

# Setting Guideline Values for PFAS in Drinking Water: Decision Making Process in Israel

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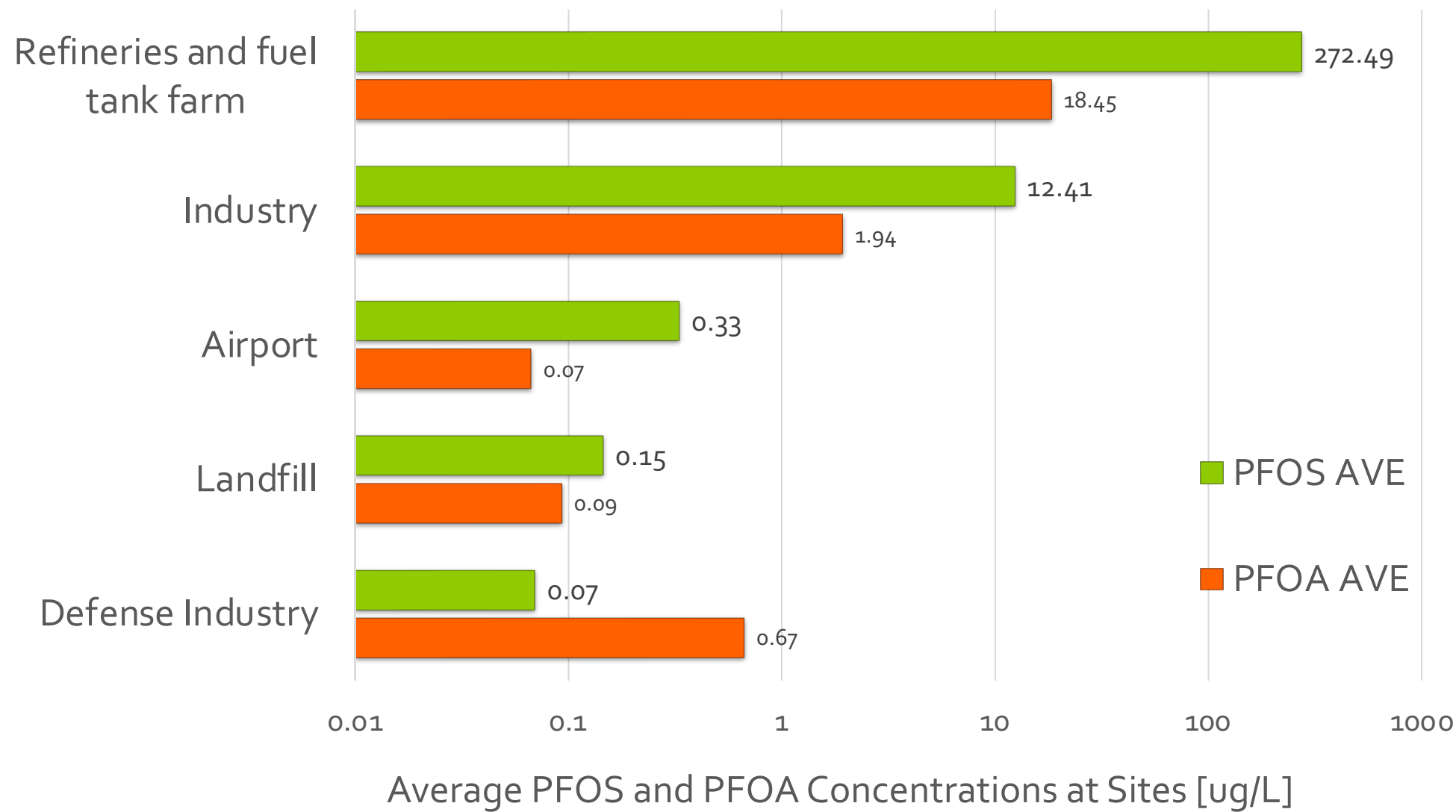


# Process for Developing the Guideline Values

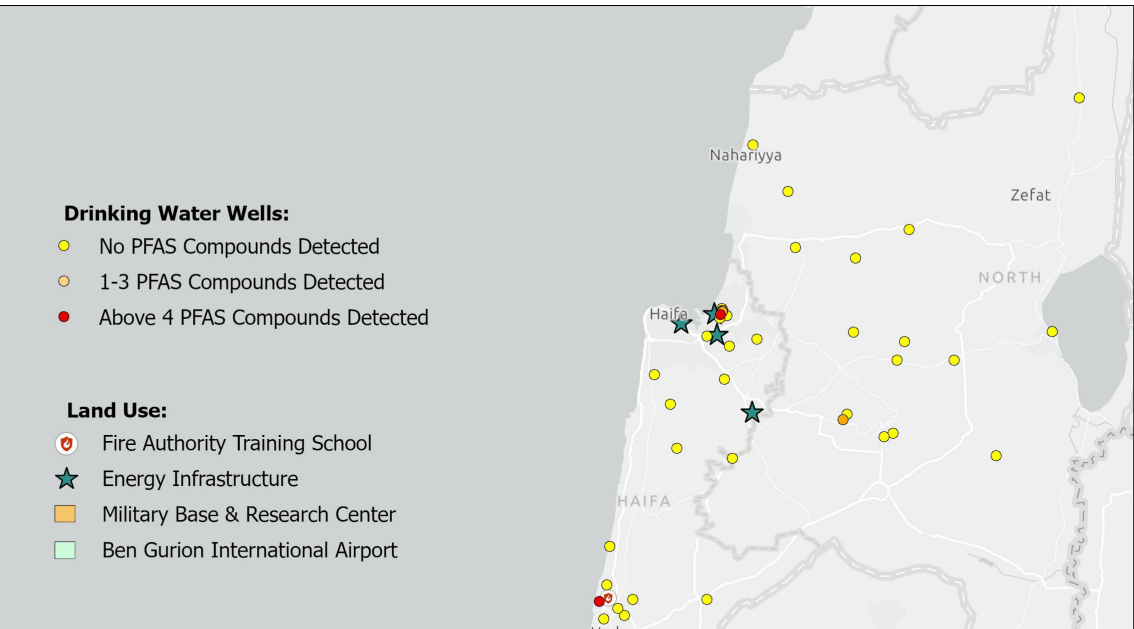
| WHO Europe Recommendation (2017)                                                                                        | EU Decision (draft)                                          |
|-------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
| PFOS = 0.4 µg/l (changes in lipids and thyroid hormones)<br>PFOA = 4.0 µg/l (liver effects)<br>Based on EFSA TDI (2008) | 0.1 µg/l for individual PFAS and 0.5 µg/l for PFASs in total |



