

Here to stay: per- and polyfluoroalkyl substances (PFAS) in food and in the environment

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Per- and polyfluoroalkyl substances (PFAS) are a large group of industrial chemicals that are used in numerous industrial processes and consumer products because of their special technical properties.

In the polyfluoroalkyl 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 everywhere in the environment, in 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 other PFAS, namely perfluorononanoic acid (PFNA) and perfluorohexanesulfonic acid (PFHxS), have been included in the exposure assessment and health risk assessment in addition to PFOA and PFOS. <u>http://www.efsa.eu-ropa.eu/de/news/pfas-food-efsa-assesses-risks-and-sets-tolerable-intake</u>

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

The use of PFOS has been largely banned since 2006 and that of PFOA since July 2020. On 7 February 2023, the European Chemicals Agency (ECHA) published the proposal for a ban on the production, use and placing on the market (including import) of the entire group of per- and polyfluoroalkyl substances (PFAS). <u>https://www.bfr.bund.de/cm/349/per-and-polyfluoroalkyl-substances-pfass-proposal-for-re-striction-under-the-reach-regulation-submitted-to-the-european-chemicals-agency.pdf</u>

What are per- and polyfluoroalkyl substances (PFAS)?

Per- and polyfluoroalkyl substances (PFAS) are industriallyproduced substances that do not occur naturally. Chemically, these are organic compounds in which the hydrogen atoms bonded to a carbon atom are completely (perfluorinated) or partially (polyfluorinated) replaced by fluorine atoms. The substance group currently comprises at least 10,000 different compounds, 4,730 of which have a known chemical structure. An overview of this large group of substances is provided in a report by the Organisation for Economic Co-operation and Development (OECD) at <u>https://www.oecd.org/chemi-</u> calsafety/portal-perfluorinated-chemicals/terminology-per-and-polyfluoroalkyl-substances.pdf.

The various PFAS differ in the length of their carbon chains and in the additional structures (functional groups) present in the molecule, e.g. a carboxyl group in the case of perfluoroalkylcarboxylic acids (PFCA) or a sulfonate group in the case of perfluoroalkylsulfonic acids (PFSA). Perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) are the best-studied compounds to date. These two compounds are part of the so-called "C8 fluorochemistry" (along with other related compounds).

In addition, there are PFAS with longer or shorter carbon chains. With regard to PFCA, a "short-chain" compound refers to a compound with a shorter carbon chain than PFOA. PFSA are only refered to as "short-chain" compounds when the carbon chain is shorter than that of PFOS by more than two per-fluorinated carbon atoms. Short-chain PFAS are excreted more quickly after being absorbed by the human and mammalian organism than those with longer carbon chains.

Since the problematic properties of PFOA and PFOS have been recognised, other compounds have been used as alternatives, e.g. PFAS with shorter perfluorinated carbon chains such as perfluorohexanoic acid (PFHxA). Furthermore, numerous so-called "precursors" are in use, e.g. 6:2 fluorotelomer alcohol, which can be converted into poorly degradable PFAS, such as PFHxA, both in the environment as well as in organisms. Therefore, precursors may additionally contribute to exposure to PFAS that are not readily degradable, e.g. PFCA and PFSA.

Do the acronyms "PFT" and "PFC" also refer to the "PFAS" substance group?

In addition to the term "PFAS" for per- and polyfluoroalkyl substances, the acronyms "PFT" for perfluorosurfactants and "PFC" for per- and polyfluorochemicals are frequently used. However, these terms do not correctly encompass the compounds belonging to the PFAS group and should therefore be avoided.

Which products contain PFAS?

The industrial chemicals in the PFAS group, such as PFOS and PFOA, have been produced since the middle of the 20th century. PFAS are extremely stable and are widely used in numerous industrial processes and technical applications because of their special chemical properties. PFAS are used to manufacture water-, grease- and dirt-repellent finishes for various consumer products, such as paper (e.g. fast-food packaging, baking paper), textiles (e.g. outdoor clothing, carpets) and cookware (e.g.pans with non-stick coating) and are used in electronic devices, cosmetics, impregnating products and ski waxes. Consumers cannot always tell whether products contain PFAS.

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

These compounds may also be present in consumer products as impurities or unintended by-products.

How do PFAS enter 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 longlasting 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 enter the food chain. The German Federal Environment Agency (UBA) determines and assesses the entry paths of PFAS into the environment. More information can be found on the UBA website at https://www.umweltbundesamt.de/themen/chemikalien/chemikalienreach/stoffe-ihre-eigenschaften/stoffgruppen/pfc-portal-start.

