Department
for Environment
Food & Rural Affairs

UK PFAS Workshop

Day 2 – April 28th 2021

Agenda

Morning

Addressing the concern

- Global perspectives on PFAS risk management
- Overview of proposed EU approach
- Consideration of possible grouping approaches and essential uses

Afternoon

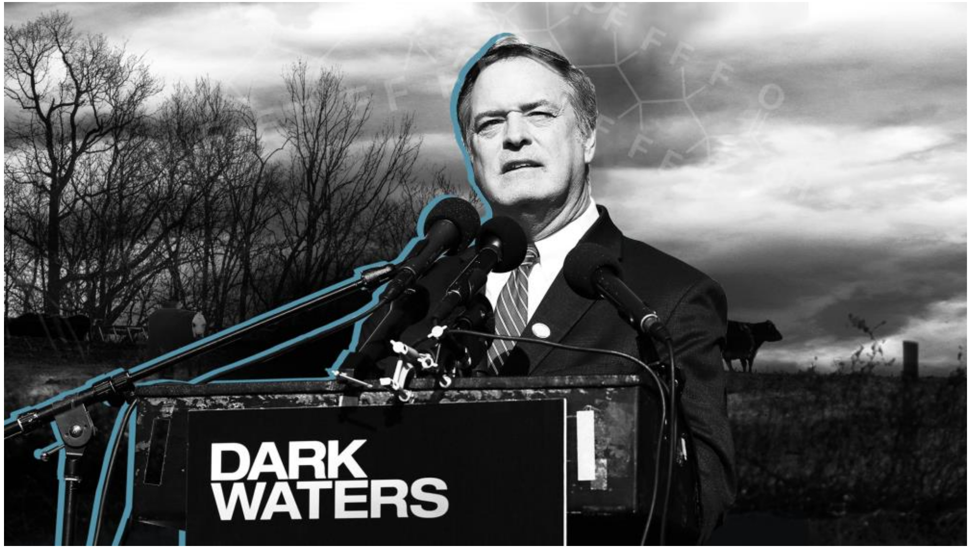
Where do we go from here?

- What do we want to achieve?
- Product stewardship

Global perspectives on PFAS risk management

Presented by: **Gershwinder Rai** (Defra)

There has been significant media coverage of PFAS contamination in the US



- The Dark Waters movie renewed the PFAS concern across the US, as well as globally
- In January, firefighting equipment firm, Tyco, agreed to a class action settlement of $17.5m for the people living near a firefighting training facility
- In the Biden Plan, there is a commitment to improving water quality by setting enforceable limits with the Safe Drinking Water Act and accelerating toxicity studies

As a result, the US has taken a number of actions towards management of PFAS

Combination	The US EPA uses a combination of voluntary and regulatory approaches to address the PFAS concern
Action Plan	The EPA's PFAS Action Plan outlines short-term solutions and long-term strategies to address PFAS. It outlines the tools the EPA is developing to address PFAS in drinking water, clean up PFAS contamination, expand monitoring and increase research
Stewardship	The PFOA stewardship program worked towards elimination of long chain PFCAs, and gained commitment from 8 major manufacturers to phase-out PFOA by 2015
SNUR	The Significant New Use Rule imposes notification and reporting requirements on manufacturers of a variety of PFAS

EPA: Environment Protection Agency

There has also been media coverage in Australia as they move to phase out PFAS in firefighting foams

- The NSW government is moving to outlaw foams featuring PFAS chemicals
- It looks like other states will follow the same trend due to extensive media coverage
- Bringing the state in line with Queensland and South Australia where they have already banned certain PFAS containing foams

Australia has taken numerous actions against PFAS

Combination

Australia under AICIS uses a combination of voluntary, regulatory and policy approaches with a focus on importation and use, rather than manufacture

Action Plan

There has been a Publication of National PFAS Position Statement, with voluntary industry consultations to try and increase awareness and encourage phase-outs of long-chain and short-chain PFAS

Guidelines

For pre-market entry applications there are additional data requirements for new PFAS. This regulatory stance assesses the risk that new PFAS pose, prior to their introduction

Foam

Transitioning away from fluorinated fire-fighting foam to non-fluorinated firefighting foam including the destruction of remaining stockpiles.

AICIS: Australian Industrial Chemicals Introduction Scheme. OECD: Risk Reduction Approaches for PFAS

Canada uses regulatory and voluntary approaches for various long-chain PFAS

Voluntary	Environmental Performance Agreement reached to encourage action from industry to significantly reduce residuals from perfluorinated products sold in Canada. This is a signed agreement that requires annual reporting of progress
Action Plan	In 2006 CELA implemented an “Action Plan for the Assessment and Management of Perfluorinated Carboxylic Acids and their Precursors” – comprehensive plan to eliminate such substances
Guidelines	In December 2018, drinking water quality guidelines updated for PFOS and PFOA. The path they have taken is to have MAC concentrations of PFOS and PFOA
Regulation	Introduction of regulations through ‘Prohibition of certain Toxic Substances Regulations’. A multi-substance risk management instrument to prohibit the toxic substances and products containing PFOA and PFOS, with few exemptions

CELA: Canadian Environmental Law Association. MAC: Maximum Acceptable Concentrations

There are a number of similarities between global approaches to PFAS management

Similarities in approach

Blended approaches

- Countries have taken a mix of regulatory and voluntary approaches

Collaborative efforts

- Collaboration among governments and organisations has helped to exchange information on risk reduction strategies that can help prioritise or inform action by others

Risk reduction paths

- Despite PFAS not being manufactured in certain countries like Australia and Canada, there is still a concerted effort to restrict or at least minimise the use, importation and export

Tackling toxic firefighting foams

- Numerous countries such as the USA, Australia, certain Member States of the EU are transitioning from operational fluorinated fire-fighting foam to fluorine-free foam

Overview of proposed EU approach

Presented by: **Mike Holland** (EMRC)

My role

- Consultant, part of a team working on 2 contracts regarding the ‘Universal PFAS’ restriction
    - F-gases (use phase)
    - Food contact materials and generic packaging (use phase)
- Socio-economic analysis
- Analysis of alternatives

- Decisions on what is in the restriction, exemptions, time scales, etc. to be made by the Competent Authorities

Basic details of the Restriction

- ‘Universal PFAS Restriction’
- Competent Authorities in 5 countries are leading the work:
  - DE, DK, NE, SE and Norway
- PFAS are defined in this process as substances that contain at least one aliphatic -CF2- or -CF3 element
  - 4,700+ substances
  - More comprehensive approach than many were expecting
  - But still excludes some substances (e.g. vinyl fluoride)
  - Covers a large number of activities

Process

Call for Evidence (2020)

⇓

Competent Authorities commission series of studies (August to November 2020)

⇓

Further consultation to clarify issues from the call for evidence (October 2020-March 2021)

⇓

Studies completed (February to May 2021)

⇓

Decisions reached by responsible Authorities

⇓

Restriction proposal submitted to ECHA

⇓

Appraisal by RAC and SEAC

⇓

Recommendations submitted to European Commission

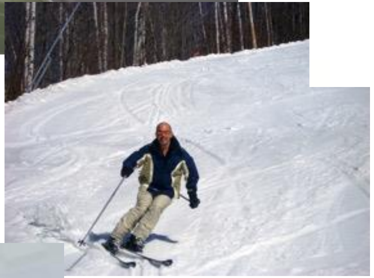
Focus on persistence as a key driver for the restriction

- Action has already been taken regarding:
    - Toxicity, where it is known (various restrictions)
    - Ozone depletion (Montreal protocol)
    - Climate (F-gas regulation)
- But not on persistence
    - Alternative positions:
        - Is persistence on its own sufficient for action?
            - Costs to society of not using PFAS
        - Across 4,700+ substances, when some PFAS have been found to cause harm, is it appropriate to wait for evidence of harm?
            - Costs of impacts incurred +
            - Clean up costs if clean up is possible +
            - Increased costs for industry to change to alternatives as PFAS use expands
- Other factors including toxicity are considered to the extent possible (e.g. to avoid regrettable substitution)

Studies commissioned for the Restriction

- Production of PFAS including polymers
- Applications
  - Textiles, leather
  - Food contact material, packaging
  - Consumer mixtures
  - Lubricants and construction products
  - Cosmetics
  - Chrome plating
  - Ski treatments
  - Transportation
  - Extractive industries
  - Medical devices
  - F-gases
  - Electronics and energy
  - Possibly others
- Waste management



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  - Electronics and energy
  - Possibly others
- Waste management