# Water Authority Survey – PFAS in Groundwater (2019)



# Water Authority Survey – PFAS in Groundwater (2019)



PFOS in black  
PFOA in blue



# Interim Guideline Value for PFAS in Drinking Water (2020)

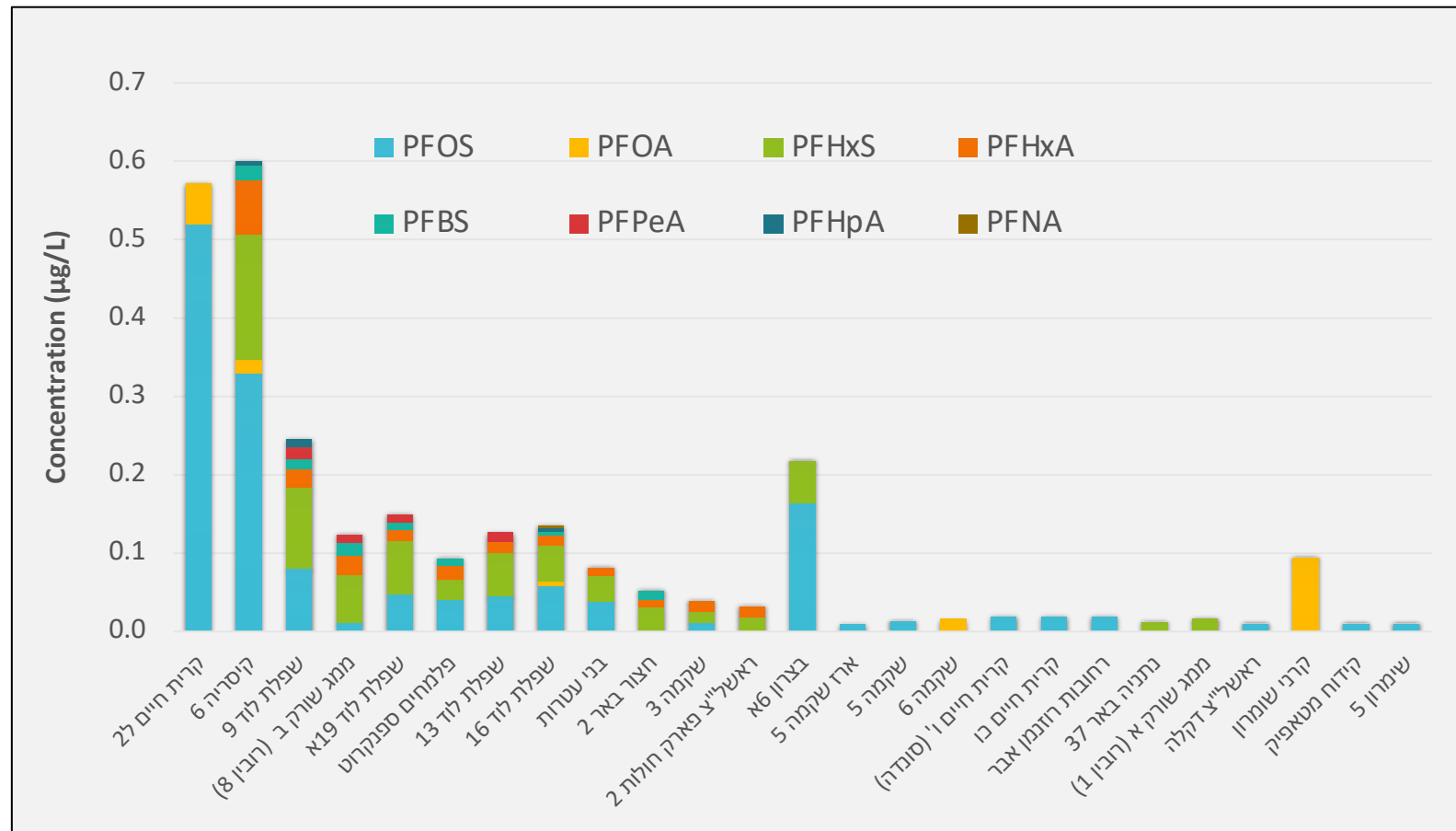
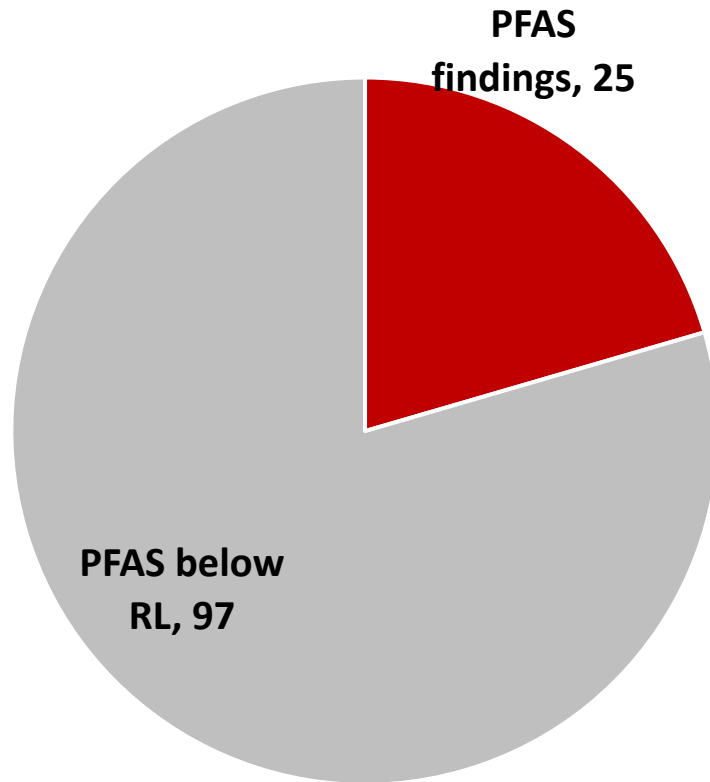
- Policy to adopt regulatory requirements implemented in other countries (not advisory levels or state specific levels)
- Looking at global regulatory landscape, Health Canada Standard for PFOA and PFOS was chosen

