

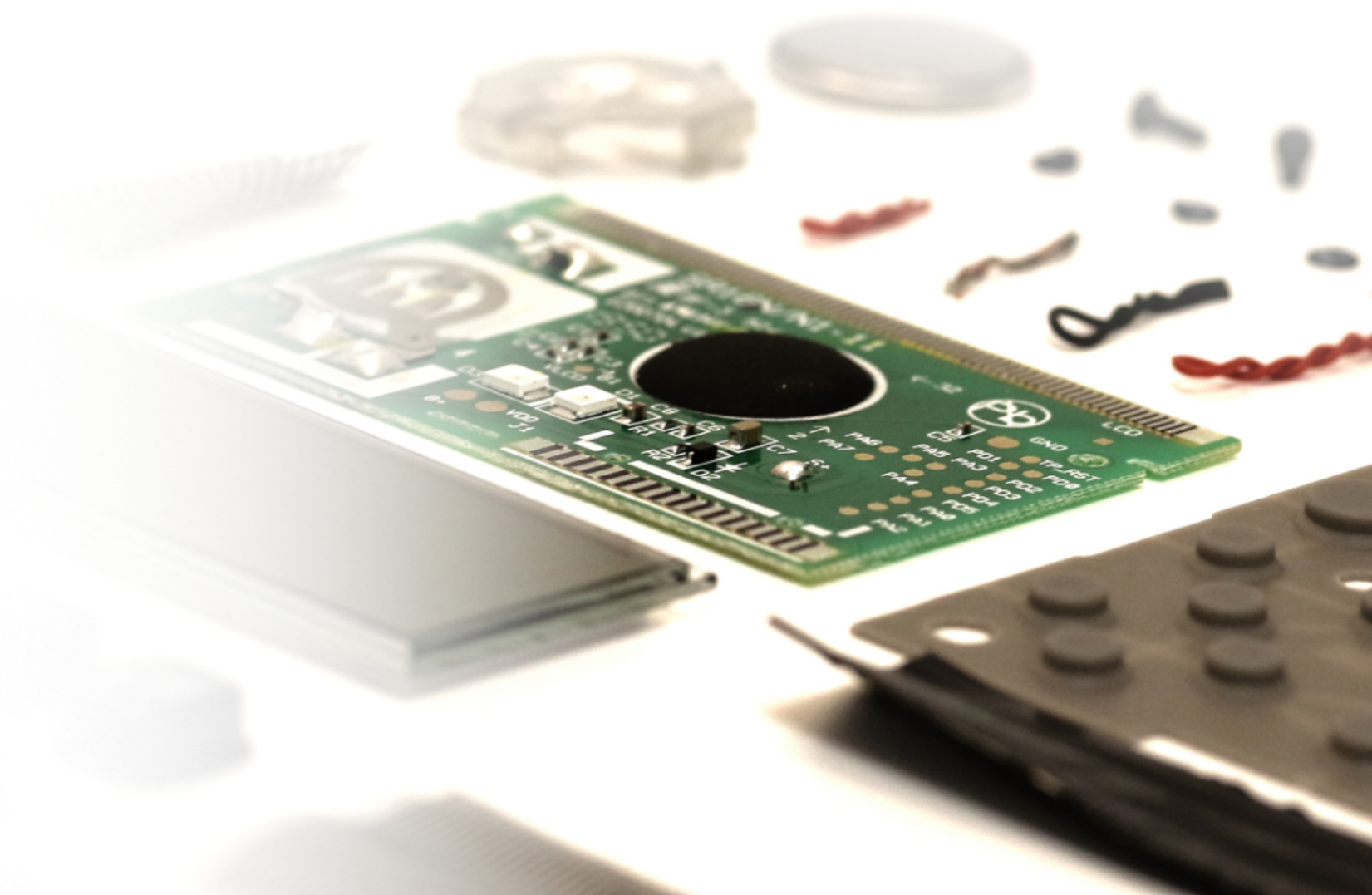


# Substance Restrictions in 2024

## *Claigan webinar*

Presented by:  
Bruce Calder  
VP Consulting

October 18, 2023



# Today's Webinar

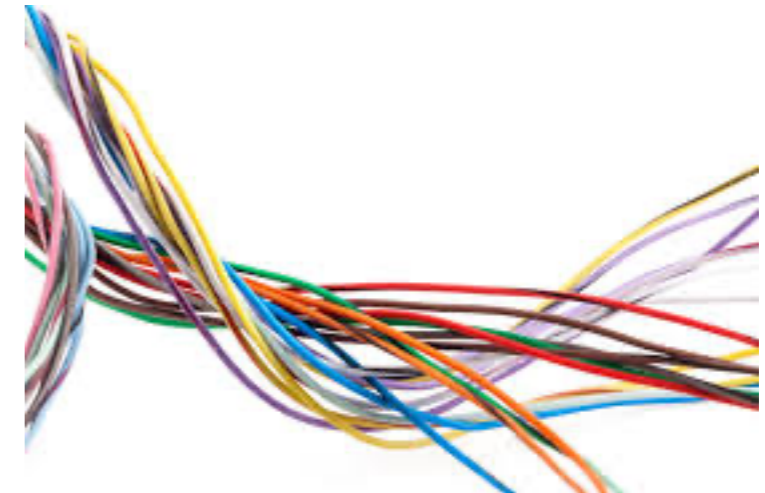
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- **Substance Restrictions 2024**
  - Substance restrictions that go into effect in 2024, or
  - Work needs to be completed in 2024 to meet deadlines
- Primarily restrictions
  - But with some reporting requirements included
    - such as US PFAS reporting

# Overview - Agenda

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- RoHS exemptions excel sheet issue
- POP
  - PFHxS
  - PFOA
  - China
- REACH
  - PFOA+ (long chain perfluorocarboxylates)
  - Microplastics
  - Formaldehyde
  - Dechlorane Plus
  - MCCP
- TSCA
  - PIP 3:1
  - PFAS Reporting



# RoHS Exemption Formula Issue

- The [EU commission exemption tracker](#) contains formulas
- Older versions of excel cannot process that formula and makes it look like exemptions are expiring

<a href="#">Annex III n. 7(c)-I</a>	1 to 7 and 10	22/07/2016	<del>21/07/2021</del>	C
Annex III n. 7(c)-I	8 and 9 other than in vitro and industrial	22/07/2014	<del>21/07/2021</del>	C
Annex III n. 7(c)-I	8 in vitro	22/07/2016	<del>21/07/2023</del>	C
Annex III n. 7(c)-I	9 industrial	22/07/2017	<del>21/07/2024</del>	C
Annex III n. 7(c)-I	11 other EEE	22/07/2019	<del>21/07/2024</del>	C

Formula error

- Correct version of excel - exemption still in renewal

6	Annex III n. 7(b)	8 and 9 other than in vitro and industrial	22-07-2014	21-07-2021		No longer valid
7	Annex III n. 7(b)	8 in vitro	22-07-2016	21-07-2023		No longer valid
8	Annex III n. 7(b)	9 industrial	22-07-2017	21-07-2024		Valid - no longer renewable
9	Annex III n. 7(b)	11 other EEE	22-07-2019	21-07-2024		Valid - no longer renewable
0	<a href="#">Annex III n. 7(c)-I</a>	1 to 7 and 10	22-07-2016	<del>21-07-2021</del>	02-01-2020	Valid - requested for renewal
1	Annex III n. 7(c)-I	8 and 9 other than in vitro and industrial	22-07-2014	<del>21-07-2021</del>	02-01-2020	Valid - requested for renewal
2	Annex III n. 7(c)-I	8 in vitro	22-07-2016	<del>21-07-2023</del>	02-01-2020	Valid - requested for renewal
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4	Annex III n. 7(c)-I	11 other EEE	22-07-2019	<del>21-07-2024</del>	09-10-2020	Valid - requested for renewal
5	<a href="#">Annex III n. 7(c)-II</a>	1 to 7 and 10	22-07-2016	<del>21-07-2021</del>	19-12-2019	Valid - requested for renewal
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Correct formula

# New Restrictions 2024





# New Restrictions 2024



The infographic features a central '2024' label surrounded by logos and restriction categories. On the left, the ECHA logo is highlighted with a blue border. The EPA logo is shown twice at the top. The ECHA logo is repeated four times around the central '2024' label, each associated with a specific restriction category in a white callout box.

**ECHA**  
EUROPEAN CHEMICALS AGENCY

POP  
PFHxS

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

TSCA  
PIP 3:1

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

TSCA  
PFAS

**ECHA**  
EUROPEAN CHEMICALS AGENCY

REACH  
Dechlorane Plus

**2024**

**ECHA**  
EUROPEAN CHEMICALS AGENCY

REACH / POP  
PFOA+

**ECHA**  
EUROPEAN CHEMICALS AGENCY

REACH  
MCCP

**ECHA**  
EUROPEAN CHEMICALS AGENCY

REACH  
Microplastics

**ECHA**  
EUROPEAN CHEMICALS AGENCY

REACH  
Formaldehyde

# New EU POP - PFHxS

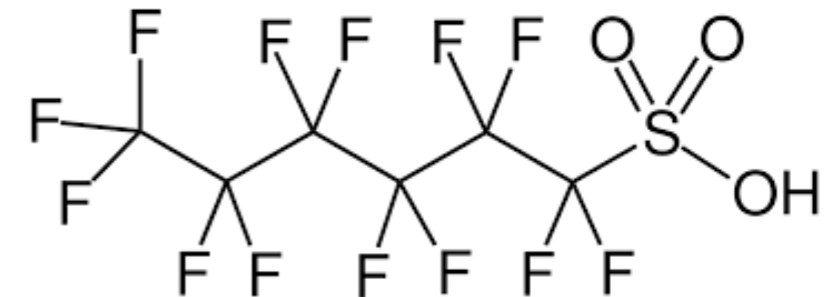
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- **Details**

- Perfluorohexane sulfonic acid (PFHxS)

- **Timeline**

- August 28, 2023



- Restriction on PFHxS

- 25 ppb
- 1,000 ppb of PFHxS related substances

- Risks

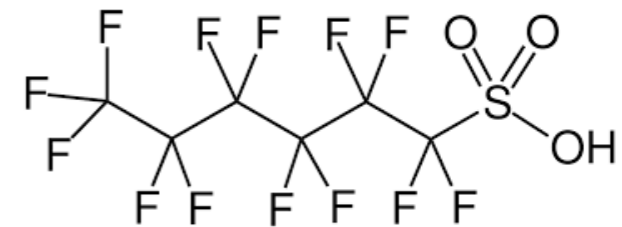
- Do not exist in physical products
- Not an additive or degradation product of any PFAS substance

# Why is PFHxS Restricted?

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- **Details (Legacy)**

- Was a degradation product of a PFOS based fire fighting foam from decades ago
- Still found in legacy burn pits at military installations, airports, or firefighting centres



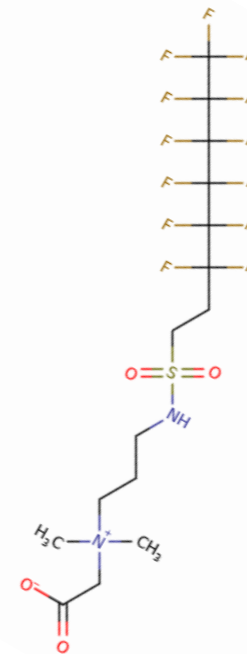
- **Today**

- Firefighting foam is based on C6 fluorotelomers
- Degrades into 6:2 FTS, and smaller version of PFOA (such as PFHxA)



# Fluorosurfactant Degradation

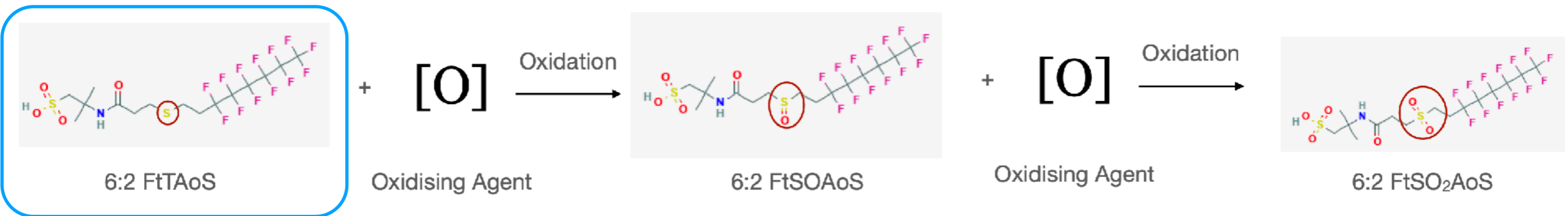
- Fluorosurfactant uses
  - Fire fighting foam
    - C6 fluorotelomers based surfactants
  - FKM and FFKM (fluoroelastomers)
  - C6 fluorotelomer based surfactant for manufacturing



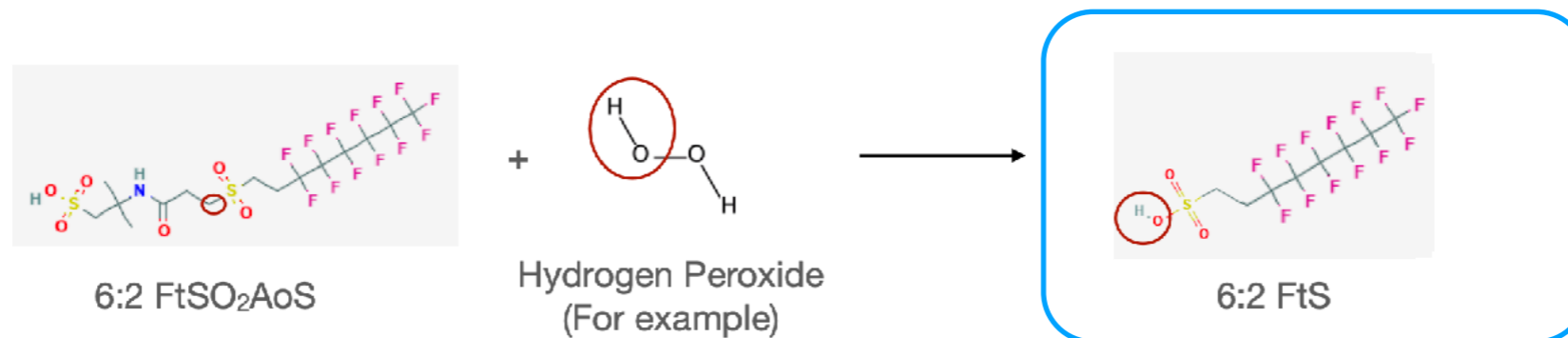
Fluoro surfactant

# Non-Ionic Surfactant Used in Fluoroelastomers (ie. Viton)

## Regular Chemical Transformation into 6:2 FTS



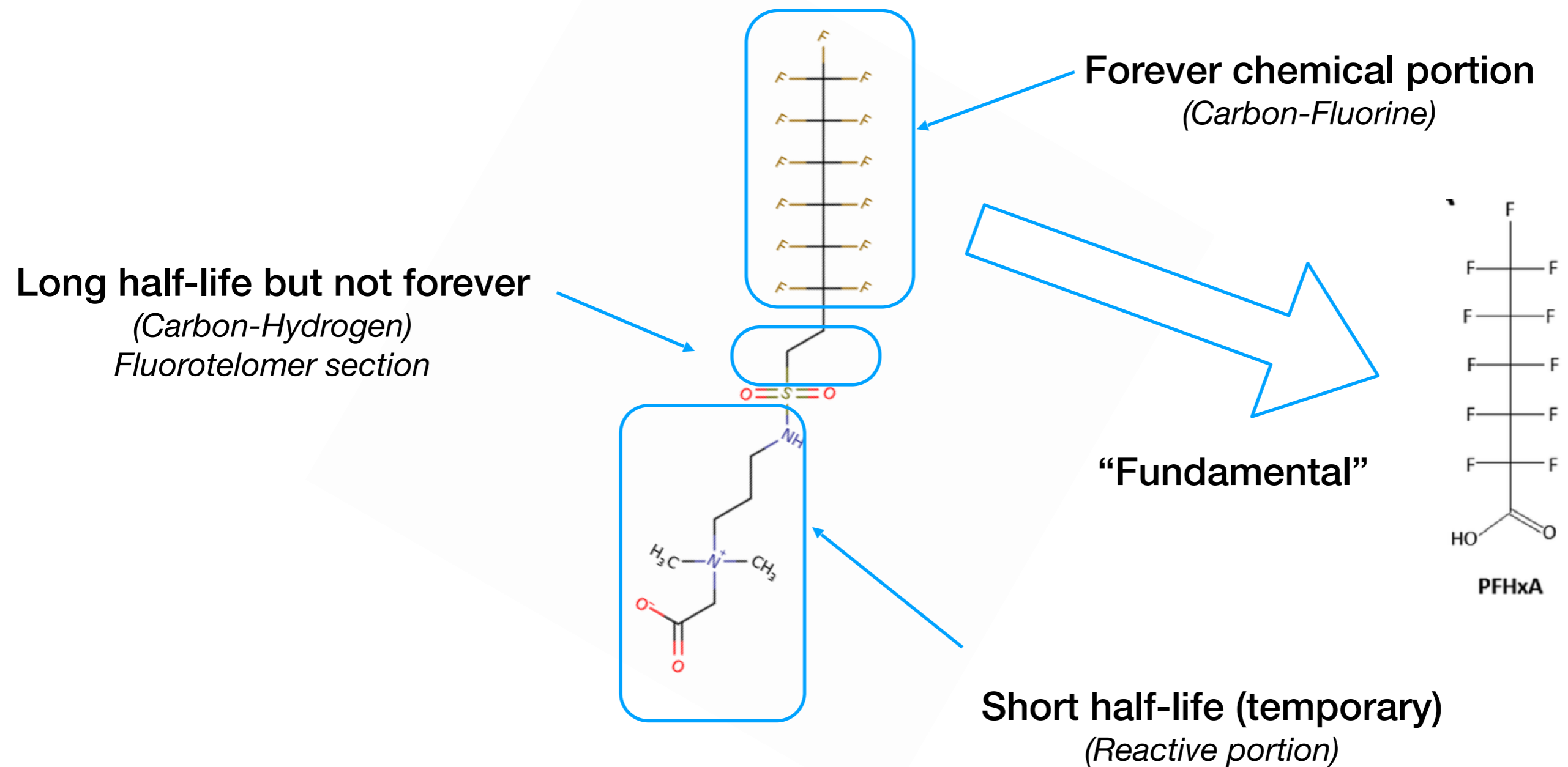
- For 6:2 FtTAoS to transform into 6:2 FtSO<sub>2</sub>AoS it must undergo a double oxidation
- Sulphur is able to make many bonds at once. This is because it is a larger atom and therefore can have an expanded octet



Starting surfactant in Fluoroelastomers

Measured sulphonate in end fluoroelastomer  
+ some smaller PFOA family (C4-C6)

# Reactive Portions of PFAS Surfactants



# New Restrictions 2024









# Example

## PFOA Containing Components

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- **Dense electronics**

- Tablets, cell phones, laptops
- PFA wiring



- **Fluid and Gas Components**

- PTFE tape

- **Medical devices**

- Implantable parts are commonly PFA coated
- PTFE tape wrap
- PFA wiring

- **Water proof fabric**

- Fluoroacrylate coated fabric including “Made in China” tag

# Important Note on POP China

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- **Restriction (China)**
  - [List of key control new pollutants \(2023 edition\)](#)
- EU POP Restrictions transposed word for word
- Details
  - EU POP restrictions in effect in China
    - Up to and including PFHxS
    - Started March 1 2023



# New Restrictions 2024



# EU REACH Restrictions

## Microplastics

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- **Published**
  - Restriction of micro plastics in mixtures (not articles)
    - 0.01%
- **Details (Restrictions - consumer only)**
  - Microbead abrasives (rinse-off products) - Oct 17 2023
  - Rinse off products (non-industrial or abrasive) - Oct 17 2027
  - Detergents - Oct 17 2028
  - Fertilizers - Oct 17 2028
  - Fragrances - Oct 17 2029
  - Medical devices Oct 17 2029
  - Leave on products - Oct 17 2029
  - Plant Protection Products - Oct 17 2031
  - Sports Fields - Oct 17 2031
  - Make-up (including lip and nail products) - Oct 17 2035

# EU REACH Restrictions

## Microplastics

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- **Exclusions (from restrictions)**
  - Professional and industrial mixtures
  - Pharmaceuticals
  - IVD
  - Fertilizers
  - Food additives
  - Food
  - Permanently incorporated into a solid matrix

# EU REACH Restrictions

## Microplastics - Declaration

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- **Declarations**

- Industrial products (mixtures) - Oct 17 2025
  - Instructions for disposal
  - Microplastics statement (see legislation)
  - Information on quantity and concentration of microparticles
  - Generic information on identification of polymers
- IVD Products - Oct 17 2026
  - Prevention of release instructions
- Makeup - Oct 17 2031
  - Microplastics statement



# EU REACH Restrictions

## Microplastics - Declaration

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- **Declarations details**

- The information shall be provided in the form of clearly visible, legible and indelible text or, where appropriate in the form of pictograms.
- The text or pictograms shall be placed on the label, the packaging, or the package leaflet of the products containing synthetic polymer microparticles or, (where applicable) on the safety data sheet.
- In addition to the text or pictograms, suppliers may provide a digital tool that gives access to an electronic version of that information.

