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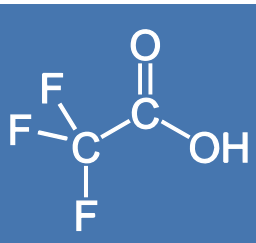
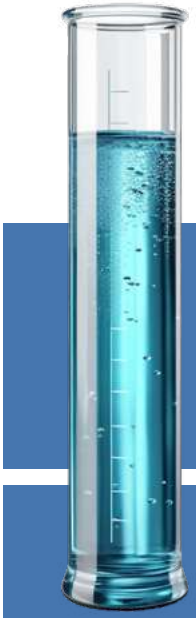


TFA The Forever Chemical in the Water We Drink

Only a rapid ban on PFAS pesticides and F-gases can save our water

July 2024



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Contents

TFA:The Forever Chemical in the Water We Drink

List of Abbreviations

ECHA: European Chemicals Agency

EFSA: European Food Safety Authority

LOD: Limit of Detection

LOQ: Limit of Quantification

PAN: Pesticide Action Network

PFAS: Per- and polyfluoroalkyl substances

PFOA: Perfluorooctanoic acid

PFOS: Perfluorooctane sulfonic acid

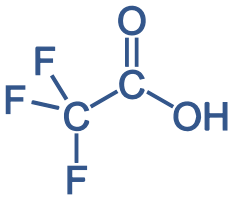
REACH: Registration, Evaluation, Authorisation, and Restriction of Chemicals

RIVM: Rijksinstituut voor Volksgezondheid en Milieu (Dutch Agency for Public Helath and the Environment)

TFA: Trifluoroacetic acid

UBA: Umweltbundesamt (Federal Environment Agency of Germany)

Summary



A recent exploratory survey of rivers, lakes, and groundwater conducted by members of the Pesticide Action Network (PAN) Europe showed alarming levels of contamination by the forever chemical TFA (trifluoroacetic acid) in all samples analysed across Europe. PFAS pesticides are considered the main cause of water contamination with TFA in rural areas, followed by refrigerants, sewage treatment, and industrial pollution.

In the present study, we have analysed drinking water (both tap water and bottled water) for the presence of TFA.

Test Results

- **TFA was detected in 34 of 36 European tap water samples** (94 %) from eleven EU countries and in 12 of 19 bottled mineral and spring waters (63 %).
- **TFA values in tap water** ranged from "undetectable" (corresponding to < 20 nanograms/litre (ng/L[1])) to 4,100 ng/L, with an average of 740 ng/L.
- **TFA values in mineral and spring waters** ranged from "undetectable" (< 20 ng/L) to 3,200 ng/L, with an average of 278 ng/L.
- **Analysis of 24 additional PFAS** in 4 mixed samples confirms that, beyond contamination hotspots, TFA is the dominant (> 98 %) PFAS contamination in the water.

Health Implications

- **Assessing the health risks posed by environmental pollutants** is always a challenge, especially when the data is sparse. This is the case with TFA, for which, given its widespread occurrence, surprisingly few toxicological studies are available.
- **Two recent studies** on TFA's chronic toxicity and reproductive toxicity show similar effects to those of the better-studied and more well-known PFAS (liver toxicity and birth defects), albeit at much higher concentrations.
- **A drinking water guideline value** for TFA that takes into account the current state of scientific knowledge of PFAS was proposed by the Dutch Institute for Public Health and the Environment (RIVM). Based on a risk assessment approach using relative potency factors for liver toxicity of PFOA, the RIVM has derived an **indicative drinking water guideline value of 2,200 ng/L**.
- **TFA was detected below this threshold in 97% of the tested samples**. It was set in such a way that the consumption of drinking water only fulfils 20% of the tolerable daily intake.
- **Older guideline values for TFA** are one to two orders of magnitude higher and give the impression of a large safety margin. However, their reliability appears limited as they are built on old data and optimistic assumptions.

[1] While in the past toxicological guideline values and legal limits for PFAS were often given in micrograms (µg/L), they are now increasingly given in nanograms per litre (or ppt) in the literature and legislation. Therefore in this report, for reasons of clarity, concentrations of PFAS in water and corresponding limits are uniformly stated in nanograms per litre.

Summary

- **Based on current scientific knowledge** of the chemical's toxicity, the TFA levels we have found still appear to be within safety limits. However, the toxicity data are limited and incomplete, so underestimation of the risk cannot be excluded. Indeed, since many PFAS are considered non-threshold chemicals, it is reasonable to ask whether this also applies to TFA.

- **Moreover, TFA inputs are increasing day by day** and our (assumed) safety buffer is limited - and is already filled by TFA entry pathways other than drinking water. In addition, we are unduly burdened by PFAS other than TFA. **Measures to prevent further TFA contamination are therefore essential**.

Legal Background

- **Although TFA is widespread**, there is currently no legal limit in the EU for TFA in surface water, groundwater or drinking water.

- **In 2026, a standard limit value for "PFAS total"** of 500 ng/L in drinking water is due to come into force in the EU. By definition, this value should also include TFA. However, as we understand, there are still discussions about how - and even whether this will be the case. As it stands today, and in light of our TFA results in drinking water, the following can be said:

    - **Half of the tap water samples analysed exceed** the limit value of 500 ng/L for "PFAS total" if TFA will be included in this parameter starting from January 2026.

    - **In this case, investments in the multi-digit billion range** will become necessary to technologically upgrade the European drinking water supply to ensure that the limit value of 500 ng/L is not exceeded.

    - **The end product** of such a costly, non-environmentally-friendly high-tech purification process would be an 'artificial water' depleted of its natural components, which water companies would need to re-mineralize with high energy expenditure before supplying it to their customers.

    - **There is still no clarity on the analytical method** for monitoring the parameter "PFAS total", in particular on the question of how - and even whether - TFA can and should be detected with this method.

    - **Member States can choose whether** or not to include the parameter "PFAS total" in their national drinking water regulations. Some Member States, including Austria, the Czech Republic, Germany, Denmark, Spain, the Netherlands, and Hungary have not implemented this value.

    - **The revision of the EU Water Framework Directive**, expected to be finalised in trilogue before the end of 2024, opens the opportunity for the overdue establishment of quality standards (=limit values) for TFA in natural water bodies.

    - **A revision of the EU Drinking Water Directive** is (to our knowledge) currently under discussion and would allow the existing PFAS limits in drinking water to be brought in line with the state of the science, and also open up the possibility of setting an individual limit for TFA at European level.

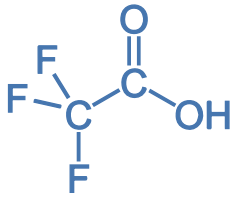
Summary

Conclusions

While the TFA levels we have found appear to be still within what are considered safety limits, their input continues to increase with each passing day due to the use of PFAS pesticides and coolants ("F-gases"). And the “safety buffer” is small. To ensure that European citizens can still drink tap water safely in ten or fifty years' time, **the governments that have enabled this pollution must now take swift and decisive action**. The most important measures are as follows:

1. An immediate ban on PFAS pesticides.
2. An immediate ban on F-gases.
3. Swift Implementation of the general PFAS restriction according to REACH.
4. Establishment of a safe drinking water limit for TFA at EU level.
5. Setting quality standards for TFA for waters regulated under the Water Framework Directive
6. Wherever it is necessary to purify water due to chemical contamination, the Polluter Pays principle shall be applied
7. Support to farmers in replacing the use of PFAS pesticides with other, ideally chemical-free, forms of crop protection.

TFA in Drinking Water Test Results



2.1 Study Approach

The aim of this sampling study was to investigate whether and how the high TFA levels we detected in May in European surface and groundwater samples are reflected in European drinking water. **The main focus was on tap water. Bottled water was included to determine whether TFA has also entered the deep groundwater bodies from which mineral water is extracted.**

PAN Europe members were invited to collect tap water samples **and, optionally, mineral water** in their respective EU countries for TFA-analysis. Eleven PAN members from eleven EU countries responded to our request, received appropriate sampling containers (BITEFU, 50-ml centrifuge tubes for laboratory chemistry) and sampling instructions, and provided us with one or more samples from the following countries: Austria (GLOBAL 2000), Belgium (Nature & Progrès), Bulgaria (Via Pontica Foundation), Croatia (Earth Trek), France (Generations Futures), Germany (PAN Germany), Hungary (MTVSZ/ Friends of the Earth Hungary), Luxembourg (Mouvement Ecologique), Netherlands (PAN Netherlands), Spain (Ecologistas en Acción), and Sweden (Naturskyddsforeningen). Many of the aforementioned NGOs also contributed to the production and publication of this report. Sampling took place between April and June 2024.

A total of 26 tap water samples (including 2 tap water samples from domestic wells) were collected in eleven countries and were sent, together with 12 mineral and 2 spring water samples (originally packaged) to the Water Technology Center in Karlsruhe for TFA analysis. Additionally, we received analysis results of 9 more tap water samples and 5 mineral and spring waters from Germany, kindly provided by Bund für Umwelt und Naturschutz Deutschland (BUND), whose results were already presented by BUND in April this year (these samples are indicated with an asterisk*), We also received one additional analysis result from Générations Futures (indicated with two asterisks**)

All tap and bottled water samples were individually analysed for TFA. Additionally, four mixed samples were prepared to analyse for a total of 24 other PFAS[2]. One mixed sample included 13 tap water samples from 10 EU countries other than Austria, mixed in equal parts. Another mixed sample included 9 tap water samples from Austria, also mixed in equal parts. A third mixed sample consisted of 5 Austrian mineral waters, and a fourth of 9 bottled waters from EU countries other than Austrian. The reason for choosing an approach where individual determination was performed only for TFA, while the larger set of 24 PFAS was determined as average contamination through the analysis of mixed samples, lies in the specific focus of this study on investigating TFA contamination in European tap and bottled

[2] The mixed samples were analysed for the ultrashort-chain PFAS, Trifluoroacetic acid (TFA) Perfluoroethane sulfonic acid (PFES), Perfluoropropionic acid (PFPrA), and Perfluoropropane sulfonic acid (PFPrS) as well as for the 20 PFAS regulated as «Sum of PFAS» in the EU Drinking Water Directive: Perfluorobutanoic acid (PFBA), Perfluoropentanoic acid (PFPA), Perfluorohexanoic acid (PFHxA), Perfluoroheptanoic acid (PFHpA), Perfluorooctanoic acid (PFOA), Perfluorononanoic acid (PFNA), perfluorodecanoic acid (PFDA), perfluoroundecanoic acid (PFUnDA), perfluorododecanoic acid (PFDoDA), perfluorotridecanoic acid (PFTrDA), perfluorobutane sulfonic acid (PFBS), Perfluoropentane sulfonic acid (PFPS), Perfluorohexane sulfonic acid (PFHxS), Perfluoroheptane sulfonic acid (PFHpS), Perfluorooctane sulfonic acid (PFOS), Perfluorononane sulfonic acid (PFNS), Perfluorodecane sulfonic acid (PFDS), Perfluoroundecane sulfonic acid, Perfluorododecane sulfonic acid, Perfluorotridecane sulfonic acid

mineral and spring water samples. TFA is a PFAS that has received little to no attention in water and especially drinking water analyses in some member states, unlike other PFAS listed in the EU Drinking Water Directive (cumulative limit for 20 PFAS) or the EU Water Framework Directive (PFOS as a priority substance).