|                             |      |                             |
|-----------------------------|------|-----------------------------|
| Health Canada<br><br>(2018) | PFOA | 0.6 µg/L                    |
|                             | PFOS | 0.2 µg/L (sum of ratios< 1) |

| Compound | TDI              | Endpoint      | Percent consumption water of total intake | Water intake              |
|----------|------------------|---------------|-------------------------------------------|---------------------------|
| PFOA     | 0.0019 µg/kg/day | Liver effects | 20%                                       | 1.5 L/ day<br>70 kg adult |
| PFOS     | 0.006 µg/kg/day  | Liver effects | 20%                                       | 1.5 L/ day<br>70 kg adult |

# Results of the 1<sup>st</sup> Survey in Drinking Water

One well not suitable for human consumption – based on Health Canada Standard (0.6 PFOS, 0.2 PFOA, sum of ratios <1)



# Rationale for Adoption of Stricter Guideline Values (2023)

*Change in Approach at US EPA*

|                              | 2016                                                        | 2022                                                            |
|------------------------------|-------------------------------------------------------------|-----------------------------------------------------------------|
| Critical effect (RfD)        | 0.00002 mg/kg/day<br><br>(developmental effects in animals) | 0.0000000015 mg/kg/day<br><br>(immune system effects in humans) |
| Intake                       | 0.054 L/kg lactating women                                  | 0.07 L/kg children                                              |
| Relative source contribution | 20%                                                         | 20%                                                             |

$$\begin{aligned} \text{Lifetime iHA} &= \left( \frac{0.0000000079 \frac{\text{mg}}{\text{kg bw-day}}}{0.0701 \frac{\text{L}}{\text{kg bw-day}}} \right) * 0.2 \\ \text{Lifetime iHA} &= 0.00000002 \frac{\text{mg}}{\text{L}} \\ &= 0.00002 \frac{\mu\text{g}}{\text{L}} \\ &= 0.02 \frac{\text{ng}}{\text{L}} \end{aligned}$$

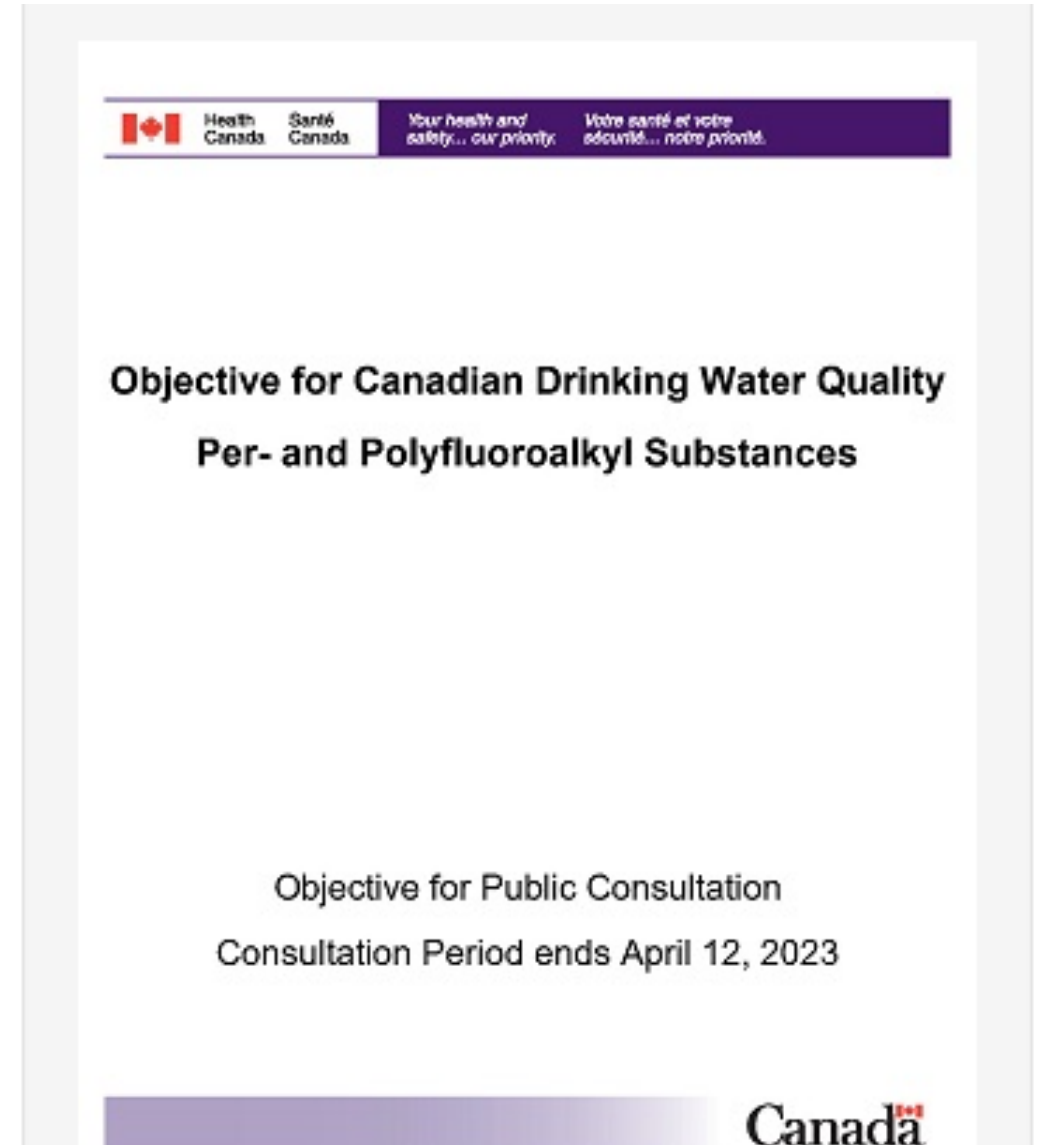
# Rationale for Adoption of Stricter Guideline Values (2023)

World Health Organization (draft) :

...reduced antibody response following vaccination has been considered by some agencies as the most robust end point based on epidemiological data, it is unclear whether this correlation results in increased rates of infection

**Pragmatic solution is therefore proposed for the derivation of provisional guideline values (pGVs).**

Individual pGVs of 0.1 µg/L for PFOS and PFOA are proposed based on the following considerations....these values correspond to greater than 90% removal achievability with high pressure membrane filtration (NF and RO), activated carbon adsorption or ion-exchange

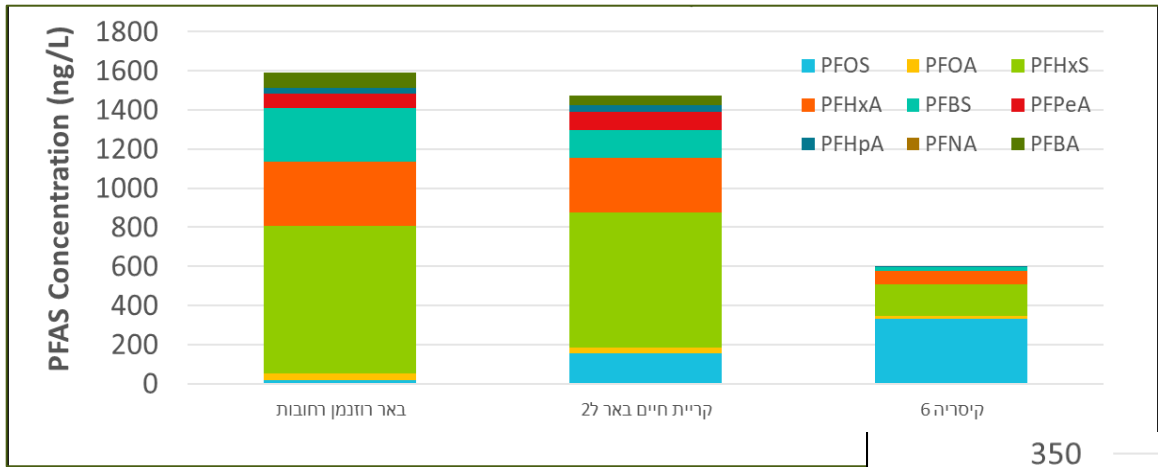


# Rationale for Adoption of Stricter Guideline Values (2023)

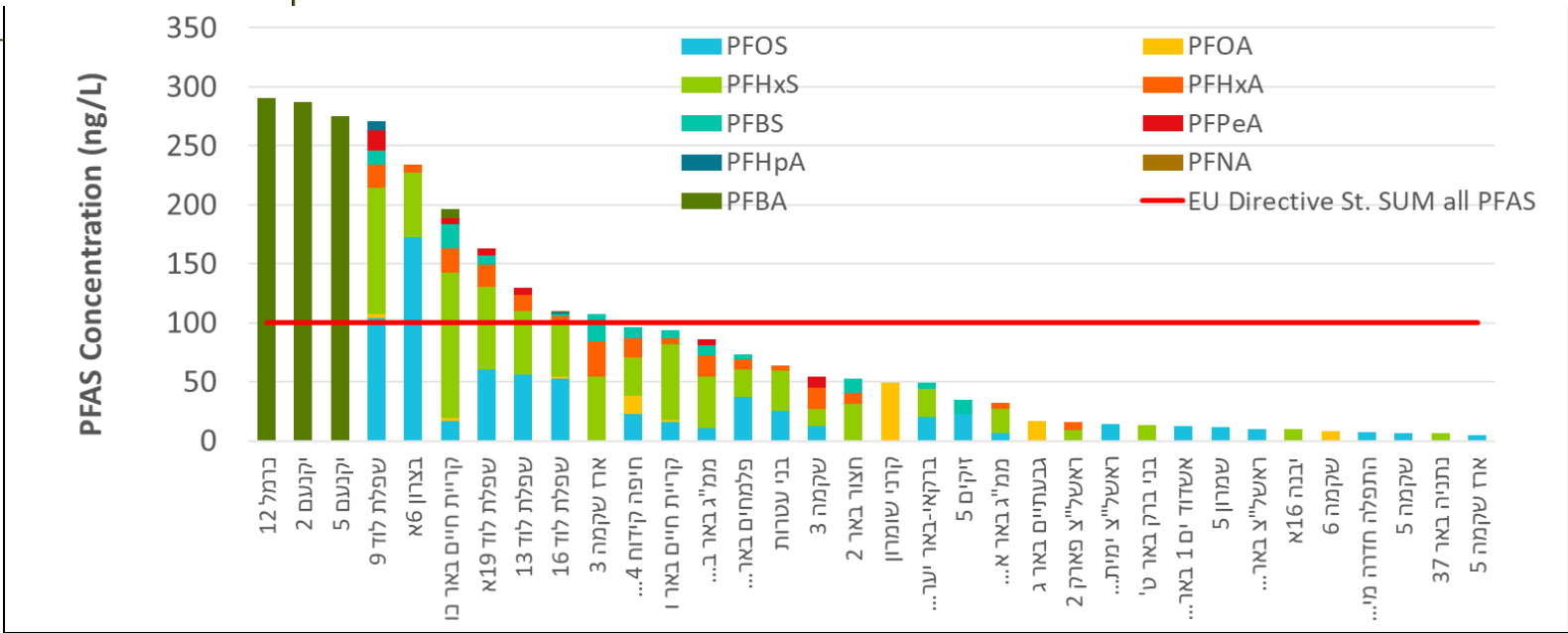
- In light of further reductions in EPA advisory level, and evidence of critical effects occurring at concentrations lower than previous RfDs, Health Canada's standards no longer up to date
- Treatment technologies widely available and in use
- Grouping approach is appropriate for PFAS because of common chemical, environmental, toxicological properties (as opposed to pesticides)
- **Recommendation is to adopt EU standard of 0.1 µg/L sum of PFAS (January 2026)**

