PFAS thresholds in European regulation: inconsistencies and ways for improvement

Bouhoulle Elodie, Reinikainen Jussi, Sorvari Jaana

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Partnership FOR THE Assessment OF Risks FROM Chemicals

Wallonie environnement SPW

Cofinancé par l'Union européenne

European Partnership for the Assessment of Risks from Chemicals

Horizon Europe project, 7 years (2022 – 2029)

Official start: 1st May 2022

196 scientific partners + ECHA EUROPEAN CHEMICALS AGENCY + efsa + European Environment Agency

Budget (total): 400 M€

Global objective : Contribute to the EU's zero pollution ambition

by developping a new generation of risk assessment for chemicals

Background, regulatory context and aim of the study

- Chemicals Strategy for Sustainability (OS-OA approach)
- In the EU, chemical risks are managed by numerous regulatory frameworks. Regulatory silos.
- Our study identifies and evaluates similarities and inconsistencies, gaps in certain EU regulatory frameworks, focusing on their associated decision thresholds, and then proposes ways for improvement

Methodology and scope

- Focus on recent PFAS threshold values designed for protecting human health
  - Current and proposed (draft) Environmental Quality Standards: **EQS** - *Priority Substances Directive 2008/105/EC*
  - Drinking Water Quality standards: **DWQS** - *Directive (EU) 2020/2184*
  - Maximum Levels of contaminants in foodstuffs: **ML** - *Commission Regulation (EU) 2022/2388, amending Regulation (EC) No 1881/2006*
  - Tolerable Daily/Weekly Intake: **TDI**/TWI - *European Food Safety Authority (EFSA), 2020*
- Review of their scientific foundation
- Comparative calculations based on classic risk assessment equations and EU food/water consumption data

Methodology and scope

- Classic health risk assessment equations
  - Acceptable daily oral exposure to ΣPFAS4 : $ADD_{\sum PFAS4} = TV \times IR_{food/water} / BW\ (ng/kg_{BW}/d)$
  - Hazard quotient : $HQ = ADD_{\sum PFAS4} / TDI\ (-)$
  - Maximum safe daily amounts : $IR_{max,\ food} = TDI \times BW / \mathbf{ML}\ (g/d)$

    $IR_{max,\ water} = TDI \times 10^{-3} \times BW / \mathbf{DWQS}\ (L/d)$
- Methodology corresponding to EQSs derivation
  - Continuous daily consumption via food and water, and 100% bioavailability
  - European food and water consumption rates (IR) from EFSA Foodex database
  - Allocation factors excluded

Directive (EU) 2020/2184

Drinking water

DWQS
100-500 ng/L

Commission Regulation (EU) 2022/2388

Foodstuffs

MLs = 0.2- 45 µg/kg

EFSA, 2020

Tolerable intake

∑PFAS4

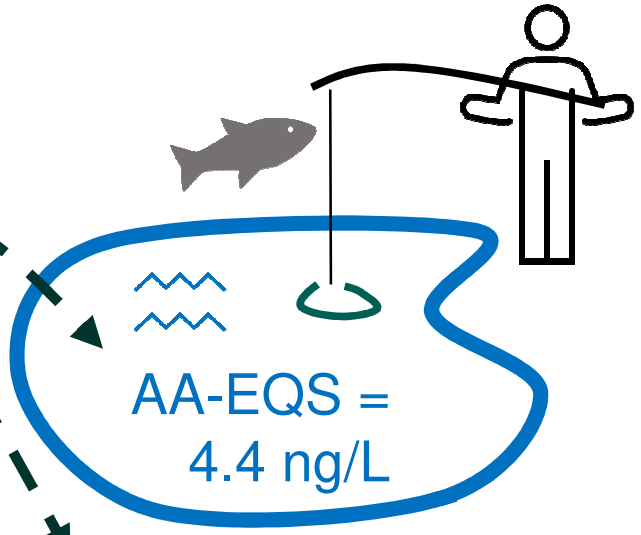
4.4 ng/kg$_{bw}$ /week

(PFOS, PFOA, PFNA, PFHxS)