All analyses were performed using HPLC-MS-MS. The respective limits of quantification (LOQ) set by the laboratory were 50 ng/L for trifluoroacetate (TFA), 1 ng/L for the 20 PFAS regulated in the EU Drinking Water Directive, 2 ng/L for perfluoropropionate (PFPrA), 1 ng/L for perfluoropropane sulfonate (PFPrS), 50 ng/L for perfluoroethane sulfonate (PFES), and 50 ng/L for trifluoromethane sulfonate (TFMS).

Since detections are possible even below the limit of quantification, we asked the laboratory to also inform us of TFA detections if they were below the limit of quantification of TFA (50 ng/L) but above the limit of detection (LOD), which lies around 20 ng/L. The laboratory complied with this request and sent us a corresponding evaluation via email. Detections below the detection limit are associated with a higher range of fluctuation. The corresponding analysis results are shown in brackets below.

2.2 TFA in Tap Water

Overall, TFA was detected in 34 out of 36 tap water samples. Two of the tap water samples came from private domestic wells (both from Austria), while the remaining 34 samples came from water abstraction points connected to a public drinking water network. TFA levels ranged from "not detectable" (< 20 ng/L) to 4,100 ng/L, with an average of 740 ng/L. Both of the samples that showed no detectable TFA contamination, came from Germany, one was from Hamburg and the other from Lower Saxony. TFA levels of all 36 drinking water samples are illustrated in Figure 1.

The observed degree of TFA contamination covers a very broad spectrum. The trend identified by the **German Federal Environment Agency (UBA)** towards higher TFA levels in regions with intensive agriculture also appears to be confirmed in many drinking water samples.

It is interesting to note that two out of twelve tap water samples from Germany remained below the limit of detection. Particularly surprising was that this was the case with the sample from Hamburg, taken not far from the location of the most polluted watercourse in our previous test (Elbe with 3,300 ng/L). According to our investigations, the drinking water comes from a deep groundwater reservoir near Hamburg.

We only tested one sample from the Netherlands, which fortunately had a low TFA level compared to other drinking water from other regions of the country. TFA has been measured in the Netherlands on a regular basis by the water companies since 2018. The average levels of TFA in Dutch drinking water range from around 1,200 nanograms with peaks up to 1,600 nanograms per litre according to the 2022 water quality report (‘trifluorazijnzuur’).

The same accounts for different regions of Belgium. The Brussels water company informed us that the level of TFA in Brussels drinking water ranges from 500 up to 1500 nanograms per litre.

TFA in Drinking Water Test Results

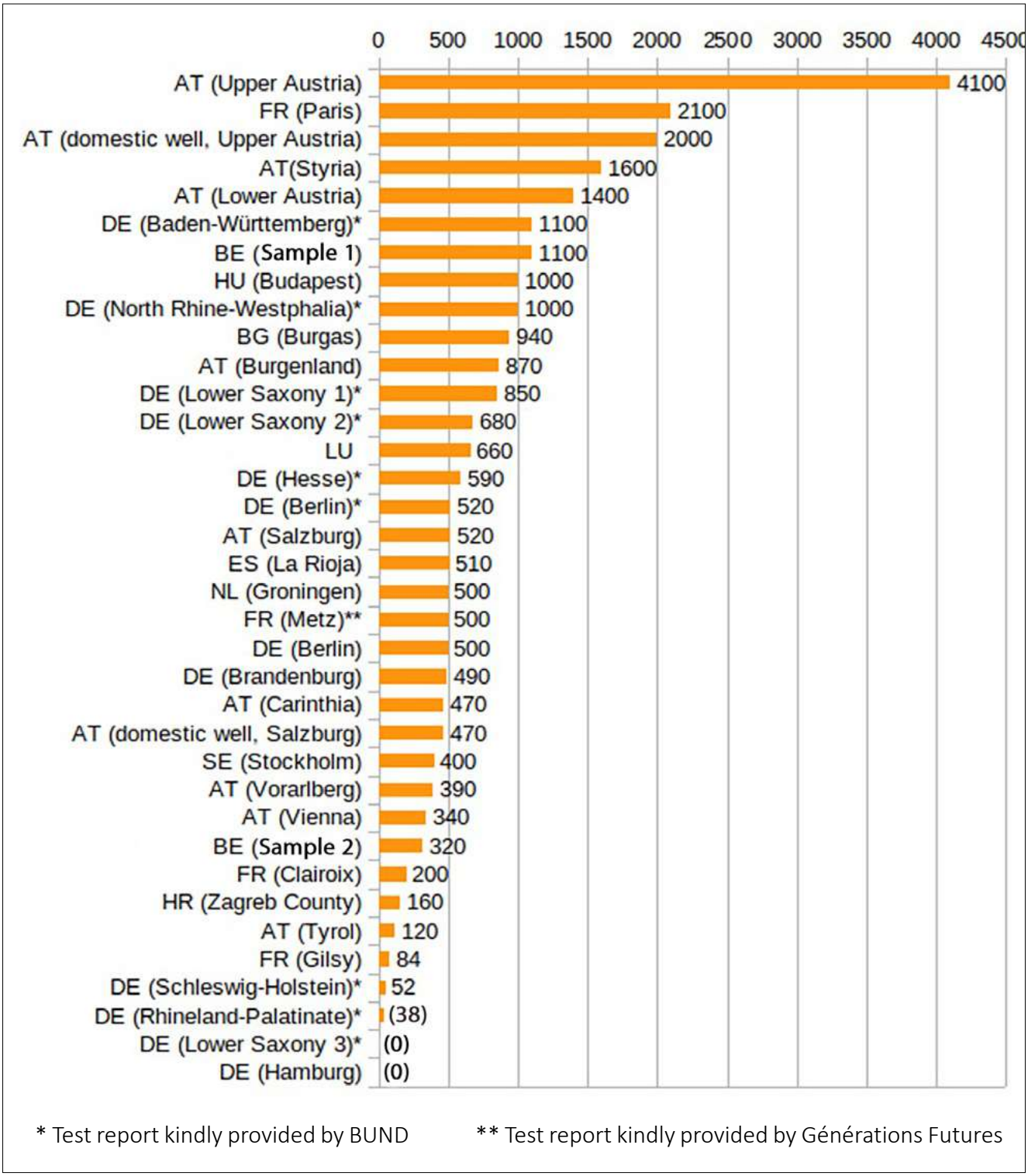


Figure 1. *TFA in Drinking Water in ng/L (34 tap water samples come from public and 2 from private sources)*

2.3 TFA in Mineral and Spring Water

TFA was also detected in 12 out of 19 bottled water samples (63 %) consisting of 17 mineral and 2 spring water samples. TFA levels ranged from "not detectable" (< 20ng/L) to 3,200 ng/L. The average TFA contamination in mineral and spring water was significantly lower than in tap water, with an average value of 278 ng/L.

Figure 2 illustrates the broad range of TFA levels in bottled waters, with a higher share of samples that don't have detectable levels of TFA (37 %) compared to tap water (6 %).

Please note: The decision to publish the results anonymously for the time being is due to the fact that it was not yet possible to thoroughly confirm the analysis results of the mineral and spring water samples through repeat analyses because of time and resource constraints. However, we believe that such care is necessary, especially for established and well-known brands.

In the meantime, we have written to all the concerned producers, informed them of their individual results, and asked for their statements. We will commission control analyses over the summer and publish the results in the autumn. Until then, we ask for your understanding that we can only present anonymized data at this stage.