# EU REACH Restrictions

## Microplastics - Reporting

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- **Reporting to the ECHA**
  - Manufacturers and industrial users of feedstock with microparticles
    - Starting from 2026
  - All industrial microparticles users
    - Starting from 2027
- And every May 31 of each year

# EU REACH Restrictions

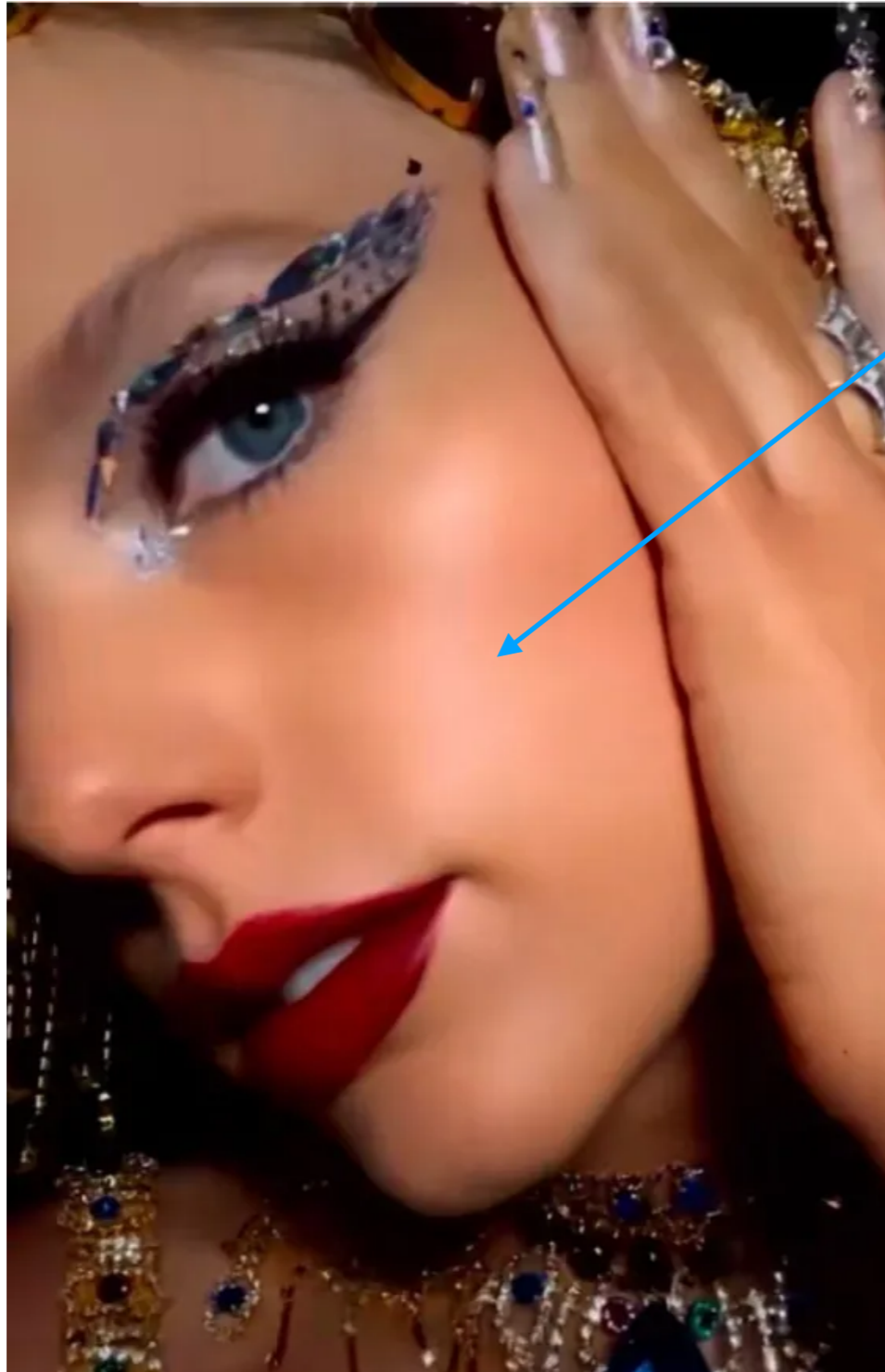
## Microplastics - Reporting

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- **Details to be reported to ECHA**
  - End use
  - Identification of polymers
    - For each use
  - Estimation of the quantity of synthetic polymer microparticles released to the environment
  - Reference to derogation used that allows continued use



# Example



**Concealer  
(Now)  
Silicone Rubber based**



## **Silicone rubbers**

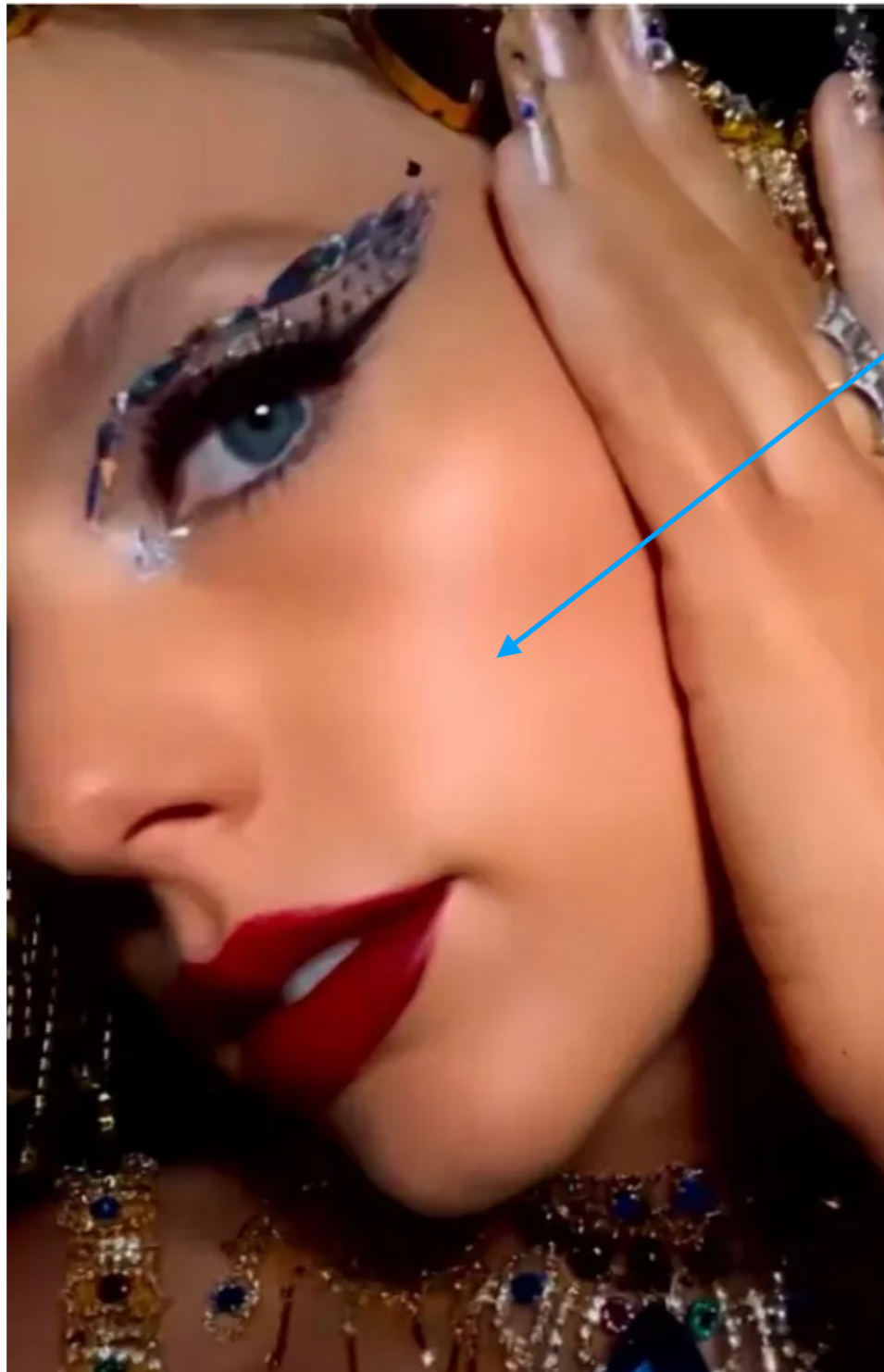
- Dimethicone
- Trimethylsiloxysilicate
- Cetyl PEG/ PPG-10/ 1 Dimethicone
- Trimethylsiloxyphenyl Dimethicone
- Dimethicone/ Vinyl Dimethicone Crosspoly.
- Trisiloxane

## **Regulations**

- Will contain some level of EU banned D4 and D5 siloxanes



# Example



## Setting Powder Microplastics

### Microplastics

- Nylon-12
- Polymethyl Methacrylate



## Regulations

- Banned in the EU (2035)