Can PFAS also be detected in humans?

Data on the occurrence of some PFAS in humans (in human blood plasma or serum and in breast milk) is available worldwide. The amount of PFAS present in the body ("internal exposure") is different for each individual compound.

According to the opinion of the European Food Safety Authority (EFSA) of September 2020, seven compounds, PFOA, perfluorononanoic acid (PFNA), perfluorohexanesulfonic acid (PFHxS), PFOS, per-fluoroheptanesulfonic 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 to date. The highest concentrations in human blood plasma and serum in adults are detected for PFOA, PFNA, PFHxS and PFOS. About 90 % of the PFAS concentrations detectable in human blood are represented by these four PFAS.

Concentrations of PFAS in human blood and the relative proportions of individual PFAS can differ significantly from person to person. Influencing factors are the region in which a person lives, as well as gender and eating habits. Available data indicates that in certain regions of Germany there are higher concentrations of various PFAS in the environment and, therefore, also a higher exposure of humans.

There are no representative studies on PFAS concentrations in the blood plasma of the adult general population in Germany. Measurements of PFOS and PFOA concentrations in current studies indicate a trend towards decreasing concentrations in the blood. In studies on concentrations in blood serum in 158 individuals from Munich in 2016, the median concentration for PFOS was 2.1 micrograms (μ g) per litre (95th percentile 6.4 μ g/L) and 1.1 μ g/L for PFOA (95th percentile 2.4 μ g/L).

Concentrations of PFNA and PFHxS in the blood of the adult population in Germany and in Europe are, according to current data, lower than the values for PFOA and PFOS and are below 1 μ g/L (median concentration).

A study on PFAS concentrations in the blood plasma of three to 17-year-old children and adolescents in Germany shows median concentrations of 2.4 µg PFOS/L, 1.3 µg PFOA/L and 0.4 µg PFHxS/L. Median concentrations of the nine other PFAS investigated in this study, including PFNA, are below the analytical limits of quantification (cf. <u>https://www.umweltbundesamt.de/publikationen/deutsche-umwelt-studie-zur-gesundheit-von-kindern-0</u>).

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 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.

What happens to PFAS following absorption into the body?

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

PFAS are primarily excreted via the urine. The human organism can excrete long-chain PFAS, such as PFOS and PFOA only slowly. Therefore, long-chain PFAS have long half-lives of several years in humans. @BfR, page 3 of 11

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 can lead to an accumulation in the human body if larger amounts are absorbed than excreted in the same period of time.

Animal experiments demonstrate that mice, rats, dogs and apes excrete the substances depending on the species and sex of the animal. These laboratory animal species excrete PFAS significantly faster than humans. Therefore, the assessment of human excretion rates is based on data from epidemiological studies.

Short-chain PFAS are excreted more quickly than long-chain compounds in all mammalian species studied, including humans. For example, the half-life of the short-chain perfluorohexanoic acid (PFHxA) in human blood is in the range of days, whereas it is in the range of years for the long-chain perfluorooctanoic acid (PFOA).

How have PFAS concentrations developed in human blood serum or plasma in recent years?

The concentrations of the four long-chain PFAS (PFOA, PFNA, PFOS and PFHxS) in blood serum or plasma were at their highest in Germany around 1990. Since then, the blood serum concentrations of these four compounds have decreased significantly in the population in Germany. Today, the values for PFOS are around 10 % and those for PFOA, PFNA and PFHxS around 30 %, respectively, compared to concentrations at that time. Further information can be found in the FAQs on PFAS from the German Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (BMUV) and following the link contained therein to the German Environmental Specimen Bank: https://www.bmuv.de/faqs/per-und-polyfluorierte-chemikalien-pfas/.

What are the potential health effects of PFAS?

The following sections describe the hazard potential that may be associated with PFAS. The risk of harmful effects arising from a substance depends on the amount to which people are exposed and the duration of exposure (see also the question "Are there health-based guideline values for the assessment of PFAS in food?" and the questions that follow).

Population-based studies indicate a relationship between concentrations of certain PFAS in blood serum and the occurrence of potentially health-relevant changes. For example, children with higher concentrations of the sum of PFOA, PFNA, PFHxS and PFOS in their blood serum were found to have lower concentrations of antibodies following common vaccinations. In addition, higher concentrations of PFOS or PFOA were associated with higher cholesterol levels and lower birth weights. Higher levels of a liver enzyme were also found with higher exposure to PFOA.

It is known from animal studies that many PFAS, including PFOA, PFNA, PFHxS and PFOS, damage the liver at higher doses in some of the animal species studied. In animal studies, some PFAS such as PFOA and PFOS also elicit developmental toxicity and can impair lipid metabolism, thyroid hormone levels and the immune system. Some PFAS are also suspected of causing cancer in laboratory animals. However, on the basis of information currently available, these substances 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 with food.

Population-based studies also investigated whether there is an increased risk of cancer for humans associated with exposure to PFOS and PFOA. According to EFSA (2020), a correlation between this exposure and an increased risk of cancer for humans could not be clearly proven at present. A reassessment of the carcinogenic potential of PFOA and PFOS for humans is currently being carried out by the World Health Organization (WHO)'s International Agency for Research on Cancer (IARC). With regard to other PFAS, hardly any human data on carcinogenicity are available so far.

Are there health-based guidance values for the assessment of PFAS in food?

An important health-based guidance value is the tolerable weekly intake (TWI). The TWI value represents the amount of a substance ingested weekly over a lifetime (per kilogram of bodyweight), which is not expected to have any adverse effects on health.

In its opinion from September 2020, the European Food Safety Authority (EFSA) derived a TWI value for the sum of four PFAS, namely PFOA, PFNA, PFHxS and PFOS, of 4.4 nanograms (ng) per kilogram (kg) of body weight 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 data pool is not sufficient for this.

The TWI derivation is based on results of a study in one-year-old children <u>https://www.bfr.bund.de/cm/349/new-study-shows-one-year-old-children-demonstrate-lower-con-</u> <u>centration-of-vaccine-antibodies-with-high-pfoa-concentration-in-the-blood.pdf</u>.

In this and other studies, a lower concentration of antibodies was observed after common vaccinations (lower antibody titres) with higher concentrations of the four PFAS in the blood serum. This indicates an effect of the substances on the immune system. Comparable effects on the immune system also occurred in animal studies.

Breastfed infants have the highest exposure to PFAS via breast milk. Compliance with the TWI ensures that no adverse health effects from PFAS are to be expected, even for children who are breastfed for a long time. According to current data, the other population groups are also protected against adverse health effects from PFAS if the TWI is complied with.

This applies both to the possible occurrence of lower antibody titres after vaccination and to other observed changes for which links with exposure to PFOA, PFNA, PFHxS or PFOS have been described in epidemiological studies.

For other PFAS, there are no health-based guidance values for the assessment of occurrence in food.

What does it mean if the EFSA health-based guidance value is exceeded for the sum of PFOA, PFNA, PFHxS and PFOS?

After ingestion with food, drinking water or via other sources, some PFAS can accumulate in the human 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 because of their slow excretion. Whether exceeding the TWI will result in concentrations in the body at which adverse health effects are possible depends on several factors: the extent of the exceedance, the amount actually absorbed into the organism (internal dose), the duration of exposure, the ratio of intake to excretion and the amount of the substances already present in the body.

In its 2020 opinion, EFSA assumes a reduced formation of antibodies after vaccinations as the first expected reaction of the body that might occur in children with higher PFAS concentrations in the blood serum. Since then, new studies on the toxicity of PFAS have been published. With regard to carcinogenicity of PFOA and PFOS, these are currently being reviewed by the World Health Organization (WHO)'s International Agency for Research on Cancer (IARC).

What does a lower formation of antibodies mean after vaccinations in children with higher concentrations of PFAS in the blood serum?

A lower formation of antibodies in the blood serum after vaccinations in children with higher concentrations of PFAS 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.

This 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?

Only a limited amount of toxicological data is currently available for these substances. So far, there are no health-based guidance values, e.g. tolerable weekly intake (TWI) values with which to assess the health risks of short-chain PFAS in food.

In the current restriction proposal for PFHxA and its salts, DNELs (derived no-effect levels, meaning the level of exposure derived from toxicological study data below which human health is not affected) were calculated for systemic effects in the general population after long-term exposure. For oral intake, the DNELs for PFHxA range from 0.03 mg/kg body weight/day for reduced level of thyroid hormones to 1 mg/kg body weight/day for reduced birth weight (<u>https://echa.europa.eu/documents/10162/c41acb41-9ed0-3a35-504f-255292abdc1f</u>).