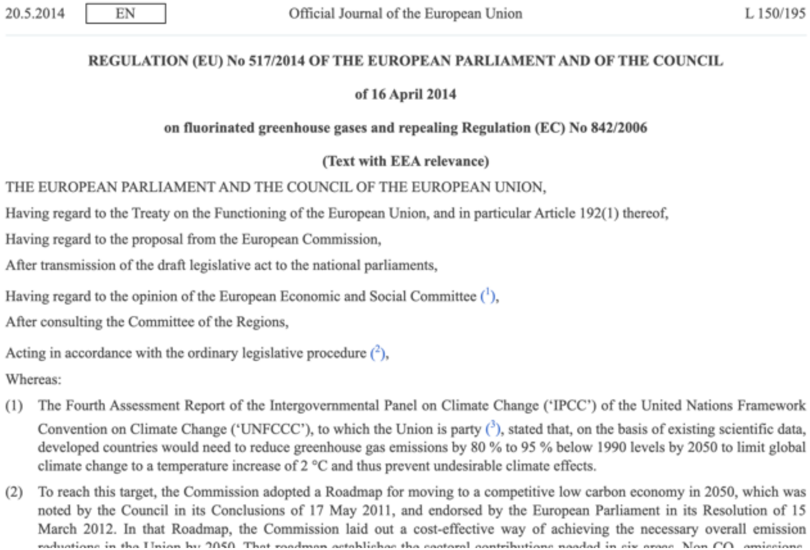
- Complexity varies
  - Ski waxes, vs.
  - F-gases
    - HVACR
      - Heating
      - Air conditioning
      - Refrigeration
        - Domestic
        - Commercial
        - Industrial
        - Transport
    - Foam blowing
      - …
    - Fire suppressants
      - …
    - Propellants
    - Solvents
  - Niche applications
    - Many

Are there alternatives?

- According to several stakeholders:
  - “There are no alternatives”
- Review of the market shows that there normally are
  - But what are the limitations of alternatives?
- Some are not disputed:
  - Hydrocarbons in domestic refrigeration
- Some are disputed:
  - Hydrocarbons in domestic air conditioning systems replacing F-gases
  - CO_2 in mobile air conditioning

Legislative overlaps?

- F-gas regulation
  - Earlier legislation addressed ozone depletion
  - F-gas regulation addresses climate impacts
  - Neither address persistence
- Building regulations
  - Insulation standards
  - Flammability
- Circular economy
  - Recyclability of materials
- …



20.5.2014 EN Official Journal of the European Union L 150/195

REGULATION (EU) No 517/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 16 April 2014

on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) The Fourth Assessment Report of the Intergovernmental Panel on Climate Change ('IPCC') of the United Nations Framework Convention on Climate Change ('UNFCCC'), to which the Union is party ([3]), stated that, on the basis of existing scientific data, developed countries would need to reduce greenhouse gas emissions by 80 % to 95 % below 1990 levels by 2050 to limit global climate change to a temperature increase of 2 °C and thus prevent undesirable climate effects.

(2) To reach this target, the Commission adopted a Roadmap for moving to a competitive low carbon economy in 2050, which was noted by the Council in its Conclusions of 17 May 2011, and endorsed by the European Parliament in its Resolution of 15 March 2012. In that Roadmap, the Commission laid out a cost-effective way of achieving the necessary overall emission

Assessing proportionality

- Valuation of persistence
- Dutch study (Oosterhuis 2017) established indicators to show when, based on previous legislation, regulators have considered the costs of measures to be acceptable and when they have not.

Graphical representation of the principle of establishing an "orders-of-magnitude" zone where the costs of PBT measures (in €/kg) may (green) or may not (red) be acceptable for cost-effectiveness reasons.

Integrated Environmental Assessment and Management, Volume: 13, Issue: 6, Pages: 1100-1112, First published: 26 May 2017, DOI: (10.1002/ieam.1949)

Summary

- Proposal under development by 5 EU Member States
- Very broad scope at the outset
- Analysis, disaggregated by sector, undertaken of:
    - Size of market
    - Emissions
    - Availability and performance of alternatives
    - Proportionality
- Decisions to be taken later this year by the 5 Member States on how to proceed

Consideration of possible grouping approaches and essential uses

Presented by: **Ian Cousins** (Department of Environmental Science, Stockholm University)

Stockholm University

Consideration of possible grouping approaches and essential uses

Ian T. Cousins

Department of Environmental Science,

Stockholm University, Sweden

UK Environment Agency, 28th April 2021

Strategies for Grouping PFAS

Stockholm University

- Motivation:
  - Grouping strategies are needed for PFAS because it would be time and resource intensive to test and regulate the thousands of PFAS on the global market on a chemical-by-chemical basis.
- Two main categories of grouping strategies (for protecting human and environmental health):
  1. those based on the intrinsic properties (e.g. P, B, M & T) of PFAS and
  2. those that inform risk assessment through estimation of cumulative exposure and/or effects

Environmental Science Processes & Impacts
ROYAL SOCIETY OF CHEMISTRY
CRITICAL REVIEW
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Cite this: *Environ. Sci.: Processes Impacts*, 2020, **22**, 1444

Strategies for grouping per- and polyfluoroalkyl substances (PFAS) to protect human and environmental health

Ian T. Cousins,[*a] Jamie C. DeWitt,[b] Juliane Glüge,[c] Gretta Goldenman,[d] Dorte Herzke,[ef] Rainer Lohmann,[g] Mark Miller,[h] Carla A. Ng,[i] Martin Scheringer,[c] Lena Vierke[j] and Zhanyun Wang[k]

OXFORD
SOT | Society of Toxicology
academic.oup.com/toxsci
TOXICOLOGICAL SCIENCES, 2020, 1–19
doi: 10.1093/toxsci/kfaa123
Advance Access Publication Date: 31 July 2020
Research Article

Application of a Framework for Grouping and Mixtures Toxicity Assessment of PFAS: A Closer Examination of Dose-Additivity Approaches

Philip E. Goodrum,[*,1] Janet K. Anderson,[*] Anthony L. Luz,[†] and Graham K. Ansell[*]

Intrinsic Properties

P-sufficient Approach

Stockholm University

- All PFAS are themselves, or degrade into, highly persistent substances (definition of P in EU)
- Continual release of high P chemicals results in increasing levels and increasing probabilities of known and unknown effects. Exposure poorly reversible
- Basis for grouping all PFAS, but no legal basis

Environmental Science Processes & Impacts
ROYAL SOCIETY OF CHEMISTRY
PERSPECTIVE
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Cite this: Environ. Sci.: Processes Impacts, 2019, 21, 781

Why is high persistence alone a major cause of concern?

Ian T. Cousins, Carla A. Ng, Zhanyun Wang and Martin Scheringer

Commentary
A Section 508-conformant HTML version of this article is available at https://doi.org/10.1289/EHP7431.

Regulating PFAS as a Chemical Class under the California Safer Consumer Products Program

Simona Andreea Bălan,[1] Vivek Chander Mathrani,[1] Dennis Fengmao Guo,[1] and André Maurice Algazi[1]
[1]Safer Consumer Products Program, California Department of Toxic Substances Control, Sacramento, California, USA

Environmental Science Processes & Impacts
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Check for updates
Cite this: Environ. Sci.: Processes Impacts, 2020, 22, 2307

The high persistence of PFAS is sufficient for their management as a chemical class

Ian T. Cousins, Jamie C. DeWitt, Juliane Glüge, Gretta Goldenman, Dorte Herzke, Rainer Lohmann, Carla A. Ng, Martin Scheringer and Zhanyun Wang

American Chemistry @AmChemistry · 15h

Although the grouping of some substances within the class based on similar physical, chemical, and biological properties may be possible – a proposal to regulate all #PFAS as a single class is neither scientifically accurate nor appropriate.
americanchemistry.com/PFAS-Grouping....

Bioaccumulative PFAS

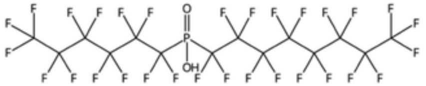
- Long-chain PFAAs regulated because they are vP, B (and T). There are more bioaccumulative PFAS…

▪ Non-target/suspect screening reveal other potentially bioacccumulative PFAS in wildlife and humans

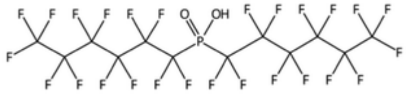
▪ Can be identified using structure-property methods
  - typically 6 perfluorinated carbons

▪ *In vitro* protein binding

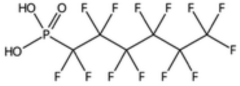
Potassium perfluoro-4-ethylcyclohe-xane sulfonate (CAS No. 335-24-0)



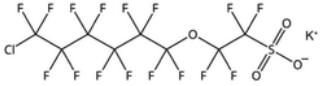
Perfluoro(hexyl/octyl) phosphinic acid (CAS No. 610800-34-5)



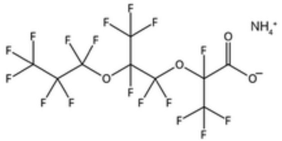
Bis(perfluorohexyl) phosphinic acid (CAS No.40143-77-9)



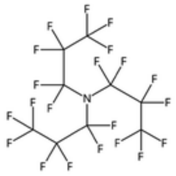
Perfluorohexyl phosphonic acid (CAS No. 40143-76-8)



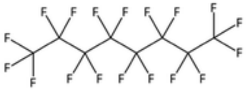
6:2 Cl-PFAES (CAS No. 73606-19-6)



Ammonium perfluoro-2-[(propoxy)propoxy]-1-propanoate (CAS No. 13043-05-5)



Perfluorotripropyl amine (CAS No. 338-83-0)



Perfluorooctane (CAS No. 307-34-6)

Stockholm University

Mobile PFAS

- German Environment Agency (UBA) proposed a PMT/vPvM approach for identifying threats to drinking water
- Mobility in soil estimated using K_{OC} or K_{OW}
- Consequence is that based on log K_{OW} cut-offs for B (typically >5) and M (proposed <4) most of partitioning space is covered
  - Hydrophobic and hydrophilic
  - What is left? Polymers and some volatile PFAS


Environmental Science & Technology

Feature

pubs.acs.org/est

Mind the Gap: Persistent and Mobile Organic Compounds—Water Contaminants That Slip Through

Thorsten Reemtsma,[*,†] Urs Berger,[†] Hans Peter H. Arp,[‡] Hervé Gallard,[§] Thomas P. Knepper,[‖] Michael Neumann,[⊥] José Benito Quintana,[#] and Pim de Voogt[∇,○]

Polymer of Low Concern (PLC)?

Stockholm University

- **<u>Some fluoropolymer products</u>** deemed PLC due to their high molecular weight (assumed low bioavailability), narrow molecular weight distribution, negligible oligomer content and organic and inorganic leachables
- But PLC only focuses on the use phase
- Lifecycle considerations important because
  - PFAS processing aids (PFOA, HFPO-DA) and other PFAS emitted during production
  - Concerns about persistent fluoropolymer solid waste

Integrated Environmental Assessment and Management — Volume 14, Number 3—pp. 316–334
316 Received: 26 Septe

Critical Review

A Critical Review of the Appl
and Regulatory Criteria to Flu

Barbara J Henry,*† Joseph P Carlin,† Jon A Har
Heidelore Fiedler,§ Jennifer Seed,|| and Oscar

Environmental Science & Technology
pubs.acs.org/est Policy Analysis

Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS?

Rainer Lohmann,* Ian T. Cousins, Jamie C. DeWitt, Juliane Glüge, Gretta Goldenman, Dorte Herzke, Andrew B. Lindstrom, Mark F. Miller, Carla A. Ng, Sharyle Patton, Martin Scheringer, Xenia Trier, and Zhanyun Wang

Approaches that Inform Risk Assessment:

Cumulative Exposure

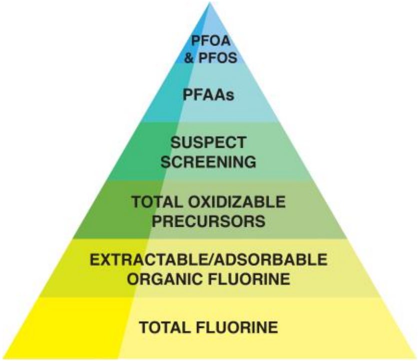
Ideal Exposure Assessments vs Reality

- Accurate measurements of all relevant PFAS in exposure media in time and space
- Want to make probabilistic estimates of exposure (rather than single points "deterministic")
- External and internal exposure relationships
- Reality
  - We only measure a few PFAS compared to those present and only in a few places and certain times
  - Know little about pharmacokinetics
  - Precursors and PFAAs present

Total Organofluorine Approach

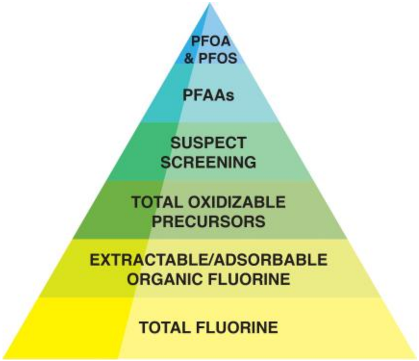
Stockholm University

- TF/EOF/AOF – surrogates for PFAS cumulative exposure
- EU 'PFAS total' limit of 500 ng/L set in a recast of the Drinking Water Directive
  - EOF/AOF could be used to pre-screen samples
- Uncertainties in translating the EOF/AOF measurements into risk-based guidelines
  - Which PFAS are represented?
  - EOF/AOF would capture non-PFAS derived organic fluorine
- Still maybe promising as pre-screening approach
  - Lab inter-comparison studies underway

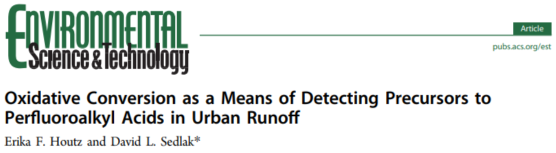


Precursor exposure?

- Lack of methods for measuring all relevant precursors to a specific PFAA
- Total oxidizable precursor assay (TOPA)?
- Levels of PFAAs in samples could be compared to guidelines after applying TOPA
- TOPA does not accurately simulate environmental degradation or metabolism



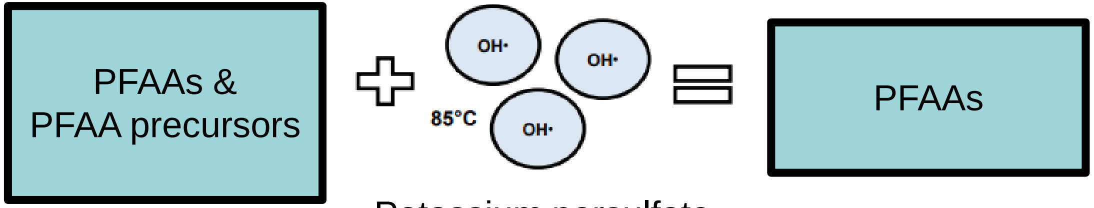
TOP Assay



Environmental Science & Technology — Article — pubs.acs.org/est

Oxidative Conversion as a Means of Detecting Precursors to Perfluoroalkyl Acids in Urban Runoff

Erika F. Houtz and David L. Sedlak*

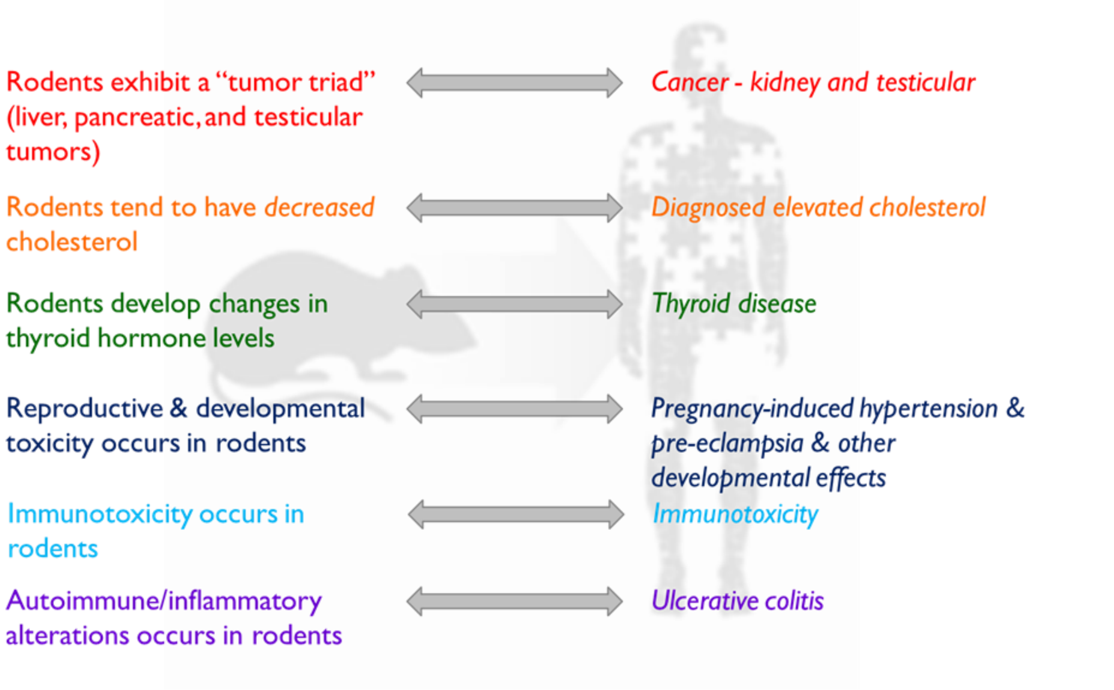


Potassium persulfate
Sodium hydroxide

- Analyse PFAAs in sample before and after oxidation
- Difference is ΣPFAA precursors
- Developed for water but now being applied to soils

Approaches that Inform Risk Assessment:

Mixture toxicity



- No consensus on a single critical adverse effect
- Few adverse effects studied for multiple PFAS, and even fewer mixture toxicity studies
- Even if common effects for multiple PFAS, common mode of action is not established

Simple Additive Toxicity

- Assumes multiple PFAS have the equivalent toxicity of a “lead PFAS” (often PFOS or PFOA)
  - Guideline set based on sum of multiple PFAS (mostly PFAAs) in sample
  - Used in drinking water guidelines in Sweden (11 PFAS), Denmark (12 PFAS), US states, etc.
- Limitations:
  1. the identified critical adverse effects, as well as modes of action vary
  2. elimination kinetics vary
  3. mixture toxicity may not be simply additive
  4. many PFAS are neglected

Hazard Index

Stockholm University

$$HI = \sum_{i=1}^{n} HQ_i \qquad HQ_i = \frac{Dose_i}{Rfd_i}$$

Where HI is the Hazard Index and HQ_i is the Hazard Quotient for component *i*

$Dose_i$ is the average daily dose (mg/kg/d) and Rfd_i can be any relevant toxicity reference dose (mg/kg/d) (liver, development, kidney, etc.)

Hazard Index Application

Stockholm University

Table 3. Hypothetical Example Illustrating Application of the HI Approach for Infants Consuming Drinking Water

Chemical	C (ng/l)	DW (l/day)	BW (kg)	EF (days/year)	Dose[a] (mg/kg/day)	Oral RfD (mg/kg/day)	Critical Effect Target Organ	HQ[b]	Source for RfD
PFNA	11	0.78	15	350	5.5E-07	2E-06	liver	0.3	Health Canada (2019)
PFOA	43	0.78	15	350	2.1E-06	2E-05	development	0.1	USEPA (2016b)
PFHxA	87	0.78	15	350	4.3E-06	0.25	kidney	0.00002	Luz *et al.* (2019)
PFOS	446	0.78	15	350	2.2E-05	2E-05	development	1	USEPA (2016a)
PFHxS	92	0.78	15	350	4.6E-06	6E-05	liver	0.1	Health Canada (2019)
PFBS	21	0.78	15	350	1.0E-06	2E-03	kidney	0.0007	USEPA (2014)
Sum:	700						Sum (HI):	1.6	

Abbreviations: BW, infant body weight; C, concentration; DW, infant drinking water ingestion rate; EF, exposure frequency; HQ, hazard quotient.

[a]Dose = $(C/1 \times 10^6) \times DW \times (EF/365)/BW$.

[b]HQ = dose/RfD.

- HI > 1 so more refined risk assessment needed

OXFORD SOT Society of Toxicology academic.oup.com/toxsci

TOXICOLOGICAL SCIENCES, 2020, 1–19

doi: 10.1093/toxsci/kfaa123
Advance Access Publication Date: 31 July 2020
Research Article

Application of a Framework for Grouping and Mixtures Toxicity Assessment of PFAS: A Closer Examination of Dose-Additivity Approaches

Philip E. Goodrum,[*,1] Janet K. Anderson,[*] Anthony L. Luz,[†] and Graham K. Ansell[*]

Higher tier mixture risk assessments?

- Mixture toxicity methods should ideally be applied to same critical organ/system
- Hepatocellular hypertrophy and kidney effects remain the only endpoints for which there are similar toxicity data from similar study designs, for multiple PFAS
  - Kidney data not amenable for dose-response modelling
  - But liver hypertrophy data are amenable
  - Applied by RIVM in Relative Potency Factor (RPF) Approach

Relative Potency Factor (RPF) approach

Stockholm University

$$RPF_i = \frac{BMD_{PFOA}}{BMD_i}$$

$$C_{PFOA\ Equ} = \sum_{i=1}^{n} RPF_i * C_i$$

$$HQ = \frac{C_{PFOA\ Equ}}{POD_{PFOA}}$$

- Liver hypertrophy
- 22 PFAS rat, oral

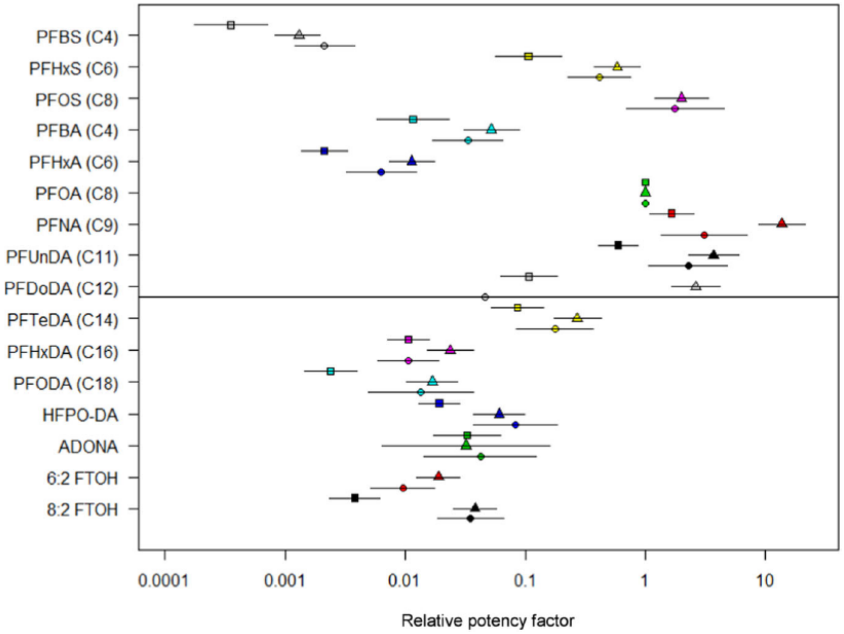
Environmental Toxicology and Chemistry—Volume 00, Number 00—pp. 1–12, 2020
Received: 4 April 2020 | Revised: 5 May 2020 | Accepted: 27 July 2020

Hazard/Risk Assessment

Risk Assessment of Per- and Polyfluoroalkyl Substance Mixtures: A Relative Potency Factor Approach

Wieneke Bil,* Marco Zeilmaker, Styliani Fragki, Johannes Lijzen, Eric Verbruggen, and Bas Bokkers
National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands

RPFs for multiple PFAS



- Differences in RPFs largely explained by elimination rates
- Internal dose normalization indicated similar potencies for all PFAAs (Gomis et al., 2015)

RPF approach: application to drinking water

Stockholm University

TABLE 2: The occurrence of per- and polyfluoroalkyl substances in drinking water in Rotterdam, The Netherlands, as presented in Brandsma et al. (2019) and the resulting sum of perfluorooctanoic acid equivalents based on the relative potency factors

Per- and polyfluorinated congeners	Concentration (ng/L)	RPF	PEQ[c] (ng/L)	PEQ[d] (ng/L)
PFBS	4.8	0.001	0.0048	0.0048
PFHxS	0.6[b]	0.6	0.36	0.36
PFHpS	0.5[a]	$0.6 \leq RPF \leq 2$	$0.3 \leq PEQ \leq 1$	NA
PFOS	1.3[b]	2	2.6	2.6
PFBA	5.0[a]	0.05	0.25	NA
PFPeA	5.1[b]	$0.01 \leq RPF \leq 0.05$	$0.051 \leq PEQ \leq 0.26$	$0.051 \leq PEQ \leq 0.26$
PFHxA	5.6	0.01	0.056	0.056
PFHpA	3.1[b]	$0.01 \leq RPF \leq 1$	$0.031 \leq PEQ \leq 3.1$	$0.031 \leq PEQ \leq 3.1$
PFOA	3.9	1	3.9	3.9
PFNA	0.5[a]	10	5	NA
PFDA	0.5[a]	$4 \leq RPF \leq 10$	$2 \leq PEQ \leq 5$	NA
PFUnDA	0.5[a]	4	2	NA
PFDoDA	0.5[a]	3	1.5	NA
HFPO-DA	5.9	0.06	0.35	0.35
Sum PEQ			$18 \leq PEQ \leq 25$[e]	$7.4 \leq PEQ \leq 11$[e]

- PFOA equivalent concentration 25 ng/L which is under the drinking water guideline limit for PFOA in the Netherlands of 87.5 ng/L

EFSA opinion: mixture approach

- Tolerable weekly intake (TWI) of 8 ng/kg BW for sum of 4 PFAS (PFOA, PFNA, PFHxS and PFOS)
- Decreased response of the immune system to vaccination was used as the critical human health effect in determining the new TWI value
- 4 PFAS have similar elimination half-lives
- Immunotoxicity effects observed for all four PFAS although potencies inconsistent
- Mode of action unknown
- Pragmatic protective approach adopted

Ongoing in the European Union

Stockholm University

- Authorities of Denmark, Germany, Netherlands, Norway and Sweden are preparing a REACH restriction proposal for a wide range of PFAS
  - Unclear which PFAS included
  - Derogations granted according to essentiality
- Are all PFAS equally bad?
  - Only common property is high P

c&en CHEMICAL & ENGINEERING NEWS

PERSISTENT POLLUTANTS

PFAS restriction plan developing in EU

by *Cheryl Hogue*

MAY 16, 2020 | APPEARED IN VOLUME 98, ISSUE 19

Take homes/challenges

- For mixture risk assessment, strictly one should only group PFAS that have the same mode of action, accounting for PK differences
  - Then grouping PFAS for risk assessment is challenging!
  - RPF approach only “higher tier” method available
- Huge data gaps have caused regulators to make pragmatic and protective solutions
  - Phasing out all PFAS based on high P with derogations for essentiality
  - Cumulative exposure and simplified mixture risk assessment

The way forward?

- US EPA and NTP testing 150 PFAS for hepatotoxicity, immunotoxicity, developmental toxicity, mitochondrial toxicity, developmental neurotoxicity, hepatic clearance, and toxicokinetics with high-throughput in vitro assays
  - By maximizing structural diversity, this research may inform mixture risk assessment
- Precautionary approaches warranted for continued use
- Contaminated sites
  - Because of clean-up cost implications, pragmatic risk assessment approaches warranted
  - Precautionary risk assessment for soils halting building in the Netherlands!

Thank you for your attention!

Acknowledgements

- The work behind this presentation has been performed by the scientists collaborating in the OECD/UNEP PFC Group and the Global PFAS Science Panel (GPSP).
- GPSP thanks the Tides Foundation for supporting our cooperation.

What do we want to achieve in terms of PFAS Risk Management?

Presented by: **Richard Dean** (Environment Agency)

Developing a UK Risk Management Options Analysis

Managing PFAS through UK REACH

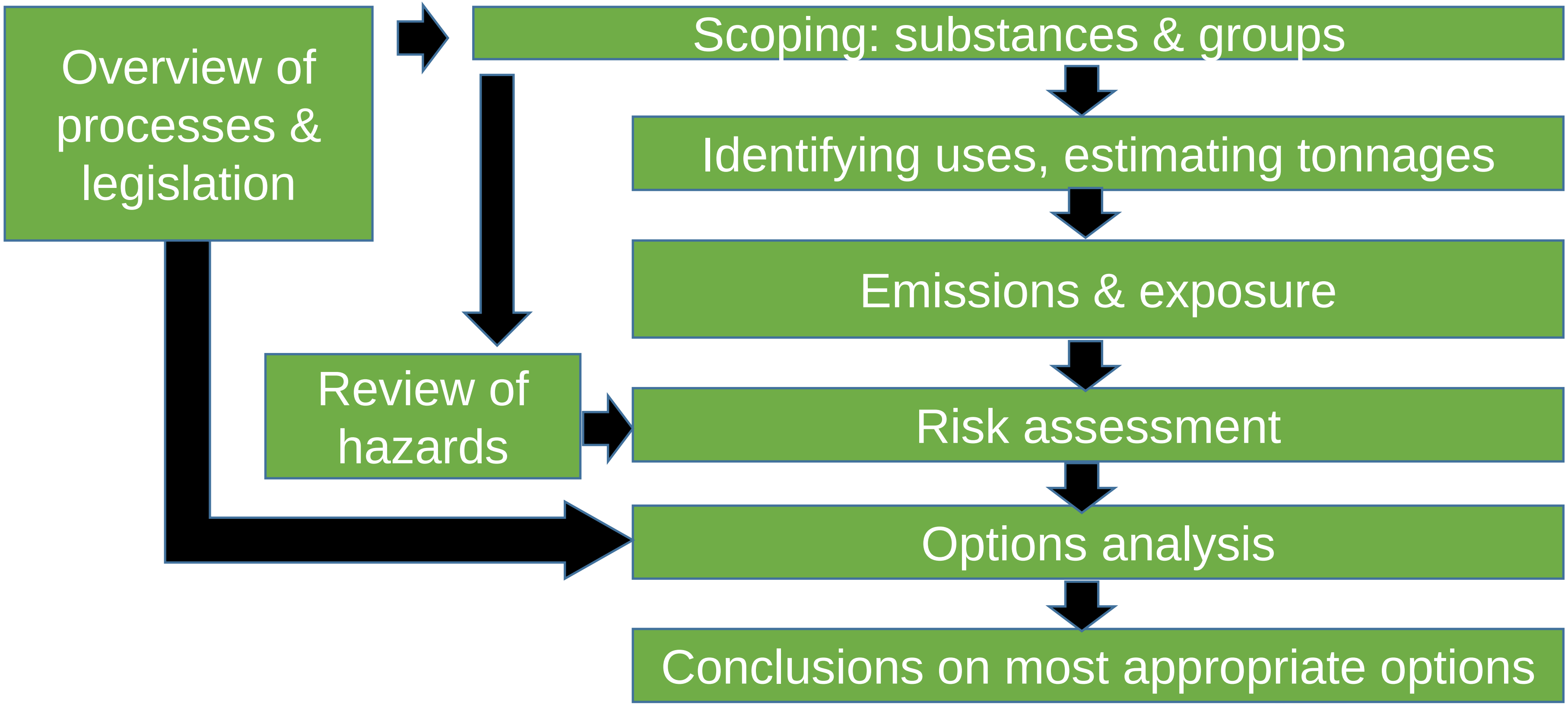
Richard Dean, Senior Specialist,
Chemicals Assessment Unit

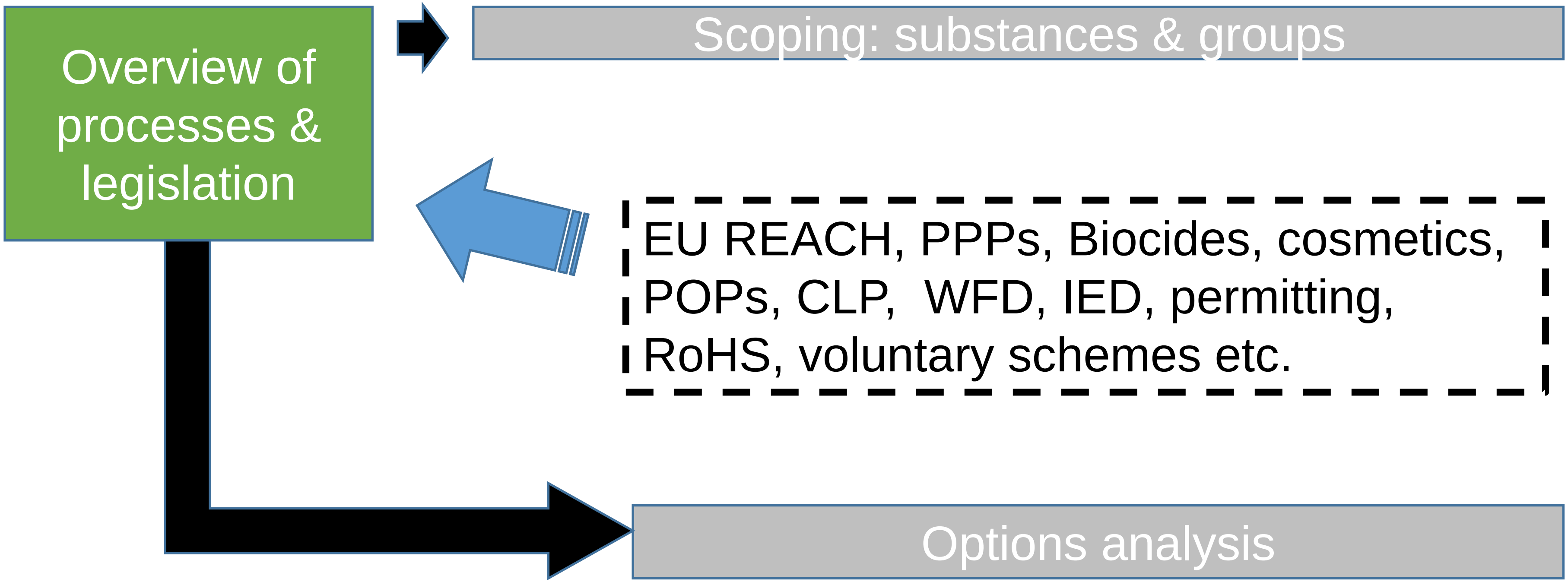
Environment Agency

UK PFAS RMOA: purpose and context

- To give the Appropriate Authorities sufficient information to decide upon the best risk management option(s) to take forward.
- Deliver within financial year 2020-21
- No statutory prescription for the process, but an EU model we can follow or adapt.

RMOA overview




Overview of processes & legislation
Scoping: substances & groups
EU REACH, PPPs, Biocides, cosmetics, POPs, CLP, WFD, IED, permitting, RoHS, voluntary schemes etc.
Options analysis

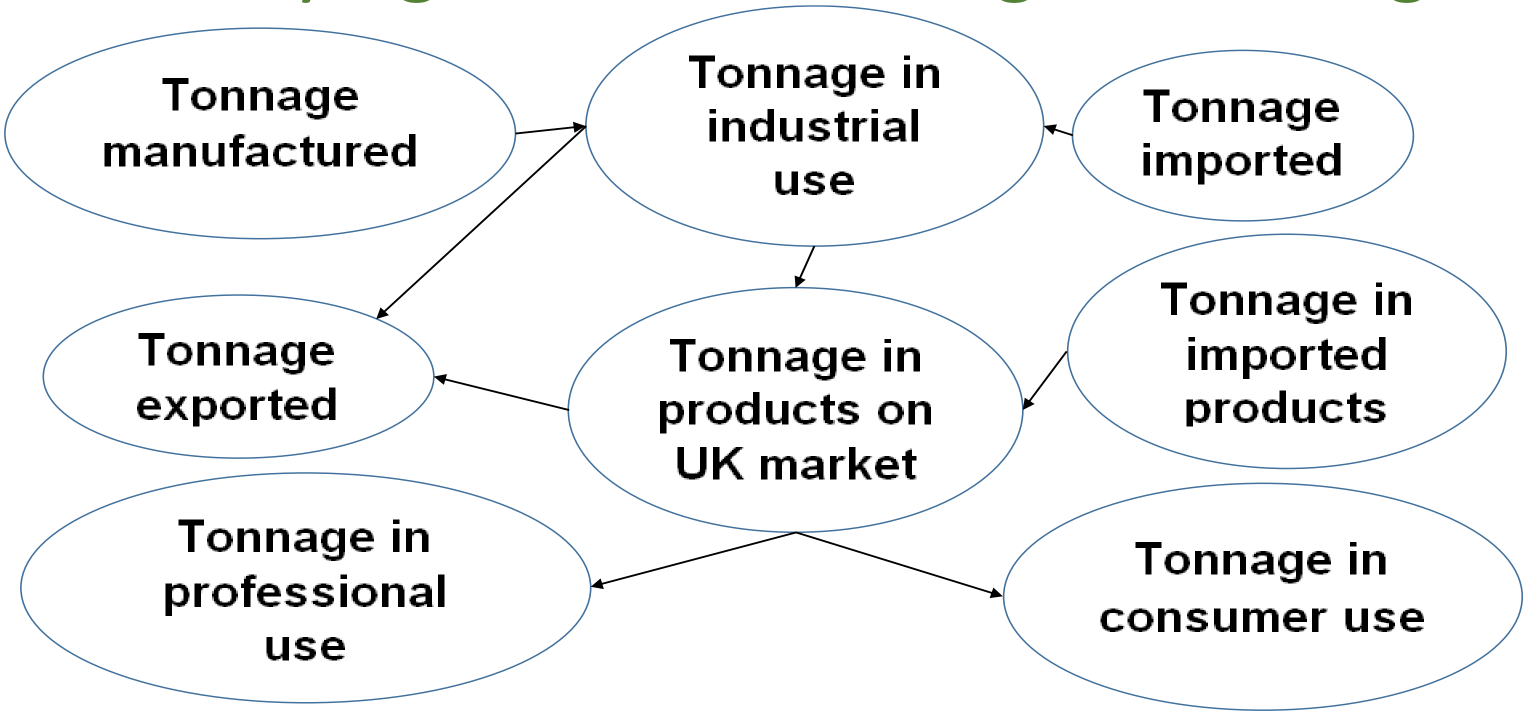
Scoping: substances & groups

- Consider stakeholders & perspectives
- Describe concerns – environment & human health via environment
- Consider relevant strategies & assumptions
- A manageable RMOA – definition & grouping

Review of hazard information

- Review classification information
- Review evidence for CMR, PBT, vPvB, EDC or other ELoC
- Assess relevance & reliability of info
- Consider read-across to group level
- PNECs for threshold substances

Identifying uses, estimating UK tonnages



Emissions & exposure

- Environmental emissions from PFAS life cycle – manufacture, use, disposal or recycling
- via air – volatilisation, dust
- via water – “down-the-drain”, aerial deposition
- via land – sewage sludge, food waste, aerial deposition, landfill
- Review monitoring data on exposure

Risk assessment

- Summarise evidence for risk for each group
- RCRs may be possible for threshold substances
- Main exposure sources for non-threshold substances

Options analysis & conclusions

Effective?

- Expected to address the concern, reducing risks to acceptable levels

Efficient?

- Targets relevant emissions, timely, minimises disbenefits, consistent

Compare options & select most appropriate

Next steps

- EA & HSE agree initial RMOA scope
- EA develops first iteration with HSE
- Stakeholders review scope & first iteration
- EA develops second iteration with HSE
- Defra reviews second iteration and instructs HSE on regulatory approach

Thank you!

"If you don't know where you are going, chances are you'll end up someplace else."

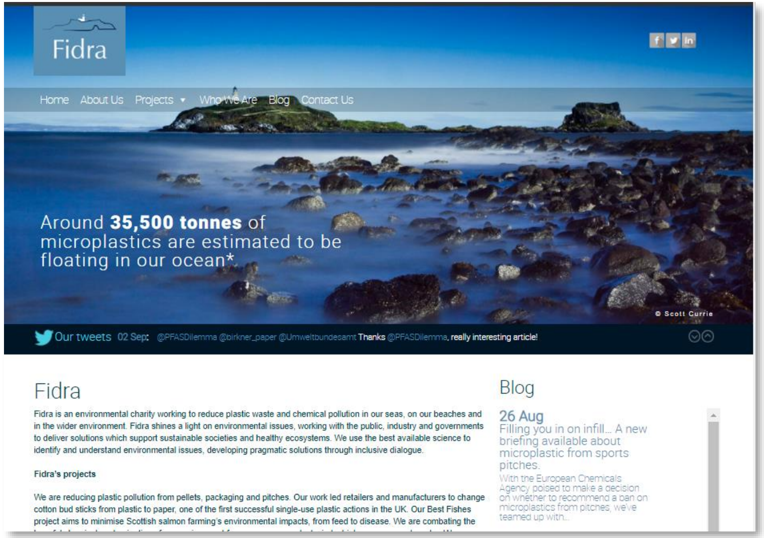
Attributed to Yogi Berra

Product stewardship – NGO perspective

Presented by: **Kerry Dinsmore** (Fidra)

Who are Fidra, why are we here?

- Scottish registered charity
- Science and evidence-based approach to influencing positive environmental change
- Focus on working collaboratively with industry, retail and policy makers
- Involved in international consortia, e.g. POPFREE, and rely on dialogue with primary research and scientific expertise



www.fidra.org.uk

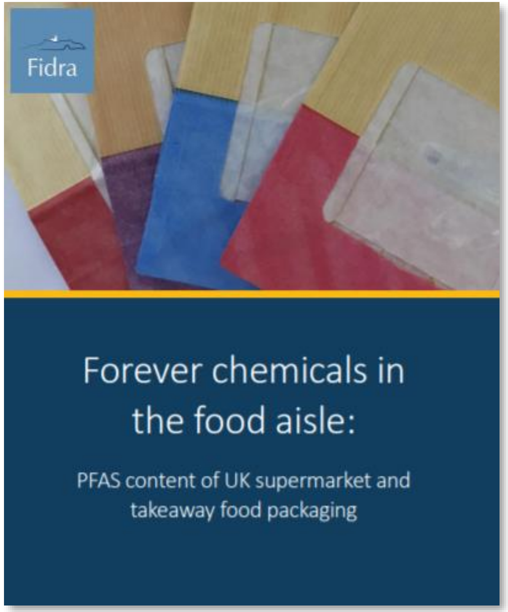
Fidra

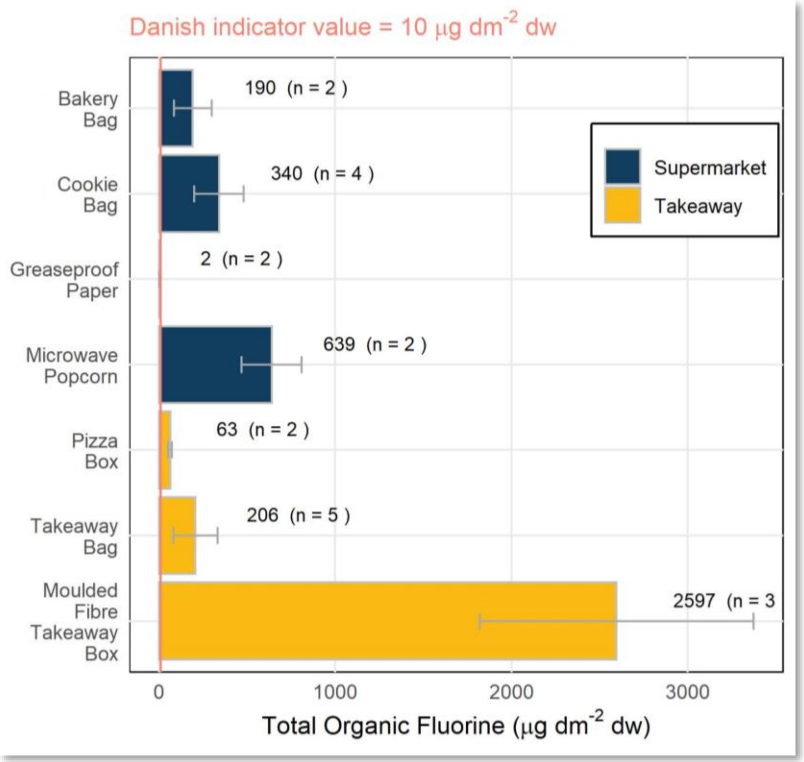
PFAS in food packaging

- High turnover, single-use item
- Potential for market growth when pitched as sustainable alternative to plastic
    - Regrettable substitution
    - Cost to industry of making ‘wrong’ choice
    - Undermining public confidence and risk of mixed messaging

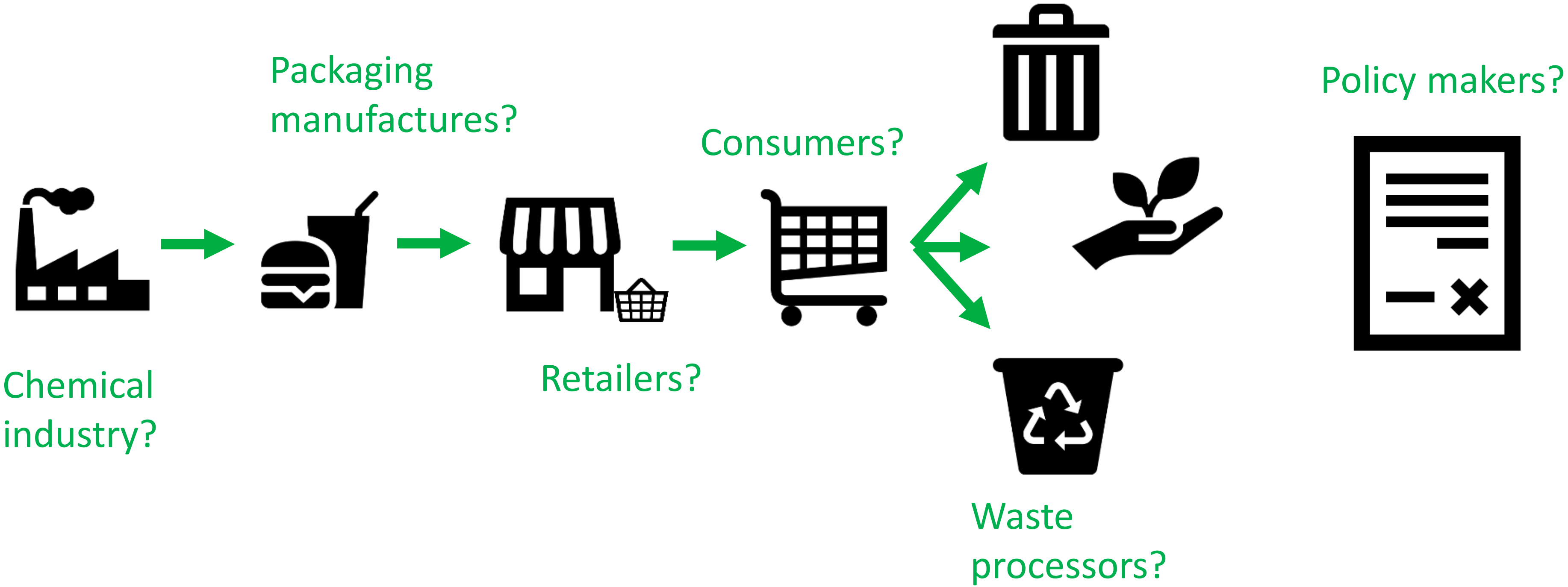
PFAS in food packaging

Forever Chemicals in the Food Aisle Report





Who's responsible?



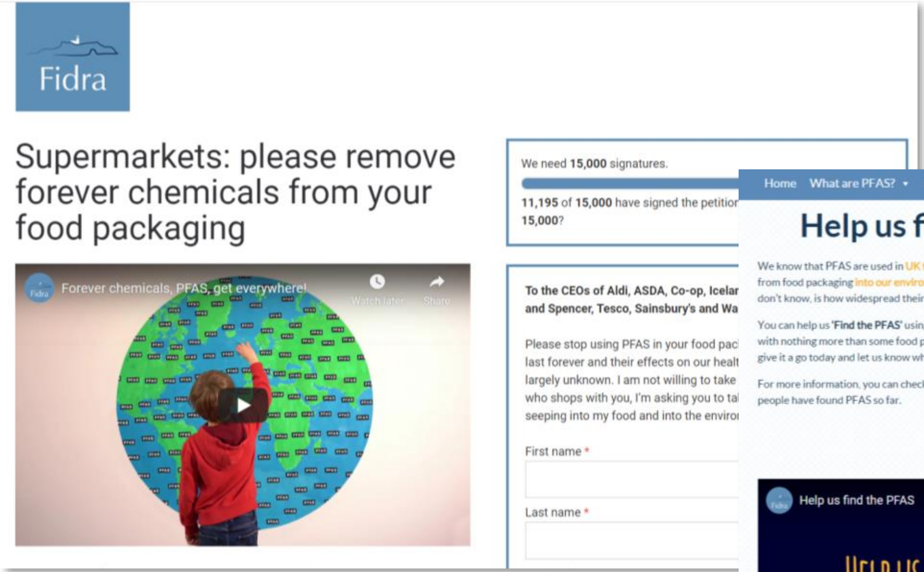
Fidra's model for change

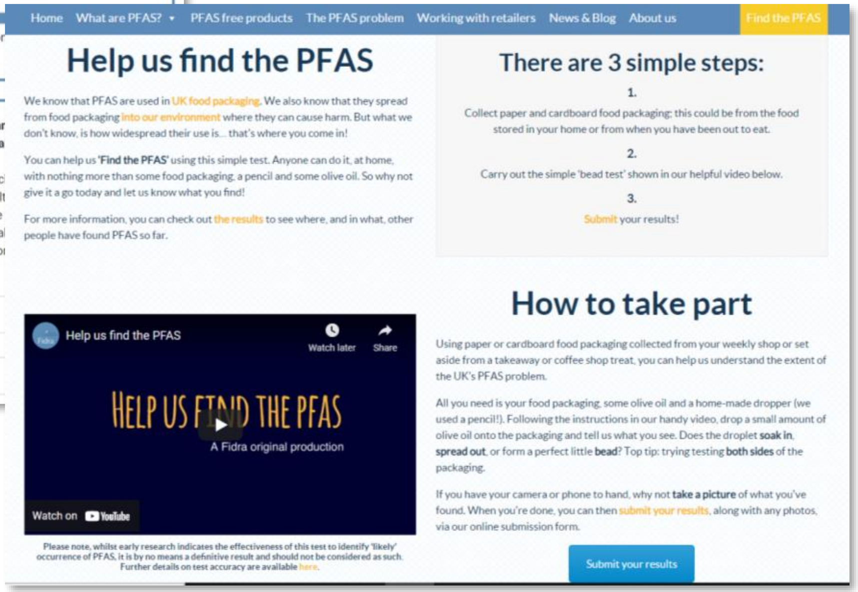
Fidra

1	2	3	4	5
Voluntary phase out from food packaging	UK ban on PFAS in food packaging	UK commit to PFAS ban across non-essential uses	Industry action to phase-out PFAS ahead of legislation	Significant reduction in PFAS use, pollution & exposure
Immediate action to avoid regrettable substitution from plastic	Level playing field Ensure everyone playing their part	Recognition of many different PFAS uses Need for group-based approach	Cut PFAS pollution as quickly as possible PFAS phase out as part of wider sustainability goals	**Healthy environment** **Functioning circular economy** **Holistic approach to sustainability**

Research; Innovation; Green Chemistry; Positive Messaging

Demonstrating support for change





Demonstrating support for change

13th July 2020

[redacted]
Investment relations director
McDonald's
[redacted]

Dear [redacted]

RE: Preventing PFAS pollution by removing forever chemical from fo

We are a group of long-term investors who are committed to investing in co
uphold the highest environmental standards. As consumers, retailers and re
minimise packaging, waste and pollution, many companies are rising to the
looking to use safe, sustainable packaging. However, there is increasing con
group of industrial chemicals, PFAS, that are added to paper, cardboard anc
food packaging to repel oil and water[1]. PFAS, per- and poly-fluorinated alkyl
group of over 4700 industrial chemicals widely used in everyday products. F
associated with a range of environmental and health issues and two chemic
group have already been banned due to their toxicity and persistence. As in
concerned about the widespread presence of PFAS in food packaging and th
consequences of their continued use.

PFAS are known as *forever chemicals* because they can last in the env

3rd December 2020

Sustainable packaging brand, Delipac, proudly adds PFAS-free to their list of environmental credentials

International food packaging board and paper supplier, Delipac, has built its brand on the concept of sustainability. Offering packaging solutions that already came with an impressive set of environmental accolades including plastic-free, recyclable, compostable and carbon balanced, they are now proudly adding PFAS-free to the list. And we're thrilled that Fidra have been part of that journey.

Per- or poly-fluorinated alkyl substances (PFAS) are a group of over 4,700[1] industrial chemicals, widely used in everything from carpets to cosmetics, cookware and food packaging, and widely linked to major human health and environmental concerns[2].

The Persistent Problem with PFAS

The carbon-fluorine bond that characterises this chemical group makes them both water and oil repellent, properties highly sought-after in food packaging. However, this carbon-fluorine bond is also one of the strongest known in nature, meaning these chemicals are extremely difficult to break-down or destroy. Some forms of PFAS are known to persist in soils for thousands of years[3]. They accumulate in our bodies and in those of our wildlife, cross the placenta into unborn children and circulate the globe in both air and water[4]. Recognised as endocrine disruptors (meaning they interfere with the body's hormone system), many of these chemicals are linked to human fertility and reproductive problems, reduced immune responses to vaccinations and even neurological changes in polar bears[3,4]. With new evidence of their harmful impacts emerging every day, and concentrations continuing to build in our environment, this is not a problem we can put off until tomorrow.

Product stewardship – industry perspective

Presented by: **Makiko Yada** (ATCS)

UK PFAS Workshop

Product Stewardship

28 April 2021

Alliance for Telomer Chemistry Stewardship

Agenda

1. C6 Fluorotelomer Chemistry
2. C6 Fluorotelomer Applications
3. Emissions
4. Closing remarks

C6 Fluorotelomer Chemistry

Alliance for Telomer Chemistry Stewardship, in a nutshell

The Alliance for Telomer Chemistry Stewardship (ATCS) is a global organization of companies that manufacture C6 fluorotelomer-based products in Europe, North America and Japan. Our mission is to promote the responsible production, use, and management of fluorotelomers, while also advocating for a sound science and risk-based approach to regulation.

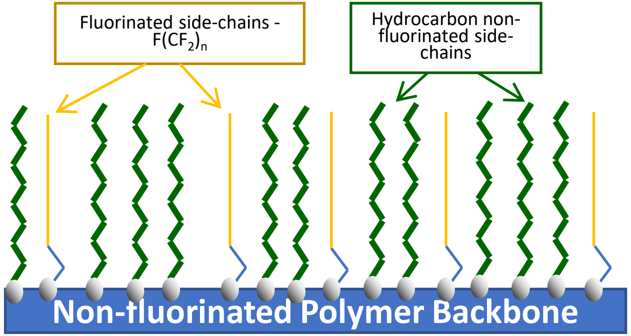
ATCS was created in 2020, following the dissolution of the FluoroCouncil, to focus on fluorotelomers. The association responsible for representing the fluoropolymer business is the Fluoropolymers Product Group (FPG).

ATCS member companies include:

- AGC, Inc.
- Daikin America, Inc.
- Dynax Corporation
- JCI (Johnson Controls, Inc.)

FluoroChemistry

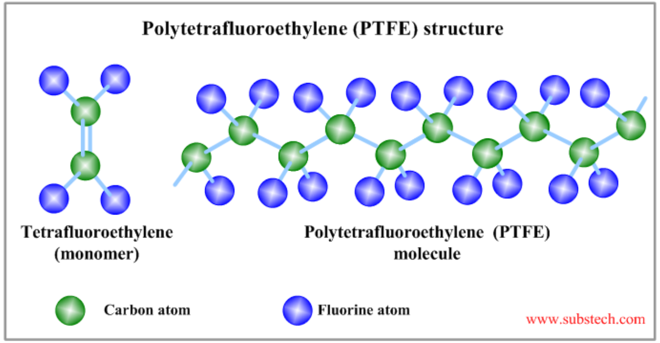
Fluorotelomers



C6 fluorinated chains attached to a non-fluorinated organic polymer backbone

- Fluorinated polymers (surface treatment)
- Surfactants (class B firefighting foams, electroplating)

Fluoropolymers



High molecular weight polymers with fluorinated "backbone"

- Fluoroplastics (e.g., PTFE, ETFE, PVDF, FEP)
- Fluoroelastomers (flexible, rubber-like)

Key Properties of C6 fluorotelomers

Low surface tension resulting in unique water- and oil-repellency (DWOR)

Exceptional stability leading to long lifetime of products

High heat and chemical resistance

C6 Fluorotelomer Applications

Main applications of C6 fluorotelomers (non-exhaustive)

PPE for fire fighters, first aid responders and sports equipment for extreme weather

Woven and nonwoven medical textiles

Interior/exterior textiles in transport

Military and police equipment

High-performance air and liquid filtration media

Nonwovens used in transport, including electric vehicles

Rescue equipment outside of PPE

Construction textiles

Solar/marine textiles

Main applications of C6 fluorotelomers (non-exhaustive)

Firefighting foams used in case of high hazard fires in industrial sites

Batteries, photovoltaics

Sealing materials for transport applications

Hard chrome plating

Pulp-based repellent medical equipment

Semiconductors/ electronics

Paints and coatings used in transport and construction

Coating of mechanical parts

Emissions

Emissions minimisation

There are ex situ treatment technologies currently available for the removal of fluorotelomer-based chemistry from water, such as ion exchange resins and/or membrane filtration. In addition, other techniques such as closed-loop water cycles are in place.

ATCS members have also actively promoted the use of Best Available Techniques to promote responsible production and use by downstream sectors:

- ➢ Development of best practice guidance for the textile sector.
- ➢ Guidance on for firefighting foams used in case of high hazard fires in industrial sites.

Downstream users example – EU textile sector: Emissions of PFHxA estimated at 80g/year.

- ➢ Figures are expected to decrease further due to the review of existing BATs on textile production under the IED.

Emissions minimisation (ctd)

Emissions to air and waste management:

- Off-air is either incinerated or captured and filtered via vent condensers and scrubbers or activated carbon beds.
- Liquid or solid waste potentially contaminated with fluorinated substances are sent for incineration in dedicated facilities.

Worker protection:

- Well-managed process control.
- Gloves, safety shoes, workwear and respiration masks.
- Up to date Safety Data Sheets.

Closing remarks

Conclusions

C6 fluorotelomer chemistry is used in **high-performance applications** for which currently **no alternatives** are available.

- Due to crucial role of C6 Fluorotelomers in the value chain of several key enabling technologies and markets, the UK's strategic autonomy could be undermined without access to this chemistry.
- Technologies are available to minimise emissions of facilities producing and processing C6 fluorotelomers.

ATCS is committed to supporting regulations that **focus on responsible manufacture and use.**

ATCS is willing to engage with the UK authorities on how to secure effective emission control of C6 fluorotelomer chemistry while ensuring its continued use in critical applications.

In case you have **questions**, please visit americanchemistry.com or contact us by email at shawn_swearingen@americanchemistry.com.

Thank you!

Alliance for Telomer Chemistry Stewardship