# Decision Implications and Results of the 2<sup>nd</sup> Survey in Drinking Water

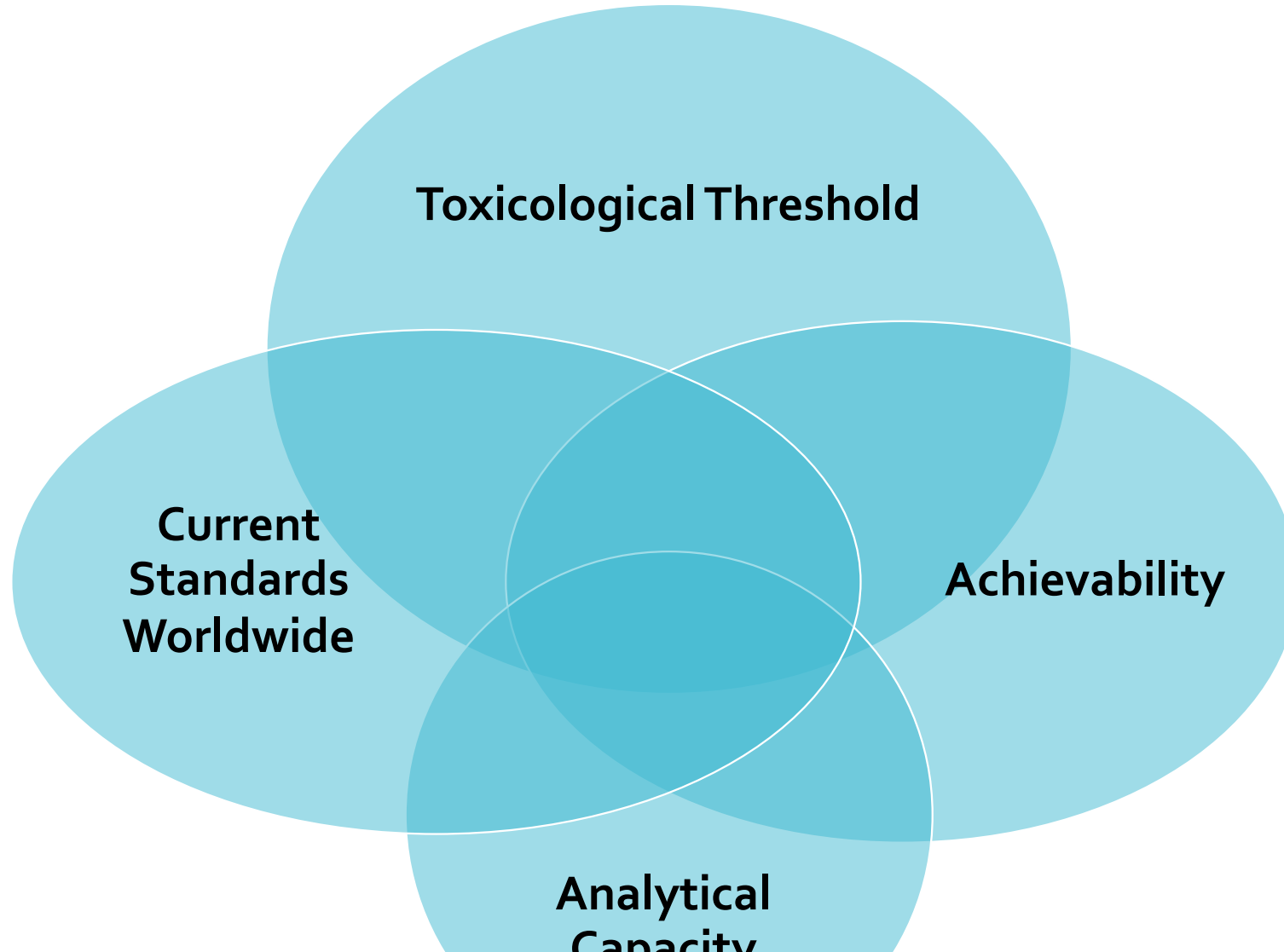
Water Sources – Unsuitable for Drinking



Results compared to EU Standard



# Considerations in Setting Guideline Value – Contaminants