



Better Food. Better Health. Better World.

# Water for human use: PFAS and Bisphenol A, from the new directive [\(UE\) 2020/2184](#) to lab tests

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**REMTECH**  
**Europe**



# Chemical Mobility of emerging contaminants



The **mobility of chemicals released into the environment governs their bioavailability** to organisms and their partitioning between environmental compartments, and thus represents a direct link between environmental pollution and ecotoxicity.

**This combined exposure** on water, food, and consumer products, such is an arising issue.  
The main challenge is to tackle the **cumulative impact** of different chemicals.

## FOCUS ON PFAS AND BPA

- Widely used in consumer goods and food contact applications
- Some PFAS are classified as Persistent, Bioaccumulative and Toxic (PBT) and very Persistent and very Bioaccumulative (vPvB) under REACH
- BPA is an endocrine disruptor and SVHC under REACH

# The road to the new directive EU 2020/2184

## In ancient times

The requirements for describing water were sensory ones:

- Waters had to be **clear, odourless, colourless and of pleasant taste**
- Malodorous or **turbid water was considered contaminated**
- Recognised as **sources of contamination: droppings, metals, algae**
- Few or **no analytical methods**



Pont du Gard  
Roman aqueduct

## Nowadays

The scientific approach has greatly developed:

- Quality requirements with parameters, frequencies of analysis, analytical methods
- **Emerging contaminants monitoring**
- **Regulation open to future scientific and technical development**



European  
Regulations

# The importance of the new Directive

**UE DIRECTIVE 2020/2184**  
**on the quality of water**  
**intended for human**  
**consumption**



It substitutes EU Directive  
83/1998

In many States it will be the  
new **National reference for**  
**water for human**  
**consumption**

**Member States must introduce it in national law  
before 2023**

In Italy, European Delegation Law.127 (4/8/2022) gives to  
the Government the delegation to transpose this Directive  
into Italian law

## **MAIN CHANGES**

- **new parameters**
- redefinition of **scope**
- approach to safety based on **risk analysis**
- minimum hygiene requirements for **materials in contact with water** for human use
- minimum requirements for **chemical products and filtering materials** used for water treatment
- control parameters and **frequencies depending on the amount of water used**
- search for the method of **analysis for microplastics**

# Changes introduced by the new Directive

| Parameters introduced by EU Directive 2020/2184 | Field of application                                                                                                                                                                                                                                                                                                                      | Materials and chemical in contact with waters                                                                                                                           |
|-------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| BISPHENOL A                                     | <b>spring waters</b> used for drinking purposes <b>INCLUDED</b>                                                                                                                                                                                                                                                                           | An initial <b>list of authorised substances</b> will be defined at European level, as well as procedures and methods for testing and validating materials and products. |
| PFAS                                            | <b>mineral and medicinal waters</b> , which are regulated by other directives, <b>EXCLUDED</b>                                                                                                                                                                                                                                            |                                                                                                                                                                         |
| CHLORITES AND CHLORATES                         | <b>Analysis</b><br><br>The <b>frequency of monitoring</b> depends on the volume of water distributed or produced each day in a supply zone<br><br>The analytical methods used for monitoring purposes must be validated and documented in accordance with <b>EN ISO/IEC 17025</b> or other equivalent internationally accepted standards. | Similarly for treatment chemicals and filter material that come into contact with water intended for human consumption                                                  |
| MICROCYSTINE L-R                                |                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                         |
| HALOACETIC ACIDS                                |                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                         |
| URANIUM                                         |                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                         |

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| <b>MICROCYSTINE L-R</b>                         |                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                         |
| <b>HALOACETIC ACIDS</b>                         |                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                         |
| <b>URANIUM</b>                                  |                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                         |



# New approach to emerging contaminants

## WATER SAFETY PLANS

**Site-specific** water monitoring plans:

- contaminants present in particular polluted areas should be included in monitoring plans

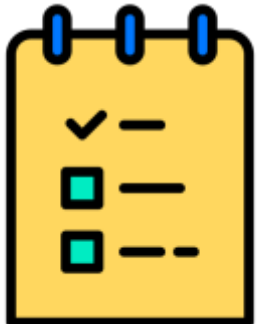


## WATCH LIST MECHANISM

- to respond to **growing concerns**
- to enable **follow-up on new knowledge** about the relevance for human health of those emerging compounds and most appropriate monitoring approaches and methodologies

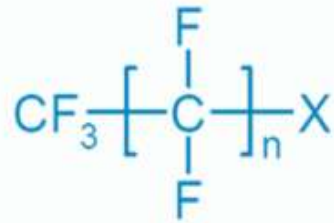
**By 12 January 2024:**

- **technical guidelines on analytical methods for PFAS**
- **methodology for measuring microplastics** with the aim to include them in the watch list



# PFAS and BPA as emerging contaminants

## PFAS



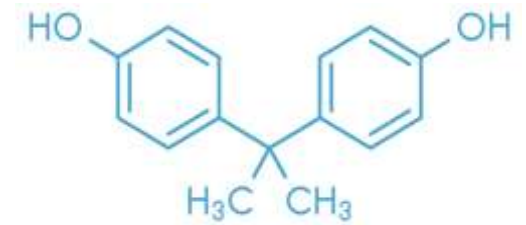
Anti greasing and water repellent

**INTENTIONALLY ADDED FOR THEIR PROPERTIES**

**SUBJECT TO RESTRICTIONS OR HEALTH LIMITS  
IN WATER, ARTICLES AND FOOD,  
DUE TO THEIR EFFECTS ON HUMAN HEALTH**

**«USEFUL» MOLECULES THAT ARE ALSO CONTAMINANTS AND WHICH PRESENCE IN  
DIFFERENT ENVIRONMENTAL MATRICES, FIRST OF ALL WATER, CAN BE UNCONTROLLED  
DUE TO THEIR UBIQUITARY.**

## BPA



Important structural additive for  
plastics and epoxy resins

**REGULATED IN WATER FOR HUMAN CONSUMPTION THANKS TO UE DIRECTIVE 2020/2184**



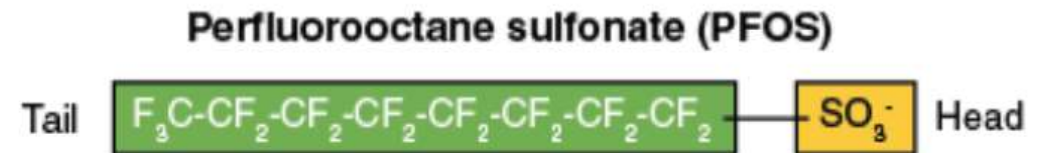
# Focus PFAS

# PFAS: emerging contaminants

The **most known PFAS** are **Perfluorooctanesulfonic acid (PFOS)** and **Perfluorooctanoic acid (PFOA)** belonging to (per) fluorinated organic surfactants.

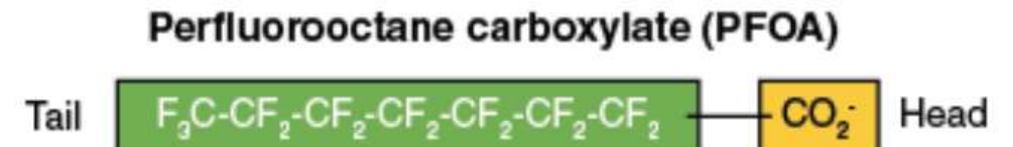
## PFOS:

- Completely fluorinated compound containing 8 carbon atoms and a sulphonated group
- Wide variety of applications due to its surface- active properties



## PFOA:

- Completely fluorinated organic acid
- Used primarily as emulsifier in industrial applications
- Linear 8 carbons- chain structure



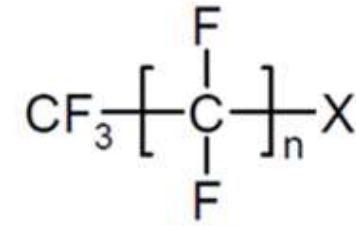
# PFAS: emerging contaminants

Per- and polyfluoroalkyl substances (PFAS):

