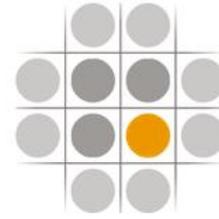




SoBRA

The Society of Brownfield Risk Assessment



# Per- and Polyfluorinated alkyl substances - EFSA activities

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MARTIN ROSE

MEMBER OF EFSA PANEL ON CONTAMINANTS IN THE FOOD CHAIN (CONTAM)

Current Issues in Contaminated Land Risk Assessment – 2017  
*Royal Society of Chemistry, Burlington House, London, 5th December 2017*

Working with:



# MANDATE OF CONTAM PANEL

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- ORIGINAL: to prepare an opinion on the risks to human health related to the presence of perfluoroalkylated substances (PFASs) in food
- LATER: Following an agreement with EC, the CONTAM Panel decided to address the mandate in 2 separate opinions, one on perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) and another on other PFASs

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# CURRENT POSITION

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- Opinion still not adopted
- All approaches are subject to change before adoption by Panel
- Likely to be adopted early 2018
  
- Opinion for 'other PFASs' will be finalised later in 2018

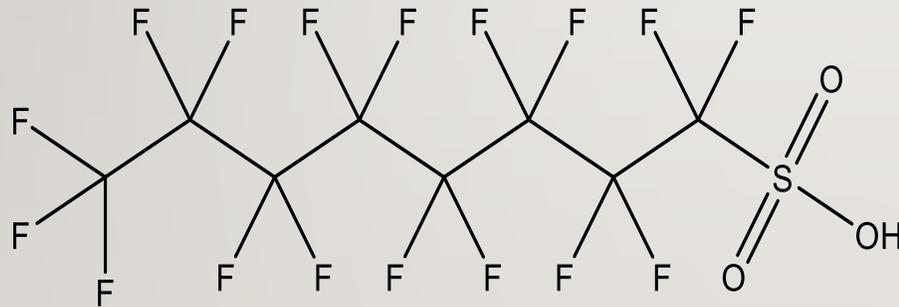
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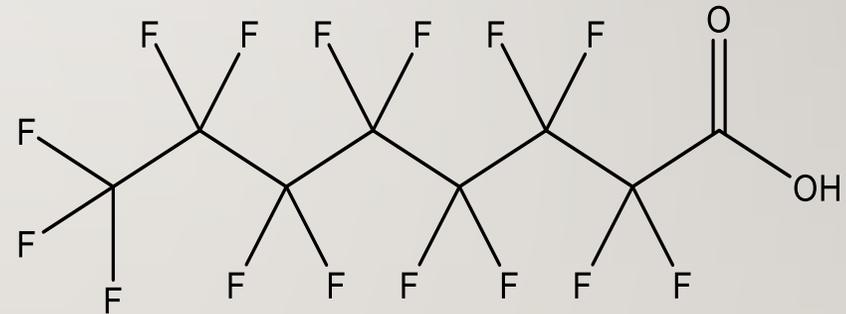
# CHEMICAL STRUCTURES

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- PFOS



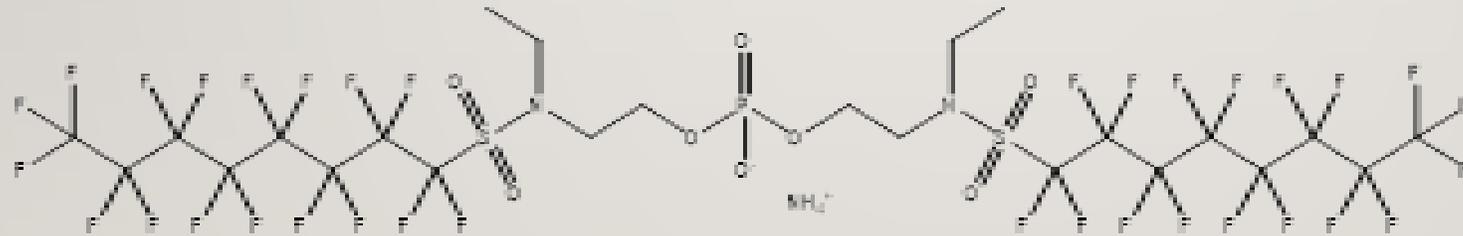
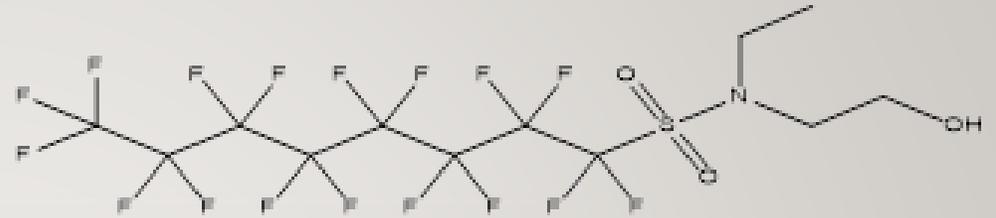
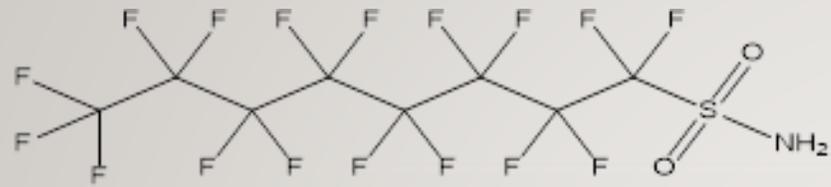
- PFOA