# New Restrictions 2024

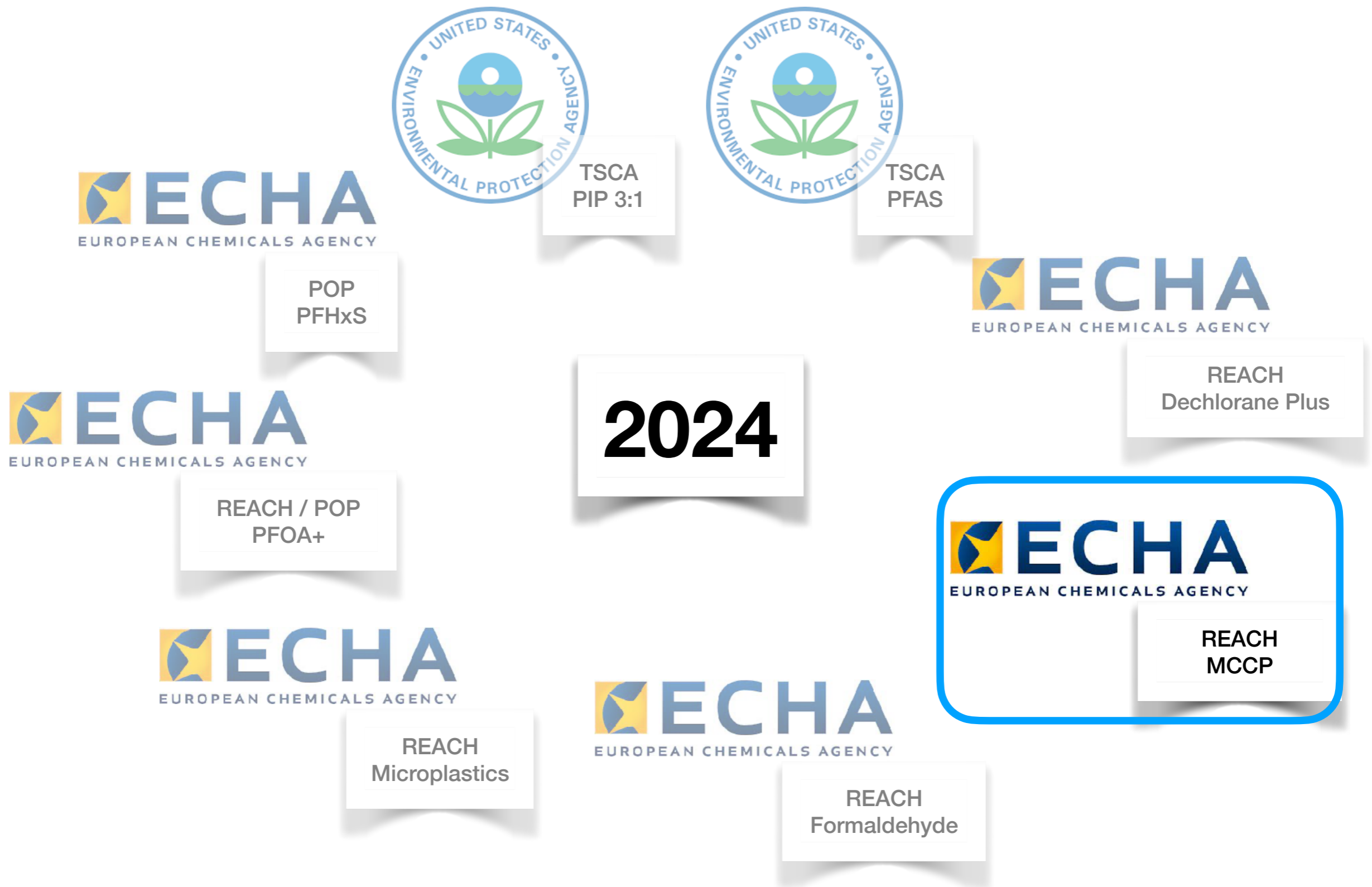


# EU REACH Restriction Formaldehyde

- [Published](#)
  - Deadline - August 6 2026 (2027 for vehicles)
  - Maximum of 0.08 mg/m<sup>3</sup> released from products
- **Excluded**
  - Naturally present formaldehyde
  - Articles exclusively for outdoor use
  - Outdoor constructions
  - Articles exclusively for industrial or professional use unless formaldehyde released from them leads to exposure to the general public under foreseeable conditions of use
  - Biocidal products
  - Medical devices and medicinal products
  - Textiles covered by REACH Restriction 72
  - Personal protective equipment
  - Food contacting materials



# New Restrictions 2024



# EU REACH Restrictions MCCP

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- **Restriction of MCCPs**

- Medium chain chlorinated paraffins
- [Consultation ended Aug 2023](#)
- Was going to be an RoHS substance. But restriction now intended to be under REACH

- **MCCP Usage**

- Plasticizer aid for phthalates such as DEHP and DINP
- Found primarily in PVC
  - Often with the smaller SCCPs



- **Option 'B' of restriction expected**

Table 2: Proposed REACH Annex XVII entry (option B)<sup>3</sup>

Designation	Conditions of restriction
Linear chloroalkanes with the following molecular formulae:  $C_{14}H_{30-y}Cl_y$ where $y = 3$ to $11$  $C_{15}H_{32-y}Cl_y$ where $y = 3$ to $8$  $C_{16}H_{34-y}Cl_y$ where $y = 3$ to $8$  $C_{17}H_{36-y}Cl_y$ where $y = 6$ to $9$	<ol style="list-style-type: none"><li>1. <ol style="list-style-type: none"><li>a. <b>REMOVED</b></li><li>b. Chloroalkanes listed in column 1 <b>shall not be placed on the market</b> in substances, in mixtures and in articles if their overall concentration in such substances, mixtures and articles is [equal to or greater than 0.1 % (w/w)].</li></ol><p>Paragraph 1 shall apply [2 years after entry into force of the restriction].</p></li><li>2. <b>REMOVED</b></li><li>3. <b>Paragraph 1</b> shall not apply to articles already in use and second-hand articles which were in end-use in the Union before [date of entry into force].</li><li>4. <b>Paragraph 1</b> shall not apply to reference materials and standards for analytical purpose.</li></ol>

- **Option 'B' of restriction expected**

7. [Within 6 months after entry into force] of the restriction, the supplier placing on the market substances, mixtures, or articles containing [substances containing the chloroalkanes listed in column 1 or referred to in paragraph 5], irrespective of the concentration, shall inform their downstream users and customers of (i) the presence and overall concentration of the chloroalkanes listed in column 1, and (ii) the appropriate risk management measures and operating conditions to minimise the releases and exposure in case of presence of chloroalkanes listed in column 1.

# EU REACH Restrictions MCCP - Summary

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- **Requirements**

- Banned two (2) years after entry into force
- Reporting requirement to customers six (6) months after entry into force

- **Next steps**

- Entry into force - ~Feb 2024
- Reporting requirements - ~Aug 2024
- Restriction - ~Feb 2026



# New Restrictions 2024



# EU REACH Restrictions

## Dechlorane Plus

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- **Not yet published**
  - Restriction will go into place 18 months from entry into force (publication)
  - Restriction likely mid 2025
- **Dechlorane plus**
  - Flame retardant for thin plastics
  - Primarily heat shrinks
  - Also a REACH SVHC
    - With 872,470 listings in the SCIP database



# New Restrictions 2024



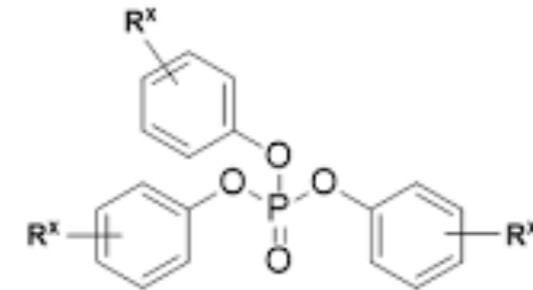
# US EPA TSCA PIP 3:1 Restriction

- **Restriction of PIP 3:1**

- [October 31 2024](#)

- **Use**

- Common flame retardant in thin PVC



Where R<sup>x</sup> = H or CH(CH<sub>3</sub>)<sub>2</sub> and all three rings have at least one -CH(CH<sub>3</sub>)<sub>2</sub> group.



# New Restrictions 2024



 **ECHA**  
EUROPEAN CHEMICALS AGENCY

POP  
PFHxS



TSCA  
PIP 3:1



TSCA  
PFAS

 **ECHA**  
EUROPEAN CHEMICALS AGENCY

REACH  
Dechlorane Plus

 **ECHA**  
EUROPEAN CHEMICALS AGENCY

**2024**

REACH / POP  
PFOA+

 **ECHA**  
EUROPEAN CHEMICALS AGENCY

REACH  
MCCP

 **ECHA**  
EUROPEAN CHEMICALS AGENCY

REACH  
Microplastics

 **ECHA**  
EUROPEAN CHEMICALS AGENCY

REACH  
Formaldehyde

# US TSCA PFAS Reporting

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- New reporting requirement [published](#)
  - For importation / manufacturing back to 2011
- Deadline
  - **120M in sales in US (including parent company)**
    - May 8 2025
  - **<120M in sales in US (including parent company)**
    - November 12 2025
- **Excluded** (FDA regulated products)
  - Medical devices
  - Food contact materials

# Reporting Requirements

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- **For each PFAS in articles (example PTFE)**
  - Chemical identity (*Poly(tetrafluoroethylene)*)
    - Generic name (*PTFE*)
  - CAS number (*9002-84-0*)
  - Import volume
    - # of units containing PTFE
  - Industrial processing or use (*U*)
    - Sector (*IS42 - Electrical equipment, appliance, and component manufacturing*)
    - Functional use (*F034 - Insulators, F999 - Other - Friction resistance*)
      - And % volume of each use
    - Product category (*CC219 - Machinery, mechanical appliances, electrical/electronic articles*)
  - Consumer or commercial (*Y/N*)
    - Intended for children (*Y/N*)
  - Maximum concentration in product (*0.1% to 1%*)



# Claigan Testing

- **For any modern tested product (2023+)**
  - Claigan provides full details with PFAS reportable testing
    - State and federal level

PFAS	Co-Axial Connector	Solid PTFE (General)	
Intentionally added	Yes	Yes	Y
Chemical	PTFE	PTFE	F
Cas number	9002-84-0	9002-84-0	9
Concentration in component	50%	100%	
Concentration in product	0.1% to 1% ▼	0.1% to 1% ▼	
Process or Use Operation	U - Use - non-i... ▼	U - Use - non-i... ▼	
Industrial Sector (IS)	IS42 - Electrical... ▼	IS42 - Electrical... ▼	
Product Category Codes	CC219 - Machi... ▼	CC219 - Machi... ▼	
Function Category	F034 - Insulators ▼	F999 - Other - Friction resistance ▼	
Purpose of PFAS	PTFE is a polymer with chemical, thermal, mechanical and	PTFE is a polymer with chemical, thermal, mechanical and	F c n

# Integrated Data

- **Data integrated for reporting to EPA**
  - EPA data for submission requires consolidation

Product		
# of units		
Consumer	Commercial	
Intended for Children	No	
	<b>Chemical</b>	<b>PTFE</b>
		<b>Fluoroelastomer</b>
Chemical	Poly(tetrafluoroethylene)	Vinylidene fluoride-hexafluoropropene polymer
Generic Name	PTFE	FKM
Gas number	9002-84-0	9011-17-0
Concentration in product	0.1% to 1%	0.1% to 1%
Process or Use Operation	U - Use - non-incorporative...	U - Use - non-incorporative ...
Industrial Sector (IS)	IS42 - Electrical equipment...	IS42 - Electrical equipment,...
Product Category Codes	CC219 - Machinery, mecha...	CC219 - Machinery, mecha...
Function 1	F034 - Insulators	F006 - Sealant (barrier)
% 1	50%	100%
Function 2	F029 - Flame retardant	
% 2	25%	0
Function 3	F999 - Other - Friction resistance	
% 3	24%	0
Function 2	F041 - Lubricating Agent	
% 4	1%	0
Total %	100%	100%

# Claigan 2024 Testing Campaigns

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- **PFAS**
  - PFAS reportable testing of representative product
  - Test for PFOA in high risk parts in representative product
  - Build state or federal PFAS declaration



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  - PFAS reportable
  - PFAS restricted
  - REACH SVHC (January and July 2023 SVHC updates)
    - Primarily melamine, tetrabromo phthalate, TBBPA
  - TSCA PIP 3:1
  - POP restrictions
    - PFHxS
  - REACH restrictions
    - MCCP and formaldehyde emissions

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# New Restrictions 2024

**ECHA**  
EUROPEAN CHEMICALS AGENCY

POP  
PFHxS



TSCA  
PIP 3:1



TSCA  
PFAS

**ECHA**  
EUROPEAN CHEMICALS AGENCY

REACH  
Dechlorane Plus

**ECHA**  
EUROPEAN CHEMICALS AGENCY

**2024**

REACH / POP  
PFOA+

**ECHA**  
EUROPEAN CHEMICALS AGENCY

REACH  
MCCP

**ECHA**  
EUROPEAN CHEMICALS AGENCY

REACH  
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**Q&A**