Frequently asked questions about per- and polyfluoroalkyl substances (PFAS)

FAQ created by the BfR on 21 September 2020

Per- and polyfluoroalkyl substances (PFAS) are industrial chemicals which are used in several industrial processes and consumer products, due to their special technical properties. This group of substances includes more than 4,700 different compounds.

In the perfluoroalkyl substances sub-group, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) are the most thoroughly studied substances. Like many PFAS, these two compounds are not readily degradable, and are now detectable in the environment, the food chain, and in humans.

In September 2020, the European Food Safety Authority (EFSA) published a reassessment of the health risks related to the presence of PFAS in food. This is the first EFSA opinion in which, in addition to PFOA and PFOS, other PFAS, namely perfluorononanoic acid (PFNA) and perfluorohexanesulfonic acid (PFHxS), were included into the exposure assessment and health risk assessment.
http://www.efsa.europa.eu/de/news/pfas-food-efsa-assesses-risks-and-sets-tolerable-intake

In the reassessment, EFSA referred to the results of studies indicating an effect of certain PFAS on the immune system. A value of 4.4 nanograms (ng) per kilogram (kg) of bodyweight per week for the sum of four PFAS, namely PFOA, PFNA, PFHxS and PFOS, was derived as the tolerable weekly intake (TWI).

The use of PFOS has been largely banned since 2006 and that of PFOA since July 2020. At the European level, restrictions and bans on the production and use of other PFAS are currently being worked on.

The German Federal Institute for Risk Assessment (BfR) has compiled a list of questions - and their answers - on the subject of PFAS.

What are PFAS?
Per- and polyfluoroalkyl substances (PFAS) are industrially produced substances that do not occur naturally. Chemically, they are organic compounds in which the hydrogen atoms bonded to the carbon are replaced by fluorine atoms, either completely (perfluorinated) or partially (polyfluorinated). This group of substances includes more than 4,700 different compounds. For an overview of this large group of substances, please see a report by the Organization for Economic Cooperation and Development (OECD):

https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV-JM-MONO(2018)7&doclanguage=en

The various PFAS can be differentiated on the basis of the length of their carbon chains and other molecular structures (the functional groups). So far, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) are the best studied compounds. These two compounds belong (along with other related compounds) to what is known as “C8 fluorochemistry”. But there are also PFAS with longer or shorter carbon chains. Since the problematic properties of PFOA and PFOS have been recognised, other compounds are used as alternatives, including PFAS with shorter perfluorinated carbon chains. In addition, numerous so-called precursors are used, for example PFAS that contain ether linkages. These precursors can be converted, for example, into poorly degradable PFAS such as PFOA or PFOS.

What are short-chain PFAS?
The various PFAS differ in the length of their carbon chains and other molecular structures (functional groups), e.g. a carboxy group in the perfluoroalkylcarboxylic acids (PFCA) or a sulfonate group in the perfluoroalkylsulfonic acids (PFSA).

According to the length of the fluorinated carbon chains, a distinction is made between short-chain and long-chain PFAS.

In relation to PFCA, compounds with shorter carbon chains than perfluorooctanoic acid (PFOA) are called “short-chain”. The short-chain PFCA therefore include perfluorobutanoic acid (PFBA), perfluoropentanoic acid (PFPeA), perfluorohexanoic acid (PFHxA) and perfluoroheptanoic acid (PFHpA). PFOA, perfluorononanoic acid (PFNA) and compounds with longer carbon chains are referred to as long-chain PFCA.

In relation to PFSA, compounds with shorter carbon chains than perfluorohexane sulfonic acid (PFHxS) are called “short-chain”. The short-chain PFSA thus include e.g. perfluorobutane sulfonic acid (PFBS). Thus, PFHxS and perfluorooctane sulfonic acid (PFOS) are long-chain PFSA.

Short-chain PFAS are excreted more quickly after absorption into the human and mammalian organism than those with longer carbon chains.

