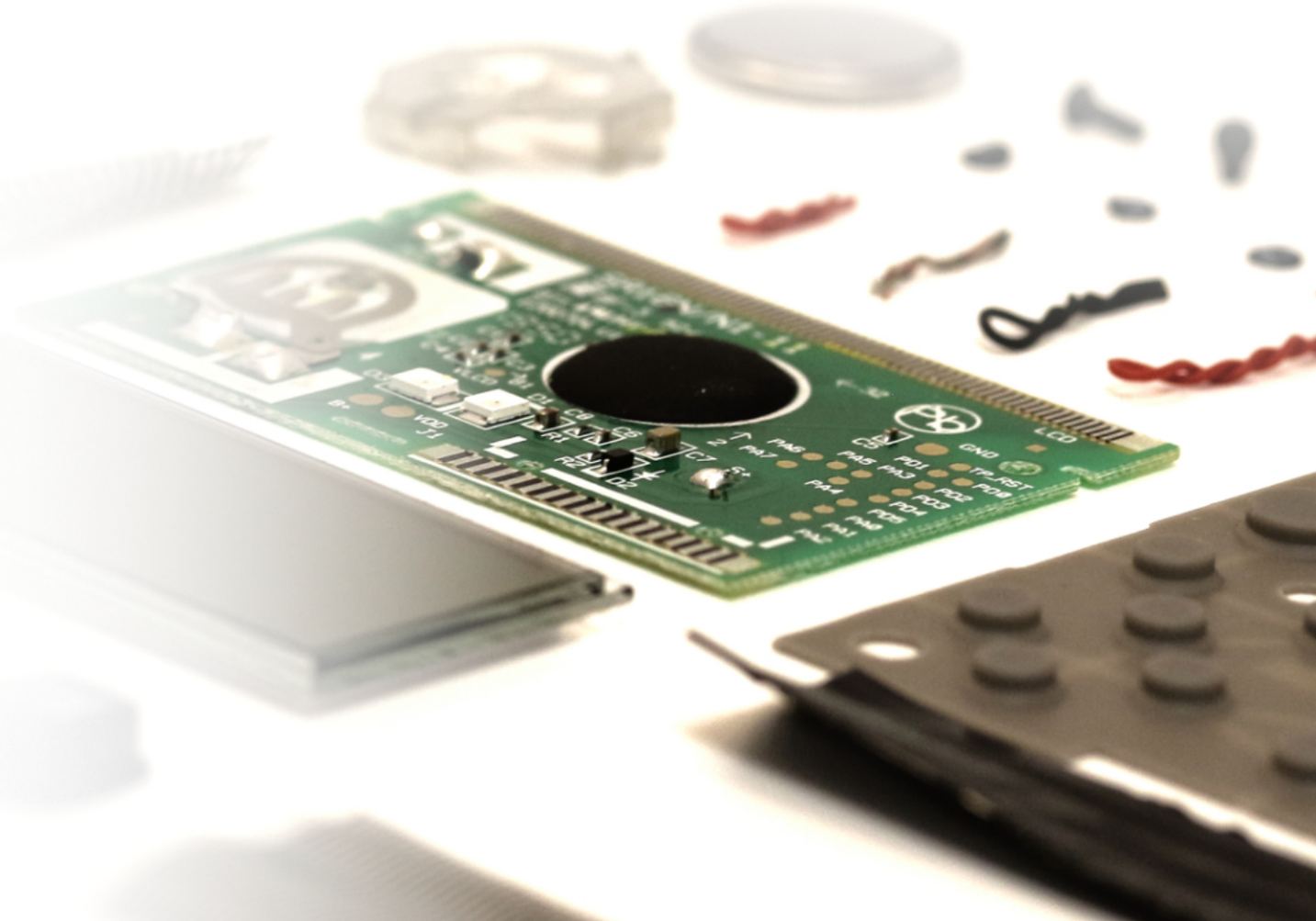
Claigan
Less Journey. More Results.

Claigan EU PFAS Restriction Submission Project

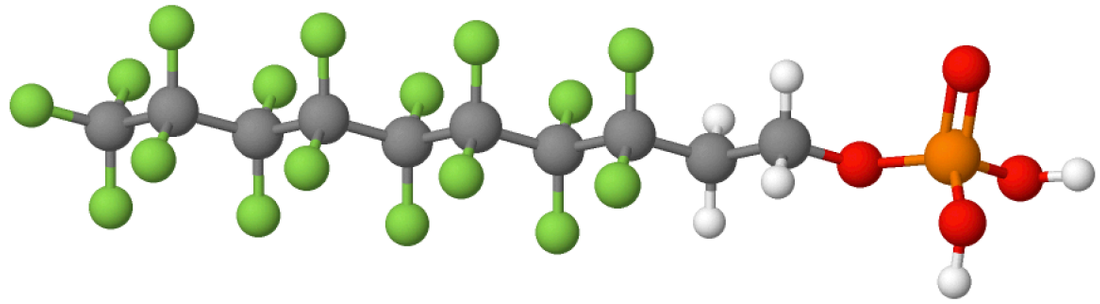
Presented by:
Bruce Calder
VP Consulting and Chief Scientist

June 20, 2023



Overview - Agenda

- EU REACH PFAS Restriction Timeline
- PFAS Restriction
  - Derogations (Exemptions)
  - Consultation
- Claigan EU PFAS Restriction Submission Project
  - Program details
  - Timelines
- Planned submissions to the ECHA
  - Uses of PFAS in articles
  - PFOA in articles
  - PFOA in the environment
  - Review of alternatives
  - Derogations needed by industry
- Further details on derogation process for project
- How to join

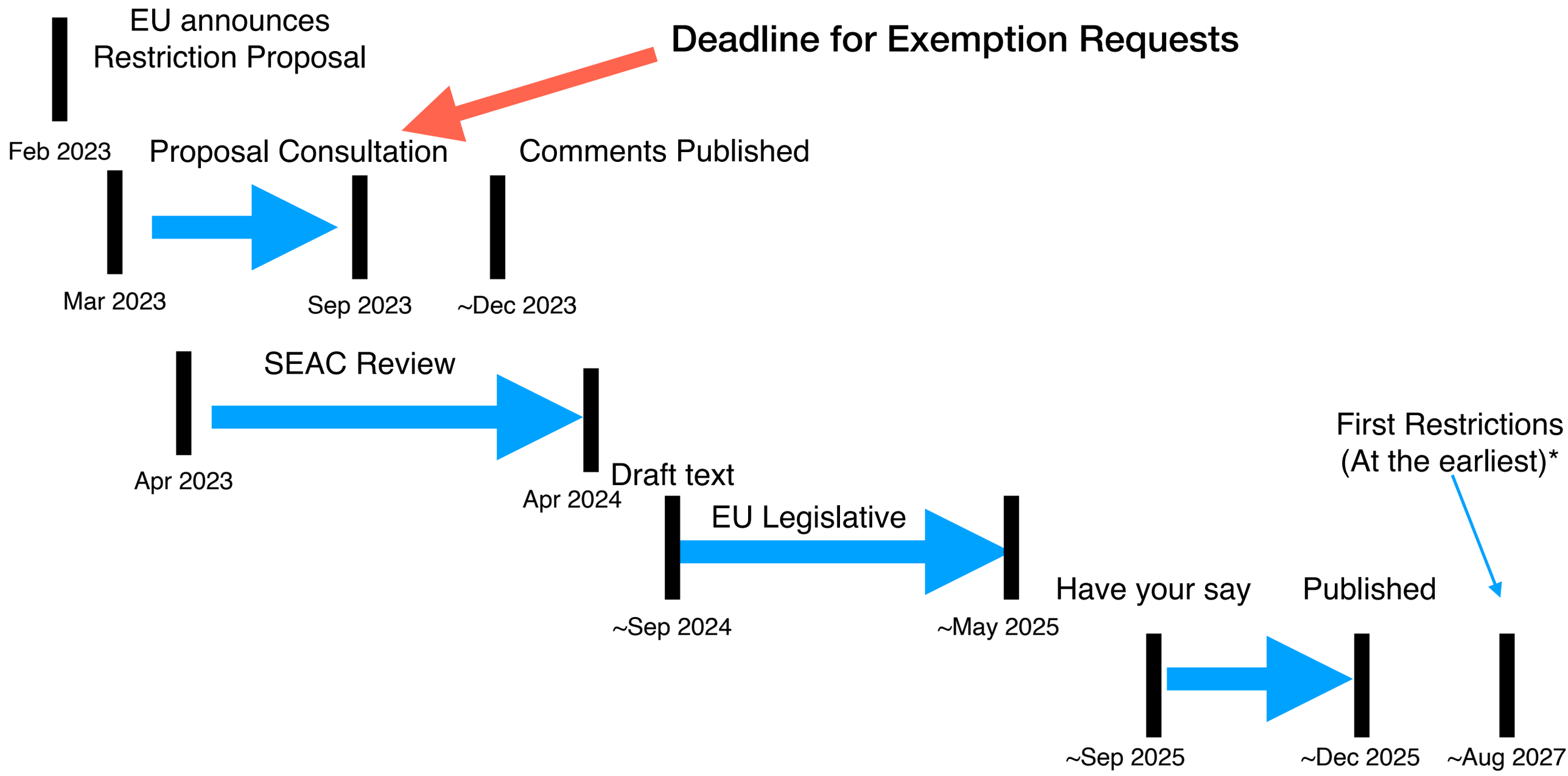


8:2 monoPAP

Webinar is 45 minutes with 15 minutes of Q&A (hopefully)

Timeline for EU PFAS Ban

- EU proposes a broad ban on PFAS in products



EU PFAS REACH Restriction Consultation

- Deadline
  - By Sept. 30 2023, industry needs to have submitted and justified all the PFAS uses they need
    - Called ‘derogations’

- Problems
  - Short deadlines
  - Highly technical
  - Very business impacting
    - Currently 90% of products will require redesign in next 3 years

- Solution -
  - **Claigan EU PFAS Consultation Submission Project**

REACH Restriction Derogations

- Derogations
  - Regulation version of exemptions

- REACH Restriction
  - All derogations exist because they were requested during the 5 country preliminary consultation

- Any new derogations need to be submitted by **September 25**

Column 1 Designation of the substance, of the group of substances or of the mixture	**Column 2** Conditions of restriction
	aa. [preservation of cultural paper-based materials until 13.5 years after EiF]; bb. [cleaning and heat transfer: engineered fluids for medical devices until 13.5 years after EiF]; cc. [membranes used for venting of medical devices until 13.5 years after EiF]; dd. [use as refrigerants and for mobile air conditioning in vehicles in military applications until 13.5 years after EiF]; ee. [the semiconductor manufacturing process until 13.5 year after EiF]. 6. By way of derogation, paragraphs 1 and 2 shall not apply to fluoropolymers and perfluoropolyethers for the use in: a. food contact materials for the purpose of industrial and professional food and feed production until 6.5 years after EiF; b. implantable medical devices (not including meshes, wound treatment products, tubes and catheters) until 13.5 years after EiF; c. tubes and catheters in medical devices until 13.5 years after EiF; d. coatings of Metered Dose Inhalers (MDIs) until 13.5 years after EiF; e. proton-exchange membrane (PEM) fuel cells until 6.5 years after EiF; f. fluoropolymer applications in petroleum and mining industry until 13.5 years after EiF.

Claigan EU PFAS Consultation Submission Project

- Project
  - Claigan is running a project to submit five (5) submissions to the EU REACH PFAS Consultation
    - *4 technical submissions*
    - *plus 1 submission of derogations needed by industry*

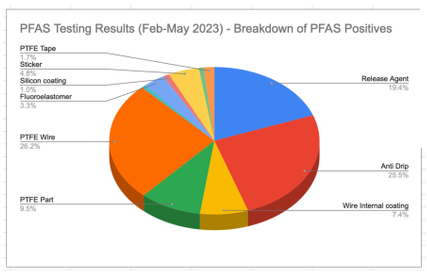
- Companies are invited to participate

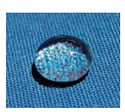
- Project - July to September 2023

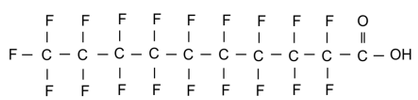
Claigan EU PFAS Consultation Submission Project

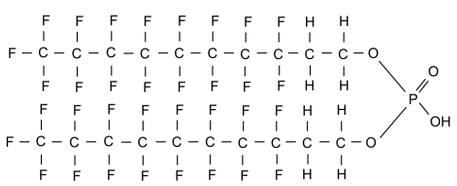
Submissions

- PFAS in Articles
- Sources of PFOA
- PFOA in the Environment
- Comparison of Alternatives
- Derogations Needed









Comparison	PTFE	PEEK	Silicone	Polyurethane	PFA	Irradiated PTFE	ePTFE	Fluoroacrylate
Low Friction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Chemical Restriction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Water Resistance	Excellent	Excellent	Decent	Decent	Excellent	Excellent	Excellent	Excellent
Oil Resistance	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent
Temperature resistan	Excellent	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent
Flexibility	Decent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Forever Chemicals	Excellent	Excellent	Poor	Excellent	Decent	Decent	Decent	Poor
Biocompatibility	Excellent	Excellent	Decent	Excellent	Excellent	Excellent	Excellent	Decent

PFAS	Co-Axial Connector
Intentionally added	Yes
Chemical	PTFE
Cas number	9002-84-0
Concentration in component	50%
Purpose of PFAS	PTFE is a polymer with chemical, thermal, mechanical and electrical properties that are capable of satisfying the most demanding requirements in the industry. It is anti-adherent, low friction, resistant to almost all chemical products, inflammable and has excellent dielectric properties. Dielectric constant - The speed of a signal traveling through a coaxial cable depends on the dielectric constant of the insulating material between the center conductor and the outer conductor. Thus, cable assemblies use poly-tetrafluoro-ethylene (PTFE) to minimize signal delay. PTFE bearings - PTFE has very low friction; excellent strength, stabiliyt, and wear characteristics; good heat conduction, and low thermal expansion.

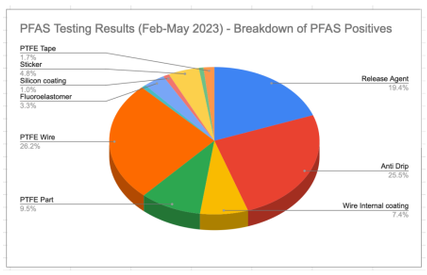
Claigan EU PFAS Consultation Submission Project

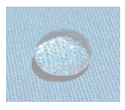
- **Advantages**
  - **Participant input and feedback**
    - Inclusion of your uses into the project
    - Opportunities to review and comment on submissions
  - **Monthly web meeting**
    - Monthly update on progress
    - Technical explanation of uses and derogations
- **EU consultation submissions**
  - Drafts provided monthly to all participants
  - Final versions provided to all participants
- **Submission of final documents to ECHA**

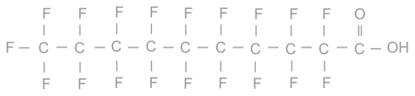
Claigan EU PFAS Submission #1

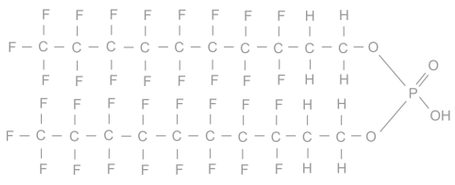
Submissions

- PFAS in Articles
- Sources of PFOA
- PFOA in the Environment
- Comparison of Alternatives
- Derogations Needed







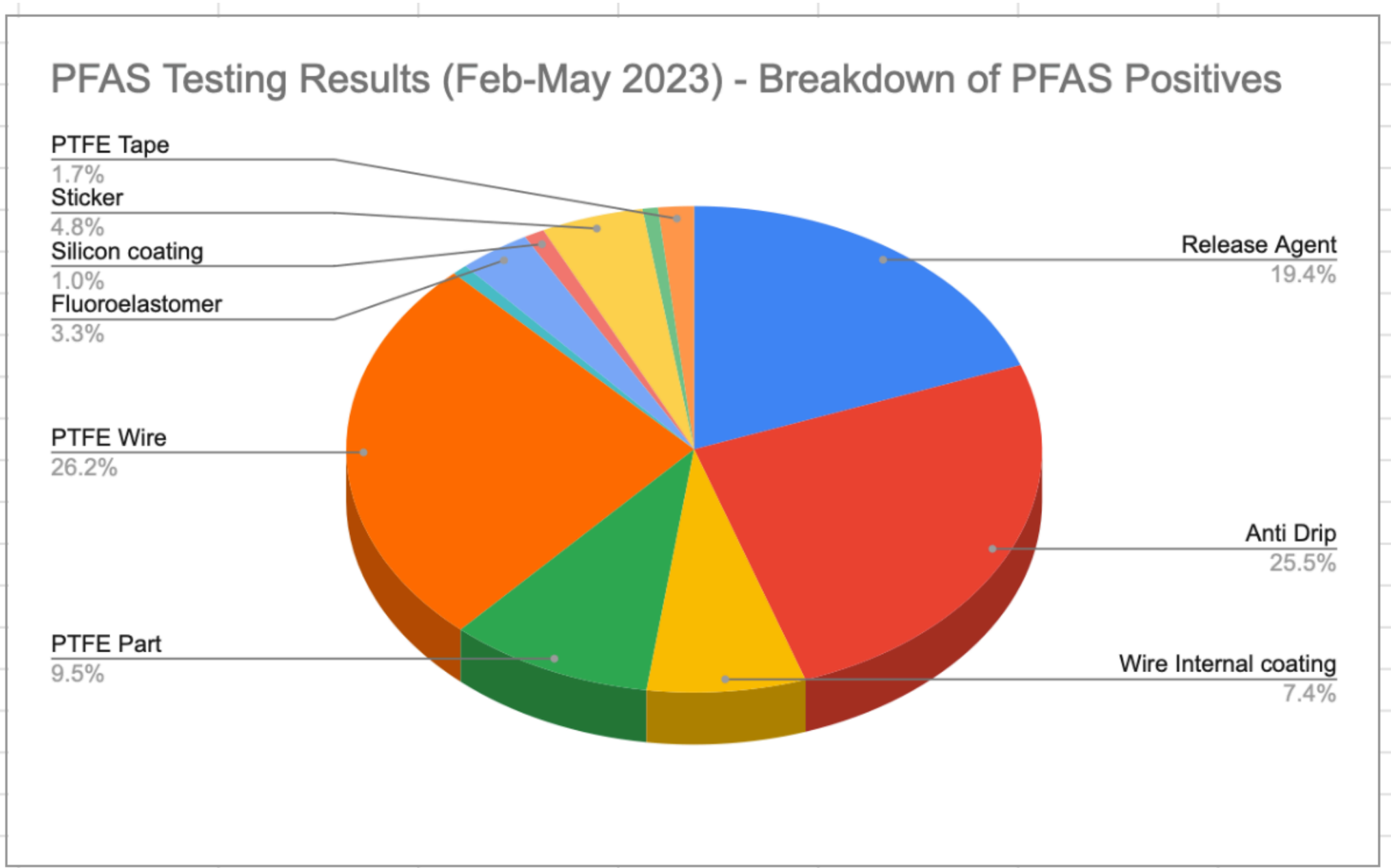


Comparison	PTFE	PEEK	Silicone	Polyurethane	PFA	Irradiated PTFE	ePTFE	Fluoroacrylate
Low Friction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Chemical Restriction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Water Resistance	Excellent	Excellent	Decent	Decent	Excellent	Excellent	Excellent	Excellent
Oil Resistance	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent
Temperature resistant	Excellent	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent
Flexibility	Decent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Forever Chemicals	Excellent	Excellent	Poor	Excellent	Decent	Decent	Decent	Poor
Biocompatibility	Excellent	Excellent	Decent	Excellent	Excellent	Excellent	Excellent	Decent

PFAS	Co-Axial Connector
Intentionally added	Yes
Chemical	PTFE
Cas number	9002-84-0
Concentration in component	50%
Purpose of PFAS	PTFE is a polymer with chemical, thermal, mechanical and electrical properties that are capable of satisfying the most demanding requirements in the industry. It is anti-adherent, low friction, resistant to almost all chemical products, inflammable and has excellent dielectric properties. Dielectric constant - The speed of a signal traveling through a coaxial cable depends on the dielectric constant of the insulating material between the center conductor and the outer conductor. Thus, cable assemblies use poly-tetrafluoro-ethylene (PTFE) to minimize signal delay. PTFE bearings - PTFE has very low friction; excellent strength, stability, and wear characteristics; good heat conduction, and low thermal expansion.

Claigan Submission #1
PFAS in Articles

- **Detailed test data from hundreds of products**
  - Explanation of each PFAS situation and use



Claigan EU PFAS Submission #2

Submissions

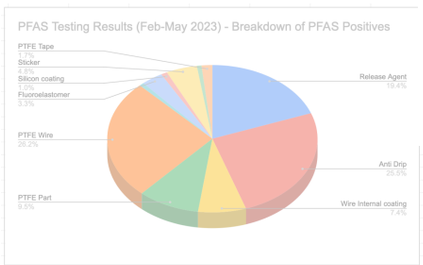
PFAS in Articles

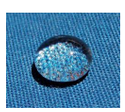
Sources of PFOA

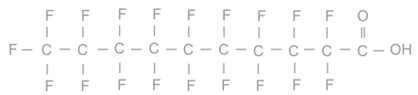
PFOA in the Environment

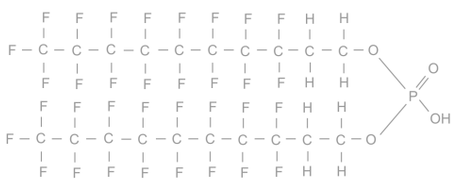
Comparison of Alternatives

Derogations Needed









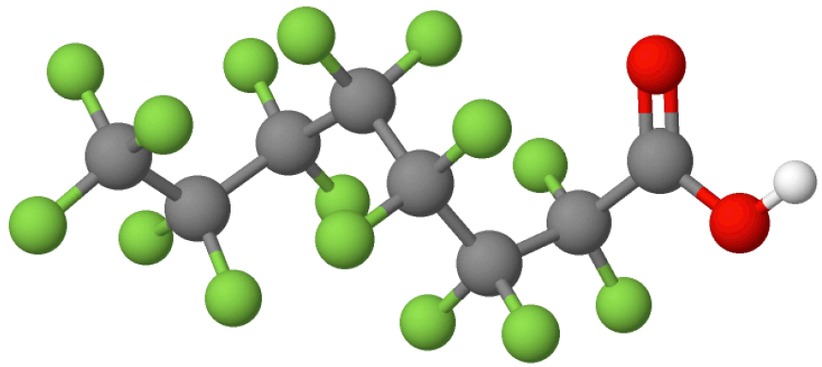
Comparison	PTFE	PEEK	Silicone	Polyurethane	PFA	Irradiated PTFE	ePTFE	Fluoroacrylate
Low Friction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Chemical Restriction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Water Resistance	Excellent	Excellent	Decent	Decent	Excellent	Excellent	Excellent	Excellent
Oil Resistance	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent
Temperature resistan	Excellent	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent
Flexibility	Decent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Forever Chemicals	Excellent	Excellent	Poor	Excellent	Decent	Decent	Decent	Poor
Biocompatibility	Excellent	Excellent	Decent	Excellent	Excellent	Excellent	Excellent	Decent

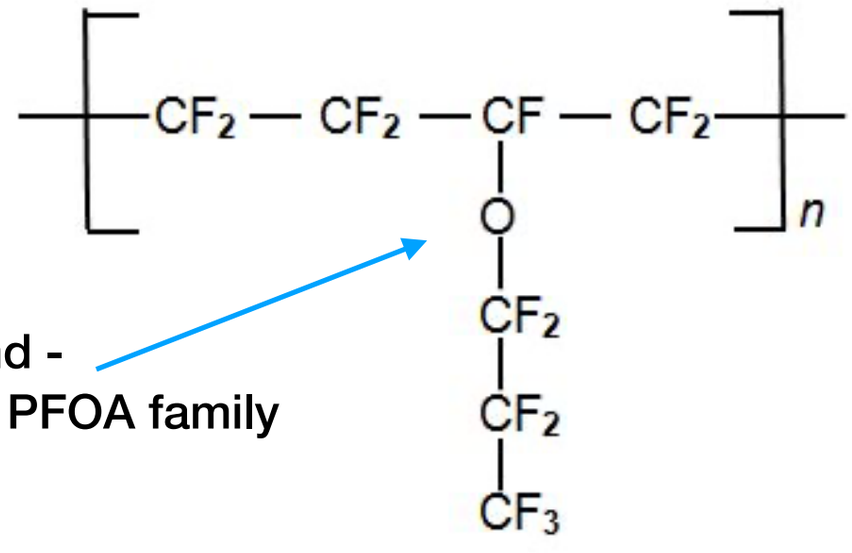
PFAS	Co-Axial Connector
Intentionally added	Yes
Chemical	PTFE
Cas number	9002-84-0
Concentration in component	50%
Purpose of PFAS	PTFE is a polymer with chemical, thermal, mechanical and electrical properties that are capable of satisfying the most demanding requirements in the industry. It is anti-adherent, low friction, resistant to almost all chemical products, inflammable and has excellent dielectric properties. Dielectric constant - The speed of a signal traveling through a coaxial cable depends on the dielectric constant of the insulating material between the center conductor and the outer conductor. Thus, cable assemblies use poly-tetrafluoro-ethylene (PTFE) to minimize signal delay. PTFE bearings - PTFE has very low friction; excellent strength, stability, and wear characteristics; good heat conduction, and low thermal expansion.

Claigan Submission #2
PFOA in Articles

- **Sources of PFOA (and other PFAC) in articles**
  - Based on hundreds of products of data
  - Explanation of reason for presence
    - Examples
      - Irradiation
      - Ester degradation
      - Surfactant during manufacturing

PFOA

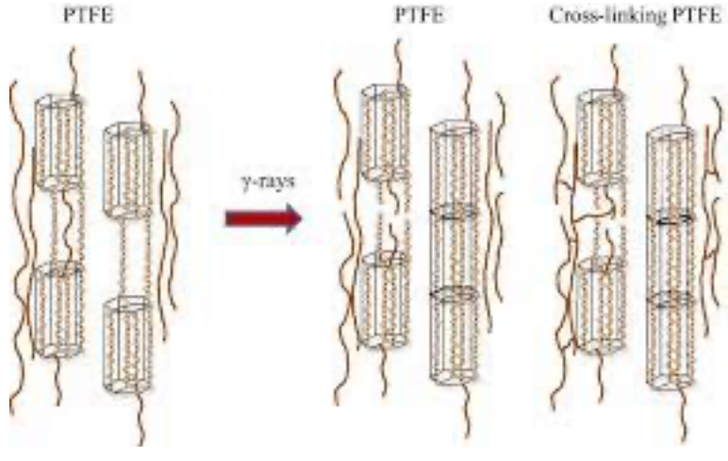




Ester bond -
Fractures to create PFOA family

PFA

Irradiation of PTFE



Claigan EU PFAS Submission #3

Claigan

Submissions

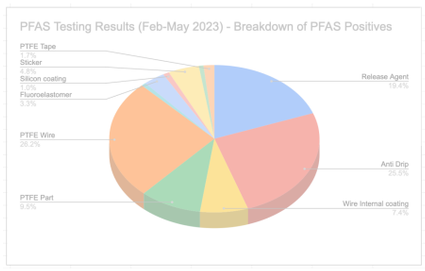
PFAS in Articles

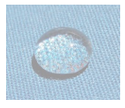
Sources of PFOA

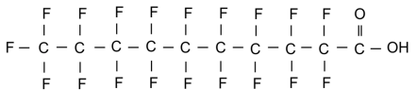
PFOA in the Environment

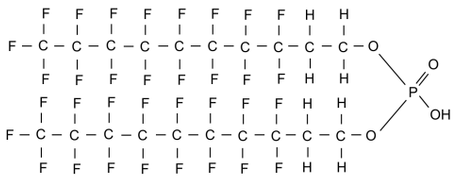
Comparison of Alternatives

Derogations Needed







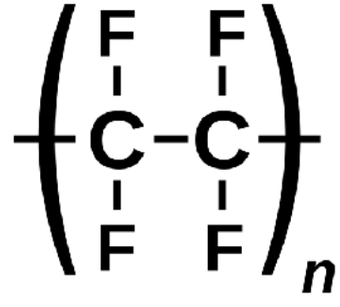


Comparison	PTFE	PEEK	Silicone	Polyurethane	PFA	Irradiated PTFE	ePTFE	Fluoroacrylate
Low Friction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Chemical Restriction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Water Resistance	Excellent	Excellent	Decent	Decent	Excellent	Excellent	Excellent	Excellent
Oil Resistance	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent
Temperature resistant	Excellent	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent
Flexibility	Decent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Forever Chemicals	Excellent	Excellent	Poor	Excellent	Decent	Decent	Decent	Poor
Biocompatibility	Excellent	Excellent	Decent	Excellent	Excellent	Excellent	Excellent	Decent

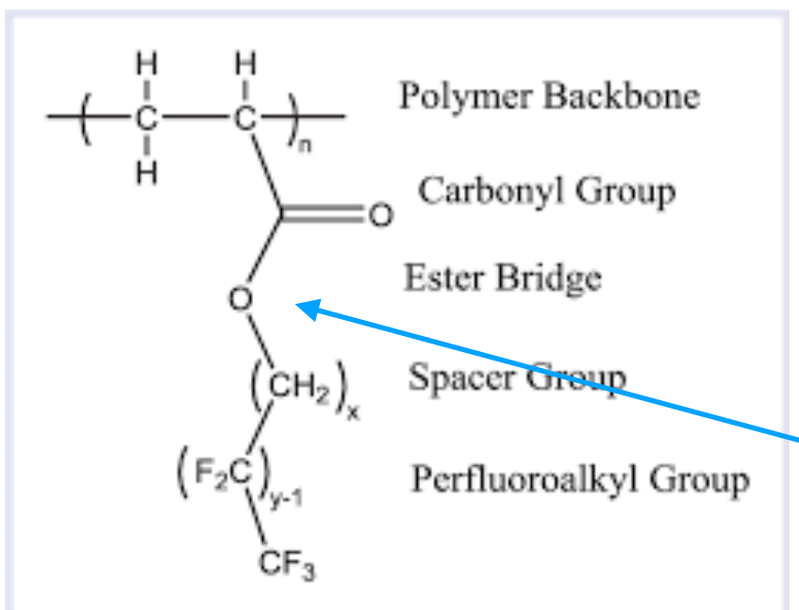
PFAS	Co-Axial Connector
Intentionally added	Yes
Chemical	PTFE
Cas number	9002-84-0
Concentration in component	50%
Purpose of PFAS	PTFE is a polymer with chemical, thermal, mechanical and electrical properties that are capable of satisfying the most demanding requirements in the industry. It is anti-adherent, low friction, resistant to almost all chemical products, inflammable and has excellent dielectric properties. Dielectric constant - The speed of a signal traveling through a coaxial cable depends on the dielectric constant of the insulating material between the center conductor and the outer conductor. Thus, cable assemblies use poly-tetrafluoro-ethylene (PTFE) to minimize signal delay. PTFE bearings - PTFE has very low friction; excellent strength, stabiliyt, and wear characteristics; good heat conduction, and low thermal expansion.

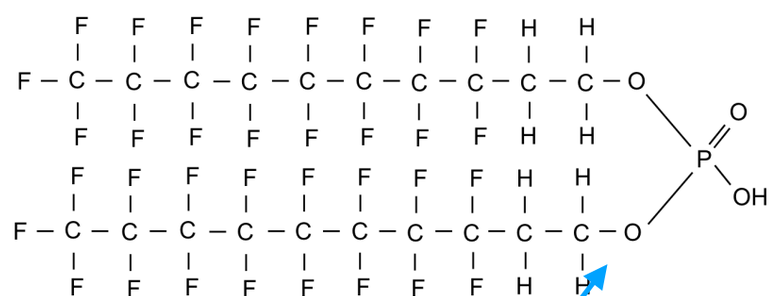
Claigan Submission #3
PFOA in Environment

- **Sources of PFOA (and other PFAC) in the environment**
  - Expected sources of PFOA in the environment
  - Contribution of articles
  - Differences between
    - PFAS non-ester (negligible source of PFOA in environment)
    - PFAS esters (significant contributors to PFOA in environment)



PFAS Non-Ester





PFAS Esters

Claigan EU PFAS Submission #4

Submissions

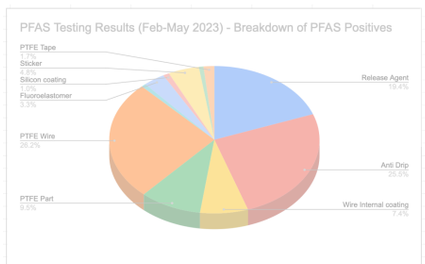
PFAS in Articles

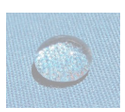
Sources of PFOA

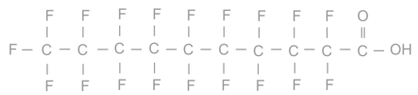
PFOA in the Environment

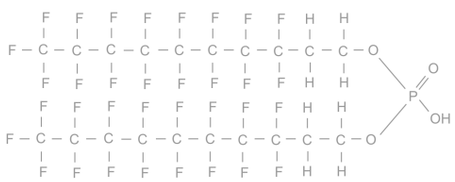
Comparison of Alternatives

Derogations Needed









Comparison	PTFE	PEEK	Silicone	Polyurethane	PFA	Irradiated PTFE	ePTFE	Fluoroacrylate
Low Friction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Chemical Restriction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Water Resistance	Excellent	Excellent	Decent	Decent	Excellent	Excellent	Excellent	Excellent
Oil Resistance	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent
Temperature resistan	Excellent	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent
Flexibility	Decent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Forever Chemicals	Excellent	Excellent	Poor	Excellent	Decent	Decent	Decent	Poor
Biocompatibility	Excellent	Excellent	Decent	Excellent	Excellent	Excellent	Excellent	Decent

PFAS	Co-Axial Connector
Intentionally added	Yes
Chemical	PTFE
Cas number	9002-84-0
Concentration in component	50%
Purpose of PFAS	PTFE is a polymer with chemical, thermal, mechanical and electrical properties that are capable of satisfying the most demanding requirements in the industry. It is anti-adherent, low friction, resistant to almost all chemical products, inflammable and has excellent dielectric properties. Dielectric constant - The speed of a signal traveling through a coaxial cable depends on the dielectric constant of the insulating material between the center conductor and the outer conductor. Thus, cable assemblies use poly-tetrafluoro-ethylene (PTFE) to minimize signal delay. PTFE bearings - PTFE has very low friction; excellent strength, stability, and wear characteristics; good heat conduction, and low thermal expansion.

Claigan Submission #4
Comparison of Alternatives

- **Comparison of PFAS Alternatives**
  - Comparison of different PFAS and PFAS alternatives
  - Summary and detailed comparisons
    - Plus definitions and criteria

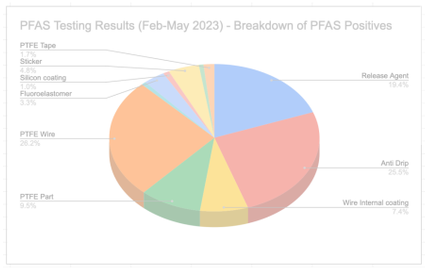
Example Summary Comparison

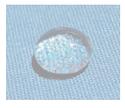
Comparison	PTFE	PEEK	Silicone	Polyurethane	PFA	Irradiated PTFE	ePTFE	Fluoroacrylate
Low Friction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Chemical Restriction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Water Resistance	Excellent	Excellent	Decent	Decent	Excellent	Excellent	Excellent	Excellent
Oil Resistance	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent
Temperature resistan	Excellent	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent
Flexibility	Decent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Forever Chemicals	Excellent	Excellent	Poor	Excellent	Decent	Decent	Decent	Poor
Biocompatibility	Excellent	Excellent	Decent	Excellent	Excellent	Excellent	Excellent	Decent

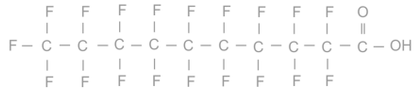
Claigan EU PFAS Submission #5

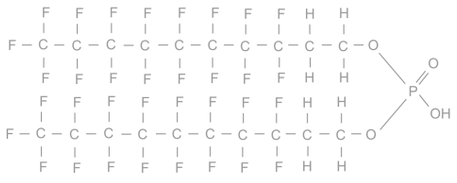
Submissions

- PFAS in Articles
- Sources of PFOA
- PFOA in the Environment
- Comparison of Alternatives
- Derogations Needed









Comparison	PTFE	PEEK	Silicone	Polyurethane	PFA	Irradiated PTFE	ePTFE	Fluoroacrylate
Low Friction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Chemical Restriction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Water Resistance	Excellent	Excellent	Decent	Decent	Excellent	Excellent	Excellent	Excellent
Oil Resistance	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent
Temperature resistant	Excellent	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent
Flexibility	Decent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Forever Chemicals	Excellent	Excellent	Poor	Excellent	Decent	Decent	Decent	Poor
Biocompatibility	Excellent	Excellent	Decent	Excellent	Excellent	Excellent	Excellent	Decent

PFAS	Co-Axial Connector
Intentionally added	Yes
Chemical	PTFE
Cas number	9002-84-0
Concentration in component	50%
Purpose of PFAS	PTFE is a polymer with chemical, thermal, mechanical and electrical properties that are capable of satisfying the most demanding requirements in the industry. It is anti-adherent, low friction, resistant to almost all chemical products, inflammable and has excellent dielectric properties. Dielectric constant - The speed of a signal traveling through a coaxial cable depends on the dielectric constant of the insulating material between the center conductor and the outer conductor. Thus, cable assemblies use poly-tetrafluoro-ethylene (PTFE) to minimize signal delay. PTFE bearings - PTFE has very low friction; excellent strength, stabiliyt, and wear characteristics; good heat conduction, and low thermal expansion.

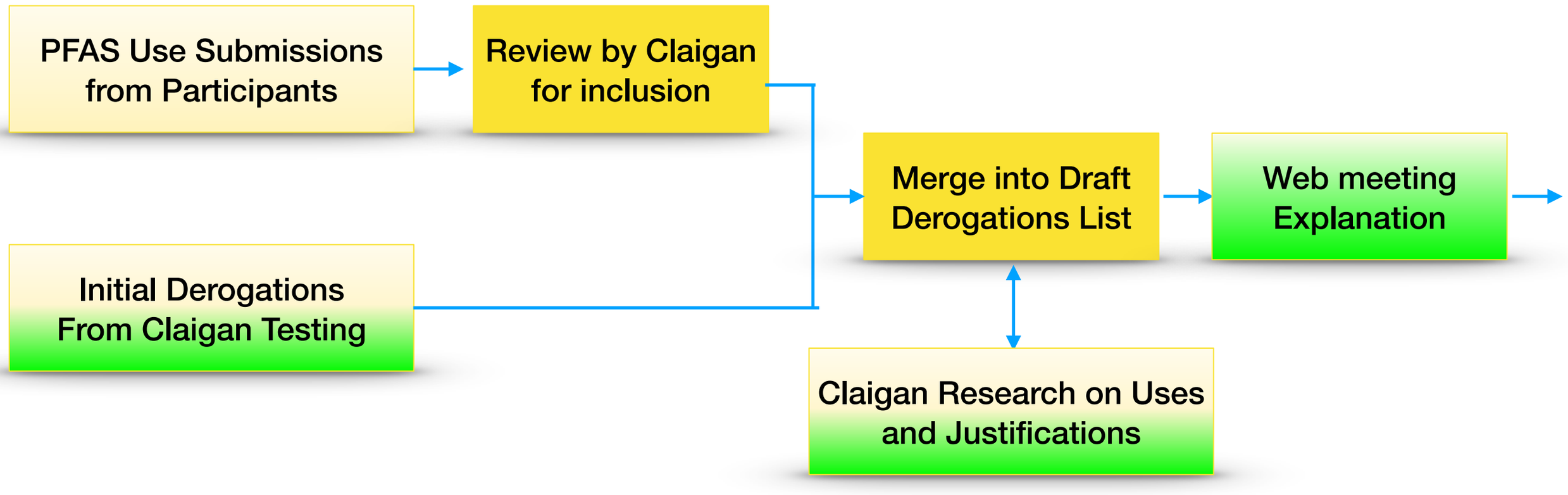
Claigan Submission #5 Derogations

- **Derogations needed by industry for articles**
  - For each derogation (summary and detailed)
    - Derogation requested
    - Use
    - Justification
    - Derogation timeline requested
      - Has replacement but will take time (6.5 years)
      - No known effective replacements (13.5 years)

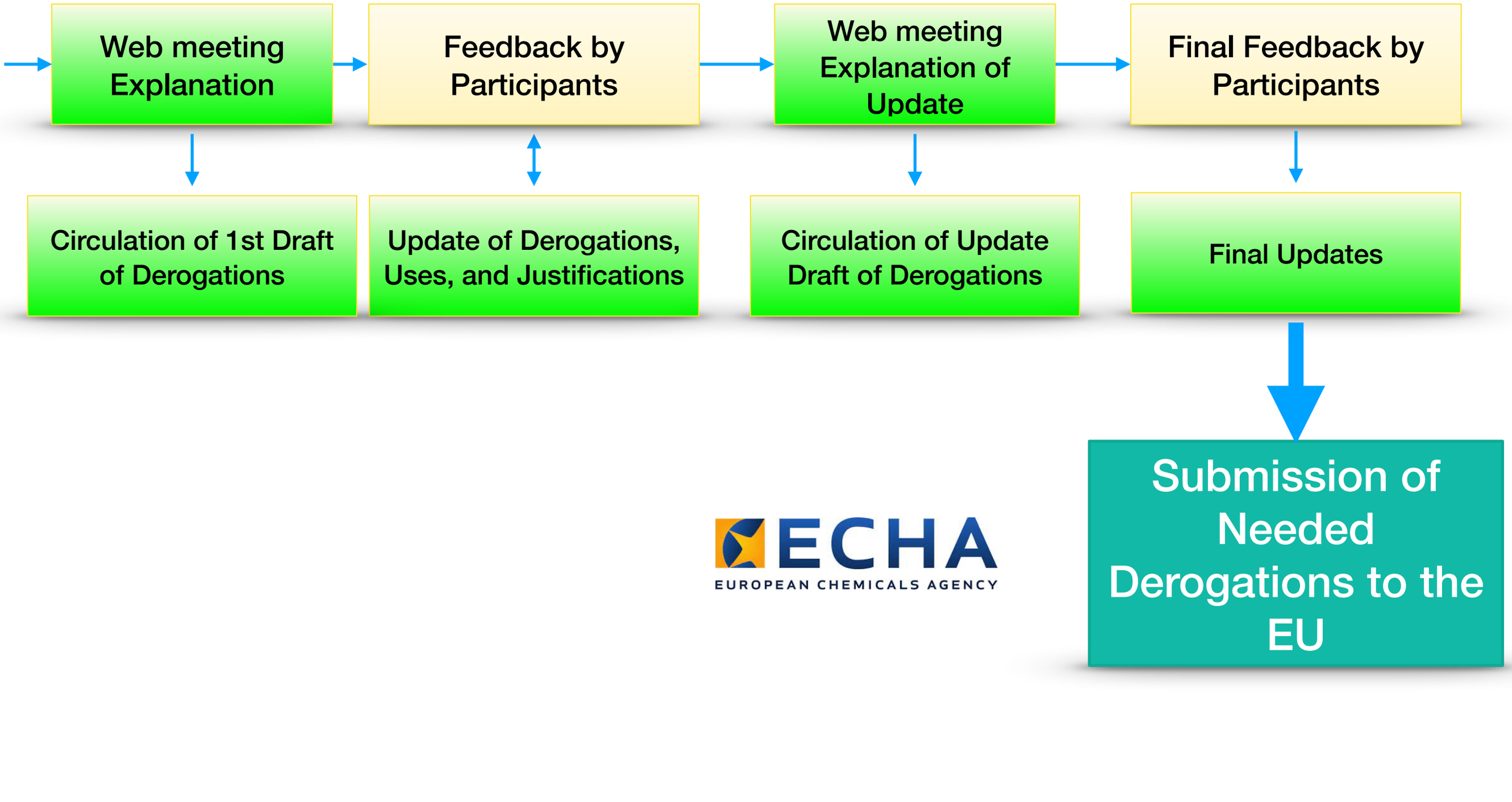
Example Summary of Derogations

Derogation	Timeline Requested	Derogation	Text
c1	13.5 Years	PFAS Polymers and Non-Polymers	Perfluoroalkoxy alkanes (PFA) polymers in professional applications not in contact with drinking water or food. Maximum of 2ppm of C4-C14 perfluoroalkyl carboxylates
c2	6.5 Years	PFAS Polymers	Fluorosilicone release agents used in manufacturing process of plastic and rubber parts.
c3	13.5 Years	PFAS Polymers	PTFE used as an additive drip agent in plastics to meet flammability safety requirements

Derogations Process Part I



Derogations Process Part 2



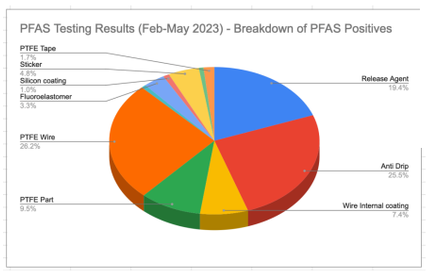
Claigan EU PFAS Consultation Submission Project

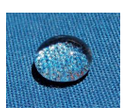
- **Advantages**
  - **Participant input and feedback**
    - Inclusion of your uses into the project
    - Opportunities to review and comment on submissions
  - **Monthly web meeting**
    - Monthly update on progress
    - Technical explanation of uses and derogations
- **EU consultation submissions**
  - Drafts provided monthly to all participants
  - Final versions provided to all participants
- **Submission of final documents to ECHA**

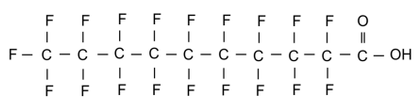
Claigan EU PFAS Consultation Submission Project

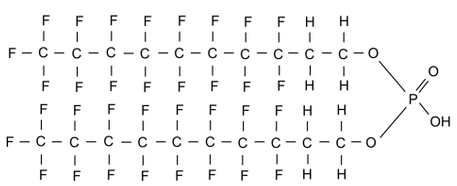
Submissions

- PFAS in Articles
- Sources of PFOA
- PFOA in the Environment
- Comparison of Alternatives
- Derogations Needed









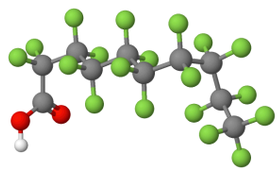
Comparison	PTFE	PEEK	Silicone	Polyurethane	PFA	Irradiated PTFE	ePTFE	Fluoroacrylate
Low Friction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Chemical Restriction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Water Resistance	Excellent	Excellent	Decent	Decent	Excellent	Excellent	Excellent	Excellent
Oil Resistance	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent
Temperature resistan	Excellent	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent
Flexibility	Decent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Forever Chemicals	Excellent	Excellent	Poor	Excellent	Decent	Decent	Decent	Poor
Biocompatibility	Excellent	Excellent	Decent	Excellent	Excellent	Excellent	Excellent	Decent

PFAS	Co-Axial Connector
Intentionally added	Yes
Chemical	PTFE
Cas number	9002-84-0
Concentration in component	50%
Purpose of PFAS	PTFE is a polymer with chemical, thermal, mechanical and electrical properties that are capable of satisfying the most demanding requirements in the industry. It is anti-adherent, low friction, resistant to almost all chemical products, inflammable and has excellent dielectric properties. Dielectric constant - The speed of a signal traveling through a coaxial cable depends on the dielectric constant of the insulating material between the center conductor and the outer conductor. Thus, cable assemblies use poly-tetrafluoro-ethylene (PTFE) to minimize signal delay. PTFE bearings - PTFE has very low friction; excellent strength, stabiliyt, and wear characteristics; good heat conduction, and low thermal expansion.

Joining the Claigan REACH PFAS Project

- **Contact Claigan**
  - info@claigan.com,
  - webinar@claigan.com, or
  - ‘Reach’ out to me

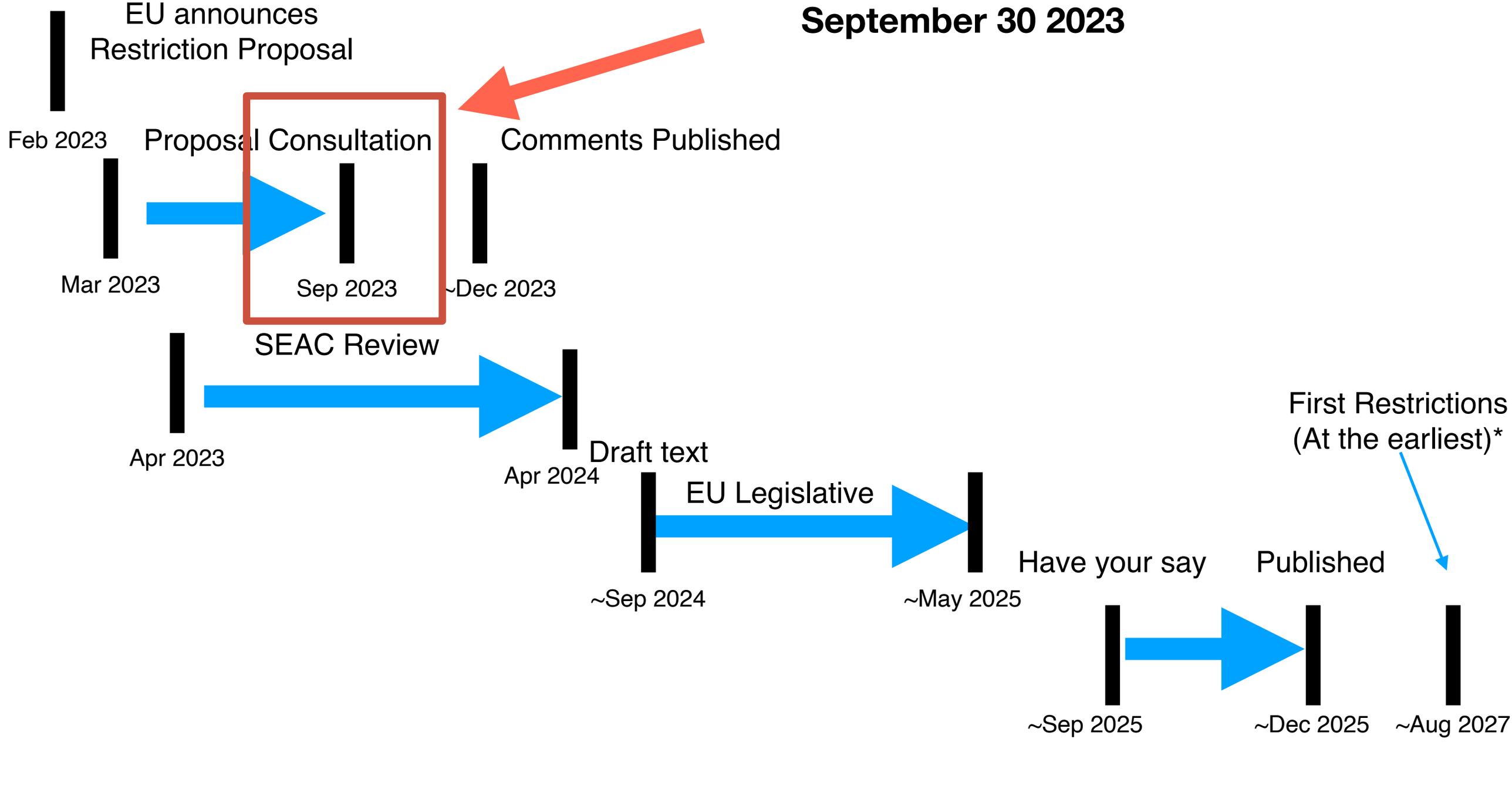
- Costs are very straight forward



PFDA

Timeline for EU PFAS Ban

- EU proposes a broad ban on PFAS in products

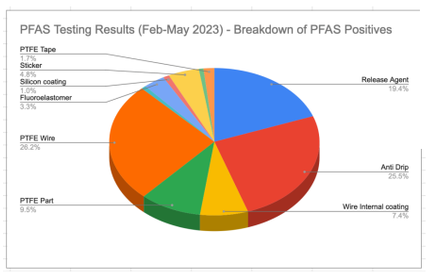


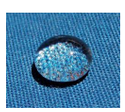
Claigan EU PFAS Consultation Submission Project

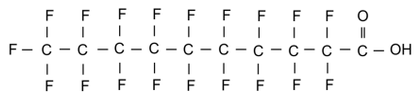
Q&A

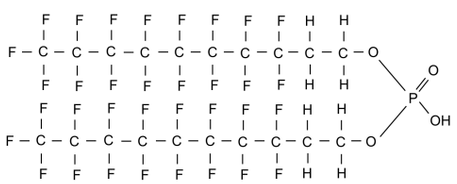
Submissions

- PFAS in Articles
- Sources of PFOA
- PFOA in the Environment
- Comparison of Alternatives
- Derogations Needed









Comparison	PTFE	PEEK	Silicone	Polyurethane	PFA	Irradiated PTFE	ePTFE	Fluoroacrylate
Low Friction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Chemical Restriction	Excellent	Decent	Decent	Poor	Excellent	Excellent	Excellent	Excellent
Water Resistance	Excellent	Excellent	Decent	Decent	Excellent	Excellent	Excellent	Excellent
Oil Resistance	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent
Temperature resistan	Excellent	Excellent	Excellent	Poor	Excellent	Excellent	Excellent	Excellent
Flexibility	Decent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent
Forever Chemicals	Excellent	Excellent	Poor	Excellent	Decent	Decent	Decent	Poor
Biocompatibility	Excellent	Excellent	Decent	Excellent	Excellent	Excellent	Excellent	Decent

PFAS	Co-Axial Connector
Intentionally added	Yes
Chemical	PTFE
Cas number	9002-84-0
Concentration in component	50%
Purpose of PFAS	PTFE is a polymer with chemical, thermal, mechanical and electrical properties that are capable of satisfying the most demanding requirements in the industry. It is anti-adherent, low friction, resistant to almost all chemical products, inflammable and has excellent dielectric properties. Dielectric constant - The speed of a signal traveling through a coaxial cable depends on the dielectric constant of the insulating material between the center conductor and the outer conductor. Thus, cable assemblies use poly-tetrafluoro-ethylene (PTFE) to minimize signal delay. PTFE bearings - PTFE has very low friction; excellent strength, stabiliyt, and wear characteristics; good heat conduction, and low thermal expansion.

Contact - info@claigan.com Web page - https://www.claigan.com/pfas-project/