- Family of nearly **5000 synthetic chemicals**
- **Persistent contaminants**, also called «forever contaminants»
- **Emerging contaminants dangerous to environment and human health** (suspected endocrine disruptors, carcinogens and affecting the immune system)

**Diet is considered the main source of exposure to PFASs for humans.**

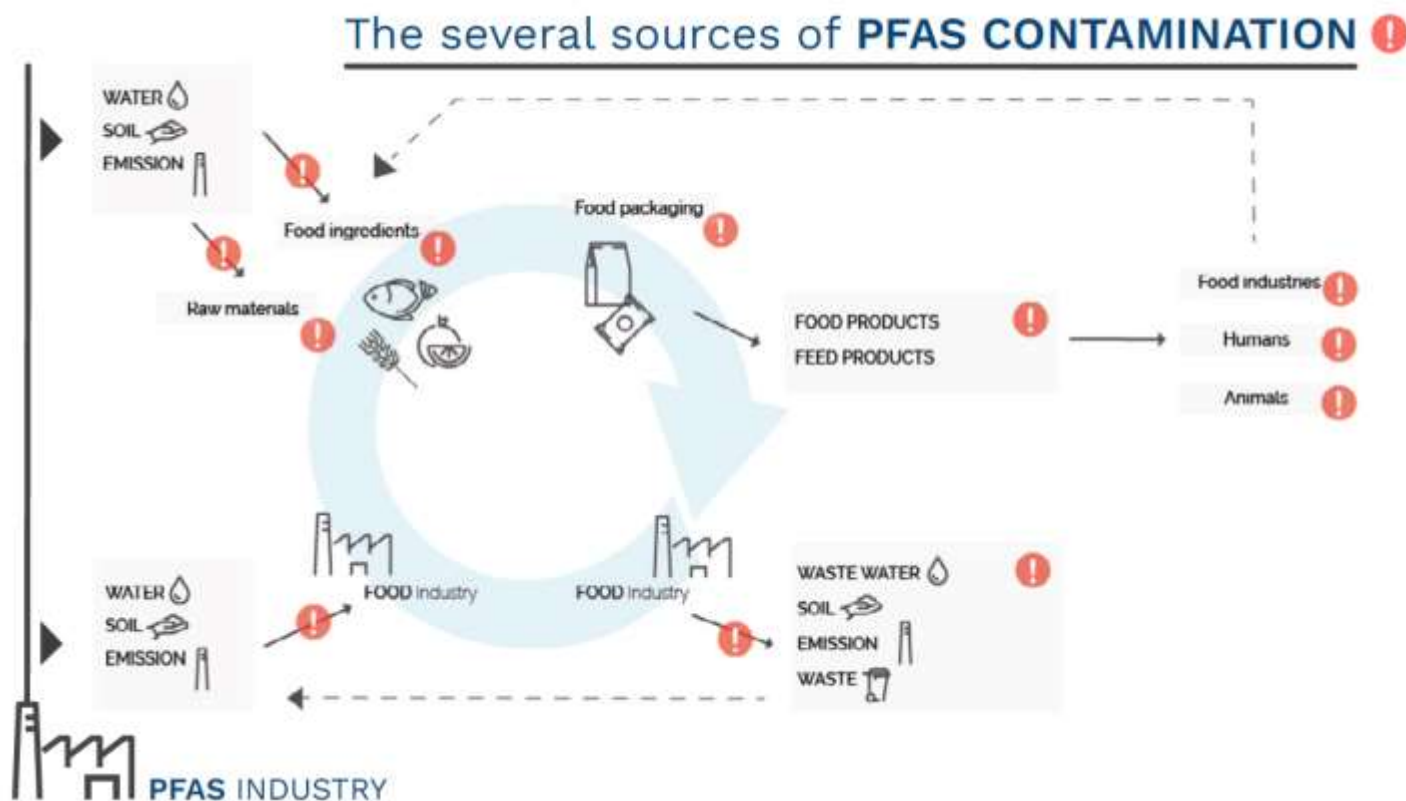
EFSA: Tolerable Weekly Intake (TWI) of 4.4 ng/kg body weight per week for the sum of PFOS, PFOA, PFNA and PFHxS



- Excellent **surfactants**
- **Strong C-F bond**
- **Applied everywhere** in society (household, industry, automotive, medical etc)



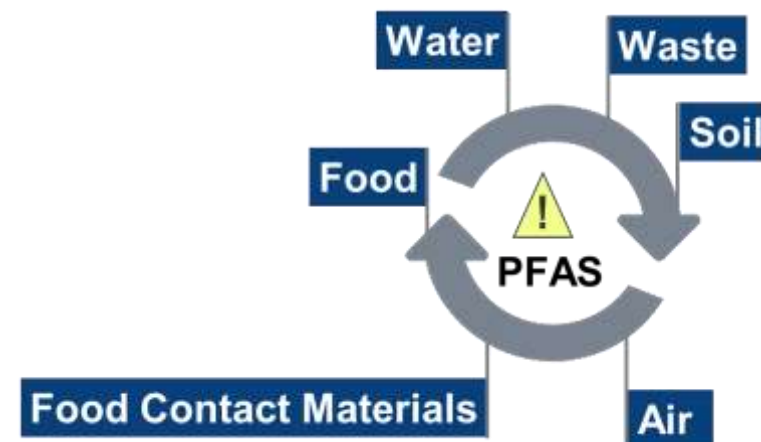
# Sources of contamination and concerned matrices



- Domestic, civil and industrial contamination → **strongly present in water environment**, also because of their mobility
- **Conventional treatment do not eliminate this contaminants** either from drinking or waste water

## BIOACCUMULATION IN FOOD CHAIN

## Concerned matrices



# EU Legislation on PFAS



**2017, PFOA and PFOS are classified as priority hazardous substances** under the Water Framework Directive (EC, 2017; EU, 2000)

**2020, EU Directive 2020/2184 on drinking water**, sum of PFAS < 0,50 µg/l – analytical guidelines to be decided before 2024 (a list of PFAS is provided in the Annex). Directive to be adopted by Member States in 2023.

**2010**, Commission Recommendation on the monitoring of PFAS in food

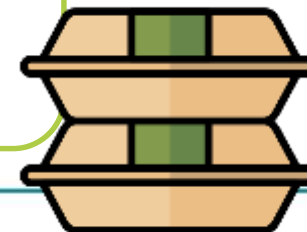
**2018/2020**, EFSA Scientific Opinions on PFAS in food 2020 - Proposal of a group TWI of 4,4ng/kg bw for PFOA, PFNA, PFHxS and PFOS, Identification of new critical health effects

**2022 Draft Recommendation** with limits up to 0,1 µg/kg for specific PFAS in some type of food and Guidelines for analytical determination with LOQ up to 0,001 µg/kg

**2020**: EU regulation restricts PFOA, PFOA salts and related substances for production and placing on the market (a maximum of 25 ppb of PFOA including its salts or 1 000 ppb of one or a combination of PFOA-related substances)

**2020, Denmark first European country to ban** all organic fluorinated compounds in food contact paper and cardboard – reference limit 20 µg/g of paper

**2022, Netherland bans** PFAS included in the EFSA Opinion in food contact paper



# PFAS limits in compostable and paper packaging

## COMPOSTABLE PACKAGING

### EN 13432:2000

Table A.1 - Maximum element content of packaging material and whole packaging

| Element | mg/kg on dry substance | Element | mg/kg on dry substance |
|---------|------------------------|---------|------------------------|
| Zn      | 150                    | Cr      | 50                     |
| Cu      | 50                     | Mo      | 1                      |
| Ni      | 25,0                   | Se      | 0,75                   |
| Cd      | 0,5                    | As      | 5                      |
| Pb      | 50                     | F       | 100                    |
| Hg      | 0,5                    |         |                        |

### ISO 17088-2021, Specification for compostable plastics

From a precautionary perspective, per- and poly-fluorinated substances compounds (PFCs) shall not be intentionally added to a plastics product or a material. The concentration of per- and poly-fluorinated compounds (PFCs) in the plastics product or material **shall be determined as fluorine**.