Do the acronyms “PFT” and “PFC” also refer to the “PFAS” substance group?
In addition to the term “PFAS” for *poly-* and *perfluoroalkyl substances*, the abbreviations “PFT” for *perfluorinated surfactants* and “PFC” for *per- and polyfluorochemicals* are often used. The dividing lines, however, are not always clearly defined. The use of these terms for the group of PFAS should be avoided as these are different groups of chemicals.

Which products contain PFAS?
The industrial chemicals of the PFAS group such as PFOS and PFOA have been manufactured since the middle of the 20th century. PFAS are water, grease and dirt repellent. Due to these properties, they are used in numerous industrial processes and technical applications and processed in numerous consumer products such as paper, textiles, non-stick coated pans, electronic devices, cosmetics or ski waxes.

In addition, PFAS are used for the surface treatment of metals and plastics, in cleaning agents and pesticides, in the vehicle and construction industry, in the energy sector, in paints and fire-fighting foams and in a variety of other areas.

In addition, these compounds may occur in consumer products as impurities or unintended by-products.

How do PFAS get into the food chain?
Due to the strong chemical bond between carbon and fluorine atoms, PFAS are chemically and physically very stable. Therefore, they are hardly broken down by means of natural degradation mechanisms such as solar radiation, micro-organisms and other processes. As a result, PFAS are very long-lasting once they have been released into the environment. Some of these PFAS can be transported to remote areas through the atmosphere. PFAS can be detected worldwide in water, soils, plants and animals, and can therefore also enter the food chain.

The German Environment Agency (UBA) determines and assesses the entry paths of PFAS into the environment. Further information can be found on the UBA website:

https://www.umweltbundesamt.de/themen/chemikalien/chemikalien-reach/stoffgruppen/per-polyfluorierte-chemikalien-pfc#was-sind-pfc

https://www.umweltbundesamt.de/themen/chemikalien/chemikalien-reach/stoffe-ihre-eigen-schaften/stoffgruppen/per-polyfluorierte-chemikalien-pfc/besorgniserregende-eigenschaften-von-pfc

https://www.umweltbundesamt.de/publikationen/schwerpunkt-1-2020-pfas-gekommen-um-zu-bleiben.

Can PFAS also be detected in humans?
For some PFAS, data are available worldwide on the occurrence in humans (in human blood plasma or serum and in breast milk). The amount of PFAS present in the body ("internal exposure") is different for each individual compound.

According to the current opinion of the European Food Safety Authority (EFSA), seven compounds, PFOA, PFNA, PFHxS, PFOS, perfluoroheptane sulfonic acid (PFHpS), perfluorodecanoic acid (PFDA) and perfluoroundecanoic acid (PFUnDA) represent around 97% of the PFAS most frequently examined in human blood in adults in Europe. PFOA, PFNA, PFHxS and PFOS show the highest concentrations in human blood plasma and serum in adults. About 90% of the PFAS levels that can be detected in human blood are represented by these four PFAS.

The levels of PFAS in human blood and the relative proportions of individual PFAS compounds can differ significantly from person to person.

No representative studies are available on the PFAS concentrations in the blood plasma of the total adult population in Germany. Measurements of the concentrations of PFOS and PFOA in current studies indicate a trend towards decreasing levels in the blood. In a study on the concentrations in blood serum of 158 people from Munich in 2016, the median concentration for PFOS was 2.1 micrograms (µg) per litre (95^{th} percentile 6.4 µg per litre) and 1.1 µg per litre (95^{th} percentile 2.4 µg per litre) for PFOA.

Levels of PFNA and PFHxS in the blood of the adult population in Germany and Europe are, according to the current data situation, lower than for PFOA and PFOS and the median is below 1 µg/l.

A study published in 2020 on PFAS concentrations in the blood plasma of 3 to 17-year-old children in Germany shows median concentrations of 2.4 µg PFOS per litre, 1.3 µg PFOA per litre and 0.4 µg PFHxS per litre. The median concentrations of the nine other PFAS compounds including PFNA examined in this study are below the analytical limits of quantification in this study.

The examination of breast milk samples shows that some PFAS can also be detected in breast milk. According to different studies, the concentrations of PFOS and PFOA measured in breast milk are approximately 0.9% to 2% and 1.8% to 9 %, respectively, of the concentrations measured in the blood of the mother.

The available data indicate that in certain regions of Germany higher concentrations of various PFAS are present in the environment and thus there is also an elevated human exposure.

What happens to PFAS following absorption into the body?
Many foreign substances that are absorbed from the environment can be changed ("metabolised") by animal or human metabolism in such a way that they are less harmful to the organism and/or can be excreted more easily. For PFAS, however, studies show that they are either excreted unchanged or metabolised to other PFAS, e.g. perfluoroalkyl acids (PFAA). These PFAAs represent a "final stage" in the metabolic degradation of PFAS.

The excretion of PFAS occurs primarily in the urine. The human organism can excrete long-chain PFAS, such as PFOS and PFOA only slowly. Therefore, long-chain PFAS exhibit long half-lives of several years in humans. A half-life is the period of time required for a substance to be reduced to one-half of its previous concentration in the body, by means of biochemical and physiological processes (metabolism and excretion). The slow excretion of long-chain PFAS leads to an accumulation in the human body.

Animal experiments have shown that mice, rats, dogs and apes can excrete the substances much more quickly than humans, depending on the species and sex of the animal.

Short-chain PFAS are excreted faster than the long-chain compounds in all mammalian species studied, including humans. For example, the half-life of short-chain perfluorohexanoic acid (PFHxA) in human blood is in the order of days, while it is in the order of years for long-chain perfluorooctanoic acid (PFOA). Compared to laboratory animals, however, also short-chain PFAS excretion is much slower in humans.

How have the PFAS concentrations in human blood serum or plasma changed in recent years?
The concentrations of the four long-chain PFAS (PFOA, PFNA, PFOS and PFHxS) in blood serum and plasma were highest in Germany around 1990. Since then, the blood serum concentrations of these four compounds in the population in Germany have decreased significantly. Today the values for PFOS are around 10% and for PFOA, PFNA and PFHxS each around 30% compared to the levels at that time. Further information can be found in the FAQs on PFAS of the German Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) and under the link contained therein to the Federal Environmental Specimen Bank:

https://www.bmu.de/faqs/per-und-polyfluorierte-chemikalien-pfas/

What are the main sources of PFAS for the consumer?
These substances are mainly ingested through food and drinking water. Breast-fed children can ingest PFAS through breast milk. Other sources include indoor and outdoor air, house dust, and contact with consumer products which are made with chemicals containing PFAS.

Which foods are the main sources of PFAS for the consumer?
Data on levels of PFAS in food is collected in Germany as part of the Food Monitoring Programme of the Federal States ("Bundesländer") PFAS are detectable in both plant-based food and food of animal origin. In most of the food samples examined by the state authorities, by means of the current analytical methods, no PFAS were detected. This can be due to the fact that the sensitivity of the analytical methods is often not yet sufficient to detect very low concentrations of PFAS in food. Nevertheless, the consumption of foods with very small

amounts of long-chain PFAS, which cannot be detected with the analytical methods, can lead to measurable concentrations in the long-term, e.g. in the blood plasma. This is because long-chain PFAS are poorly excreted and therefore accumulate in the human body.

Consumers ingest PFAS through different food groups - mainly drinking water, fish and other seafood. Other animal products, in particular offal, but also milk and dairy products, meat, eggs and plant-based foods may contain measurable concentrations of PFAS. Compared to meat, higher levels of PFAS are detected in offal. Particularly high concentrations are found in game offal, e.g. wild boar liver. In this context, please also see a consumer recommendation from the German Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU):

https://www.bmu.de/themen/gesundheit-chemikalien/gesundheit-und-umwelt/lebensmittel-sicherheit/verbrauchertipps/

Based on the current database, it is not yet possible to conclusively determine which foods mainly contribute to the intake of PFAS. From the BfR's point of view, it is therefore necessary to develop and establish more sensitive analytical methods for PFAS in food monitoring in order to reduce the uncertainties in the measurement of the concentrations, to register changes in concentration and to be able to derive recommendations for risk management options.

What is the amount of PFAS that consumers ingest through food?
EFSA's 2020 calculation for the mean total weekly intake of PFOA, PFNA, PFHxS and PFOS in the adult population in Europe averages 6.44 nanograms (ng) per kilogram (kg) of bodyweight for the sum of these four PFAS. The intake levels for infants, toddlers, children and adolescents can be significantly higher. The concentrations in many food samples were below the analytical detection limits. For this reason, too, there are still uncertainties in the current estimate of the total intake.

The database on PFAS concentrations in food has been enlarged in the current opinion by the European Food Safety Authority (EFSA).
17 PFAS for which occurrence data in foods were available were included in the exposure assessment. PFAS that were not detected in any of the foodstuffs examined were not considered in the exposure assessment.

In addition, an exposure assessment was made for the sum of four PFAS (PFOA, PFNA, PFOS, PFHxS), for which a tolerable daily intake was derived. According to EFSA's calculations, the intake of these four PFAS through food represents around half of the total intake of all PFAS examined that are ingested by consumers in Europe.

The data on PFAS concentrations in food in Germany come from the food monitoring programme of the federal states. It should be noted that the concentrations in the majority of the food samples were below the detection limits using the current analytical methods. Therefore, there are still uncertainties regarding the levels in food products. For food monitoring, more sensitive analytical methods should therefore be developed for the detection of PFAS in food.

The respective state authorities provide information on the specific PFAS concentrations in food and drinking water in individual regions and possible regional consumption recommendations.

Is there a maximum level for PFAS in food products?
Maximum levels for contaminants such as PFAS in food are generally set at the European level.

There is currently no legally determined maximum level for PFAS in food products.

What are the potential health effects of PFAS?
The following sections describe the hazard or hazard potential that may be associated with PFAS. However, the risk of harmful effects arising from a substance also depends on the amount to which people are exposed and the duration of exposure (see the question “Are there health-based guidance values (e.g. TWI) for assessing PFAS in food?” as well as the questions thereafter).

Population-based studies indicate a relationship between the concentration of certain PFAS in blood serum and the occurrence of changes that may be relevant to health. In children who had higher levels of PFOA, PFNA, PFHxS and PFOS (all added together) in the blood serum, a lower level of antibody formation was observed after routine vaccinations. In addition, higher levels of cholesterol and lower birth weights were observed with higher levels of PFOS or PFOA. Exposure to PFOA was also associated with influencing a liver enzyme.

It is known from animal studies that many PFAS, including PFOA, PFNA, PFHxS, and PFOS, damage the liver. In animal experiments, some PFAS, such as PFOA and PFOS, also induce developmental toxicity and can impair lipid metabolism, thyroid hormone levels and the immune system. However, they do not directly damage the DNA and only have a carcinogenic effect in animal experiments at doses that are above the amounts that humans ingest through food. Population-based studies have also examined whether an increased risk of cancer for humans exists in association with exposure to PFOS and PFOA. According to EFSA, the results of these studies available so far do not sufficiently support the assumption that such a correlation exists in humans. This means that a correlation cannot currently be clearly proven. With regard to other PFAS, hardly any human data on carcinogenicity are currently available.

Are there health-based guidance values (e.g. TWI) for assessing PFAS in food?
TWI values (“tolerable weekly intake”) represent the amount of a substance (per kilogram of bodyweight) that can be ingested weekly over a lifetime with no appreciable health risk.

In its current opinion, the European Food Safety Authority (EFSA) has derived a new TWI value for the sum of four PFAS, namely PFOA, PFNA, PFHxS and PFOS of 4.4 nanograms (ng) per kilogram (kg) of bodyweight per week. No health-based guidance value such as a TWI could be derived for the other PFAS detected in food so far, as the currently available database is not sufficient for that.

The TWI derivation is based on the results of a current study in one-year-old children and previous population-based studies in which the blood of children was examined after routine vaccinations.

https://www.bfr.bund.de/cm/343/neue-studie-zeigt-bei-hohen-pfoa-gehalten-im-blut-weisen-einjaehrige-kinder-geringere-gehalte-von-impfantikoerpern-auf.pdf

In these studies, lower levels of post-vaccination antibodies (lower antibody titers) were observed in children with higher levels of these four PFAS in the blood serum. This indicates that the substances have an effect on the immune system. Similar effects on the immune system have also occurred in animal studies.

Breast-fed infants have got the highest exposure to PFAS through their breast milk. Compliance with the TWI ensures that also the group of children who are breastfed for a long time do not suffer any health impairments from PFAS. According to the current data situation, compliance with the TWI also protects the other population groups from PFAS-induced health impairments.

This applies to the possible occurrence of lower antibody titers after vaccinations as well as to other impairments for which relationships with exposure to PFOA, PFNA, PFHxS or PFOS have been described in epidemiological studies.

What does it mean if the EFSA health-based guidance value for the sum of PFOA, PFNA, PFHxS and PFOS is exceeded?
A TWI ("tolerable weekly intake") describes the amount of a substance that can be ingested weekly over a lifetime with no appreciable health risk in the population.. After ingestion with food, drinking water or other sources, some PFAS can accumulate in the body because they are excreted only slowly. Even a short-term intake of these substances can contribute to a higher concentration in the body in the long-term due to their slow excretion from the body. Whether exceeding the TWI leads to concentrations in the body, at which health impairments are possible, depends on several factors: the extent of the exceedance, the duration and the amount of the substances already present in the body.

In its opinion, EFSA assumes a reduced formation of antibodies after vaccination as the first health effect that could occur in children with higher PFAS concentration in the blood serum.

What does a lower level of antibody formation mean after vaccination in children with higher concentrations of PFAS in the blood serum?
A lower formation of antibodies after vaccination in children with higher PFAS concentrations in the blood serum indicates that the substances have an effect on the immune system. The underlying mechanism of action has not yet been clarified.

A reduced formation of vaccine antibodies is generally considered undesirable, even if the existing safety margins for vaccinations do not necessarily lead to reduced vaccination protection if the vaccination recommendations of the Standing Committee on Vaccination are observed. It is currently unclear whether infections may occur more frequently as a result of the influence of PFAS on the immune system.

Are there health-based guidance values (e.g. TWI) for short-chain PFAS?
So far, no health-based guidance values, e.g. TWI values (values for the tolerable weekly intake), exist to assess the health risks of short-chain PFAS in food.

There is currently only limited toxicological data available for these substances. Short-chain PFAS are excreted significantly faster than long-chain PFAS after ingestion.

Data from animal experiments on short-chain PFAS, for example perfluorohexanoic acid (PFHxA), which has a chain of six carbon atoms, suggest a similar toxicological effect. However, the potency seems to be lower than that of long-chain PFAS, since the toxic effects of the short-chain compounds were only observed in significantly higher doses.

Has the use of PFOA and PFOS meanwhile been banned?
PFOS and PFOA are included in regulation (EU) 2019/1021 on persistent organic pollutants (POP regulation).

For PFOS and PFOA, the manufacture, use, marketing and import as a substance itself as well as in mixtures and commodities (products) are therefore prohibited in the EU with a few exceptions. For substances, mixtures or products (e.g. textiles) that contain PFOS or PFOA or their precursor compounds as unintentional and unavoidable trace contamination, low limit values are set. A ban on PFOS and its precursor compounds has existed already since 2006; the ban on PFOA and its precursor compounds came into force on July 4, 2020.

For further information on the regulation of PFAS, please refer to the FAQ document of the BMU:

https://www.bmu.de/faqs/per-und-polyfluorierte-chemikalien-pfas/

Are there bans and restrictions on the use of other PFAS?
Various PFAS were identified as Substances of Very High Concern (SVHC) under the REACH regulation. Substances of particular concern are to be replaced in the long-term by less dangerous alternatives.

For a number of PFAS, restriction procedures have already been initiated on the basis of individual substances, which are in different process stages as of July 2020. Detailed information can be found on the website of the German Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) or the European Chemicals Agency ECHA.