in Drinking Water



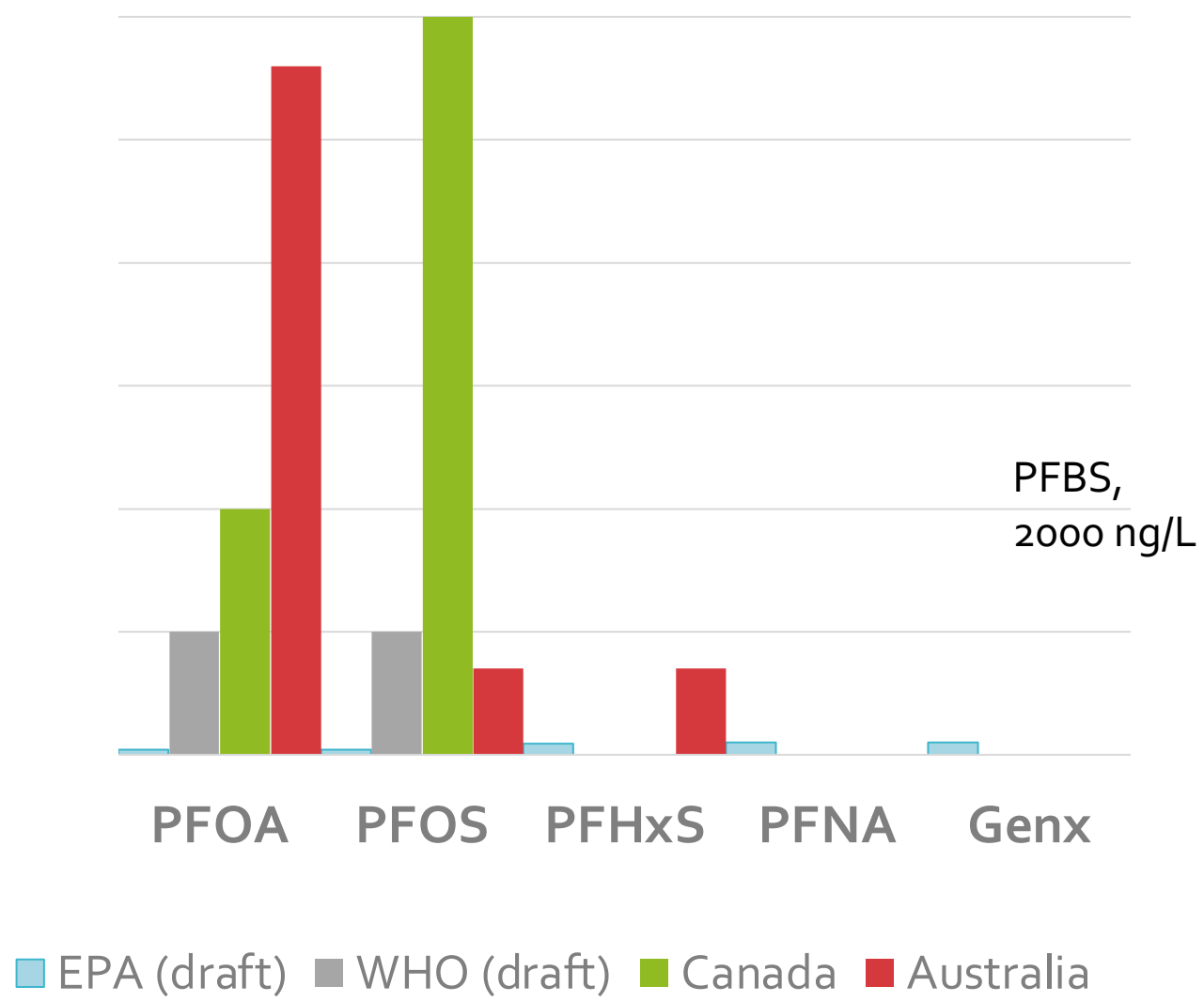
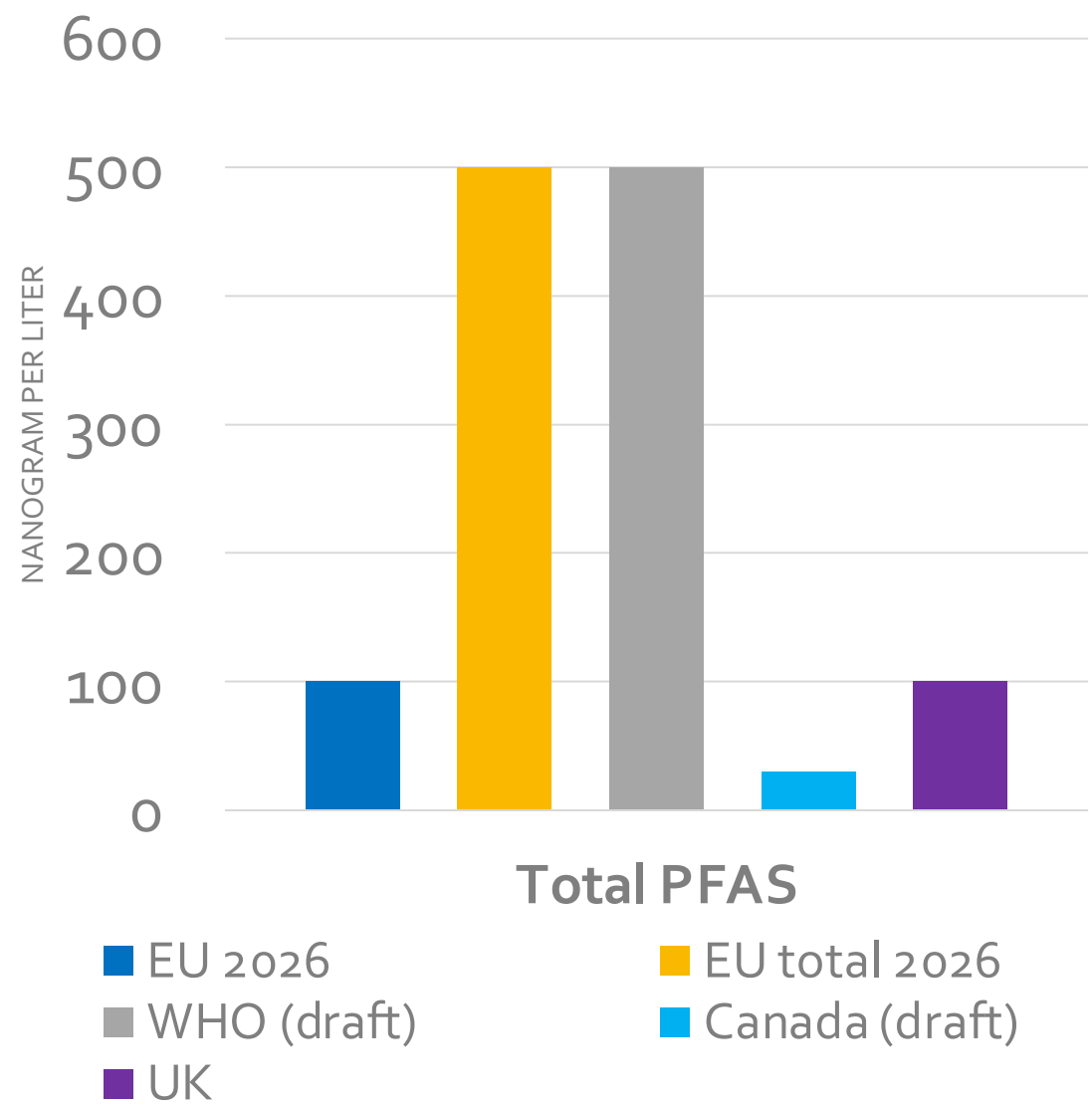
# Looking at Drinking Water Guidelines in Broader Perspective – Regulatory Requirements

Guideline value  
- can water be  
supplied to  
public ?

What are  
monitoring  
requirements  
(geographic  
representation,  
frequency) ?

Voluntary steps  
to reduce PFAS  
in supplied  
water  
  
(dilution,  
supply  
flexibility)

# Is Grouping Approach Justified ?



# Is Grouping Approach Justified ? Example of PFBA

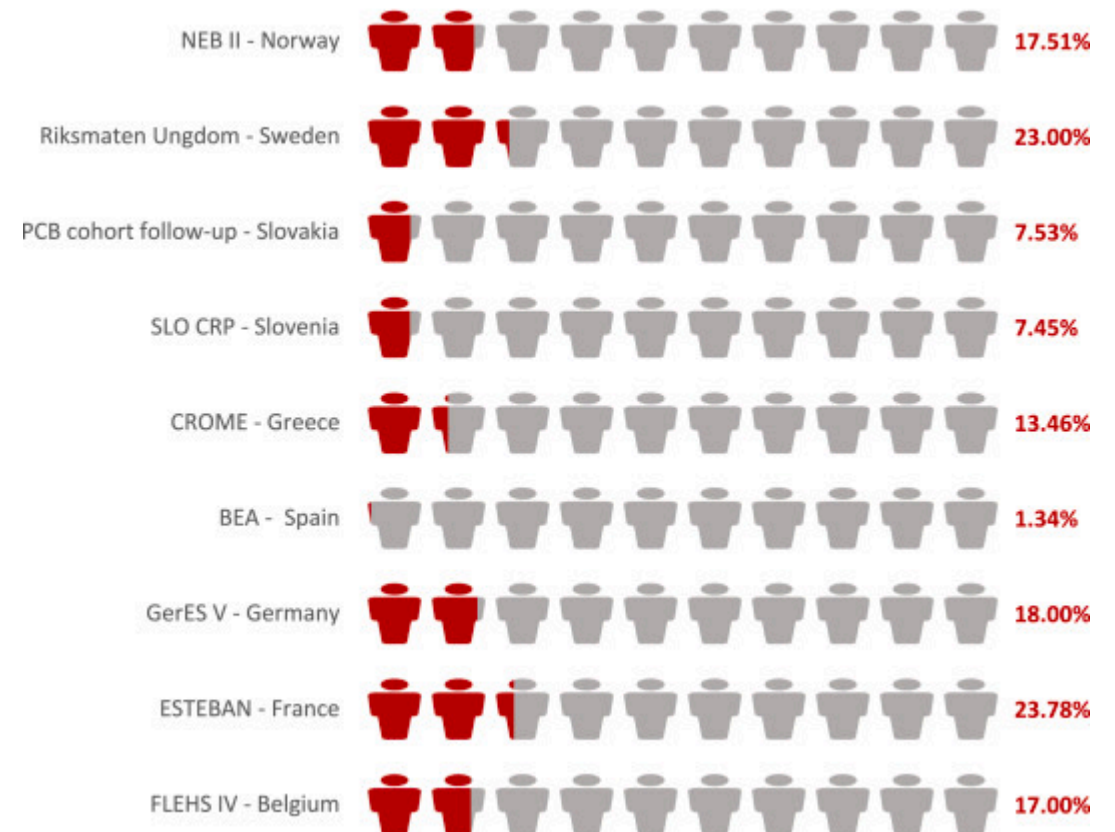
Table 6-7: Overview of Epidemiology and Toxicology Evidence of PFAS Effects on Health Outcomes

| PFAS              | Evidence Type | Health Outcomes |      |      |                                                       |               |                                     |                                               |                                                                           |                            |                                                            |                                         |                                                                           |                                      |                                                     |                  | Data Source(s)   | Notes |                                               |                                               |
|-------------------|---------------|-----------------|------|------|-------------------------------------------------------|---------------|-------------------------------------|-----------------------------------------------|---------------------------------------------------------------------------|----------------------------|------------------------------------------------------------|-----------------------------------------|---------------------------------------------------------------------------|--------------------------------------|-----------------------------------------------------|------------------|------------------|-------|-----------------------------------------------|-----------------------------------------------|
|                   |               | Lipids          |      |      | CVD                                                   | Developmental | Hepatic                             | Immune                                        | Endocrine                                                                 | Metabolic                  | Renal                                                      | Reproductive                            | Musculoskeletal                                                           | Hematologic                          | Other non-cancer                                    | Cancer           |                  |       |                                               |                                               |
|                   |               | TC              | HDLc | LDLc | BP <sup>a</sup> (human)/Heart histopathology (animal) | Birth weight  | SGA, non-birth weight developmental | ALT (human) Organ weight, cell death (animal) | AbR <sup>a</sup> (tetanus, diphtheria) (human) Various endpoints (animal) | Thyroid hormone disruption | Leptin, body weight (human)/Body fat, body weight (animal) | Uric acid (human) Organ weight (animal) | Gestational hypertension/pre-eclampsia (human) Various endpoints (animal) | Osteoarthritis, bone mineral density | Vitamin D levels, hemoglobin levels, albumin levels | Other non-cancer | RCC <sup>a</sup> |       | Testicular                                    | Other                                         |
| PFBA <sup>a</sup> | Epi           | •               | •    | •    | •                                                     | •             | •                                   | •                                             | •                                                                         |                            | •                                                          | •                                       |                                                                           |                                      |                                                     |                  |                  |       | IRIS Assessment 2022; ATSDR 2021; NASEM, 2022 | No associations in humans                     |
|                   | Tox           | •               |      |      | •                                                     |               | X                                   | X                                             | •                                                                         | X                          | •                                                          | •                                       | •                                                                         | •                                    | •                                                   |                  |                  |       | IRIS Assessment 2022; ATSDR 2021              | Other non-cancer: ocular, respiratory (ATSDR) |
| PFNA <sup>b</sup> | Epi           | X               | •    | X    | •                                                     | X             | •                                   | •                                             | •                                                                         | •                          | •                                                          | •                                       | •                                                                         | •                                    |                                                     | •                |                  |       | ATSDR 2021; NASEM, 2022                       | Other non-cancer: respiratory effects         |
|                   | Tox           | •               | •    | •    | •                                                     | •             | •                                   | •                                             | X                                                                         |                            | •                                                          | •                                       |                                                                           | •                                    |                                                     |                  |                  |       | ATSDR 2021                                    | Other non-cancer: general toxicity            |
| PFDA <sup>b</sup> | Epi           | X               | •    | X    | •                                                     | •             | X                                   | •                                             | X                                                                         | •                          | •                                                          | •                                       | •                                                                         | •                                    |                                                     | •                |                  |       | ATSDR 2021; NASEM, 2022                       |                                               |
|                   | Tox           | •               | •    | •    | •                                                     | X             | X                                   | X                                             | X                                                                         | •                          | •                                                          | •                                       |                                                                           | •                                    | •                                                   | •                | •                | •     | ATSDR 2021                                    | Other non-cancer: general toxicity            |

# Comments on Threshold Values and Interpreting Human Biomonitoring Data for PFAS (HBM4EU)

- **Sum value approach** for PFOA, PFNA, PFHxS and PFOS (hereafter called 'EFSA-4')
- Based on assumption that the EFSA-4 are equipotent for immunotoxic effects in humans, no correction for potential differences in toxic potencies
- EFSA-4' - modelled serum level of 6.9 ng 'EFSA-4' PFASs/mL in mothers at the age of 35, protection of children from reaching a body burden of 17.5 ng 'EFSA-4' PFASs/mL via breastfeeding.

Share of European teenagers with combined exposure levels to PFOA + PFNA + PFHxS + PFOS exceeding health-based guidance value of EFSA (6.9 µg/L)

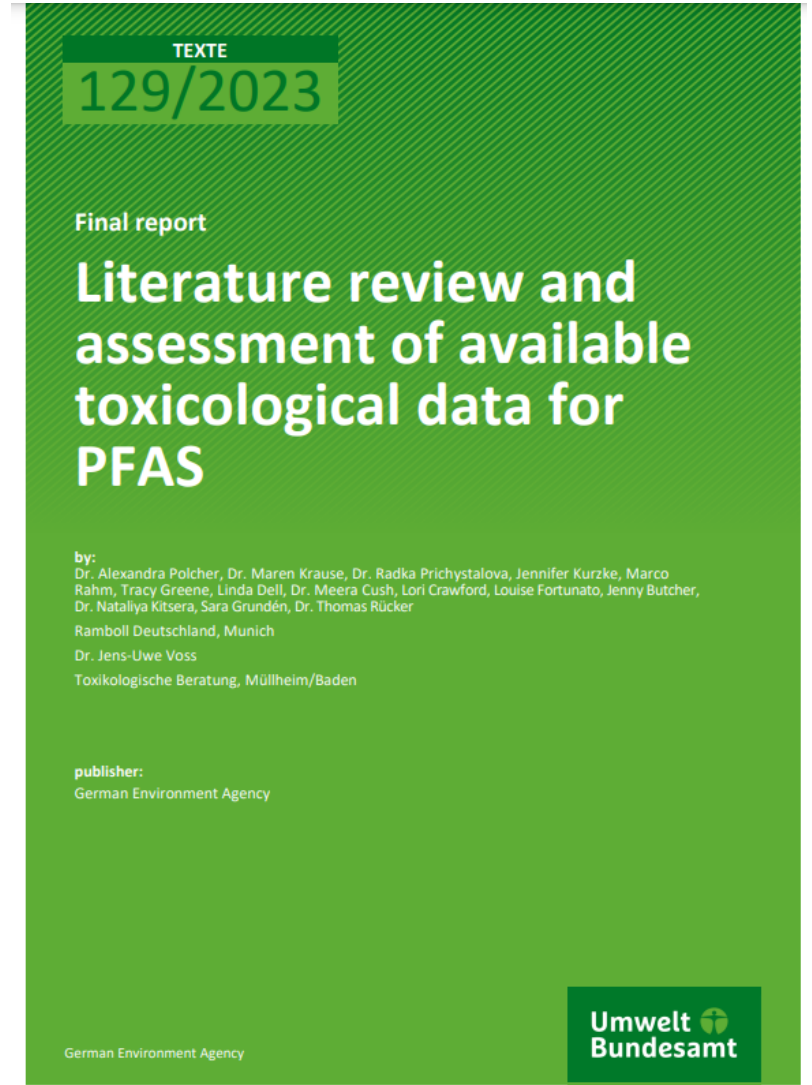


Source: Bil et al IJHEH 2023

# Interpreting Human Biomonitoring Data for PFAS: Sum Value Approach

UBA report, Sept 2023

- Evaluation of recent toxicological findings for 4 PFAS (PFOA, PFNA, PFHxS, PFOS) that might change the assessment by EFSA in 2020
- Epidemiological studies of PFOA that could potentially change the TWI developed by EFSA include studies which (1) reported a dose-response association for an adverse effect and (2) the adverse effect was observed at PFOA concentrations below approximately 30 ng/ml
- Further modelling similar to the EFSA approach would be necessary to check how these study results might influence the TWI developed by EFSA



# Summary and Conclusions

- Supply from 3 drinking water wells has been disrupted due to PFAS contamination; another 10 wells will require treatment by 2026
- Quarterly or annual monitoring required for tens of wells, depending on measured PFAS concentrations
- Work on HBM Guideline Value for PFAS for interpreting human biomonitoring data underway as part of PARC (Partnership for Chemical Risk Assessment)