### BAN ON PFAS IN SEEDLING CERTIFICATE MATERIALS

From October 2021 holders of this certification will be required to submit a self-declaration confirming that no PFAS has been intentionally added to the certified material or product, nor used at any stage of the production process.

## PAPER PACKAGING

### Danish Veterinary and Food Administration

Indicator value **20 microgram organic fluorine** per gram of paper.

Content **below the indicator value is considered as unintentional background pollution**. For both the analytical methods proposed, companies **should ensure that inorganic fluorine is subtracted from the result, since inorganic fluorine can cause an error** in the analysis methods for total organic fluorine and extractable organic fluorine.



# PFAS in food



## *SANTE/11183/2018 - Last draft version*

- **DRAFT - COMMISSION REGULATION (EU) amending the Regulation (EC) 1881/2006** – as regards maximum levels of perfluoroalkyl substances in certain foodstuffs

The determination of the following analytes in the concerned foods will be **mandatory**

|              |                               |
|--------------|-------------------------------|
| <b>PFOS</b>  | Perflorooctane sulfonic acid  |
| <b>PFOA</b>  | Perfluorooctanoic acid        |
| <b>PFNA</b>  | Pefluorononanoic acid         |
| <b>PFHxS</b> | Perfluorohexane sulfonic acid |

**TO BE IN COMPLIANCE**

**4**  
analytes  
to monitor

sum of the  
**4**

## *SANTE/10010/2021 - official*

- **COMMISSION RECOMMENDATION** on the **monitoring of perfluoroalkyl substances in food** as discussed in the Working Group on Persistent Organic Pollutants in Foods

EU Member States should **collect monitoring data on the presence of PFAS in food**, also from different type of production, including organic production: animal products, plant-based products and food for infants and young children.

**+27**  
analytes to  
monitor,  
limits up to  
1 ppt

# Mérieux NutriSciences

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# Global context



United States  
Environmental Protection  
Agency

**PFAS Strategic Roadmap:  
EPA's Commitments to Action  
2021–2024**

Establish a national primary drinking  
water regulation for PFOA and PFOS  
*Proposed Rule Expected Fall 2022,  
Final Rule Expected Fall 2023*