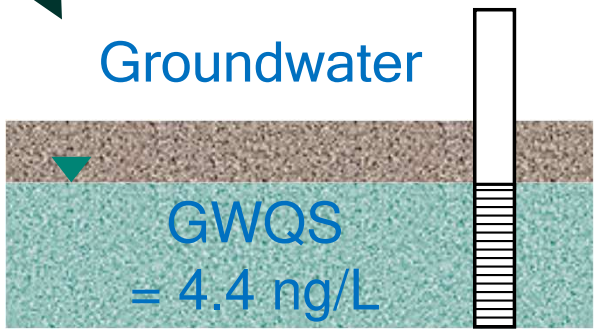
Priority Substances Directive 2008/105/EC

Surface water - fish

0.077 µg/kg = EQS$_{biota}$



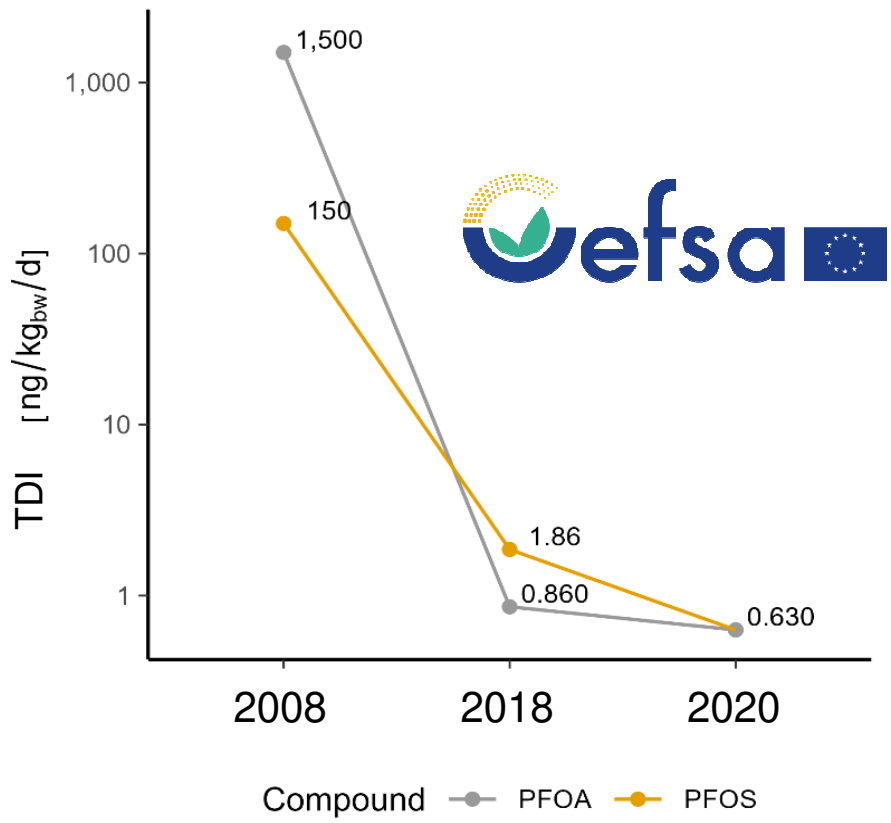
Groundwater



Foundation of the thresholds – EFSA TDI

- TDI (TWI): estimated amount of non intentionally added substance in food/drinking water that can be consumed daily (weekly) over a lifetime without causing an appreciable health risk.
- New **TWI = 4,4 ng/kg$_{BW}$ per week** = 0,63 ng/kg$_{BW}$-d

  for the sum of 4 PFAS (PFOA, PFOS, PFNA, PFHxS)
- Based on immunosuppression in a human observational study
- Not legally binding threshold



Foundation of the thresholds – current and draft EQS

For priority substances under the Water Framework Directive
(Directive 2013/39/EU amending Directive 2008/105/EC on the EQSs)

Current EQS for PFOS

- $EQS_{biota} = \frac{150 * 70 * 0,1}{10^6 * 0,115} = 9,1.10^{-3}$ mg/kg
  - **TDI_{PFOS} = 150 ng/kg_{BW}/d (EFSA, 2008)**
  - Daily fish consumption (adult consumer) = 115 g/d
  - BW = 70 kg
  - Resources allocation factor = **10%**
- $AA\text{-}EQS_{water} = \frac{EQS_{biota}}{2800 \times 5} = 6,5.10^{-7}$ mg/L = 0,65 ng/L
  - BCF_{PFOS} = 2800 L/kg
  - BMF_{PFOS} = 5 kg/kg

Proposed EQS for 24 PFAS

- $EQS_{biota} = \frac{0,63 * 70 * 0,2}{10^6 * 0,115} = 0,077.10^{-3}$ $mg_{PFOA\ eq}$/kg
  - **$TDI_{\Sigma 4PFAS}$ = 0,63 ng/kg_{BW}/d (EFSA, 2020)**
  - BW = 70 kg
  - Resources allocation factor = **20%**
  - Daily fish consumption (adult consumer) = 115 g/d
- $AA\text{-}EQS_{water} = \frac{0,63 * 70 * 0,2}{2} = 4,4$ $ng_{PFOA\ eq}$/L
  - Based on drinking water consumption: **2L/d**
- In PFOA equivalents, applying the RPF (Bil et al., 2021)
- AA-EQS also proposed as GWQS

Foundation of the thresholds – Drinking water quality directive

- EU/2020/2184 Directive
- Aims to safeguard human health and regulates the quality of all water intended for human consumption
  - For the sum of 20 PFAS → $DWQS_{\Sigma 20PFAS}$ = 100 ng/L
  - For Total PFAS → $DWQS_{PFAS,total}$ = 500 ng/L
- No publicly available documentation on the derivation of the DWQS

Foundation of the thresholds – Maximum levels in food

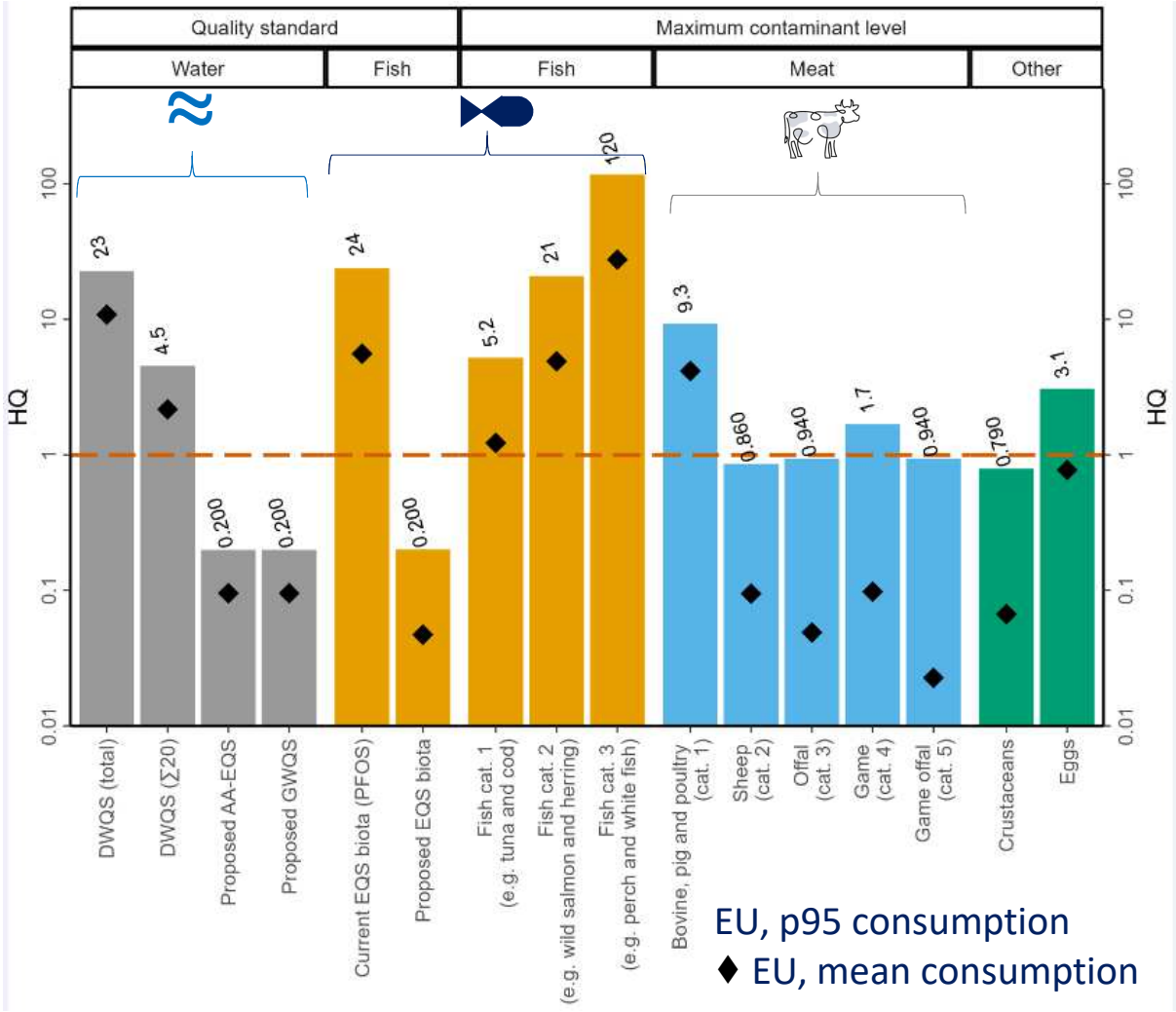
- Regulation (EU) 2022/2388 Amending Regulation (EC) No 1881/2006 on setting maximum levels for certain contaminants in foodstuffs
- MLs established for PFOS, PFOA, PFNA, PFHxS and their sum
- No easily accessible information specifically on the foundation of those MLs
- ALARA principle
- Generally set around the 90th percentile of "background concentrations" in foodstuffs