TFA in Drinking Water Test Results

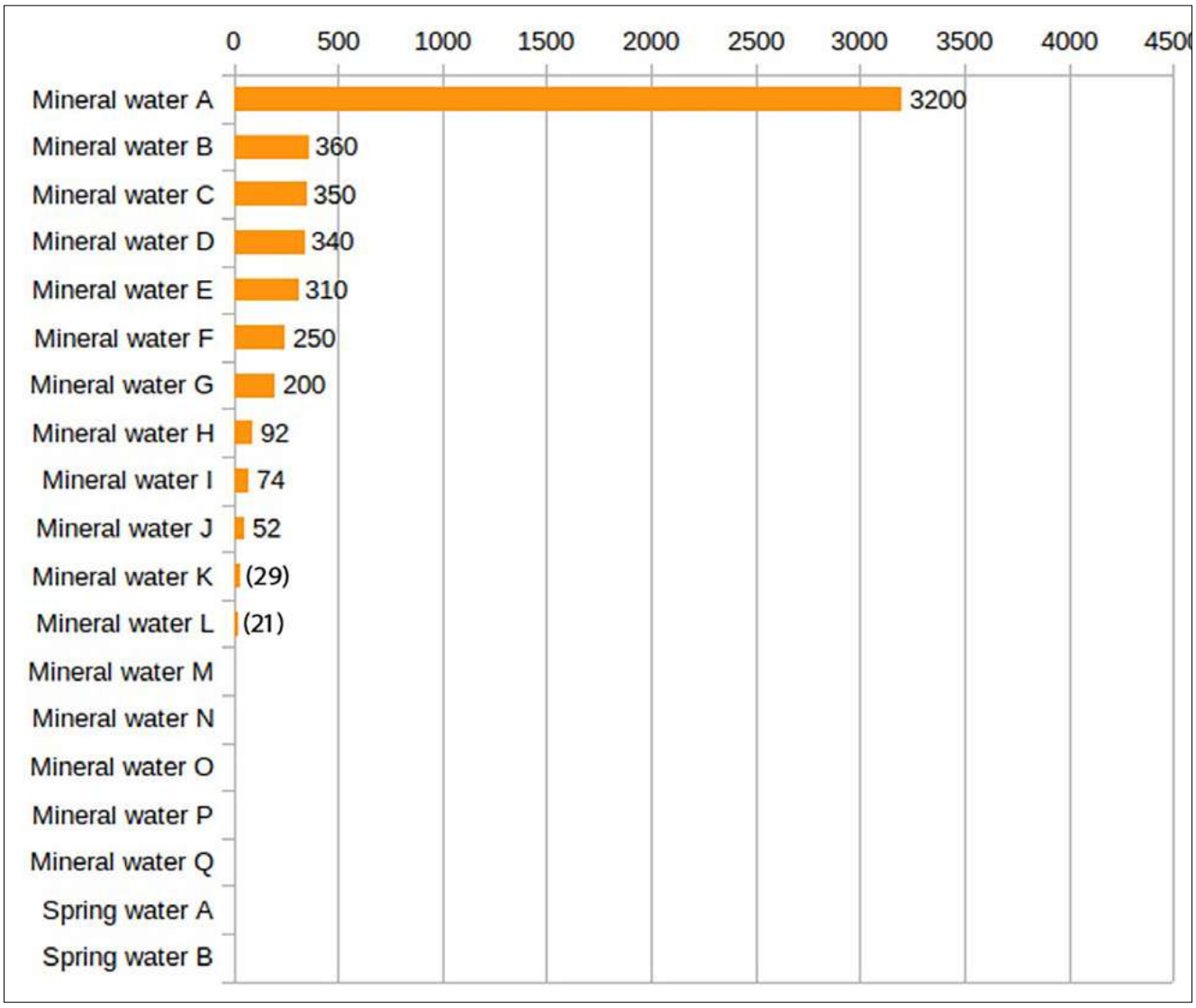


Figure 2. *TFA in Mineral and Spring Water in ng/L (data is provisional and anonymized until confirmatory analyses are available. The complete information and data is expected to be presented in autumn).*

Natural mineral waters must, according to European law, particularly meet the requirement of original purity, which has *been preserved intact because of the underground origin of such water, which has been protected from all risk of pollution.* The fact that only five out of 17 mineral waters are free from pollutants, and that even deep-lying water resources are not sufficiently protected from contamination by TFA, is due to its fatal combination of extreme persistence and extreme mobility. This has been a foreseeable consequence of the chemical structure of TFA from the time the chemical (and its precursors) were first synthesised.

2.4 Multi-PFAS Analysis in Mixed Samples

To better contextualise the TFA concentrations in drinking water, we prepared four mixed samples alongside the individual analyses. These mixed samples, named *'Tap Water EU, except Austria'* (Figure 3a), *'Tap Water Austria'* (Figure 3b), *'Mineral and Spring Water EU, except Austria'* (Figure 3c), and *'Mineral and Spring Water Austria'* (Figure 3d), were analysed for those 20 PFAS regulated in the EU Drinking Water Directive. In addition to these 20 PFAS, four other ultrashort-chain PFAS - Perfluoroethane sulfonate (PFES), Perfluoropropionate (PFPrA), Perfluoropropane sulfonate (PFPrS), and Perfluoromethane sulfonate (PFMS) - were analysed.

Our findings in these mixed drinking water samples confirm what we already observed with environmental water samples: the mean contamination by TFA accounts for more than 98% of the PFAS total contamination, while the 20 PFAS regulated in the Drinking Water Directive, together with the additional 4 short-chain PFAS, account for less than 2% on average.

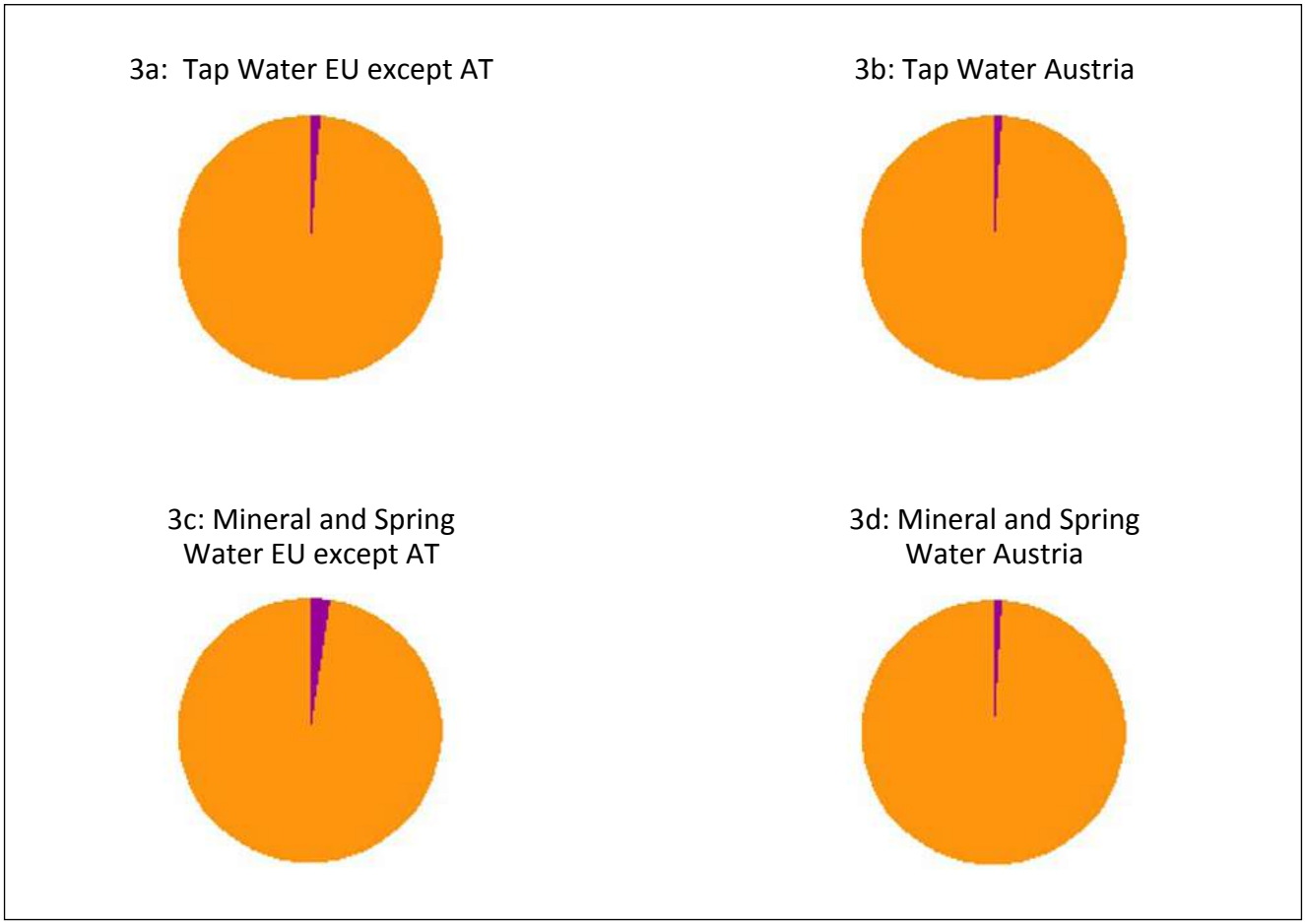


Figure 3. *Comparison of the mean concentration of TFA (**orange**) with the mean concentration of 20+4 PFAS (**purple**) in mixed samples, which were compiled by mixing individual samples in equal parts.*

TFA in Drinking Water Test Results

The quantitative composition of the respective fractions "mean concentration of TFA" and "mean concentration of 20+4 PFAS" is shown below for all four composite samples (in Table 1).

The weighted average share of TFA in the total PFAS load is 98.1 %.

Concentration in [ng/l]	**Tap Water EU, except Austria** (n=13)	**Tap Water Austria** (n=9)	**Mineral and Spring Water EU except Austria** (n=9)	**Mineral and Spring Water Austria** (n=5)
Trifluoroacetic Acid (TFA)	613	1,090	483	118
Perfluoropropanoic acid (PFPrA)	4.4	2.6	9.1	<LOQ
Perfluorobutanoic acid (PFBA)	2.5	2.0	3.7	1.1
Perfluoropentanoic acid (PFPeA)	<LOQ	1.2	<LOQ	<LOQ
Perfluorooctanoic acid (PFOA)	<LOQ	1.2	<LOQ	<LOQ
Perfluorooctane sulfonic acid (PFOS)	1.2	3.3	<LOQ	<LOQ
Proportion of TFA in the sum of 25 PFAS [%]	**98,7 %**	**99,1 %**	**95,5 %**	**99,1%**

LOQ = Limit of Quantification

Table 1. *Average concentrations (in ng/L) of the 20+4 PFAS analysed in mixed samples in comparison to average concentrations of TFA*

Relevance to Human Health

The presence of TFA in drinking water, including in cocktails with other PFAS, inevitably raises a critical question: What does this contaminant mean for consumers, and could it pose a health risk? Answering this question is as important as it is difficult. TFA has often been portrayed as a harmless chemical - by the industry and by some authorities. However, history has shown that many substances once deemed safe later proven to be problematic and dangerous. Well-known examples include persistent organochlorine compounds like DDT, ozone-depleting CFCs, or the endocrine disrupting chemical Bisphenol A[3].

