder (*Platichthys flesus* and *Glyptocephalus cynoglossus*) Grey mullet (*Mugil cephalus*) Horse mackerel (*Trachurus trachurus*) Pike (*Esox* species) Plaice (*Pleuronectes* and *Lepidopsetta* species) Sardine and pilchard (*Sardina* species) Seabass (*Dicentrarchus* species) Sea catfish (*Silurus* and *Pangasius* species) Sea lamprey (*Petromyzon marinus*) Tench (*Tinca tinca*) Vendace (*Coregonus albula* and *Coregonus vandesius*) Silverly lightfish (*Phosichthys argenteus*) Wild salmon and wild trout (wild *Salmo* and *Oncorhynchus* species) Wolf fish (*Anarhichas* species)						
4.2.2.1.3	Muscle meat of the following fish, in case it is not intended for the production of food for infants and young children: Anchovy (*Engraulis* species) Babel (*Barbus barbus*) Bream (*Abramis* species) Char (*Salvelinus* species) Eel (*Anguilla* species) Pike-perch (*Sander* species) Perch (*Perca fluviatilis*) Roach (*Rutilus rutilus*) Smelt (*Osmerus* species) Whitefish (*Coregonus* species other than those listed in 4.2.2.1.2)	35	8,0	8,0	1,5	45	
4.2.2.2	Crustaceans and bivalve molluscs	3,0	0,70	1,0	1,5	5,0	For crustaceans, the maximum level applies to muscle meat from appendages and abdomen, that means, that the cephalothorax of crustaceans is excluded. In case of crabs and crab-like crustaceans (*Brachyura* and *Anomura*), the maximum level applies to the muscle meat from appendages. In case of *Pecten maximus*, the maximum level applies to the adductor muscle and gonad only. For canned crustaceans, the maximum level applies to the whole content of the can. As regards the maximum level for the whole composite product, Article 3(1), point (c) and Article 3(2) apply.
4.2.3	Eggs	1,0	0,30	0,70	0,30	1,7	

(2) Food as defined in Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

Appendix II

Reproduced from Commission Recommendation (EU) 2022/1431

Further investigation of the causes of the contamination should be carried out when the following indicative levels are exceeded:

(a) 0,010 µg/kg for PFOS, 0,010 µg/kg for PFOA, 0,005 µg/kg for PFNA and 0,015 µg/kg for PFHxS in fruits, vegetables (except wild fungi), starchy roots and tubers;

(b) 1,5 µg/kg for PFOS, 0,010 µg/kg for PFOA, 0,005 µg/kg for PFNA and 0,015 µg/kg for PFHxS in wild fungi;

(c) 0,020 µg/kg for PFOS, 0,010 µg/kg for PFOA, 0,050 µg/kg for PFNA and 0,060 µg/kg for PFHxS in milk;

(d) 0,050 µg/kg for PFOS, 0,050 µg/kg for PFOA, 0,050 µg/kg for PFNA and 0,050 µg/kg for PFHxS in baby food*.

* Babyfood as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

Appendix III

Reproduced from EU Commission Regulation 2023/915

Perchlorate	Maximum level (mg/kg)	Remarks
Fruits and vegetables except those mentioned below	0,05	
Cucurbitaceae and kale	0,10	
Leaf vegetables and herbs	0,50	
Tea (*Camellia sinensis*) (dried product) Herbal and fruit infusions (dried product) and ingredients used for herbal and fruit infusions (dried products)	0,75	'Herbal infusions (dried product)' refers to: — herbal infusions (dried product) from flowers, leaves, stalks, roots, and any other parts of the plant (in sachets or in bulk) used for the preparation of herbal infusion (liquid product); and — instant herbal infusions. In the case of powdered extracts, a concentration factor of 4 has to be applied.
Infant formulae, follow-on formulae, food for special medical purposes intended for infants and young children (3) and young-child formulae (4)	0,01	The maximum level applies to the products ready to use (placed on the market as such or after reconstitution as instructed by the manufacturer).
Baby food (3)	0,02	The maximum level applies to the products ready to use (placed on the market as such or after reconstitution as instructed by the manufacturer).
Processed cereal-based food (3)	0,01	The maximum level applies to the product as placed on the market.

(3) Food as defined in Article 2 of Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L181, 29.6.2013, p. 35).

(4) 'Young-child formulae' refers to milk-based drinks and similar protein-based products intended for young children. These products are outside the scope of Regulation (EU) No 609/2013 (Report from the Commission to the European Parliament and the Council on young-child formulae (COM(2016) 169 final) https://eur-lex.europa.eu/legal-content/EN/ TXT/?uri=CELEX%3A52016DC0169&qid=1620902871447).

About the Superior Health Council (SHC)

The Superior Health Council is a federal advisory body. Its secretariat is provided by the Federal Public Service Health, Food Chain Safety and Environment. It was founded in 1849 and provides scientific advisory reports on public health issues to the Ministers of Public Health and the Environment, their administration, and a few agencies. These advisory reports are drawn up on request or on the SHC's own initiative. The SHC aims at giving guidance to political decision-makers on public health matters. It does this on the basis of the most recent scientific knowledge.

Apart from its 25-member internal secretariat, the Council draws upon a vast network of over 500 experts (university professors, staff members of scientific institutions, stakeholders in the field, etc.), 300 of whom are appointed experts of the Council by Royal Decree. These experts meet in multidisciplinary working groups in order to write the advisory reports.

As an official body, the Superior Health Council takes the view that it is of key importance to guarantee that the scientific advisory reports it issues are neutral and impartial. In order to do so, it has provided itself with a structure, rules and procedures with which these requirements can be met efficiently at each stage of the coming into being of the advisory reports. The key stages in the latter process are: 1) the preliminary analysis of the request, 2) the appointing of the experts within the working groups, 3) the implementation of the procedures for managing potential conflicts of interest (based on the declaration of interest, the analysis of possible conflicts of interest, and a Committee on Professional Conduct) as well as the final endorsement of the advisory reports by the Board (ultimate decision-making body of the SHC, which consists of 30 members from the pool of appointed experts). This coherent set of procedures aims at allowing the SHC to issue advisory reports that are based on the highest level of scientific expertise available whilst maintaining all possible impartiality.

Once they have been endorsed by the Board, the advisory reports are sent to those who requested them as well as to the Minister of Public Health and are subsequently published on the SHC website (www.hgr-css.be). Some of them are also communicated to the press and to specific target groups (healthcare professionals, universities, politicians, consumer organisations, etc.).

In order to receive notification about the activities and publications of the SHC, please contact: info.hgr-css@health.belgium.be.

www.shc-belgium.be

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