Foodstuffs	Maximum Levels µg/kg wet weight				
	PFOS	PFOA	PFNA	PFHxS	Σ 4 PFAS
Eggs	1	0,3	0,7	0,3	1,7
Fish, cat. 1 (eg. tuna)	2	0,2	0,5	0,2	2
Fish, cat.2 (eg. wild salmon)	7	1	2,5	0,2	8
Fish, cat.3 (eg. perch)	35	8,0	8,0	1,5	45
Crustaceans	3	0,7	1	1,5	5
Meat of bovine, pig and poultry	0,3	0,8	0,2	0,20	1,3
Meat of sheep	1	0,2	0,2	0,2	1,6
Offal	6	0,7	0,4	0,5	8
Meat of game animals	5	3,5	1,5	0,6	9
Offal of game animals	50	25	45	3	50

Comparison of health risks/protection

The level of health protection associated with the different PFAS thresholds varies dramatically.

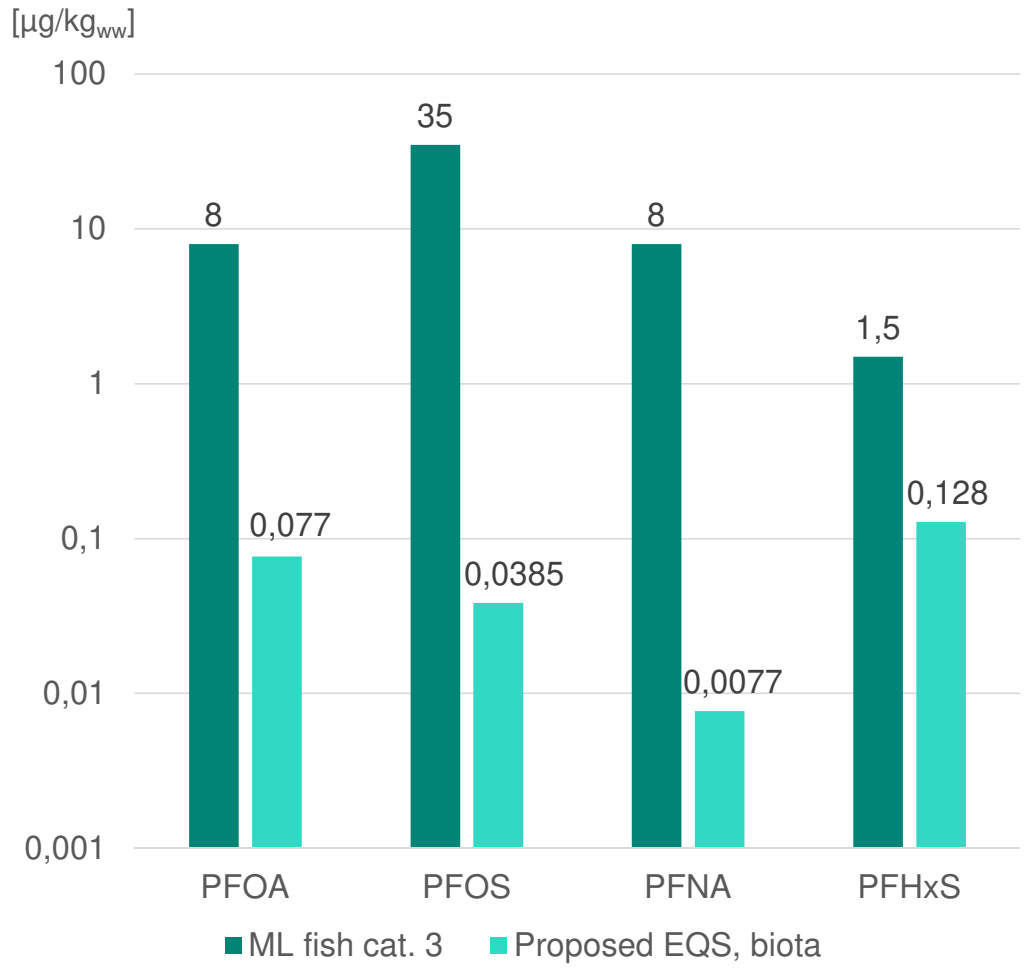
- When HQ < 1 : no significant risk of adverse health effect is expected



Health risk estimates (as HQ) for oral exposure to ΣPFAS4 at concentrations corresponding to the regulatory thresholds

Comparison of health risks/protection

- assuming each would be the only detectable PFAS in fish
- applying the RPF approach for the proposed EQSs



Variability of PFAS thresholds in fish

Comparison of health risks/protection

RPFs by Bil et al. 2021

Aim : Facilitate the RA of mixture exposure.

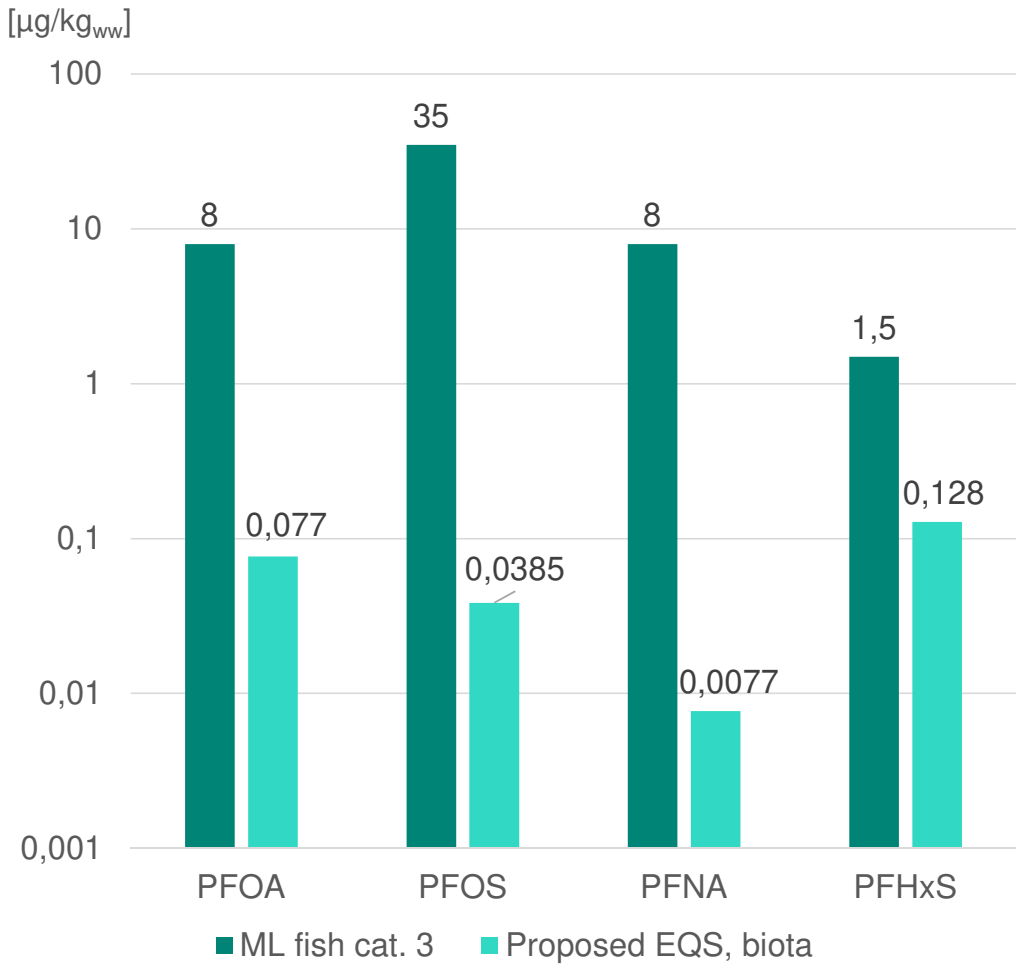
Liver endpoints established for 16 PFAS in male rats exposed by oral route during comparable exposure duration (42-90 d).