Similarly, the risk assessment of chemicals from the PFAS group provides numerous examples of misjudgment, as illustrated by one of their best-known and most toxic representatives, PFOA (perfluorooctanoic acid). PFOA belongs to the same subgroup of PFAS as TFA, with TFA being practically the prototype: the so-called perfluorinated alkyl carboxylates. TFA is the smallest member of this PFAS group, and the others differ from TFA only by a longer perfluorinated carbon chain (see Figure 4)

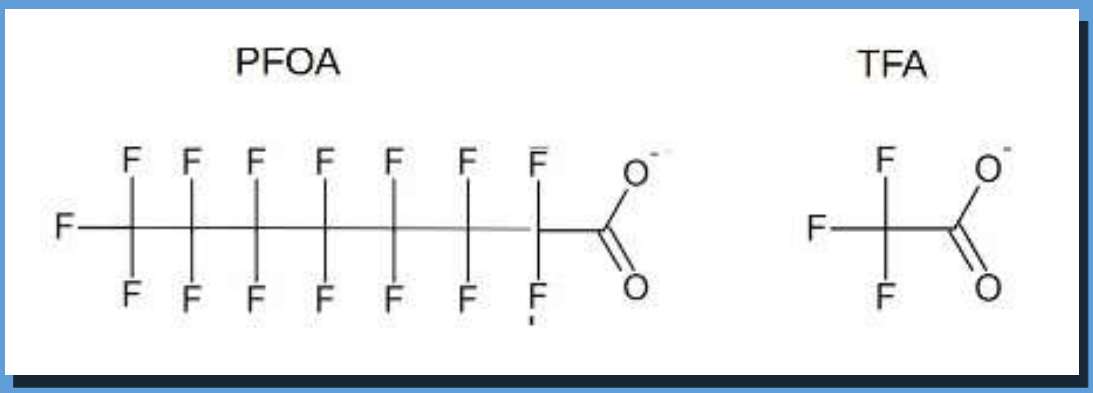


Figure 4. *TFA and PFOA both belong to the group of polyfluorinated carboxylic acids. While PFOA has 8 carbon atoms in its chain (and was therefore often referred to as "C8"), TFA, the smallest member of this PFAS subgroup, has only 2 carbon atoms.*

[3] It was not until 2023 that the EFSA set a TDI of 0.2 ng BPA/kg body weight per day, lowering the previous limit from 2015 by a factor of 20,000 (!). Remarkably, the German Federal Environment Agency had already warned in 2008 that the EFSA's risk assumptions on BPA severely underestimated the risks, as they did not take into account the current state of knowledge. Even then, the UBA (and also NGO experts) considered it necessary to lower the ADI by at least three orders of magnitude based on published studies.

Relevance to Human Health

PFOA was the first PFAS whose devastating effects on human and animal health were uncovered as a result of the Dark Waters scandal, after the industry had downplayed and covered up its dangers for half a century. However, the authorities continued to massively underestimate the true toxic potential of PFOA until a few years ago, as shown in Figure 5. The figure compares the daily intake of PFOA deemed tolerable by EFSA until 2018 (left bar: 1500 ng/kg body weight per day[4]) with the intake considered tolerable today (0.63 ng/kg body weight per day[5], right bar).

To understand how such significant misjudgments can occur — and how they can be avoided — we need to examine the principles and rules of risk assessment for pollutants, particularly pesticide residues and their metabolites.

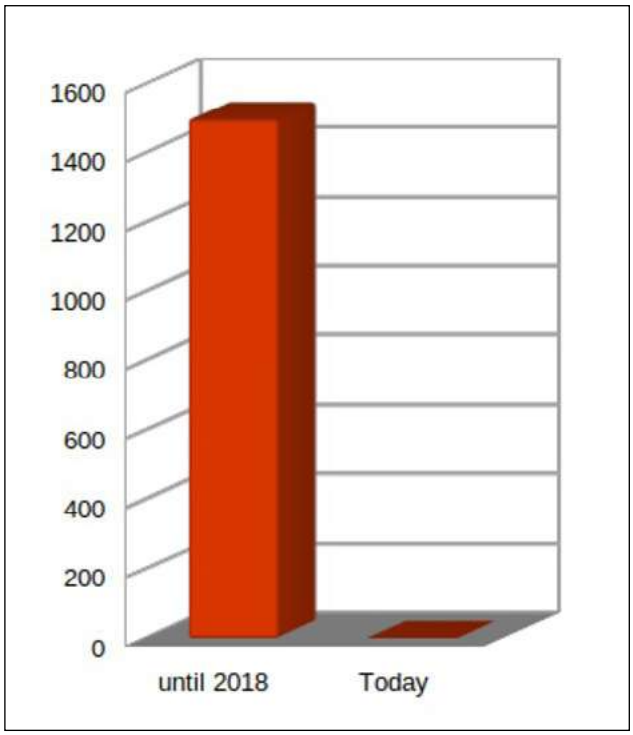


Figure 5. *The underestimation of the risk of PFOA by the EFSA meant that an "tolerable daily intake" of 1500 ng PFOA per kg body weight and day was considered safe until 2018 (left bar). Today, as low as only 0.63 ng kg/d is deemed tolerable from a health perspective (right bar).*

[4] EFSA 2008: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2008.653

[5] EFSA 2020: https://www.efsa.europa.eu/en/news/pfas-food-efsa-assesses-risks-and-sets-tolerable-intake

3.1 Of Mice and Men - Dealing with Uncertainty

The central guidance value for assessing potential health risks of pollutants and setting corresponding exposure limits in food and water is the *'Tolerable Daily Intake'* (TDI[6]). This value is based on the assumption that there is a dose below which no adverse effects will occur. The TDI is defined as the daily dose of a pollutant per kilogram of body weight that a person can ingest over a lifetime without harm, according to current knowledge. It is important to note that there is scientific consensus that such a 'safe' dose cannot be derived for all chemicals, such as certain carcinogenic, hormone-disrupting, or mutagenic substances (more on this in section 3.2.5)

To derive a TDI (or to determine that a TDI cannot be derived), risk assessors typically rely on the results of toxicological studies conducted with laboratory animals (e.g., mice, rats, or rabbits). The typical design of such toxicological studies aims to identify toxic effects by comparing baseline values of a control group with possible changes in three different test groups to which the test substance is administered - a low-dose group, a mid-dose group, and a high-dose group.

This study design is used in various types of tests, including chronic toxicity studies (lasting 12 or more months), carcinogenicity studies (lasting 18 or more months), genotoxicity studies (both *in vitro* and *in vivo*), and three different study types for reproductive toxicity (including prenatal exposure), to name a few of the most important ones.

Each of these toxicological studies essentially has to answer two questions: Firstly, does the test substance show one or more adverse effects detectable with the corresponding study design? Secondly, what is the so-called "No Observed Adverse Effect Level" (NOAEL), i.e., the dose at which no adverse effects occur compared to the control group?

A sufficiently complete database will cover different toxicological parameters, so-called *endpoints*, leading to different individual NOAELs, the lowest of which shall be used and extrapolated to the TDI for humans. In this conversion of an animal-derived NOAEL into a TDI for humans, different uncertainty factors (UF) are applied depending on the data situation. Typically, the NOAEL is divided by a *default* uncertainty factor (UF) of 100, which is composed of two components: a UF of 10 for variability between species (i.e., between animals and humans), multiplied by another UF of 10 for variability within species (i.e., within human populations), resulting in a default UF of 100.

If the database is *"complete[7]"*, i.e. all important tests of the test battery conducted with studies of sufficient quality, this default UF of 100 is considered sufficient for determining a TDI for humans.

[6] Sometimes the term ADI (Acceptable Daily Intake) is used instead of TDI (Tolerable Daily Intake). Both terms describe the same toxicological situation. However, it is common to use the term ADI in cases where the foreign substance is intentionally added (such as additives, pesticides, preservatives, etc.) and TDI in cases where it is a classic pollutant from the environment or a manufacturing process that has entered the food.

[7] WHO (1997): Assessing human health risks of chemicals: derivation of guidance values for health-based exposure limits (see p.21)

However, for many chemicals, not all relevant tests have been performed, resulting in an incomplete database. According to the WHO criteria[8] for the derivation of guidance values for health -based exposure limits, *major deficiencies in a toxicity database [...] that increase the uncertainty of the extrapolation process should be taken into account by using an additional uncertainty factor*. Such additional uncertainty factors for limited databases range typically from greater than 1 to 10, but can be as high as 100 according to WHO criteria[9].Moreover, the severity and irreversibility of effects may require the application of an additional uncertainty factor between greater than 1 and 10. According to the WHO guidelines for drinking-water quality, this applies particularly to studies in which *the end-point is malformation of a foetus*.[10]

The WHO guidelines emphasise that such factors should adequately cushion the worst-case scenario, resulting in conservative risk estimates that can be adjusted when more data becomes available: It is to be expected that the values set with high risk factors will present the risks as greater than they actually are, so that the corresponding limits can generally be raised as soon as more data is available. Unfortunately, in practice we often observe the exact opposite. A poor or inadequate data situation leads to unfounded optimistic risk assumptions and resulting health-based guidance values that are far too high, which are then corrected downwards - often with a long delay.

In the following section, we will encounter a prime example of disregarding the WHO recommendations to take into account uncertainties due to data gaps.

3.2 Assessing TFA

Equipped with the information from section 3.1, we can now take a look at the actual risk assessment of TFA by EFSA, which led to the establishment of an over-optimistic TDI[11] that carries a high risk of trivialising and underestimating the real health risks posed by this forever chemical. The failure to recognise these risks has resulted in the market approval of PFAS pesticides, which degrade to TFA and have become an important source of TFA water pollution.

EFSA established the TDI of TFA back in 2014, in

[8] Ibid., p. 21

[9] The WHO emphasises, however, that f the risk assessment would lead to a total UF higher than 10 000, “the resulting TDI would be so imprecise as to lack meaning” and: *the total factor for limitations of the pivotal study plus adequacy of the overall database should not exceed 100 and that in order to maintain the credibility of the risk assessment process, the total default uncertainty factor should not exceed 10,000. Additionally, the WHO Guideline for Drinking Water Quality states: For substances for which the uncertainty factors are greater than 1,000, guideline values are designated as provisional in order to emphasise the higher level of uncertainty inherent in these values.*

[10] WHO (2022): Guidelines for drinking-water quality (p. 175)

[11] Please note: EFSA referred to this Health Based Guidance Value as an *Acceptable Daily Intake* (ADI) and not as a *Tolerable Daily Intake* (TDI). The choice of term depends on the context: HBGVs for food additives and pesticide residues present in food for technological or plant protection reasons are referred to as ADIs. For chemical contaminants, which generally have no intended function, the preferred term is «tolerable daily intake» (TDI), as it emphasises permissibility rather than acceptability. Both terms are applicable to TFA.
When discussing TFA exposures in food resulting from intentional pesticide use, ADI is the proper term. In the case of unintentional contamination of environmental compartments such as water, TDI is the correct term.

the course of the risk assessment of saflufenacil, one of the PFAS pesticides that degrades to TFA. At that time no animal studies on chronic toxicity were available to EFSA, let alone animal studies on carcinogenicity, genotoxicity, teratogenicity, developmental toxicity, immunotoxicity, or endocrine disruption. The very limited dataset on TFA available to EFSA included (only) *in-vitro* tests for genotoxicity, from which EFSA concluded that TFA is not genotoxic, an incompletely reported[12] developmental toxicity study in rats, which apparently led EFSA to the (incorrect[13]) conclusion that TFA is not toxic to the unborn foetus, as well as a 90-day feeding study in rats, which EFSA - in the absence of a more comprehensive one-year chronic toxicity study - used as its pivotal study to derive a lifetime acceptable daily intake for humans. And this is how EFSA proceeded:

In the 90-day feeding study in rats commissioned by Bayer in 2007, liver damage was reported, with a NOAEL of 10 mg/kg body weight per day according to EFSA. Based on this NOAEL, EFSA derived an TDI value of 50 µg/kg body weight per day by applying the standard obligatory uncertainty factor of 100 for inter- and intraspecies variability, while taking into account the exorbitant data gaps by only adding a minimal additional uncertainty factor of 2[14]. It is no surprise that EFSA's risk assessment on TFA has not aged well.