Data from animal experiments on short-chain PFAS – e.g. perfluorohexanoic acid (PFHxA) which includes a chain of six carbon atoms – suggest similar toxicological effects. However, the toxic effects of the short-chain compounds are only observed at significantly higher doses. Short-chain PFAS are excreted much faster after ingestion than long-chain PFAS.

What are the main sources of PFAS for the consumer?

The substances are mainly ingested through food and drinking water. Other sources include indoor and outdoor air, house dust, and contact with consumer products that are made with chemicals containing PFAS.

Breastfed infants can ingest PFAS via breast milk. In consideration of the possible risks from the intake of PFAS in breastfed infants, the National Breastfeeding Committee sees no reason to deviate from the existing breastfeeding recommendation based on the proven benefits of breastfeeding given the current data situation. <u>https://www.mri.bund.de/fileadmin/MRI/Themen/Stillkommission/2021-01-28_Stellungnahme-NSK_PFAS.pdf</u>.



Which foods are the main sources of PFAS for the consumer?

Consumers ingest PFAS through different food groups: mainly drinking water, fish and seafood. Other products of animal origin, especially offal, but also milk and dairy products, eggs, and plant-based foods may contain measurable levels of PFAS. Compared to meat, higher levels of PFAS are found in offal. Levels are particularly high in offal from game, such as wild boar liver. In this context, see also the consumer tip from the BMUV at https://www.bmuv.de/themen/gesundheit-chemikalien/gesundheit/lebensmittelsicherheit/verbrauchertipp#c15516.

What is known about PFAS concentrations in individual foods?

Data on levels of PFAS in food is collected in Germany as part of the Food Monitoring Programme of the German federal states ("Bundesländer"). PFAS are detectable in both plant-based foods and foods of animal origin. However, in most of the food samples examined by the state authorities, by means of the current analytical methods, no PFAS were detected. This may be due to the fact that the sensitivity of the analytical methods used is high, but not always sufficient to detect very low concentrations of PFAS in food.

The consumption of food with very small amounts of long-chain PFAS, which cannot be detected with current analytical methods, can still lead to measurable concentrations in the long term, e.g. in blood plasma. This is due to the fact that long-chain PFAS are poorly excreted and can, therefore, accumulate in the human body.

The available data does currently not allow any statement on which foods mainly contribute to the intake of PFAS. Information on specific PFAS concentrations in food and drinking water in individual regions and on possible regional consumption recommendations can be obtained from the respective state authorities.

Information on PFAS is provided, for example, in Bavaria by the Bavarian State Office for Health and Food Safety (LGL) at <u>https://www.lgl.bayern.de/lebensmittel/chemie/kontaminanten/pfas/index.htm</u>, for Baden-Wurttemberg by the Karlsruhe Regional Council at <u>https://rp.baden-wuerttem-berg.de/rpk/abt5/ref541/stabsstelle-pfc/pfc-problematik-mittelbaden-mannheim/</u> and by the State Office for Consumer Protection and Food Safety in Lower Saxony (LAVES) <u>https://www.laves.nieder-sachsen.de/startseite/lebensmittel/ruckstande_verunreingungen/perfluorierte-alkylsubstanzen-187637.html</u>.

What is the amount of PFAS that consumers ingest through food?

In 2021, the BfR prepared a health assessment on the occurrence of PFAS in food. The BfR's estimate of the total intake of the sum of the four PFAS (PFOS, PFOA, PFNA and PFHxS) is on average (median) in the range of the TWI of 4.4 nanograms (ng) per kilogram (kg) of body weight per week. This means that the long-term exposure to these four PFAS is above the TWI for around half of the adult population. This exposure estimate was based on data on concentrations of PFAS in food in Germany from the federal states' food monitoring programme from 2007 to 2020.

According to a calculation by EFSA from 2020, the mean value of the total weekly intake of PFOA, PFNA, PFHxS and PFOS in the adult population in Europe is 3 to 22 nanograms (ng) per kilogram (kg) of body weight for the sum of these four PFAS. The intake related to body weight for infants, toddlers,

children and adolescents may be significantly higher. Therefore, it is above the TWI for adults as well as for children and adolescents.

The data basis on PFAS levels in food was increased in the BfR's and EFSA's current opinions compared to previous opinions. However, also in the current exposure estimates, the concentrations in the majority of food samples were below the analytical limits of detection. This is another reason why the current estimates of total intake still include considerable uncertainties regarding the actual intake.

