Policy challenges related to diffuse pollution – case PFAS

Jussi Reinikainen, Finnish Environment Institute, Senior adviser

KUVA: KAI WIDELL / SYKE

Policy challenges related to diffuse pollution – case PFAS

Jussi Reinikainen

ENSOr
March 14, 2024 Brussels

Suomen ympäristökeskus
Finlands miljöcentral
Finnish Environment Institute

Content

- **EU regulation of environmental PFAS as case example - study on PFAS regulatory thresholds**
  - Tolerable intake
  - Surface water (and groundwater)
  - Drinking Water
  - Foodstuffs
- **Implications to managing soil contamination**
- **Conclusions**

Our study

Comparative analysis of EU regulatory thresholds for the management of PFAS

- **Objective**
  - Demonstrate potential weaknesses and inconsistencies in current procedures on regulatory risk assessment of PFAS and provide some outlooks and proposals for their development and/or application

- **Focus on recent PFAS threshold values designed for protecting human health**
  - Tolerable Daily/Weekly Intake (TDI/TWI) - European Food Safety Authority (EFSA)
  - 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 in foodstuffs (ML) - Commission Regulation (EU) 2022/2388, amending Regulation (EC) No 1881/2006

- **Study is part of the European Partnership for the Assessment of Risks from Chemicals (PARC)**
  - Co-funded by the Horizon Europe research and innovation framework programme

Co-funded by the European Union

Suomen ympäristökeskus
Finlands miljöcentral
Finnish Environment Institute

Starting points

- **EU Zero Pollution Action Plan and Chemical Strategy**
  - Preventing and reducing pollution; vision for toxic-free environment
  - Phasing out per- and polyfluoroalkyl substances (PFAS) from the European market
  - Harmonising EU's regulatory chemical risk assessment by 'one-substance once-assessment' (OS-OA) approach
  - Emphasizing transparency and science-based approaches, promoting accessibility and usability of data

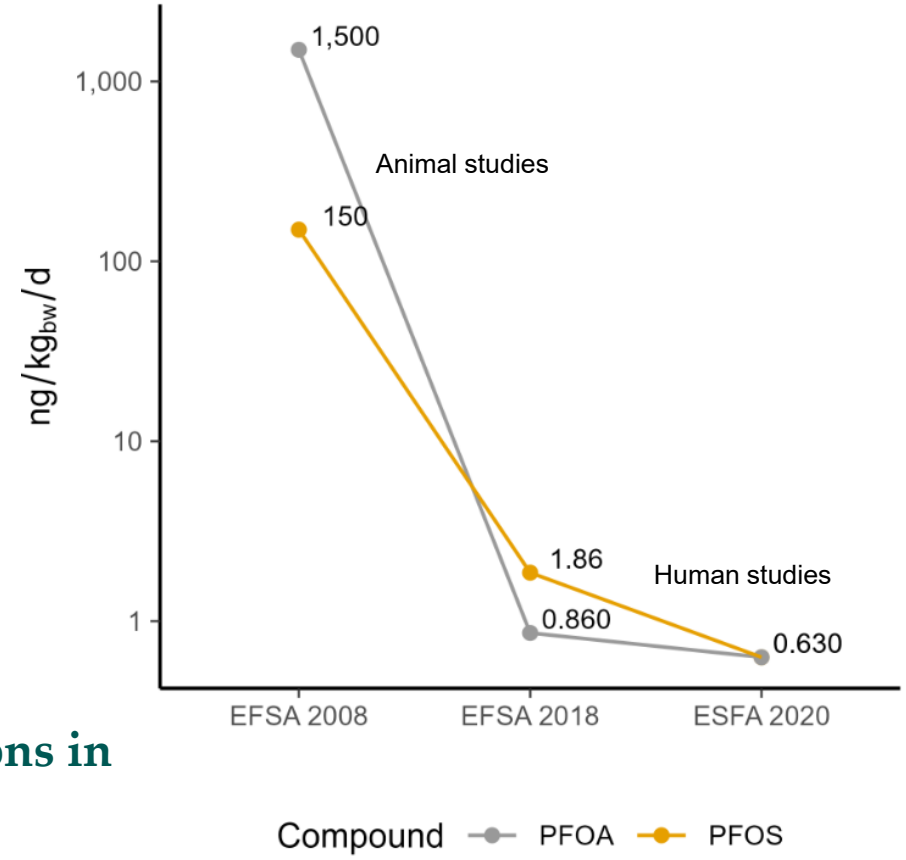
- **PFAS managed and regulated by specific policy instruments, e.g.**
  - REACH restrictions for long-chain PFAS since 2008; restriction proposal for all PFAS pending
  - Quality standards for PFAS in different environmental matrices; variable approaches to characterize risks
  - Proposal for soil monitoring and resilience; criteria for organic contaminants established by Member States (incl. PFAS)