Risk assessment screening tool

Used to derive draft EQSs for ΣPFAS24

Address legagy PFAS

Need further research to validate the selected endpoint and the kinetics for the other PFAS.



Variability of PFAS thresholds in fish

Maximum allowable ingestion rate of certain foodstuffs

The theoretical safe daily consumption rates are notably lower than the actual EU consumption.

Without considering additional dietary sources or background exposure.

Foodstuffs	IR max food (g/d)	EU p95 IR (g/d)	EU mean IR (g/d)	Max number of servings **per month** (*egg 55g ; fish/meat servings 150 g*)
Eggs	25,9	**80**	20	14,6
Fish, cat.1 (eg. tuna)	22,1	**115**	**27**	4,6
Fish, cat.2 (eg. wild salmon)	5,5	**115**	**27**	1,1
Fish, cat.3 (eg. perch)	0,98	**115**	**27**	0,2 (**2,4 per year**)
Crustaceans	8,8	7	0,59	1,8
Meat, cat.1 (bovine, pig, poultry)	33,9	**316**	**141**	7
Meat, cat.2 (sheep)	27,6	24	2,6	5,7
Meat, cat. 3 (offal)	5,5	5,2	0,27	1,1
Meat, cat. 4 (game)	4,9	**8,3**	0,48	1
Meat, cat. 5 (game offal)	0,88	0,83	0,02	0,2 (2,2 per year)
Drinking water	IR max water (L/d)	Intake, EU p95 (L/d)	Intake, EU mean (L/d)	Max safe consumption of water glasses (*20 cL*) **per day**
Drinking water, sum PFAS	0,44	**2**	**0,956**	**2,2**
Drinking water, total PFAS	0,09	**2**	**0,956**	**0,4**

Discussion / conclusions

- The level of health protection embedded in PFAS thresholds varies significantly → Improve coherence
- The foundation of the thresholds are not consistent, and not transparent for some of the thresholds → Improve transparency
- The setting of regulatory thresholds is a risk management decison at the sience-policy interface → Call for an open dialogue between regulators and scientists

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Full length article

Inconsistencies in the EU regulatory risk assessment of PFAS call for readjustment

Jussi Reinikainen [a,*], Elodie Bouhoulle [b], Jaana Sorvari [a]

Recommendations / Suggestions:

- Include environmentally relevant PFAS in regulatory thresholds: commonly used precursors and substitutes of PFAAs (such as FTOHs and PFECAs, FASAs…).
- Adaptable thresholds function of the chain length, functionality, etc. could be established.
- Research is needed to improve the understanding of PFAS toxicokinetics.
- Propose separated MLs for aquaculture and wild fish.
- Consider Risk-Benefit Analysis and establish (national/regional/local) dietary recommendations on food consumption (eg. fish).

Contact

BOUHOULLE Elodie

Rue du Chéra 200 – 4000 Liège

el.bouhoulle@issep.be

04/229.83.56

Visit issep.be