Laws and draft laws in the  
different States about  
PFAS in consumer goods

**EUROPE**



**Our Focus**

- Stockholm Convention on POPs
- Changes and updates about PFAS residues in food

**CHINA**



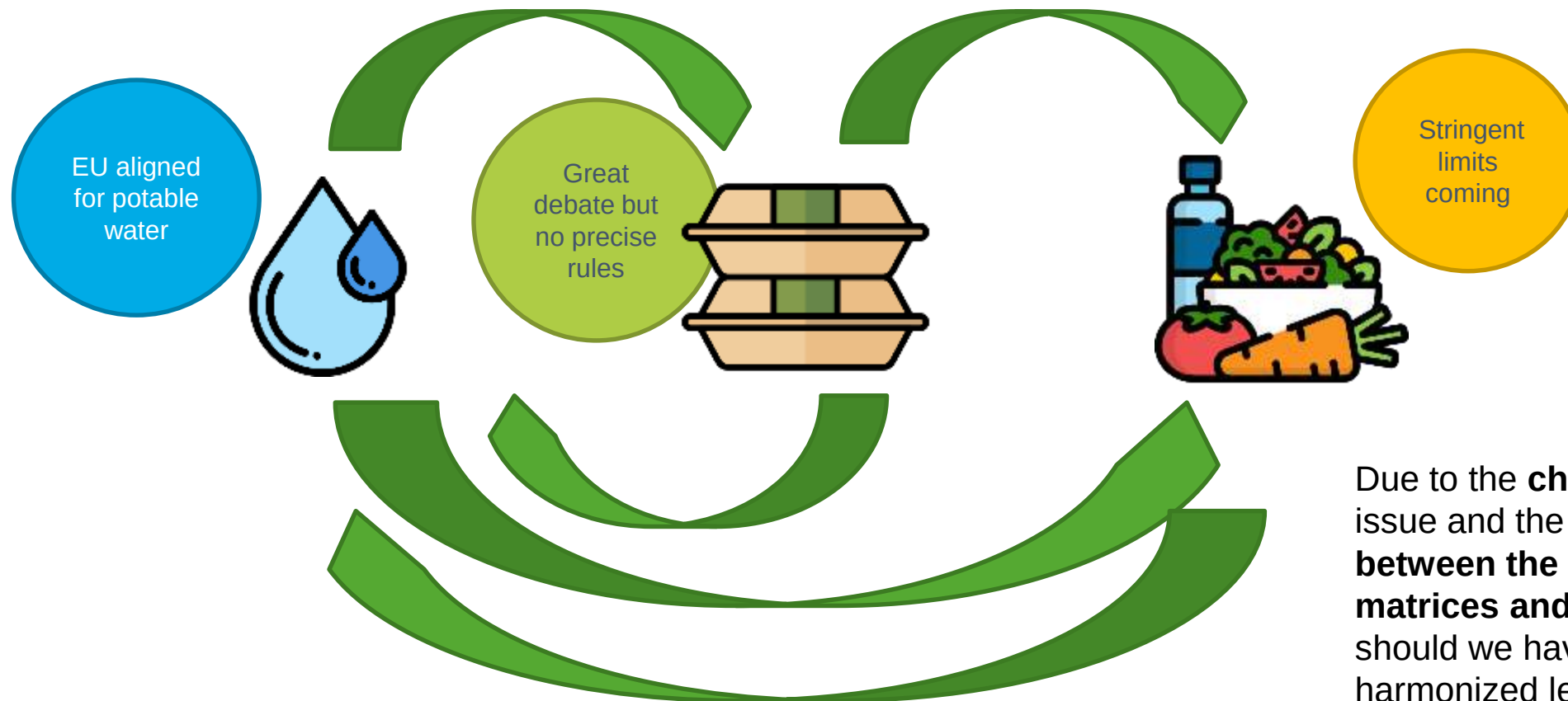
- No official limits
- Standard methods for food contact materials

**AUSTRALIA**



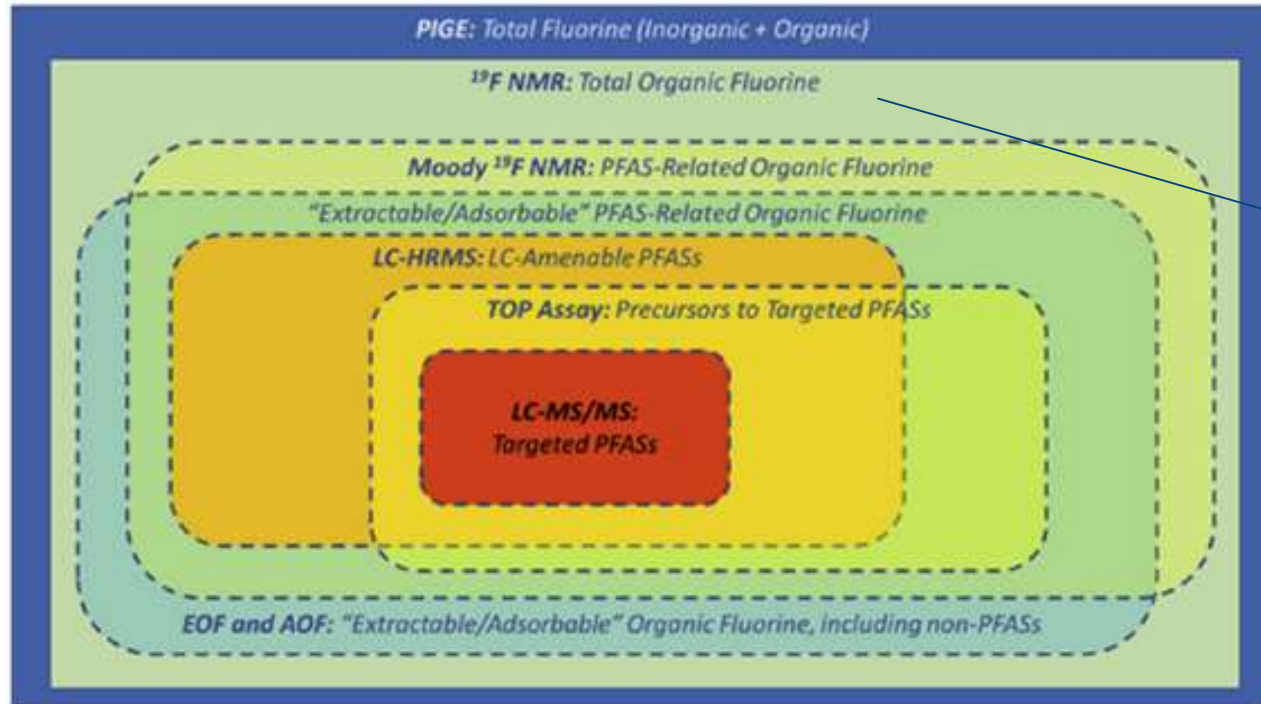
Epidemiological studies and  
concern about the topic