- **PFAS is ubiquitous**
  - PFAS present in all the environmental matrices, as well as in humans and biota

- **Challenge…**
  - How to incorporate the above policy objectives and approaches into practice for PFAS in a coherent manner considering constantly evolving regulatory and scientific domains and the fact that PFAS is everywhere?

Tolerable Daily Intake

- **EFSA 2008 -> 2018 -> 2020**
  - 2020:TWI of 4.4 ng/kg_{bw}/week; ∑PFAS4 (PFOA, PFOS, PFHxS, PFNA)
  - BMDL10: decreased vaccine antibodies, 1-year old (17,5 ng serum /L)
  - PBKM: 12 months breastfeeding (TDI 0,63 ng/kg_{bw}/d derived for mother)



- **Association between PFAS in plasma and decreased vaccine antibodies found only for PFOA**
  - Influenza, tetanus, and diphtheria vaccines

- **No relationship between PFAS in plasma and number of infections in studied group of children**
  - Same conclusion in other studies
  - PFOA seems to impair immune function but evidence inconsistent/lacking whether there's causal link between exposure and risk of infectious diseases (at least low exposure levels)
  - E.g. Burgoon et al., 2023: safe PFOA intake to be 10-70 ng/kg_{bw}/day (based on animal studies)

- **Mean dietary exposure (∑PFAS4) in European population**
  - 0.86 - 4.87 ng/kg_{bw}/d > TDI of 0,63 ng/kg_{bw}/d

Environmental Quality Standards

- **Current EQSs for PFOS**
  - Health risk-based (TDI of 150 ng/kg_{bw}/d); fish intake
  - EQS biota: 9,1 µg/kg ww
  - AA-EQS (inland surface waters): 0,65 ng/L

$$EQS_{biota} = \frac{1.5 * 10^{-4}(mg/kg_{bw}/d) \times 70\ (kg_{bw}) \times 0{,}1}{0{,}115\ (kg/d)} = 9.1 * 10^{-3}(mg/kg\ ww)$$

$$AA - EQS_{water} = \frac{9.1 * 10^{-3}(mg/kg)}{2800\ (L/kg) \times 5(kg/kg)} = 6.5 * 10^{-7}\ mg/L = 0.65\ n\,g/L$$

- **Proposed EQSs for ∑PFAS24 (2022)**
  - Health risk-based (TWI of 4,4 ng ∑PFAS4/kg_{bw}/d)
  - AA-EQS (surface waters) and GWQS (groundwater): 4,4 ng/L (drinking water intake)
  - EQS biota: 0,077 µg/kg ww (fish intake)
  - RPF(Relative Potency Factor) approach: 24 PFAS expressed as PFOA toxicity equivalents (RPFs); RPF (PFOA) = 1
  - RPFs based on PFAS liver toxicity to rats; RPFs from 0,001 (PFBS) to 10 (PFNA); RPF = 2 (PFOS)
    - Example, measured concentrations in water: 1000 ng PFBS/L and 1 ng PFOS/L -> (1000 * 0,001 + 1 * 2) ng/L = 3 ng/L -> below EQS
    - Example, measured concentrations in water: 100 ng PFBS/L and 3 ng PFOS/L -> (100 * 0,001 + 3 * 2) ng/L = 6,1 ng/L -> exceeds EQS

- **Mean PFOS fish concentration in a large European data set**
  - 0,16 – 14,12 µg/kg ww (0,32 – 28,2 µg/kg ww when RPF approach applied)