Apart from EFSA's highly irresponsible failure to address the significant uncertainty resulting from an extremely limited database by using an adequate uncertainty factor, one must fundamentally question if serious risk assessment is possible in a case like this, where none of the standard studies that should form the basis of a risk assessment are available. The likely answer is: No.

One thing is certain: It is better to have no guideline value than a false one. A false guideline value can lead to misguided decisions and conceal risks, whereas the absence of a toxicologically derived guideline value could encourage the establishment of precautionary limits.

The latter is exactly what a group of leading European water suppliers have been advovating for years in their surface water memoranda: *For non-evaluated anthropogenic substances and particularly for non-evaluated degradation products, they propose a value of 0.1 µg/L [i.e. 100 ng/l] for precautionary reasons, which must be met even in extreme (discharge) situations. The Water Companies describe these target values as minimum quality requirements to secure water supply in the future and are in agreement with the precautionary principle according to the EU Water Framework Directive, as the effects [of these substances] on biological systems or toxic properties cannot be excluded.*

One thing is clear: If political decision-makers had set such a target value of 0.1 µg/L for TFA when first approving PFAS pesticides back in the 1990s, the chemical status of European water bodies would be much better today.

[12] The raw data and original study report were not accessible to EFSA (according to EFSA); see EFSA 2014, p. 9.

[13] TFA was shown to be toxic to the unborn foetus in a recent rabbit study, the original data of which are available to the authorities and are considered reliable.

[14] EFSA 2014: p. 10

3.2.1 Five Drops in a Swimming Pool

Five drops dissolved in an Olympic-sized swimming pool. That's what 0.1 µg/L (100 nanograms per litre) represents. It's a very small concentration, hard to imagine exerting any harmful effect. Not only is 100 ng/L the target value for little-studied man-made chemicals desired by Europe's water suppliers, but it is also the legal threshold value for pesticide active substances and their relevant metabolites. However, the failure of European decision-makers to classify TFA as a relevant metabolite (more on that in section 4.1) has allowed TFA levels in our drinking water reservoirs to rise to an average of around 740 ng/L, as found in our measurements. That corresponds to 44 drops in an Olympic-sized swimming pool, which also doesn't seem like a lot.

However, certain PFAS can pose a health risk even in amounts as small as one drop. This became particularly evident in April this year when the U.S. Environmental Protection Agency (EPA) set a drinking water limit of as low as 4 ng/L for the two forever chemicals PFOA and PFOS each, while acknowledging that from a health perspective, the goal should be *"zero exposure"*. The authority stated: ***This reflects the latest science showing that there is no level of exposure to these contaminants without risk of health impacts, including certain cancers.*** In other words: For PFOA, the long-chain structural analogue of TFA, a threshold limit of 4 ng/L, which corresponds to as little as half a drop diluted in an Olympic-sized swimming pool, cannot be regarded as (100 %) safe, according to US-health authorities. And some EU countries have established even stricter limits for these PFAS in their national drinking water regulations (see BOX).

Four EU countries have set even stricter limits in their national drinking water regulations than the US. These limits are 4.4 ng/L (Netherlands), 4 ng/L (Sweden and Flanders in Belgium), and 2 ng/L (Denmark) and apply to the sum of four particularly toxic "forever chemicals," further referred to as PFAS-4, which include apart from PFOA and PFOS also PFNA andPFHxA. The PFAS-4 have a strong tendency to accumulate in blood and fat tissue.

Basis for the above drinking water limits for PFAS-4 is EFSA's risk assessment[15] of the PFAS-4, which was performed in 2020 based on a rather comprehensive database, and led to the establishment of an TDI of 0,63 ng/kg body weight. The drinking water limits are set so that a woman would experience only 20% (in Denmark only 10%) of the PFAS-4 Tolerable Daily Intake, the exceedance of which could have negative effects on the baby's immune system during pregnancy and subsequent breastfeeding[16].

Other EU countries such as France, Belgium (Wallonia), the Czech Republic, Hungary, or Austria waived protective limit values for PFAS-4.

[15] EFSA (2020): Risk to human health related to the presence of perfluoroalkyl substances in food; https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2020.6223

[16] EFSA 2020: PFAS in food: EFSA assesses risks and sets tolerable intake

3.2.2 The RIVM Drinking Water Limit

In 2021, the Dutch RIVM had derived a Cumulative Drinking Water Guideline Value of 4.4 ng/L for the PFAS-4 (the sum of PFOA, PFOS, PFNA, and PFHxA) based on EFSA's assessment of PFAS-4 from 2020 and thus reflecting the state of knowledge on PFAS.

When the agency was asked in 2023 to also derive a drinking water guideline value for TFA, it chose an innovative risk assessment approach based on Relative Potency Factors. The starting point was the recognition that TFA is a PFAS and the observation that members of the PFAS family often exhibit similar toxicological properties (liver toxicity, reproductive toxicity, etc.), as far as data are available. However, they differ in the doses at which these properties become effective. In other words, different PFAS may cause similar effects but with different potencies.

A common effect observed in almost all PFAS studied so far, and for which there is data available for TFA[17], is liver damage. A PFAS that causes liver damage at very low concentrations is PFOA. Comparing the liver damage caused by TFA with that of PFOA, the TFA dose at which this adverse effect occurs is about 500 times higher than that of PFOA[18]. Based on this observation, the agency determined a Relative Potency Factor RPF=0.002 for TFA. The RIVM underlying assumption is that TFA needs to be present at around 500 times higher concentration than its longer-chain structural relative to develop comparable toxicity. Therefore, if 4.4 ng/L is a safe limit for PFOA, then 2,200 ng/L should be a comparably safe limit for TFA. Consequently, the RIVM established an indicative drinking water guideline value of 2,200 n/L for TFA.[19]

Similar to the limit value for PFAS-4, the limit value for TFA is also based on a 20 % allocation of the tolerable daily intake of TFA for drinking water consumption. This is because drinking water is not the only source of TFA. Contamination of water with TFA also leads to contamination of food with TFA. And unfortunately, TFA is not the only PFAS we are exposed to. EFSA calculations on PFAS-4 have shown that significant parts of the European population already exceed the acceptable intake of PFAS other than TFA.[20] Another reason to protect drinking water from chemical pollution.

3.2.3 The Traditional Approach to a Drinking Water Limit

A more traditional approach than the one chosen by RIVM for setting drinking water limits is based on the tolerable daily intake (TDI) of the contaminant, which is derived using uncertainty factors from the (lowest) NOAEL value observed in animal studies.

In addition to the TDI, this calculation takes into account body weight (in kilograms) and daily water consumption (in litres). It also applies an allocation factor, usually 0.2, to reserve 80% of the TDI for other exposure pathways, as drinking water is not the only exposure pathway for the pollutant, as described in the WHO guideline for Drinking Water Quality.

[17] RIVM 2023: p. 13

[18] Referring to the EFSA assessment of PFAS-4, which corresponds to a tolerable daily intake (TDI) of 0.63 ng/kg body weight for PFOA (in the absence of PFOS, PFNA, and PFHxA), using an RPF of 0.002, the TDI for TFA is calculated to be 315 ng/kg body weight (= 0.315 µg/kg body weight).

[19] RIVM 2023: p. 15

[20] EFSA 2020b: Risk to human health related to the presence of perfluoroalkyl substances in food

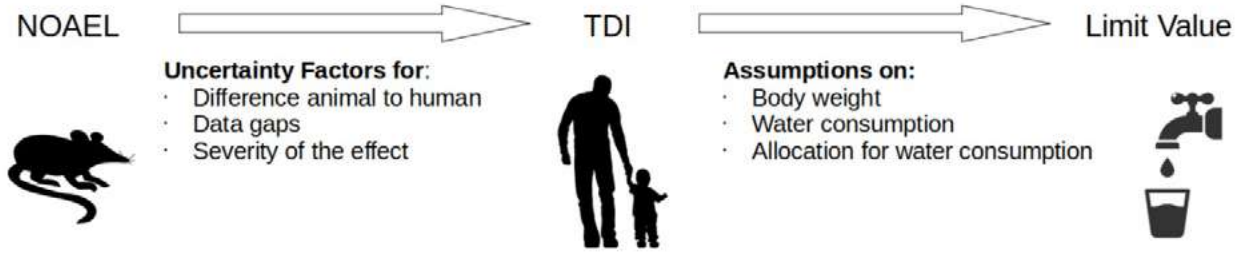


Figure 6. *The classic way to derive a drinking water limit value is via the TDI.*

The WHO Guideline for Drinking Water Quality defines three alternative **exposure scenarios** for the derivation of a drinking water limit value: For **Adults**, the default assumption for consumption is 2 litres of water per day with a body weight of 60 kg (0.033 L/kg body weight/day). For **Small Children**, a default intake of 1 litre is assumed for a body weight of 10 kg (0.1 L/kg body weight/day); and for **Bottle-Fed Infants**, an intake of 0.75 litres is assumed for a body weight of 5 kg (0.15 L/kg body weight/day).

A limit value that has been derived by using exposure assumptions for adults can therefore lead to a regular and significant exceedance of the TDI over several years, as small children consume significantly more water relative to their body weight and thus absorb significantly more pollutants. Unfortunately, the WHO takes an ambivalent stance regarding exposure scenarios and does not specifically recommend considering the most exposed population group. However, the WHO recommends calculating the limit value based on the standard water intake of bottle-fed infants, *where they are considered to be the most vulnerable group*[21].

With PFAS in particular, there is little doubt that infants are the most vulnerable group. They are not only most exposed to PFAS through food[22], but also have the highest body burden and are especially sensitive to disruptive influences during their early development[23]. For this reason, it seems prudent to use the water consumption of infants of 0.15 litres/kg[24] for calculating a drinking water limit value that is protective for all population groups (i.e. bw=5 kg and water consumption=0.75 L).

$$\text{Drinking Water Limit [µg/L]} = \frac{\text{TDI [µg/kg/day]} \times \text{Body Weight [kg]} \times \text{Allocation Factor}}{\text{Water Consumption [L/day]}}$$

[21] However, it is difficult to understand why the WHO does not generally use the protection of infants and children, who will always be the most exposed group of people, as a benchmark when setting drinking water limits (see: WHO (2022): Guidelines for drinking-water quality (p. 177)

[22] EFSA 2020: PFAS in food: EFSA assesses risks and sets tolerable intake

[23] Landrigan PJ, Kimmel CA, Correa A, Eskenazi B. Children's health and the environment: public health issues and challenges for risk assessment. Environ Health Perspect. 2004 Feb;112(2):257-65

[24] According to the EFSA Scientific Committee 2017, the average daily water intake of bottle-fed infants with high water consumption is 227.5 ml/kg body weight per day. Including this particularly exposed group within the infant population would require a 34% reduction in the recommended intake.

Based on the TDI value of 50 µg/kg derived by EFSA in 2014, a drinking water limit value of 67,000 ng/L would result. But this is only the case when taking at least a precautionary approach by considering the exposure of infants. If the TDI derived by EFSA is combined with the exposure data of an 60 kg adult drinking 2 litres per day,[25] the resulting level of protection would be even lower, corresponding to a limit 300,000 ng/l. This is 136 times higher than the indicative drinking water guideline proposed by the Dutch authorities.

In view of the considerations outlined in section 3.1, there is an unacceptable high risk that such a value underestimates the actual health risks associated with TFA due to significant data gaps in the derivation of the TDI that were not accounted for by appropriate uncertainty factors.

It goes without saying that such a value is not useful for any attempt to assess the potential health impacts of the current TFA levels in drinking water. However, in the previous sections, we have learned about the tools offered by the WHO to account for scientific uncertainty due to data gaps in the risk assessment of chemicals. This allows us to calculate what a TDI, and subsequently a drinking water limit for TFA, could have looked like if EFSA's assessment had followed a more cautious approach. And since there are now two additional toxicological studies on TFA, we can perform this calculation exercise in the following chapter using three studies.

3.2.4 Exploring a Possible 'Safe' Range for TFA Limits

First and foremost: The following exercise is far from replacing a robust risk assessment of TFA and does not intend to. It is conducted without knowledge of the original study reports and relies on the information published by EFSA, ECHA, and UBA about the respective studies. Its purpose is to investigate the range within which drinking water limit values fall when the applicable WHO guidelines[26] are applied conservatively at most.

Specifically, this means for the derivation of a TDI: For a specific data situation for which the WHO rules provide for the application of an uncertainty factor, and a corresponding range is defined for its magnitude, the most conservative —i.e. the highest—factor will be chosen (while maintaining proportionality).

An equally conservative, or one could say precautionary, approach is applied to the subsequent conversion of the TDI into a drinking water limit by allocating only 20% of the TDI to the consumption of drinking water and considering the exposure of bottle-fed infants in its calculation, as they are the most vulnerable group.

[25] Pease Note: Exposure data for adults were also used by the German UBA when deriving the drinking water guideline value for TFA of 60 µg/L (see section 3.2.4). However, in deviation from the recommendations in the WHO drinking water guideline, the UBA calculated with 70 kg body weight with 2 litres of drinking water consumption and an allocation of (only) 10 % for drinking water.

[26] The two relevant regulations that provided the framework for this exercise were the *WHO (1997) Guidelines for the Derivation of Guidance Values for Health-Based Exposure Limits and the WHO (2022) Guidelines for Drinking-Water Quality.*

Let's start with the 90-day subchronic rat study: If there is ever a situation where for major deficiencies in the database the maximum possible factor of 100 according to WHO rules[27] should be applied, it is these major deficiencies in the database that EFSA had relied on in 2014. These deficiencies include both general data gaps (no animal studies on chronic toxicity, cancer, mutagenicity, reproductive toxicity, developmental toxicity, and no data on endocrine-disrupting effects) and deficiencies of the pivotal study itself (only 90 days instead of a one-year study). Applying this additional uncertainty factor of 100[28] results in a TDI of 1 µg/kg/day. Using the exposure data for bottle-fed infants and allocating 20% of the TDI to drinking water consumption, a provisional[29] drinking water limit of 1,300 ng/L can be calculated (see Table 2).

The second study is a 52-week drinking water study with rats from the PFAS manufacturer Solvay from 2019, from which the German UBA[30] derived a drinking water guideline value of 60,000 ng/L for TFA.

Unfortunately, this guideline value harbours a considerable risk of not providing sufficient protection. The critical effect in this study was liver damage based on elevated ALT[31] levels. The NOAEL identified was 1.8 mg/kg body weight per day. The TDI was calculated by using only a default uncertainty factor of 100, whereas the least sensitive population group, represented by a 70 kg adult drinking 2 litres of water a day, was considered for the calculation of the guideline value[32]. However, when adopting a more cautious and conservative approach by applying an additional uncertainty factor of 10 for major deficiencies in the database[33] and acknowledging the significantly higher TFA exposure of infants through drinking water, this results in a TDI of 1.8 µg/kg body weight per day and a drinking water limit of 2,400 ng/L (see Table 2).

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[27] WHO (1997): *Assessing human health risks of chemicals: derivation of guidance values for health-based exposure limits* (see p.21)

[28] As explained in section 3.1, the fundamental question arises whether such a sparse data situation, as was the case with TFA in 2014, is compatible with a serious derivation of a TDI. However, if one decides to derive a TDI, there are strong arguments for applying the maximum uncertainty factor of 100 in order to account for the combination of: i) complete lack of all important studies, ii) the problematic toxicity profile of structurally related PFAS, and iii) the special status of drinking water regarding possible regular exposure at an (erroneously) unsafe limit value by a very large number of people over very long periods.

[29] According to the WHO Drinking Water Guideline, in situations where there are «significant scientific uncertainties regarding the derivation of health-based guideline values,» necessitating uncertainty factors greater than 1000, the resulting guideline values should be designated as "provisional guidelines".

[30] UBA (2020): *Ableitung eines gesundheitlichen Leitwertes für Trifluoressigsäure (TFA)*

[31] ALT (alanine aminotransferase) is a common biomarker used in clinical and toxicological studies to assess liver damage.

[32] Please note: The UBA calculation has adopted a more precautionary approach than that recommended by the WHO Drinking Water Guideline, when allocating only 10% of the TDI for exposure through drinking water.

[33] Deriving a TDI only on the basis of a single 1-year feeding study with rats, in the absence of animal studies on genotoxicity, carcinogenicity, developmental toxicity, or studies on endocrine disrupting activity, means still relying on a rather thin database, although slightly improved compared to 2014. Therefore, a (typical) uncertainty factor of 10 for *major deficiencies in a toxicity database* should be applied here, in particular with regard to the problematic toxicity profile of other PFAS and in the light of the special status of drinking water with regard to the possible regular exceedance of HBGV of a very large number of people over very long periods of time in case of (erroneously) wrong TDI.

Lastly, we consider the developmental toxicity/teratogenicity study[34] by Bayer and Solvay: Rabbits were administered different doses (180, 375, and 750 mg/kg/day) of TFA during pregnancy. Severe malformations, particularly affecting the eyes but also the skeleton, were observed at all doses. Therefore, no dose without effects and hence no NOAEL could be identified in this study. Consequently, the lowest dose was identified as a so-called *Lowest Observed Adverse Effect Level* (LOAEL), which was 180 mg/kg/day. According to WHO guidelines, in such cases, the LOAEL divided by 10 can be used as a starting point for deriving a TDI. *Deficiencies in the database*[35] and the severity and irreversibility of the effect could be addressed by applying an additional uncertainty factor of 10 each, as WHO explicitly suggests for malformations in foetuses. This results in a TDI value of 1.8 µg/kg body weight per day and a drinking water limit of 2,400 ng/L when considering exposure of infants[36] (it is coincidence that these values match those derived from the rat study).

Data basis (Study / Effect)	**NOAEL** (mg/kg bw)	**Uncertainty Factors** (UF)	**Resulting TDI** [µg/kg bw/d]	**Resulting Drinking water limit** [ng/L]
90-day feeding study in rats (liver toxicity)	10 mg/kg/d	Default: 10 x 10 Extra UF: 100 (major data deficiencies) → Total UF: 10,000	1	1,300
52 week chronic toxicity study in rats (liver toxicity)	1.8 mg/kg/d	Default: 10 x 10 Extra UF: 10 (major data deficiencies) → Total UF: 1,000	1.8	2,400
Teratogenicity study in Rabbit (foetal deformities)	**LOAEL:** 180 mg/kg/d -> "NOAEL": 18 mg/kg/d	Default: 10 x 10 Extra UF: 10 (major data deficiencies) Extra UF: 10 (severity and irreversibility of the effect) → Total UF: 10,000	1.8	2,400

Table 2. *Experimental derivation of TFA limits using the most conservative approach with the application of uncertainty factors (UF) and exposure scenarios (TDI: Tolerable Daily Intake)*

[34] Trifluoroacetic acid. Developmental toxicity / teratogenicity,ECHA https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/5203/7/9/3/?documentUUID=bbe1c0df-91db-4cef-a965-89ded98a88c8

[35] There is still no long-term carcinogenicity study, nor animal genotoxicity of mutagenicity study, or developmental neurotoxicity study available.

[36] For calculating a drinking water limit from a TDI value based on foetal malformations, one could argue that, unlike previous cases, the exposure of pregnant women is most important. Under this assumption (2 litres of water per day, 60 kg body weight, and an allocation factor of 0.2 for drinking water), the drinking water limit would be 11 µg/L. However, since it cannot be ruled out that daily TFA exposure in foetuses of pregnant women—possibly due to endocrine disruption—could also lead to malformations in infants and young children, it seems appropriate to consider infants and young children as the most sensitive group. The following table provides an overview of the uncertainty factors and exposure scenarios used in the above approaches for deriving TDI values and drinking water limits.

The fact that three drinking water guideline values, derived from very different studies using different uncertainty factors under the sole requirement that the applicable WHO guidelines are interpreted in the most conservative way possible, eventually came so close together, is interesting.

It is also noteworthy that these values fall within the same range as the indicative drinking water guideline value set by RIVM, even though the latter is based on a completely different initial assumption.

Since all three TDI values had been derived by the use of relatively high to very high uncertainty factors, it can be expected, according to the WHO Guideline for Drinking Water, that the resulting drinking water limit values tend to present risks as greater than they actually are. The principle of *"better safe than sorry"* underpins this approach: In cases of uncertainty, a conservative approach should be chosen that may overestimate risks to ensure no health harm occurs until more data is available. The goal is to minimise risks and ensure that the measures taken to comply with the limit values provide sufficient protection.

In this context, it is quite reassuring to see that all values determined using this principle were clearly above the average contamination level of 750 ng/L found in our drinking water tests. Even for the two most heavily contaminated water samples, where we found values exceeding the RIVM guideline value, it holds true that there is no (theoretical) TDI exhaustion through drinking water consumption, as the guideline setting allocated 80% of the TDI to other exposure pathways.

Overall, the results from our exercise do not indicate that the RIVM, with its chosen innovative approach for deriving an indicative drinking water guideline value, has arrived at a threshold that would be insufficiently protective. This, too, is somewhat reassuring.

However, a disclaimer must be noted. All these exercises and the resulting threshold values are based on the assumption that TFA is a so-called threshold chemical for which safe limits can be set. However, based on the available data, we cannot exclude the possibility that TFA, like many of its structural relatives, is a non-threshold chemical and may exert carcinogenic, hormone-disruptive, or teratogenic effects for which no safe threshold can be established.

3.2.5 Non-Threshold Chemicals Approach

PFAS are a highly problematic group of substances, and many, if not all, of those PFAS that have been adequately studied must be considered "non-threshold chemicals", meaning no level of exposure should be considered completely safe. Non-threshold chemicals are primarily those that are genotoxic (cause DNA damage) and carcinogenic, but also substances that cause adverse effects via an endocrine-disrupting mode of action. Endocrine-disrupting chemicals can cause reproductive disorders, hormone-dependent cancers, thyroid function disorders, developmental disorders, metabolic disorders, immune disorders, as well as neurological and behavioural disorders. Exposure to low levels of these chemicals during the early life stages of

development may lead to permanent adverse effects, making pregnant women, babies and young children the most at risk. Scientists agree that it is uncertain whether a threshold of adversity can be established for early development[37]. Therefore, it is logical to attempt to keep human exposure to such substances as low as possible.

Pesticides are purposely designed to be biologically active and toxic to living organisms. They are deliberately used in large quantities on fields, contaminating the environment and water resources, and end up as residues in our food. Not only wildlife and ecosystems, but also farm workers, residents of agricultural areas, and consumers, including the most vulnerable members of our population, are exposed to these chemicals.

In recognition of the resulting risk, the EU pesticide regulation prohibits substances with particularly hazardous properties for which no safety threshold can be established, and therefore no safe exposure levels can be determined. This means: pesticide active substances with mutagenic, carcinogenic, reproductive toxic, and endocrine-disrupting properties must be banned or (with exception of mutagens) can only be used in closed systems where no human contact is possible, and no residues are detected in food[38]. If their metabolites fall under one of these hazard classes, then the parent pesticide compound cannot be authorised either.

Since many PFAS are considered non-threshold chemicals, it is reasonable to ask whether this also applies to TFA.

In the previous report *TFA in Water - PFAS Legacy Under the Radar* (p. 12) we highlighted the *The Myth of Harmless Short-Chains* and showed that publications commissioned or funded by the fluorination industry have been, and still are, a driving force in creating and spreading this myth. Regulatory authorities and even reputable scientists sometimes take these industry-sponsored works at face value[39]. Claims and narratives are especially easy to present as if they were facts when the scientific data is scarce, as is the case with TFA. The industry's narrative roughly goes like this: *"Although TFA is formally a PFAS, it should not be compared to other PFAS. TFA is supposedly not only less potent but also cannot accumulate in the body (because it is not fat-soluble) and is therefore rapidly eliminated by the organism."* This narrative was previously used for short-chain PFAS (C4 to C7), which was debunked over ten years ago[40], but it's still used with ultra-short chain PFAS.

However, since at least 2023, this narrative should also be considered disproven for TFA, as

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[37] Munn S, Goumenou M. Thresholds for Endocrine Disrupters and Related Uncertainties. EUR 26068. Luxembourg (Luxembourg): Publications Office of the European Union; 2013. JRC83204 https://publications.jrc.ec.europa.eu/repository/handle/JRC83204

[38] According to the Pesticide Regulation (EU) 1107/2009, Annex II 3.6.3 - 3.6.5 an active substance shall not be approved if it's classified as carcinogen, toxic to reproduction or endocrine disruptor "unless the exposure of humans to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005." The default value is set at the limit of quantification which is 0.1 mg/kg.

[39] Goorden Thomas (2023); The Dark PFAS Hypothesis - Strategies of Deception

[40] Pérez F. et al. 2013: Accumulation of perfluoroalkyl substances in human tissues, Environment International, Volume 59, Pages 354-362

ultrashort-chain PFAS, primarily TFA, have been identified as the predominant 'forever chemicals' in the blood of 81 Americans in an epidemiological study[41]. Paired analyses also showed a statistically significant correlation between TFA concentrations in blood and in the drinking water. A rather concerning finding was that TFA concentrations in blood serum were on average 76 times higher than the corresponding TFA concentrations in drinking water, indicating a bioaccumulative effect. The authors suspect that, like other PFAS (including short-chains), also the *ultrashort-chain* TFA binds to serum proteins and thus accumulates in the organism. This is actually not good news. Chemicals that can bind to serum proteins are often notable as endocrine disruptors with carcinogenic and reproductive toxic properties and can cause developmental and metabolic disorders.

If there was still any need for proof that TFA is not a harmless substance, Bayer, the PFAS manufacturer, provided it with the teratogenicity study on rabbits conducted at the request of EFSA. As we previously learned, TFA caused severe birth defects in rabbits following prenatal exposure. This raised significant concerns and led to the request by German authorities to classify TFA as a 'reprotoxic' substance Category 1B.

The European Chemicals Agency has started the assessment, and if it accepts this classification proposal, then TFA will be considered a relevant metabolite and all PFAS pesticides will in further consequence lose their market approval.

[41] Zheng G. et al. (2023); Elevated Levels of Ultrashort- and Short-Chain Perfluoroalkyl Acids in US Homes and People, Environmental Science & Technology 57 (42), 15782-15793

Legal Background

As explained in the previous report *TFA in Water - PFAS Legacy Under the Radar* (p. 7), calculations by the German UBA indicate that the use of PFAS pesticides is the main source of TFA contamination in groundwater and surface water, followed by refrigerants, which belong to the group of F-gases. Although TFA represents, to the best of our knowledge, the largest area-wide contamination of **surface and groundwater** by a man-made chemical, in many EU countries it is not or hardly ever monitored. No environmental quality standards (EQS) have yet been set for TFA, nor is it listed as a priority substance in the Water Framework Directive or the Groundwater Directive, and there are no clear legal limits in drinking water. From the perspective of EU water legislation, TFA is currently an "invisible" chemical.

4.1 TFA - Not a Relevant Metabolite ... ?

The concept of relevant and non-relevant metabolites derives from the EU Pesticide Regulation 1107/2009 and water regulations. The term *"metabolite"* in this context refers to any intermediate product and end product of the degradation of pesticide active substances. A metabolite is deemed *"relevant"* when it is of toxicological concern for human health. In this respect, according to the Regulation (EU) 284/2013 on data requirements for pesticide products if a pesticide metabolite occurs in concentrations above 100 ng/L in groundwater, an assessment of their relevance should be carried out.

However, a thorough toxicological assessment has not been carried out for TFA despite being probably responsible for the largest contamination of Europe's water bodies and drinking water supplies by a man-made chemical. This is important as the Drinking water (EU) 2020/2184 and Groundwater 2006/118/EC Directives, provide that concentrations of pesticides and their relevant metabolites must not exceed 100 ng/L.

Therefore, in line with EU Pesticide Regulation and the protection of water resources from pesticide use, if the use of a pesticide results that the pesticide active substance or its relevant metabolites exceed the limit threshold of 100 ng/L in groundwater, the substance should not be authorised[42]. The fact that 37 PFAS pesticides are currently authorised in the EU is essentially due to the failure by EU regulators to consider TFA, their common persistent degradation product, as a "relevant metabolite" in the context of pesticide risk assessment. But this (mis)classification, which occurred for the first time about 25 years ago and has resulted in the approval of dozens of PFAS active substances since then, also means that the legal limit of 100 ng/L for relevant metabolites in groundwater and drinking water has never been applied to TFA in the context of water regulation. Importantly, Member States had the possibility to classify themselves TFA as relevant for their own national water management purpose, regardless of the EU assessment, but they also failed to do so.

[42] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Regulation (EC) 1107/2009. October 2021. Sanco/221/2000 – rev.11

This has deprived regulators of a key means for preventing, monitoring and capping TFA pollution in water. The classification of TFA as a relevant metabolite for 25 years would have prevented the authorisation of PFAS pesticides and thus eliminated the dominant source of TFA contamination of our waters.

This (mis)classification is a serious mistake resulting from the under-investigation of TFA formation in the environment (including water)[43], from EFSA underestimating the risk of contamination, and from the EU Commission accepting this. Substances that have certain toxicological properties that are considered unacceptable are relevant metabolites by law. The recent detection of severe malformations in foetuses of TFA-exposed rabbits is such an unacceptable toxicological property. Its detection is not really surprising. At the latest since the revelations in connection with the Dark Waters scandal in 2001, malformations and carcinogenic effects of other structurally related representatives from the PFAS group have been known[44]. Taken together, this makes the assumption that individual chemicals of the PFAS group are harmless and irrelevant - in the absence of a data basis to support this assumption - highly questionable.

It is obvious that the EFSA and the EU Commission have played a very ignoble role in this matter. However, it should not be forgotten that the Member States also have a major say in these decisions and often wield considerable influence. Therefore, it is not incorrect to speak of a collective political failure in relation to TFA.

However, limit values for PFAS in drinking water are to become legally binding for the first time from 2026. By definition, these should also include TFA.