A specific optimisation of the analytical methods and the use of sensitive measuring systems can further increase the sensitivity of PFAS analysis in the future. The establishment and further development of sensitive analytical methods for PFAS in food monitoring can contribute to lowering the limits of quantification and consequently detect low concentrations of PFAS. This would result in a more precise estimate of the total intake.

Are there other criteria for assessing the health risk of PFAS in addition to the health based guidance value TWI?

In addition to the total intake described here (external exposure), the concentrations of PFAS in blood serum or plasma (internal exposure, "body burden") provide a second assessment option for the current PFAS exposure that is not affected by the aforementioned uncertainties. According to EFSA's opinion from 2020, a TWI level exhausted over a life time (4.4 nanograms (ng) per kilogram (kg) of body weight per week for the sum of four PFAS) corresponds to an internal exposure of 6.9 μ g/L for the sum of four PFAS in women of childbearing age. If this value is not exceeded, no health impairments are to be expected even in children who have been breastfed for a long time.

There is currently no representative data on internal exposure available for Germany. In current studies of the adult population in three cities in Germany, the median levels for the sum of the four PFAS in blood serum were 5.8 μ g/L (Münster), 4.1 μ g/L (Munich) and 7.1 μ g/L (Berlin). In these studies, the blood serum concentrations in 2 to 36 % of women of childbearing age were above the value of 6.9 μ g/L on which the TWI was based. From this data (rough assumption: 25 % of women are above the blood serum concentration of 6.9 μ g/L), using current data on breastfeeding behaviour, it can be roughly estimated that around 10 % of infants in Germany at the age of one year may exceed a critical exposure level for the four PFAS, which could be linked to lower concentrations of vaccine antibodies. From the BfR's point of view, the current epidemiological data does not yet allow a conclusion with regard to the question of whether this can lead to a more frequent occurrence and/or more serious courses of infections.

Are there maximum levels for PFAS in food products?

Maximum levels for contaminants such as PFAS in food products are generally set at European level. Statutory maximum levels for PFOS, PFOA, PFNA and PFHxS as well as for the sum of these four PFAS in certain foods of animal origin (eggs, fish products and shellfish, meat and offal) have been in force in the member states of the European Union since 1 January 2023. Since then, food containing these PFAS in concentrations exceeding the established maximum levels may no longer be put on the market.

Which PFAS have been banned so far?

Even before the EU REACH Regulation (Regulation (EC) No 1907/2006) came into force, an EU-wide ban on PFOS (perfluorooctane sulfonic acid, C8) was adopted (see EC Directive 2006/122), which was incorporated into the EU POP (persistent organic pollutants) Regulation shortly afterwards. The corresponding Regulation from the international Stockholm Convention was therefore adopted (Regulation (EU) 757/2010).

PFOA was initially regulated EU-wide on the initiative of the German authorities in cooperation with the Norwegian authorities. At the same time, the inclusion of PFOA in the globally valid ban list of the Stockholm Convention on Persistent Organic Pollutants was pushed forward and adopted in 2019. Furthermore, PFHxS (perfluorohexane sulfonic acid, C6) was included in the Stockholm Convention as another POP in 2022.

Since 25 February 2023, the marketing, production and use of perfluorinated carboxylic acids with nine to fourteen carbon atoms (PFNA, PFDA, PFUnDA, PFDoDA, PFTrDA, PFTeDA) have also been restricted. Moreover, a proposal is currently being drafted by the EU Commission to restrict the production and use of PFHxA (perfluorohexanoic acid, C6). A decision regarding this regulation is expected by the end of 2023. An additional proposal to regulate fire-fighting foams that contain fluorine is currently being assessed by the scientific committees at the European Chemicals Agency ECHA. A decision is expected in 2024.

Several other PFAS, such as perfluorobutane sulfonic acid (PFBS), PFHxS and HFPO-DA (trade name "GenX"; ammonium 2,3,3,3-tetrafluoro-2-propanoate), have already been identified as substances of very high concern (SVHC) under REACH with the aim of replacing them as well.

Are further steps towards a comprehensive PFAS regulation planned?

On 7 February 2023, the European Chemicals Agency (ECHA) published the proposal for a ban on the production, use and placing on the market (including import) of the entire group of PFAS. The proposed ban was prepared as part of the EU chemicals regulation REACH by regulatory experts from Germany (with the participation of BfR), the Netherlands, Denmark, Norway and Sweden. From Germany, the Federal Institute for Occupational Safety and Health (BAuA), the Federal Environment Agency (UBA) and the German Federal Institute for Risk Assessment (BfR) were involved in the drafting. The aim of the ban is to drastically reduce the release of PFAS into the environment (see also the BfR communication of 7 February 2023: <u>https://www.bfr.bund.de/cm/349/per-and-polyfluoroalkyl-sub-stances-pfass-proposal-for-restriction-under-the-reach-regulation-submitted-to-the-european-chemicals-agency.pdf</u>). A decision by the European Commission on this proposal can be expected in 2025. If the PFAS restriction proposal is adopted, this would be one of the most extensive bans on chemical substances since the REACH Regulation came into force in 2007.

For more information on the PFAS regulation, please refer to the BMUV's FAQ document at https://www.bmuv.de/faqs/per-und-polyfluorierte-chemikalien-pfas/.

Which cosmetic products contain PFAS?

Search queries in ingredient and product databases coupled with selective analytical investigations indicate that there are PFAS in isolated cosmetic products. However, the BfR does not have any current representative studies on PFAS concentrations in cosmetic products on the market.

Bans under chemicals law, which are developed, for example, as part of the EU Chemicals Regulation (Regulation (EC) No 1907/2006), also apply to cosmetic products. The same applies to the requirements of the Regulation on Persistent Organic Pollutants ((EU) 2019/1021). Therefore, among others, the use of the harmful substance PFOA in cosmetic products is prohibited.

Are PFAS used in food contact materials such as packaging?

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

For PFOA, its salts or precursor compounds, concentration limits have been in effect since 4 July 2020, provided they are unintentional trace contamination in products such as food packaging. The limit values are 25 micrograms (μ g) per kilogram of product for PFOA and its salts and 1.000 μ g per kilogram of product for precursor compounds. In Regulation (EU) No. 10/2011 on plastic food contact materials, the ammonium salt of PFOA is still listed for the production of reusable items manufactured at high temperatures (sintered). 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 unintentional contamination.

In the BfR Recommendation XXXVI "Paper, cardboard and paperboard for food contact", the BfR has specified guideline values for the use of certain PFAS. Provided these guideline values are complied with, health risks are unlikely according to the current state of knowledge. No new PFAS have been included in the recommendations since 2018. The existing entries are continuously reviewed and, if necessary, adapted to new findings on risk assessment or changes in the European regulation.

Are PFAS used to manufacture outdoor clothing?

Polymers with fluorinated side chains, also known as fluorocarbon resins, are used to coat textiles in order to repel water, oil and dirt. This coating firmly bonds to the material. In older products, the coating may contain process-related residues of PFOA and its precursor compounds. PFOA can also occur as an unintended by-product in the production process. Because of the PFOA restriction, an alternative technology (C6 technology) is now used by the industry for coating, so that residues of e.g. PFHxA can be contained accordingly. Moreover, fluorochemical-free technologies are available that make textiles such as outdoor clothing water-repellent, but there is no oil and dirt repellency here. Furthermore, breathable membranes in outdoor textiles may consist of fluoropolymers (PTFE). The restriction proposal for all PFAS submitted by the authorities from five European countries (see above) intends to ban the use of PFAS in textiles for consumers.



Is there a health risk associated with wearing outdoor clothing with PFAS-containing coatings?

Coatings that contain PFAS are firmly bound to the outdoor clothing. On the basis of information currently available, absorption through the skin and any associated adverse health effects from wearing such clothing are therefore unlikely. In addition to the fluorochemical-free variants that make clothing water-repellent, the residual PFOA content has been reduced by C6 technology (see above), so that only traces of it are detectable in the product. Residues of PFOA are not tightly bound to textile fibres, and may be released when wearing or washing the clothing. However, health impairments from wearing jackets with coatings that contain PFAS are unlikely according to current knowledge. The main source of PFOA intake for consumers is food.

More information on the BfR website on per- and polyfluoroalkyl substances

Publications about PFAS on the BfR website at <u>https://www.bfr.bund.de/en/a-z_index/poly_and_per-fluoralkyl_substances_pfas_pfc_-130146.html</u>

BfR recommendations for food contact material, recommendation XXXVI "Paper and board for food contact", last updated 1 February 2023 (in german). <u>https://www.bfr.bund.de/cm/343/XXXVI-Papiere--Kartons-und-Pappen-fuer-den-Lebensmittelkontakt.pdf</u>



BfR "Opinions app"

About the BfR

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