Suomen ympäristökeskus
Finlands miljöcentral
Finnish Environment Institute

Drinking Water Quality Standards

- **DWQS for ∑PFAS20 = 100 ng/L**
  - Sum of 20 “common” PFAS, including short- and long-chain PFAAs
- **DWQS for total PFAS = 500 ng/L**
  - Sum of all PFAS
  - “PFAS total” will apply once technical guidelines are developed for its monitoring and Member States may then decide to use either one or both parameters
- **No publicly available information on DWQS derivation**
  - But EFSA TWI from 2018 or 2020 obviously not considered
- **DWQSs significantly higher than corresponding draft EQS (based on EFSA’s newest TWI)**

Maximum Levels in food

- **MLs for PFOS, PFOA, PFHxS, PFNA and their sum**
  - Including fish and seafood, eggs and meat (with different categories)
  - Food products with levels of contaminants higher than the MLs may not be sold or placed on the market
- **No publicly available information on ML derivation**
  - In general, MLs set based on occurrence data (around 90th percentile), following the principle 'strict but feasible'
  - The same holds true for PFAS; yet the regulation specifically indicates that EFSA's new TWI is embedded in the MLs…
- **MLs significantly higher than corresponding draft EQS biota (based on EFSA's newest TWI)**

Food	∑PFAS4 µg/kg ww	PFOS µg/kg ww	PFOA µg/kg ww	PFNA µg/kg ww	PFHxS µg/kg ww
Eggs	1.7	1	0,3	0,7	0,1
Fish, cat. 1	2	2	0,2	0,5	0,2
Fish, cat. 2	8	7	1	2,5	0,2
Fish, cat. 3	45	35	8	8	1,5
Crustaceans	5	3	0,7	1	1,5
Meat, cat.1	1,3	0,3	0,8	0,2	0,2
Meat, cat.2	1,6	1	0,2	0,2	0,2
Meat, cat. 3	8	6	0,7	0,4	0,5
Meat, cat. 4	9	5	3,5	1,5	0,6
Meat, cat. 5	50	50	25	45	3

Health risk calculations

- **To compare level of health protection embedded in each concentration threshold (∑PFAS4)**
  - $ADD_{\sum PFAS4} = TV \times IR_{food/water} / BW$
  - $HQ = ADD_{\sum PFAS4} / TDI_{\sum PFAS4}$
  - $HQ = ADD_{\sum PFAS4} / TDI_{\sum PFAS4}$
  - $IR_{\max\_EFSA,food} = TDI_{\sum PFAS4} \times BW / ML$
  - $IR_{\max\_EFSA,water} = TDI_{\sum PFAS4} \times BW / DWQS \times 10^{-3}$

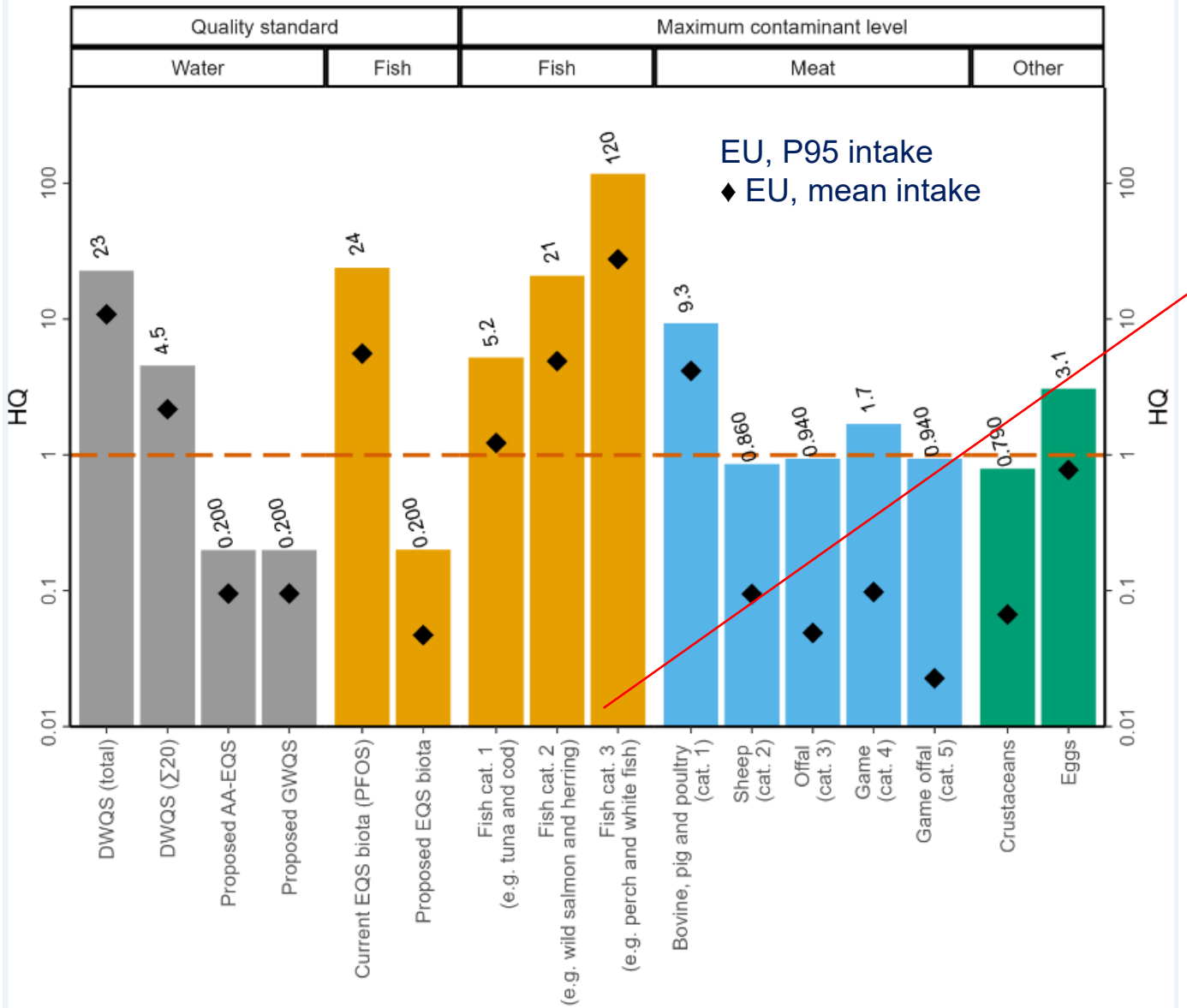
ADD = Average Daily Dose (ng/kg_{bw}/day)
TV = Threshold = ML or EQS biota (µg/kg) or AA-EQS or DWQS (µg/L)
IR = Ingestion Rate (kg/d; L/d)
BW = Body Weight, adult consumer (70 kg)
HQ = Hazard Quotient (-)

- **Methodology corresponding to derivation of current and proposed EQSs**
  - Continuous daily consumption of food or water and 100% bioavailability for the ingested PFAS in the gastrointestinal tract
  - Food and water consumption based on EFSA database; ingestion rates for food and water corresponding to EU default (p95)
  - Allocation factors used to derive the current and proposed EQSs excluded (from main calculations) to ensure coherence

Suomen ympäristökeskus
Finlands miljöcentral
Finnish Environment Institute

Comparison of health protection/risk

$HQ = ADD_{\sum PFAS4} / TDI_{\sum PFAS4, EFSA2020}$



Fish cat. 3 (e.g., perch):