There are many geometric isomers of PFOS and PFOA including branched, chain isomers, but only few have been identified in technical products, and in the environment and human tissues







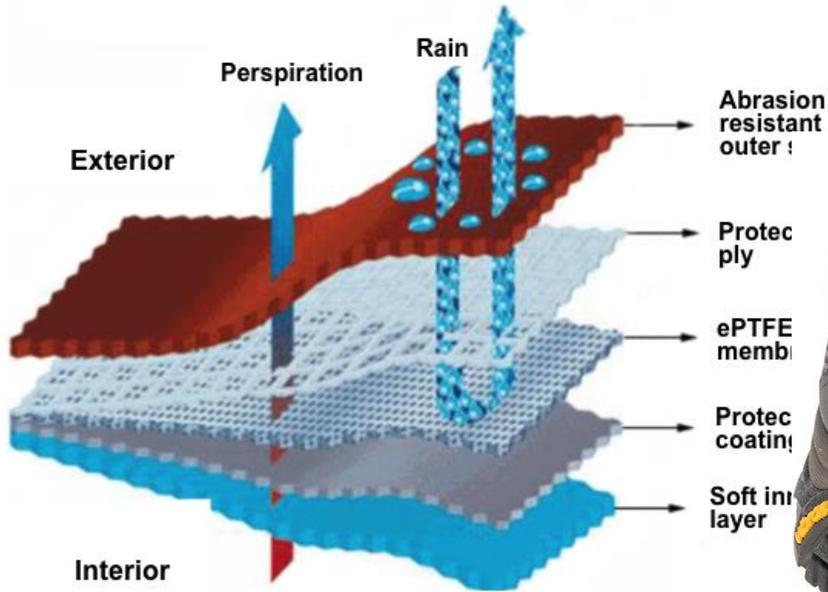
# PRODUCTION AND USAGE

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- Chemical resistance, surface tension lowering properties and the ability to create stable foams have made PFASs extremely versatile.
- 3M started production in 1947; increased in 1960s and 1970s; max in 2000 just before phase out
- total global production 1970 - 2002 was estimated at 122 500 tonnes
- largest production sites were located in the US and Belgium. Some production in Italy and Japan, and small amounts elsewhere
- Applications including textile, carpet and leather treatment (water and dirt proofing), surfactants, firefighting foams, metal plating and paper grease-proofing treatments

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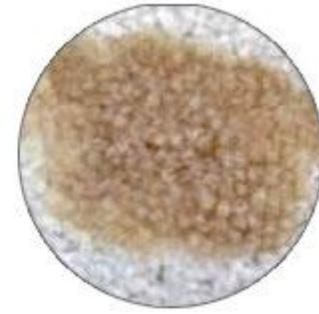
**Treated**