In May 2020, activities for a broad restriction of the entire PFAS group began. All uses of these substances that are not considered "indispensable for society as a whole" are to be banned in future.

The BfR is involved in these activities regarding the health assessment of these substances and their use in consumer products.

For further information on the regulation of PFAS, please refer to the FAQ document of the BMU:

https://www.bmu.de/faqs/per-und-polyfluorierte-chemikalien-pfas/

Are PFAS used in food contact materials such as packaging?
PFAS are used in various forms for food contact materials: for example, as fluoropolymers in non-stick coated pans, foils or in the coatings of kitchen items such as plates, cups or storage boxes. In addition, polymers with fluorinated side chains can be used in the production of paper packaging that is intended to come into contact, in particular, with hot liquid or fatty foods. Examples of this are fast food packaging, bags for microwave popcorn, muffin cups or baking paper.

The use of PFOA is prohibited across Europe by the POP Regulation (Reg. (EU) 2019/1021). POP stands for "Persistent Organic Pollutants". For PFOA, its salts or precursor compounds, concentration limits have been in effect since July 4, 2020, provided they are unintentional trace contamination in products, e.g. contained in food packaging. The limit values are 25 micrograms per kilogram of product for PFOA and its salts and 1000 micrograms per kilogram of product for precursor compounds. In Regulation (EU) No. 10/2011 on food contact materials made of plastic, the ammonium salt of PFOA is still listed for the manufacture of reusable items that are manufactured at high temperatures (sintered). The release of relevant amounts of PFOA from such items into food is not expected.

According to the POP regulation (EU 2019/1021), PFOS must not be intentionally used in the production of food contact materials. Low limit values are set for possible unwanted contamination.

For further information on the European harmonised regulation of other PFAS, please refer to the answer to the question “Are there bans and restrictions for other PFAS?”.

In the BfR Recommendation XXXVI “Paper, cardboard and paperboard for food contact”, the BfR has specified guideline values for the use of certain PFAS..According to the current state of knowledge, health risks are not to be expected provided these guideline values are complied with. Since 2018, new PFAS are not included in the recommendations. The existing entries are continuously checked and, if necessary, adapted to new findings on risk assessment or changes in European regulation.

Are PFAS used to manufacture outdoor clothing?
Polymers with fluorinated side chains, also called fluorocarbon resins, are used to coat textiles to repel water, oil and dirt. This coating firmly bonds to the material. In older products, such coatings may contain process-related residues of PFOA and its precursors. PFOA can also arise as an unintended by-product in the production process. Due to the PFOA restriction, an alternative technology for coating is now used by the industry, so that accordingly residues of perfluorohexanoic acid (PFHxA) can be contained. In addition, there are also fluorochemical-free technologies to make textiles such as outdoor clothing water-repellent, but there is no oil and dirt repellency here. Furthermore, breathable membranes in outdoor textiles can consist of fluoropolymers (PTFE).

Is there a health risk associated with wearing outdoor clothing with PFAS-containing coatings?
PFAS-containing coatings are firmly bound to outdoor clothing. According to the current state of knowledge, absorption through the skin and associated health impairments from wearing such clothing are therefore unlikely. In addition to the fluorochemical-free variants which make clothing water-repellent, the residual PFOA content has been reduced by new technologies, so that only traces of it are detectable in the product. PFOA residues are not tightly bound to the textile fibres, and may be released when wearing or washing the clothing. According to current knowledge, however, health impairments from wearing jackets with PFAS-containing coatings are very unlikely. Moreover, the skin is a good protective barrier against PFOA. The main source of PFOA intake for consumers is food.

Further information on the subject from the BfR website:

Publications about PFAS on the BfR website
https://www.bfr.bund.de/en/a-z_index/poly__and_perfluoralkyl_substances__pfas_pfc_-130146.html

XXXVI. Paper, cardboard and paper board for food contact material, BfR recommendation XXXVI, last updated 01.07.2016
https://bfr.ble.de/kse/faces/resources/pdf/360.pdf

This text version is a translation of the original German text which is the only legally binding version.