# Need of harmonized legislation?



Due to the **chemical mobility** issue and the **interactions between the different matrices and environment**, should we have a more harmonized legislation and comparable monitoring limits?

# GRAY ZONE: PFAS selectivity and inclusivity

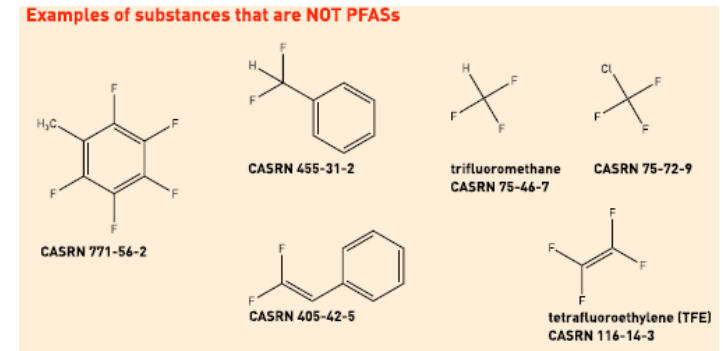


Selectivity and inclusivity associated with total organofluoride methods. Image source: McDonough, Carrie A., et al., 2019, Current Opinion in Environmental Science & Health

It is a large family of compounds; which should be the right technique to investigate them?

- **Non-specific** total determination has **limit issues** and might include also non-PFAS

not all the organic F-C are PFAS!



- A **super specific** target **won't** include all **possible dangerous PFAS**.

Future harmonized legislative indications or toxicological relevance will be the drivers to decide.



# EU DIRECTIVE 2020/2184 on PFAS

|             |      |      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------|------|------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| PFAS Total  | 0,50 | µg/l | <p>'PFAS Total' means the totality of per- and polyfluoroalkyl substances.</p> <p>This parametric value shall only apply once technical guidelines for monitoring this parameter are developed in accordance with Article 13(7). Member States may then decide to use either one or both of the parameters 'PFAS Total' or 'Sum of PFAS'.</p>                                                                                                                                                             |
| Sum of PFAS | 0,10 | µg/l | <p>'Sum of PFAS' means the sum of per- and polyfluoroalkyl substances considered a concern as regards water intended for human consumption listed in point 3 of Part B of Annex III. This is a subset of 'PFAS Total' substances that contain a perfluoroalkyl moiety with three or more carbons (i.e. <math>-C_nF_{2n}-</math>, <math>n \geq 3</math>) or a perfluoroalkylether moiety with two or more carbons (i.e. <math>-C_nF_{2n}OC_mF_{2m}-</math>, <math>n</math> and <math>m \geq 1</math>).</p> |

## 3. Sum of PFAS

The following substances shall be analysed based on the technical guidelines developed in accordance with Article 13(7):

- 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

Those substances shall be monitored when the risk assessment and risk management of the catchment areas for abstraction points carried out in accordance with Article 8 conclude that those substances are likely to be present in a given water supply.