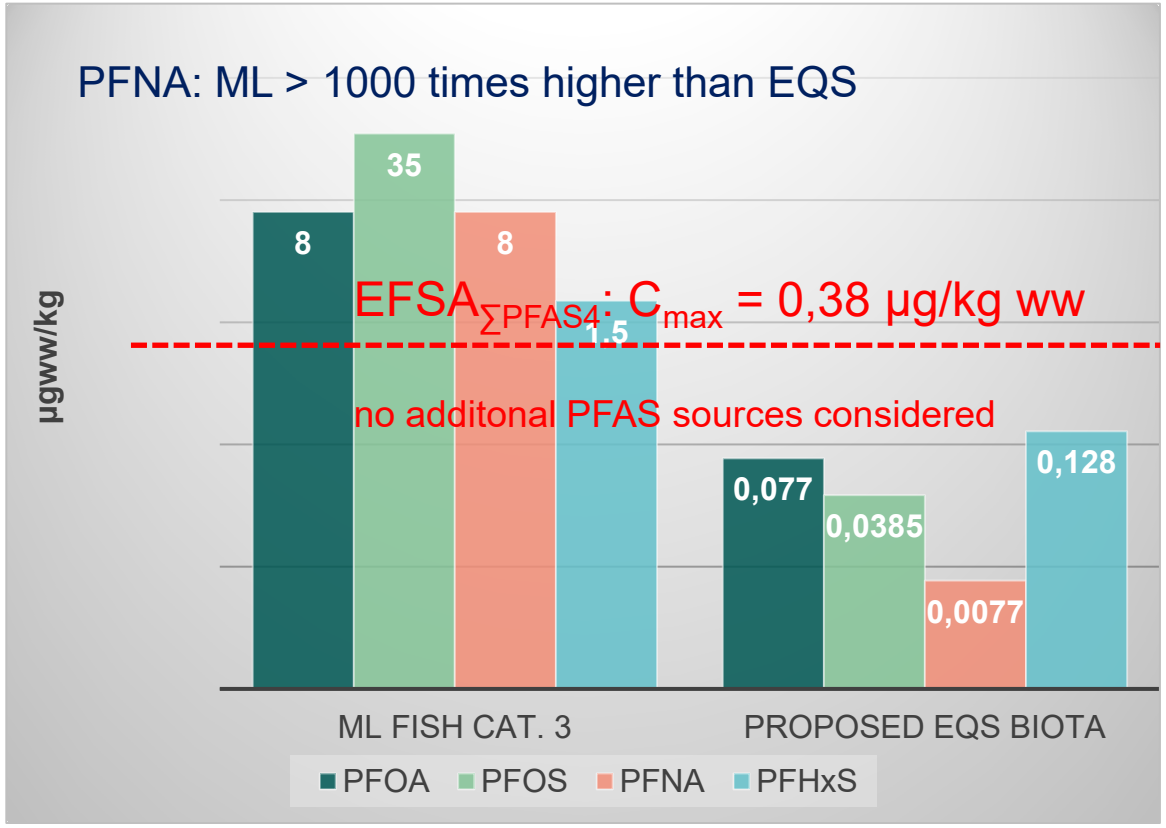
2 meals (150 g) per year

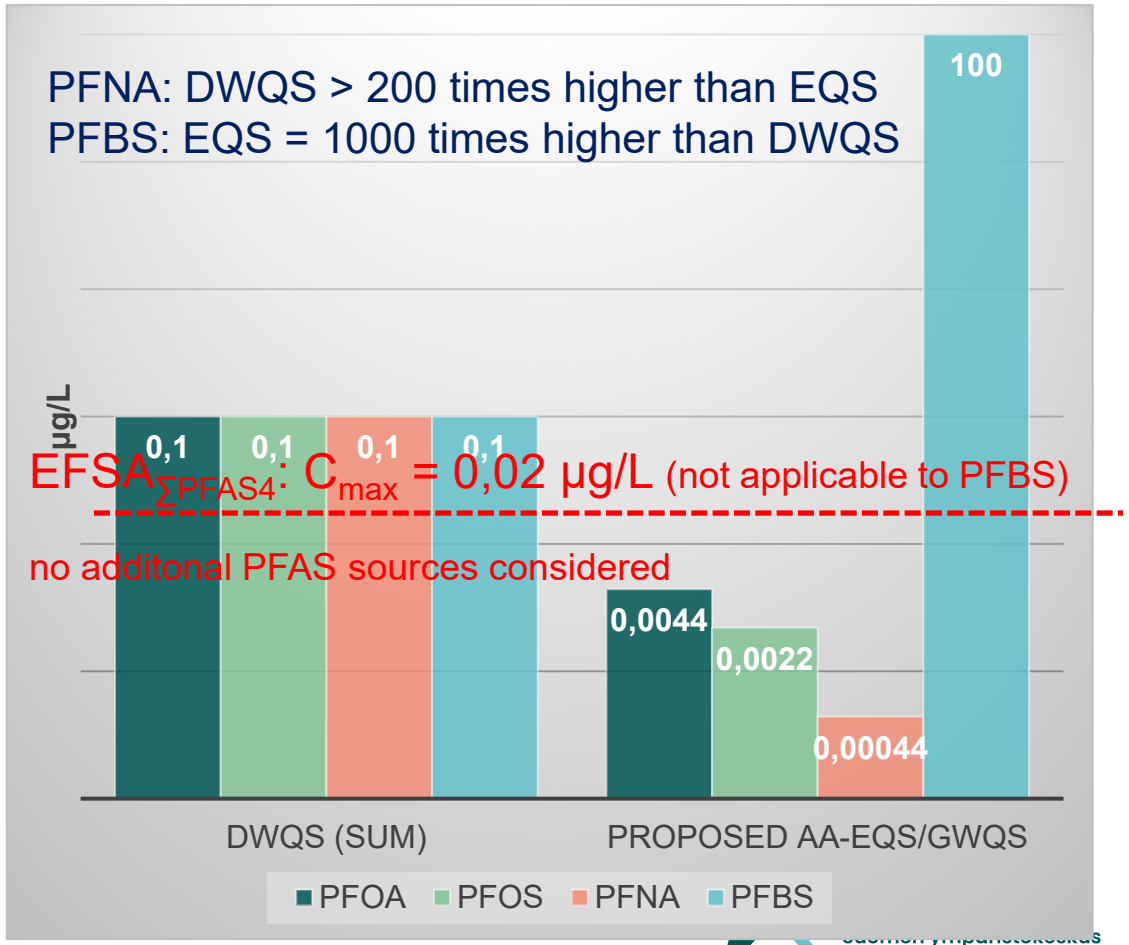
without considering additional dietary sources/background exposure

Suomen ympäristökeskus
Finlands miljöcentral
Finnish Environment Institute

Comparison of health protection/risk

Selected individual PFAS in fish and drinking water, applying RPFs for proposed EQSs (and assuming each PFAS would be the only compound in fish or drinking water)

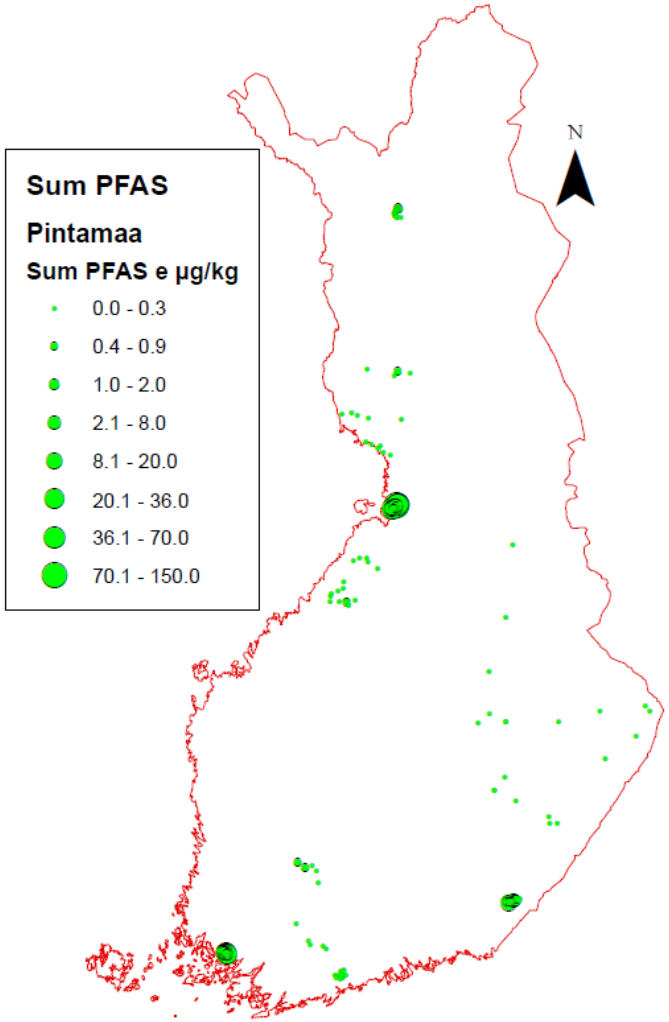




Finlands miljöcentral
Finnish Environment Institute

Implications to managing soil contamination

- **PFAS present everywhere, also in soil**
- **Background levels low in ”natural” mineral soils; around 10 times higher in top organic/humic layer**
  - National/regional variation exists; in FIN (100 samples) -> ∑PFAS37, mineral soil: 0,09 µg/kg dw (mean), 0,76 µg/kg dw (max.)
- **Background concentrations (may be) substantially higher in urban soils**
  - Variable local sources; in FIN (50 samples) -> ∑PFAS37: 10 µg/kg dw (mean), 150 µg/kg dw (max.) -> use of WWTP sludges
- **Concentrations in point sources (contaminated sites) may be orders of magnitude higher…**



Implications to managing soil contamination

- **PFAS soil contamination mainly health and/or migration risk issue**
  - Ecological risk thresholds (NOEC) for soil organisms > 1 mg/kg (1000 µg/kg)

- **In general, diffuse PFAS soil contamination not major risk factor compared with local pollution**
  - Exposure usually insignificant in comparison to other sources (especially diet)
  - Soil reuse may not increase overall environmental burden (assuming PFAS concentrations are similar in the receiving soll)

- **Applying conservative risk approaches (e.g. EFSA TDI and/or EQSs based on it) may still cause issues…**
  - Generic soil guideline values based on combined multimedia exposure can get really low
  - Is it reasonabale/necessary to use EFSA value, given its derivation basis, typical background exposure levels as well as current food MLs and drinking water standards…?

  → Site-specific assessment combined with sustainability/practical considerations (acknowledging wide-scale background levels)

- **Use of WTTP sludges (biosolids) may be concern, especially for food safety (e.g. crops and feed)**
  - Further studies and assessments needed on the topic

Conclusions 1/2

- **Regulatory risk assessment of PFAS in the EU not coherent and transparent enough…**
  - Huge variability between different thresholds, including their level of health protection, even in similar contexts (e.g. fish consumption)
  - No available information on the foundation of DWQSs and MLs, and even misleading information presented (MLs)
  - EU's policy objectives on harmonization and transparency not achieved
  - PFAS restriction policy (prevention of pollution) seems to work, though (concentrations and exposure declining for restricted PFAS)

- **… however, harmonization does not require identical concentration thresholds for all contexts**
  - Objectives differ e.g. between chemical registration frameworks (e.g. REACH) and regulation of local emissions or contamination
  - Thus, also risk assessment approaches and tolerance of risks may justifiably differ (e.g., prevention vs. management; local vs diffuse)

- **Proper justifications for any regulatory threshold should be considered and openly described**
  - Foundation of threshold needs to be transparently defined including its toxicological and other premise, such as feasibility
  - Feasibility issues do not need to be incorporated in the foundation of thresholds, but rather in their application

Conclusions 2/2

- **Important to address PFAS mixture toxicity but grouping approaches need refinement/validation**
  - Different approaches currently in place resulting in contradictions and variability; ∑PFAS4, ∑PFAS20, RPF approach, total PFAS
  - RPFs based on liver toxicity in animals; not properly validated for immunotoxicity in humans (basis of EFSA's TWI)
  - Suitability/feasibility of EFSA's TWI to address heath risks for existing/historical contamination questionable…

- **Fixed EU level thresholds for PFAS not the most reasonable option for risk management**
  - Significant variability in national/regional/local occurrence data; in most regions EQSs too low, and MLs and DWQSs too high
  - Consideration of national/regional/local background concentrations should be possible when applying the thresholds, including soil
  - Established risk-based thresholds (e.g. draft EQSs) do not define absolute limits for actual health effects (e.g. basis of TWI and RPFs, other conservative assumptions in derivation, risk-benefit analyses demostrate that eating fish outweight health risks of PFAS etc.)
  - Thresholds on food consumption could also be coupled with dietary advice
  - Note: EU level threholds are not needed for any other contaminant in soil either (cf. soil monitoring law)!

- **Open dialogue on regulatory risk assessment of PFAS and other chemicals in the context of diffuse contamination (including soil) needed!**
  - To promote rational regulatory development and sustainable management practices

Thank you!

Co-funded by
the European Union

Suomen ympäristökeskus
Finlands miljöcentral
Finnish Environment Institute

SOr

WE MAKE TOMORROW BEAUTIFUL
OVAM

EmConSoil
a Multi-stakeholder Network for Emerging Soil Contaminants

Policy challenges related to diffuse pollution – case PFAS

Jussi Reinikainen, Finnish Environment Institute, Senior adviser

belgium24.eu