**Untreated**



**Treated**

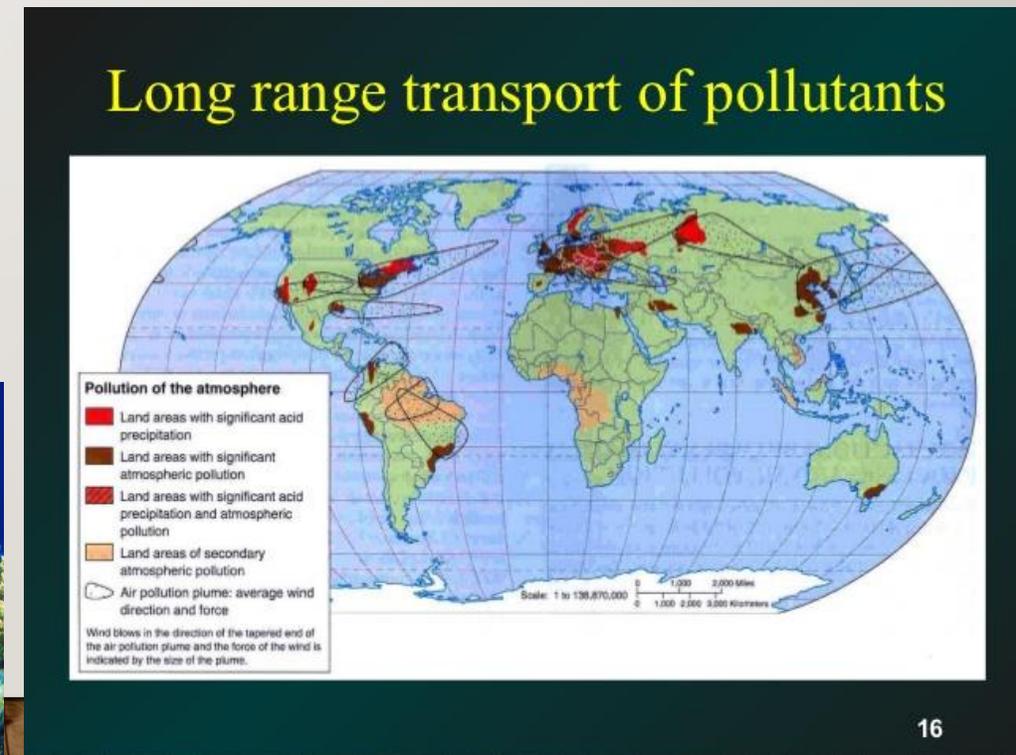
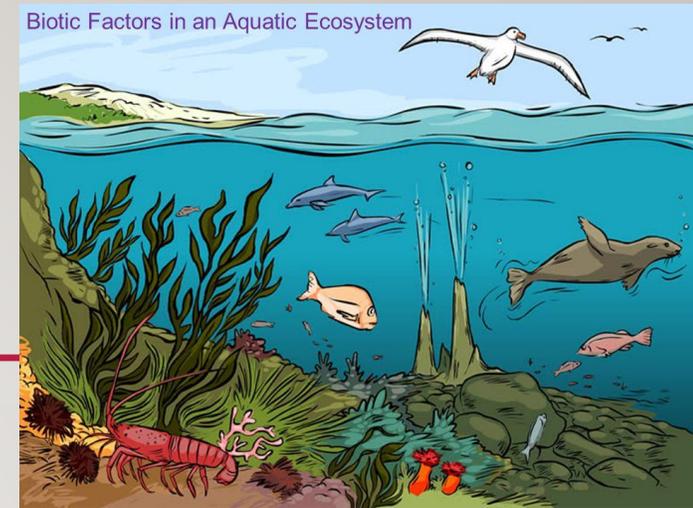


**Untreated**



# ENVIRONMENT AND ACCUMULATION

- released during production, through product use, and as a result of disposal at end of life
- ubiquitous in wildlife and humans
- Substantial release into aquatic ecosystems
- Undergo long range transport



# STOCKHOLM CONVENTION



**‘New’ POP i.e. not one of the original ‘dirty dozen’. Added in 2009.**

**Annex B** - Parties must take measures to **restrict** the production and use of the chemicals listed under Annex B in light of any applicable acceptable purposes and/or specific exemptions listed in the Annex. [PFOS, its salts and DDT are Annex B]

## **POPs characteristics of PFOS**

PFOS is extremely persistent and has substantial bioaccumulating and biomagnifying properties, although it does not follow the classic pattern of other POPs by partitioning into fatty tissues.

It binds to proteins in the blood and the liver.