# Possible answers?

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| Analytical method                                                | LoQ                                                                 |
|------------------------------------------------------------------|---------------------------------------------------------------------|
| <b>EPA 537-09</b><br>drinking water groundwater<br>(clean water) | <b>0,01 µg/Lt</b>                                                   |
| <b>ISO 25101:2009</b><br>drinking water                          | <b>0,001 µg/Lt for PFOA and PFOS<br/>and for others 0.005 µg/Lt</b> |
| <b>EPA ASTM D7979-17</b><br>waste water                          | <b>0,05-0,1 µg/Lt for all PFAS<br/>Except for PFOS a 0,01 µg/Lt</b> |



# Possible future answers?

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## Non-targeted PFAS discovery

### EPA Experience:

They are working to develop and apply high-resolution mass spectrometry techniques to conduct Non-Targeted Analysis of PFAS in the environment.

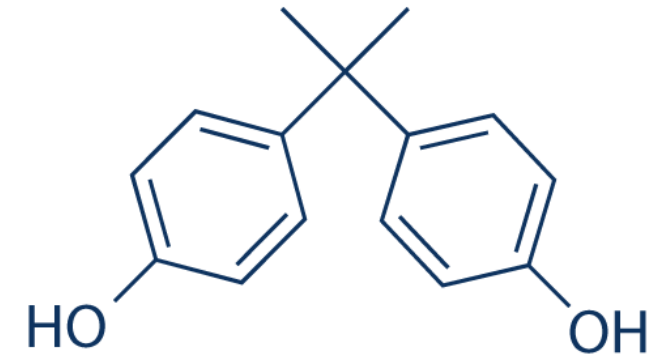
Potential: HRMS permits to detect and proposed structures for ~980 new PFAS analytes (not branched isomers)

# Focus BPA and endocrine disruptors

# Bisphenol A

## 2,2-bis (4-hydroxyphenyl) propane

- Identified as an **endocrine disruptor**
- basic component in the production of **polycarbonate**
- widely **used in the past in beverage bottles, infant feeding (baby) bottles, tableware** (plates and mugs) and storage containers
- can be present in thermal paper, ink and glue formulations
- can be present and permitted in **certain types of bottles and containers for food, drinks**, CDs, DVDs, reusable plastic tableware, mobile phones, kettles as well as various medical devices and toys



# Concern over Bisphenol

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**2011** As a precautionary measure, the European Commission **banned the use of BPA in the production of polycarbonate baby bottles**

**2016** The European **Food Safety Authority promoted restrictions** on use due to the health risk to the general public

**2017** It was added to the Candidate List of **substances of very high concern** by the European Chemical Agency

**2018** The European Union established even **stricter rules for the production of plastic materials in contact with food**, following a precautionary principle pending further clarity.

**its use in contact with food is authorized by Commission Regulation (EU) No. 10/2011, except for infant feeding bottles: the Specific Migration Limit has been recently lowered to 0.05 mg/kg**

# Bisphenol in water for human consumption

## Endocrine disruptors

In addition to the European Directive, Decision (EU) 2022/679 was also issued, adding also:

- **17 - betaestradiol**
- **nonylphenol**

For nonylphenol the suggested method was **EN ISO 18857-2**, so the lab upgrade the method used for Bisphenol A for many years, **applying this one both to Bisphenol A and nonylphenol**



## Bisphenol...or bisphenols?

There are **many Bisphenols** and some of them are used in substitution of Bisphenol A, but with similar concern about the toxicity.

The analysis is **always in GC-MS applying EN ISO 18857-2**

|                                      |                      |
|--------------------------------------|----------------------|
| 4,4'-Methylenediphenol (Bisphenol F) | 620-92-8             |
| 4-Nonylphenol                        | 104-40-5             |
| 4-Nonylphenol, branched              | 84852-15-3           |
| Bisphenol A                          | 80-05-7              |
| Nonylphenol (mixed isomers)          | 25154-52-3+84852-15- |
| Bisphenol Z                          | 843-55-0             |
| Bisphenol C                          | 79-97-0              |
| Bisphenol B                          | 77-40-7              |
| Bisphenol S                          | 80-09-1              |

# What should a lab do?



- Testing plan suitable for the goal
- Efficient extraction techniques
- Representative analytical techniques
- Markers and target substances
- Identification propaedeutical to risk assessment
- Keep the eye on legislation





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# Thank you

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