4.2 TFA and the Drinking Water Directive

The quality of drinking water in the EU is regulated by the Drinking Water Directive (2020/2184/EU). As part of the last amendment in 2020, limit values for PFAS were adopted for the first time, although compliance with and monitoring of these will only be **mandatory from 12 January 2026**. As the group of PFAS compounds comprises over 10,000 substances, but sufficient toxicological data is only available for a small group of PFAS, two group limit values were set:

- "PFAS total": **500 ng/L** applies to all per- and polyfluoroalkyl substances.
- "Sum of PFAS": **100 ng/L** applies to a group of 20 PFAS[45]

TFA is *formally included in the definition of the parameter 'PFAS total', as it is part of the totality of per- and polyfluoroalkyl substances,* as the EU Commission clarifies in its draft technical guidelines on monitoring the parameters *"PFAS total"* and *"sum of PFAS"* of January 2024[46].

[43] To our current knowledge, the relevance of TFA for groundwater was assessed and completed for only three substances: flurtamone, haloxyfop-P and tritosulfuron. Other risk assessments are ongoing (flufenacet and fluopyram)

[44] Stephanie Soechtig (2018) The Devil We Know Film Documentary

[45] The sum of PFAS is identical to the 20 PFAS that we analysed in mixed samples in this study (see section 2.1)

[46] In the draft technical guidelines regarding methods of analysis for PFAS monitoring under the recast Drinking Water Directive is is said: "TFA is formally included in the definition of the parameter «PFAS total» of the recast DWD, as it is part of the totality of per- and polyfluoroalkyl substances. Consequently, the analytical methods for PFAS Total should also include TFA."

Consequently, according to the EU Commission, the analysis methods for "PFAS total" should also encompass TFA. However, it remains unclear what these analysis methods will entail.

What we already know is that around half of the tap water samples analysed in our exploratory survey would not meet the parameter value of 500 ng/L at this moment. However, it is not a solution to require water suppliers in the EU to remove TFA from the water, a process that is technologically very difficult and expensive, requiring investments in the multi-digit billion range across Europe, and will ultimately lower water quality. The only solution here is a swift ban on PFAS pesticides and if necessary to lay the burden on the pesticide producers applying 'the polluter pays' principle.

It is not clear whether the EU Commission was aware of the level of TFA water pollution when it proposed the *"PFAS total"* parameter in 2017. However, this has now changed. The draft technical guideline cited above contains the remarkable statement that the detection of a *"significant mass concentration of TFA could lead to non-compliance with the parametric value for 'PFAS total'"* With the even more remarkable addition: *"without this being relevant to the health of the consumer."*

The second PFAS limit value, "Sum of PFAS", is also controversial. It is not in line with EFSA's risk of the PFAS-4 from 2020[47] and therefore more than a power of ten too high to be safe. In reaction to that, some EU countries, when implementing the new EU drinking water regulations including Denmark, Sweden, the Netherlands, Belgium (Flanders) and Germany, based their national drinking water limits on the EFSA opinion and set stricter limits for PFAS-4. Other countries such as France, Austria, the Czech Republic, and Hungary did not set protective limits for PFAS-4. More information on this can be found in the Policy Briefing *Toxic tide rising: time to tackle PFAS* published by the European Environmental Bureau[48].

[47] EFSA 2020: PFAS in food: EFSA assesses risks and sets tolerable intake

[48] EEB (2023): POLICY BRIEFING. Toxic tide rising: time to tackle PFAS. National approaches to address FAS in drinking water across Europe

4.3 Revision of EU Water Legislation

Drinking water in the EU comes from both surface water and groundwater. EU limits for pollutants in these natural waters from which we obtain drinking water are regulated by the Water Framework Directive (WFD, 2000/60/EC), the Environmental Quality Standards Directive (EQSD, 2008/105/EC) and the Groundwater Directive (GWD, 2006/118/EC). However, only one PFAS is currently regulated by EU water legislation: PFOS was included as a 'priority hazardous substance' in *Annex X* of the Water Framework Directive in 2013, three years after its EU-wide ban. This means that Member States must monitor the presence of PFOS in water and take measures to ensure that the EQS is not exceeded.

In October 2022, the European Commission proposed new priority substances (for surface water) and pollutants for groundwater. The proposal includes a threshold value of 4.4 ng/L for a group of 24 PFAS in surface and groundwater and a threshold value for PFAS in biota (0.077 µg/kg wet weight, also for the group of 24 PFAS). The threshold values are expressed as PFOA equivalents, and the relative potency factor approach was used in determining the threshold value for the group to account for differences in the toxicity of the different substances.

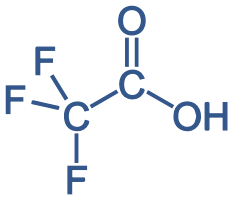
At present, EU legislation regulating chemicals (both source regulations such as REACH and environmental regulations such as the Water Framework Directive) and their effects is primarily focused on individual substances. This allows the regulated substance to be easily replaced by another with similar harmful properties, a widespread phenomenon known as regrettable substitution. There is also growing concern about the effects of chemical mixtures, which can occur even when individual substances are present in 'safe' quantities. Regulating substances as a group, for example by setting a threshold value for a group of substances with similar properties, is one way to counter this and is consistent with the aim of the Chemicals Strategy for Sustainability to regulate substances as a group.

In September 2023, the European Parliament adopted their position on the Commission's proposal, including an amendment asking the Commission to develop a 'PFAS total' parameter for surface and groundwater. By definition, this parameter should also include TFA. Reportedly, under the leadership of the European Commission's Joint Research Centre, various options are being developed to determine what a parameter under the WFD that includes TFA could look like. Possible options could be a separate quality standard or inclusion in the Commission's proposed sum of PFAS, where its relative potency could be taken into account.

However, the EU council recently adopted a position that severely weakens key elements of the proposal. It also delays dates to comply with the requirements to 2039, with possibilities to further delay until 2051. That would clearly not address the severe problems with our surface and drinking water we are currently facing. The positions of both EU Parliament and Council will now be discussed in a trilogue.

The trilogue expected in autumn 2024 under the Hungarian Council Presidency could and should make important forward-looking decisions to end the ongoing TFA contamination of European waters and thus of our drinking water.

Conclusions



Our current exploratory survey of 55 drinking water samples from 11 European countries has shown that Trifluoreacetic acid (TFA), a degradation product of certain PFAS pesticides (per- and polyfluoroalkyl substances) and F-gases, is not only an increasingly widespread man-made chemical in Europe's rivers and lakes, but is also present in drinking water in comparably high quantities.

Specifically, TFA was detected in 94% of 36 European tap water samples from eleven EU countries and in 63% of 19 bottled mineral and spring waters. The TFA concentrations in tap water ranged from below the detection limit (< 20 ng/L) to 4,100 ng/L, with an average of 740 ng/L. In bottled water, TFA concentrations ranged from below the detection limit to 3,200 ng/L, with an average of 278 ng/L. Analysis of 24 other PFAS in four composite samples confirmed that TFA is the predominant PFAS contaminant in drinking water.

The widespread occurrence and high concentrations of TFA in drinking water (approximately an order of magnitude above the legal limit for pesticide active substances and their "relevant" metabolites) raise questions about the toxicological and legal implications. Despite its prevalence, there are surprisingly few studies available on the toxicity of TFA, making risk assessment challenging.

In such cases where a meaningful risk assessment is not possible due to a lack of studies, the precautionary principle should be applied. For a pesticide metabolite like TFA this would have meant that the precautionary standard limit of 100 ng/L for relevant metabolites should have been applied, according to the EU pesticides regulation.

The establishment of a precautionary limit value of 100 µg/L for 'non-evaluated anthropogenic substances and particularly for non-evaluated degradation products' in surface- and groundwater bodies, unless potential risks to the environment and health can be ruled out, is also a decades-old demand of major European water suppliers.

The background to this appeal to decision-makers is the principle that drinking water must be and can only be protected at its source. However, the decisions of politicians and authorities were contrary to this. By failing to recognize TFA as a relevant metabolite of PFAS pesticides, they have effectively lifted the legally established limit values for 'relevant metabolites' in the case of TFA, and have opened the door to the increasingly widespread contamination of our water resources with this man-made chemical.

When the authorities had to assess the health risk of this contaminant—a contamination for which they are partly responsible due

Conclusions

to their (mis)decisions—they again chose the opposite of a precautionary approach. This has led to the establishment of Health-Based Guidance Values and threshold values that risk giving decision-makers and consumers a false sense of security.

From a legal perspective, TFA has been, and still is, an "invisible" chemical due to the previously mentioned decisions by policymakers. There are no quality standards for groundwater or surface water, and no limits for drinking water.

With the revision of the Water Framework Directive, this could change. The governments of the member states have the opportunity to set the course for water protection in the trilogue expected in autumn—and they owe this to their citizens.

The processes at the EU level must be speed up to adequately address the problem. Moreover, governments can and should decide on immediate national measures to prevent further increases in contamination, protecting their water resources and their citizens.

Although the currently detectable TFA levels in drinking water appear to be within what are considered safety limits, their input continues to increase with each passing day due to the use of PFAS pesticides and coolants ("F-gases"). The margin of safety, or safety buffer, is worryingly small. To safeguard the future availability of safe drinking water for European citizens, the most important demands are as follows:

- Immediate ban on PFAS pesticides.
- Immediate ban on F-gases.
- Implementation of a general PFAS restriction according to REACH.
- Establishment of a safe drinking water limit for TFA at the EU level.
- Setting quality standards for TFA for waters regulated under the Water Framework Directive.
- Applying the Polluter Pays principle wherever water purification is necessary due to chemical contamination.
- Closing the data gaps with regard to the toxicity of TFA by facilitating independent research
- Providing support to farmers to replace PFAS pesticides with alternative, ideally chemical-free, crop protection methods.

TFA A Forever Chemical in the Water We Drink

Only a swift ban on PFAS pesticides and F-gases can save our water

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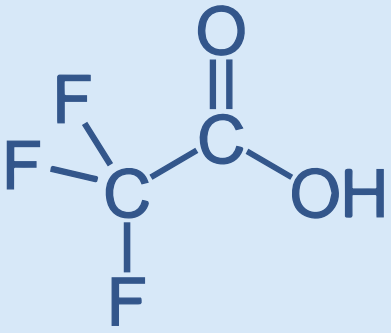

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