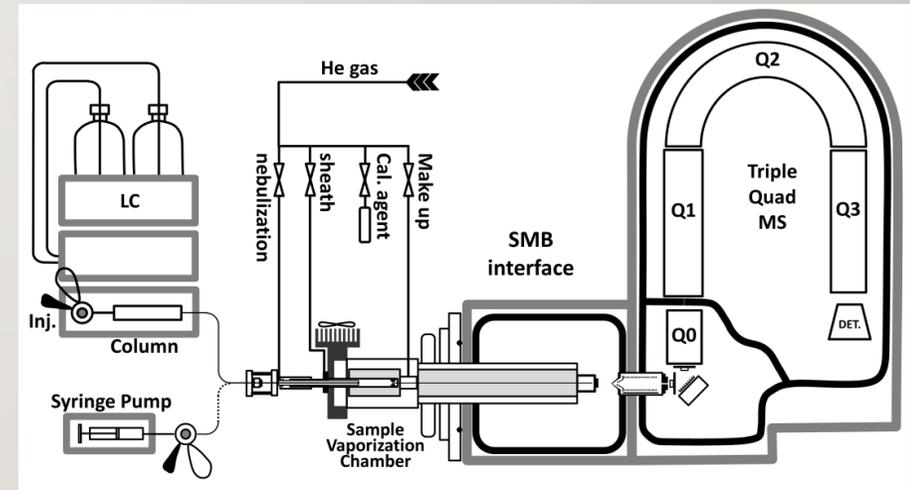
It has a capacity to undergo long-range transport and also fulfills the toxicity criteria of the Stockholm Convention.

Working with:



# ANALYSIS

- multi-analyte methods measure a range of PFASs
- Most methods use LC-MS
- Lab background and matrix effects can be problematic
- Much of the data for food is analysed by methods with insufficient sensitivity to detect background levels and is 'left censored'. Some modern 'research' methods can measure at lower levels



# LEGISLATION - PFOS

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- Directive 2006/122/EC (2006) restrictions on marketing and use of PFOS for new products in the non-food area, applied from 27 June 2008. Call for on-going risk assessment activities for PFOA.
- Reg. (EC) No 552/2009 restricts the marketing and use of PFOS for new products in the non-food area - Annex XVII of Reg. (EC) No 1907/2006 (REACH)



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# LEGISLATION - PFOA



- 2013 - PFOA included in the Candidate List of Substances of Very High Concern, SVHC, resulted inclusion into Annex XIV to Regulation (EC) No 1907/2006 (REACH)
- "Any related substance (including its salts and polymers) having a linear or branched perfluoroheptyl group with the formula  $C_7F_{15}$ - directly attached to another carbon atom, as one of the structural elements" and "any related substance (including its salts and polymers) having a linear or branched perfluorooctyl group with the formula  $C_8F_{17}$ - as one of the structural elements."
- These were specifically excluded:  $C_8F_{17}-X$ , where  $X = F, Cl, Br$ ;  $C_8F_{17}-C(=O)OH$ ,  $C_8F_{17}-C(=O)O-X'$  or  $C_8F_{17}-CF_2-X'$  (where  $X' =$  any group, including salts)

Working with:



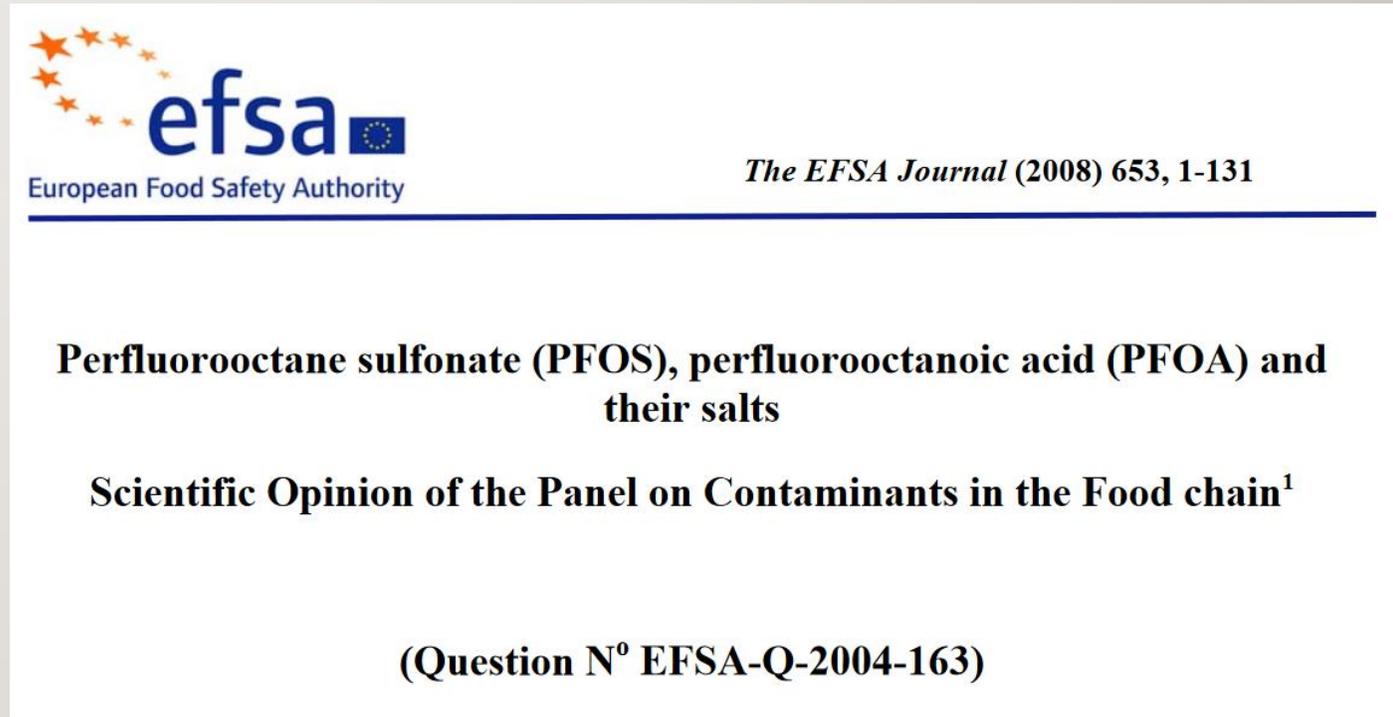
# PREVIOUS EFSA ASSESSMENT FOR PFOS

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- 2008, EFSA established a tolerable daily intake (TDI) of **150 ng/kg bw per day for PFOS**
- Based on a lowest no-observed-adverse-effect-level (NOAEL) of 0.03 mg/kg bw per day derived from a sub-chronic study on cynomolgus monkeys, where a decrease in serum total cholesterol and high-density lipoproteins (HDL), increased TSH levels and lowered triiodothyronine (T3) concentrations were observed.
- Uncertainty factor (UF) of 200 was applied to the NOAEL. A UF of 100 was used for inter and intra-species differences and an additional UF of 2 to compensate for uncertainties related to the duration of the key study and the elimination kinetics of PFOS. The EFSA CONTAM panel concluded that the exposure to the general population was well below the derived TDI

# PREVIOUS EFSA ASSESSMENT FOR PFOA

- For PFOA a benchmark dose for a 10% increase in increased liver weight (BMDL<sub>10</sub>) of 0.3 mg/kg bw per day based on studies in mice and rats was used to derive a **TDI of 1.5 µg/kg bw per day** applying a UF of 200 to the BMDL<sub>10</sub>



# OTHER RISK ASSESSMENTS

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- All use animal studies and all present TDIs in broadly the same range and conclude no adverse health effects for most of population as a result of dietary exposure based on normal occurrence levels
  - Federal Institute for Risk Assessment in Germany (BFR)
  - Swedish Environmental Protection Agency
  - United States Environmental Protection Agency (U.S. EPA)
  - Danish Environmental Protection Agency
  - Agency for Toxic Substances and Disease Registry (ATSDR),
    - etc

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# USING HUMAN DATA FOR RISK ASSESSMENT

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- Where human data exists, it should be used for human risk assessment
- Epidemiological studies are available for PFOS and PFOA, but not sufficient for all other PFASs
- This will result in a different approach for the current EFSA work and it was decided to split the task into (i) PFOS and PFOA and (ii) other PFASs.



# IMPACT – EPIDEMIOLOGICAL STUDIES:

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Human studies indicate associations with serum cholesterol, ALT, vaccination response and birthweight

Working with:



# HEALTH BASED GUIDANCE VALUE (HBGV)

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- The HBGV for PFOS and PFOA is likely to be lower if these human studies are used for risk assessment

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# EXPOSURE

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- Previous data on food demonstrated that exposure was well below established TDIs.
- Some analytical methods that have been used to date lack sensitivity and many data are left censored (i.e. <LOD) but this was not so problematic because it was possible to show that exposure was well below any level of concern; i.e. was fit for purpose
- A reduction in HBGV may mean that this is no longer the case and more sensitive analytical methods are needed for measurement of PFOS /PFOA

# IMPLICATIONS FOR BROWN FIELD RISK ASSESSMENT

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- If the HBGV for PFOS / PFOA is reduced, this may lead to a review of 'safe' or 'recommended' levels for brown field development.

Working with:



# ACKNOWLEDGEMENTS

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Especially the WG on PFASs, and the  
CONTAM Panel

The Panel on Contaminants in the Food Chain (CONTAM) provides scientific advice on contaminants in the food chain and undesirable substances such as natural toxicants, mycotoxins and residues of unauthorised substances.

Working with:

