



Chemours™

Fluoropolymer Advocacy Toolkit:
How to engage in the Public
Consultation process under REACH

April 2023

FLUOROPOLYMER ADVOCACY TOOLKIT

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The time for you to engage is now

We have entered a stage in the regulatory process where industry has a unique opportunity to make an impact on the proposal to restrict all PFAS in the EU. All data you will provide to the EU authorities will be considered when formulating the final restriction. Therefore, it is critical to engage now.

Why engaging in the Public Consultation phase is critical

- **Potential Phase Out Without Action:** The regulatory proposal, published in February 2023, plans to **phase out** the manufacture, import, sale, and use of around 10,000 PFAS in the EU, with an 18-month transition phase after the regulation enters into force (**expected 2025**). Derogations are suggested for individual applications of five or 12 years for which alternatives do not yet exist. For details and tips how to read the Restriction Dossier see also the section “The restriction proposal – what’s in it?” below.
- **You Can Shape the Final Outcome:** It is essential to understand that this is only a proposal and **not the final restriction**. In the coming months, industry and other interested stakeholders will have the opportunity to shape the final outcome by providing important data to the scientific committees of the European Chemistry Agency (ECHA).
- **Submitting Data Will Promote Science-Based Regulation:** ECHA’s two scientific committees for Risk Assessment (RAC) and for Socio-Economic Analysis (SEAC) have already begun their scientific evaluation of the proposal. During this assessment process, they consider comments from stakeholders such as companies, trade associations, or NGOs.
- **Limited Window to Submit Data – ACT NOW:** This **public consultation process** started on March 22 and will last six months **until September 25, 2023. Early submission is recommended (by early May)**; you can submit additional information/data later in the process.
- **No Data, No Derogation:** Most importantly, ECHA acts on the principle “**No data, no market.**” Industry input and data—across the entire fluoropolymer value chain— are critical to support proposed and additional derogations, as well as in helping SEAC formulate an accurate opinion.

The restriction proposal – what’s in?

A proposal for far reaching restrictions



Proposal to ban over 10,000 PFAS as defined by the OCED in sectors where the submitters assumed there are technically and economically feasible alternatives.



Certain time-bound derogations which are limited in number and focused on very specific applications, i.e. PEM in fuel cells. If a derogation for a certain sector/application is not listed, the application is automatically included in the ban.

- The so-called “Restriction Dossier” proposes a comprehensive ban of the entire substance class of PFAS with an 18-month transition phase after the regulation’s entry into force (EIF). This includes a ban on fluoropolymers such as PTFE, FEP, PFA, FKM, PFPE or PFSA ionomers. It also proposes derogations for individual applications of five or 12 years in sectors essential for society and for which alternatives do not yet exist. The duration of a temporary derogation depends on how realistic a rapid development of alternatives is.

- The Restriction Dossier is broken up into several Annexes that encompass different content areas:

Annex XV	Important overview of restriction, summary of other annexes			
	Hazard/exposure	Emissions & risk	Manufacture and use	Impact assessment and derogations
Annex A	Information on uses (applications)			
	Manufacturing	Import	Export	Applications (uses)
Annex B	Hazard and risk information			
	Hazards and risks	Classification and labelling	Environmental fate properties	Human health & environmental hazard assessment
Annex E	Detailed review of impact assessment of each application (use)			
	Baseline volumes	Alternatives	Environmental and economic impact	Cost and benefit assessment



Annex C: Justification for action on a Union-wide basis (currently empty)
 Annex D (Baseline): currently empty
 Annex F: assumptions, uncertainties and sensitivities
 Annex G: summary of stakeholder involvement to date, including CFE questionnaires

Some suggestions for Restriction Dossier review

Annex XV outlines the specific derogations for sectors and applications. You can find it [here](#).

- ➔ For your applications: read sections in annex, review claims and data, validate information
- ➔ Note where Dossier is missing information, needs more detail, or if it has weak/missing argumentation
- ➔ Identify and provide information to close the gaps to support fluoropolymers

NOTE: If your application is not mentioned, it means there is **NO** derogation, so supplying data is critical.

- **Derogations are proposed** for fluoropolymers and perfluoropolyethers for the use in (see also p.7f in [Annex XV](#)):
 - food contact materials for the purpose of industrial and professional food and feed production until 5 years after the 18-month transition phase;
 - implantable medical devices (excluding meshes, wound treatment products, tubes and catheters) until 12 years after the 18-month transition phase;
 - tubes and catheters in medical devices until 12 years after the 18-month transition phase;
 - coatings of Metered Dose Inhalers (MDIs) 12 years after the 18-month transition phase;
 - proton-exchange membrane (PEM) fuel cells until 5 years after the 18-month transition phase;
 - fluoropolymer applications in the petroleum and mining industry until 12 years after the 18-month transition phase.
- The following potential derogations are marked **for reconsideration** after the public consultation:
 - [non-stick coatings in industrial and professional bakeware until 5 years after the 18-month

- transition phase];
- [hernia meshes until 12 years after the 18-month transition phase];
 - [wound treatment products until 12 years after the 18-month transition phase];
 - [coating applications for medical devices other than Metered Dose Inhalers until 13.5 years after EIF];
 - [Rigid gas permeable contact lenses and ophthalmic lenses until 12 years after the 18-month transition phase];
 - [PCTFE-based packaging for medicinal preparations, medical devices and medical molecular diagnostics until 12 years after the 18-month transition phase];
 - [PTFE in ophthalmic solutions packaging until 12 years after the 18-month transition phase];
 - [packaging of terminally sterilized medical devices until 12 years after the 18-month transition phase];
 - [applications affecting the proper functioning related to the safety of transport vehicles, and affecting the safety of operators, passengers or goods until 12 years after the 18-month transition phase].

For these ‘potential derogations’ between brackets ([]), additional evidence is needed to justify the derogations, as the evidence base is currently too weak to propose them as derogations. After the public consultation, the newly submitted information will be reviewed and the evidence base re-assessed, on the basis of which it will be concluded whether the evidence base is strong enough to propose a derogation with an appropriate derogation duration (5 or 12 years after the transition period). In case the evidence base remains weak, no derogation will be proposed.

How this regulation will impact industry:

- Overregulating fluoropolymers would lead to a regression in the advanced technologies that enable modern life, a curtailment in the ability of companies to attract investors, and a reduction in the reliability, safety, and efficiency of a wide array of products.
 - **Derogations are delayed bans:** Even if five- or 12-year derogations apply for a sector (6.5/13.5 years after EIF), they significantly impact opportunities for future development and growth: no planning certainty, no investment in technologies’ future, and no research and development.
- ➔ **The industry needs time-unlimited derogations for fluoropolymers**



Public Consultation submission tips

The process of commenting on the restriction proposal is clearly structured and straightforward. Anyone can participate. Below, we explain this in detail, including what your response should include, and what you should consider, while engaging in the consultation.

- **Everyone is encouraged to participate:** Any stakeholder can submit comments in the **Public Consultation**; in particular on the benefits of fluoropolymers, on the availability or unavailability of alternatives and on the impact of a possible ban. It is crucial that manufacturers of substances and downstream users **participate in the consultation** – as collective voices will help to clarify to regulators the magnitude and severity of a possible ban on fluoropolymers.
- **“No Data – No market”:** Please remember that **you will have to substantiate all your answers** with supporting evidence, to justify the information submitted in the consultation. This is crucial because the ECHA can only make decisions by independently evaluating the information submitted.
- **Prepare your input early:** The sooner you submit important information and data, the higher the likelihood that the input will be considered in the first deliberations of the scientific committees. Therefore, **we recommend submitting your input ideally within the first six weeks of the consultation phase** (until May 3). Additional data can and should be submitted throughout the process– as every piece of data is valuable to the authorities; September 25 (23.59 Helsinki time) is the FINAL date for submission.
- **When providing information on socio-economic impacts**, data is critical, focus on:
 - Incremental costs and benefits, (i.e., strictly those related to implementing the proposed restriction as compared with not implementing it)
 - Relevant contextual information (e.g., what sources the estimates are based on)
 - Calculations underpinning any estimates provided
 - Scope of impacts e.g., one-off investment costs or recurring operating costs. Also consider indirect impacts resulting from the non-availability of an application
- **Connect your submission to key regional and political objectives**, such as
 - Criticality of fluoropolymers for achieving EU Green Deal, see also Appendix “Fluoropolymers and the EU Green Deal”
 - Fluoropolymers enable modern life and help achieve important societal goals such as renewable energy or more sustainable transportation.
- **No Position Papers:** It is recommended **not to submit position papers**, as these do not add any substantial value for the authorities.
- **No Edits:** Please note, that incorrectly **transmitted information can NOT be corrected** (e.g. mixing up confidential and non-confidential attachments). Therefore, particular care should be taken to submit any confidential information in the correct area.
- **Confirmation:** After submitting a comment, one should receive a **confirmation email from ECHA with a submission number**. This number should be kept for future reference, especially for any communication with ECHA. Any stakeholder should submit their comments themselves (and not

collectively via third parties), as ECHA will only give out one number per IP address, regardless of the number of submissions.

- **Publication of Comments:** ECHA will publish submitted comments on a monthly basis (only those submitted non-confidentially). In this way, participation can be continuously monitored and it becomes clear on which areas to focus mobilization efforts.
- **Zip Files:** The authorities recommend to **zip large files** before uploading.
- **Further Guidance:** ECHA published a useful guide on how to submit information and structure answers to its survey. You can find this guide [here](#). If you need further, more detailed information on the consultation process, you also have the possibility to watch a recording of an **informative ECHA webinar** on this topic from [April 5](#). If you have any questions or uncertainties, please do not hesitate to contact the Chemours team.
- **One Go-to Website:** ECHA has set up a **dedicated webpage** [here](#) to participate in the consultation. There is **NO other way** to submit information on this specific Dossier. This website essentially consists of the following segments:
 - **Introduction:** Includes process overview with link to both a [Consultation Guidance](#), as well as a specific [Information Note](#) by ECHA.
 - **Section 1:** Personal information.
 - **Section 2:** Organizational information.
 - **Section 3:** Non-confidential comments on the proposal. Your responses can be entered directly into the form or through section 4 as an attachment. The section has two parts:
 1. General comments (max. 9000 characters) - On any aspect of the Annex XV restriction report, **including on issues related to socio-economic analysis**.
 2. Specific information requests - A list of pre-written questions:

Question 1: The Dossier and possible derogations/exemptions are structured **on the basis of sectors and applications** of PFAS. Thus, in the first question area, specify which affected sector and (sub-uses) your comments concern.

Question 2: The restriction proposal is based primarily on the assumption that PFAS (including fluoropolymers) are persistent, bioaccumulative and mobile, and exhibit varying (eco)toxicological effects. Thus, when they enter the environment, they would accumulate and cause problems in the longer term. It is therefore up to the supply chain of fluoropolymers to prove otherwise.

➔ **Explain the health and environmental profile** of your products/fluoropolymers used (e.g., FP do not degrade to smaller PFAS in the environment). **Show your efforts to control PFAS emissions** over the entire life cycle of the concerned uses (manufacture, use, and end-of-life), **including the recovery and recycling** of fluoropolymers in your products. Explain what waste treatment options are available to you. Refer to any existing regulations that already affect your industry/products in terms of safety and waste management.

➔ It is also worth mentioning and providing evidence that fluoropolymers do not degrade into smaller PFAS in the environment; they are not mobile, bioaccumulative, or toxic. Thus, they should not fall under the proposed restriction's scope, as fluoropolymers' safety is guaranteed over their entire lifecycles.

Question 3: As ECHA is primarily interested in whether and how PFAS may enter the environment, the third question on end-of-life emissions focuses on the **effectiveness of waste management options**; in particular, effectiveness of incineration in **destroying fluoropolymers**. The aim should be to show that incineration in energy recovery or thermal destruction processes can **completely decompose fluoropolymers**. It should be pointed out, that when deposited in landfills there is no risk of fluoropolymers in leachate since fluoropolymers are inert, non-toxic, and non-mobile.

Question 4: Answers to question 4 should highlight the consequences of the proposed regulation for recyclers resulting from the concentration limits proposed in the Dossier.

Question 5: The Restriction Dossier proposes different derogations for different sectors and uses of PFAS (see above). A proposal for derogation is based on the assumption that there are no suitable alternatives for the respective application yet. The more challenging it is to find an alternative, the longer the granted duration of the derogation. For those derogations, Question 5 requires information on the **amount of PFAS** (tonnages) used annually and the **resulting environmental emissions** for these proposed derogations. The aim should be, analogous to question two, to show that the risk of PFAS emissions from fluoropolymers is low - and thus, **fluoropolymers should not fall under the scope of the proposed restriction**, i.e., they should be fully exempt.

Questions 6 to 8 are the centerpiece of the public consultation – as they request **information on alternatives and socio-economic impacts** for:

- uses not yet covered or identified by the current proposal (question 6),
- derogations marked for reconsideration by the Dossier (question 7),
- and listed uses for which information on alternatives and socio-economic impacts has so far only been generic and qualitative (question 8).

When providing input on these questions, your specific expertise in the application of **fluoropolymers and their unique requirement profile** will be key information in demonstrating their strengths and irreplaceability by non-existent alternatives. This information will offer useful guidance for authorities to assess whether further derogations are needed etc.

- ➔ Determine the use of fluoropolymers in critical applications; provide details on performance criteria, key functions and benefits of fluoropolymers; and share information on required standards and specifications.

The more difficult it is to find an alternative, the greater the chance that ECHA will grant another derogation/exemption. Therefore, it is fundamentally important to show whether a change to an alternative substance is possible at all and what **performance and safety losses** would be associated with this change.

- ➔ Show in detail your search for alternatives, including timelines and financial costs – so that the **hurdles** for a possible switch are clear to the regulators. Justify if and why a search for alternatives was unsuccessful. Provide details on the **availability and feasibility of any alternatives** and their application, including hazard and risk profiles.

If substituting fluoropolymers is not technically or economically feasible, the **severe socioeconomic consequences** of banning fluoropolymers should be demonstrated.

- ➔ Provide detailed information, at your discretion, on the annual affected value of EU sales and profits, as well as employment numbers, if any. Describe the economic impact both

on your company as well as your broader value chain/downstream users. In addition to the economic consequences, also describe the potential social impact of a loss of fluoropolymers.

➔ Further detailed guidance on questions 6-8 is provided in the [ECHA guide](#) (p.5f).

Question 9 concerns the **degradation potential** of specific PFAS sub-groups.

Question 10: concerns any information you might have on **new analytical methods** for PFAS yet considered in the report.

- **Section 4:** Non-confidential attachments can be added here.
- ➔ Please note: All non-confidential information submitted during the public consultation will be published monthly by ECHA
- **Section 5:** Sensitive, confidential attachments can be submitted here. Confidential information will only be available to the ECHA Secretariat, the Committees and Member State Competent Authorities. However, if ECHA receives a request for Access to Documents, they may come back to you for justification on why the information is confidential. Any information submitted otherwise may be subject to a request for information and can be made available to the wider public.

Chemours' position

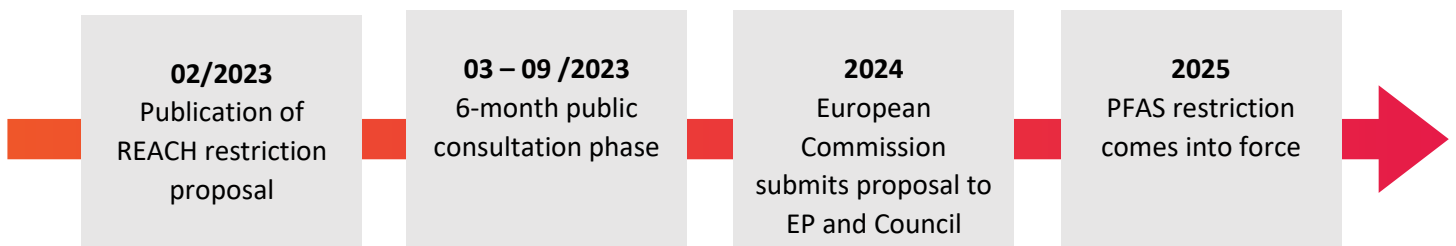
- **Time-unlimited derogations needed:** Industry needs a time-unlimited derogation for manufacturing and use of fluoropolymers – a specific class of PFAS with a unique and vital combination of properties – in designated applications now and in the future with responsible manufacturing of fluoropolymers and responsible life cycle management. A broad ban on PFAS would significantly impact European business and industries that rely on these critical substances.
- **Support for science-based regulation:** We support industry-wide government regulation that is science-based, targeted, consistent, and benefits society and the environment. A one-size-fits-all regulation is not the right approach.
- **We will continue to engage in an open dialogue** with authorities, the public, and regulators to help further develop meaningful regulation that facilitates the acceleration of innovative capacity and a sustainable transformation across the EU.
- **No viable alternatives to Fluoropolymers:** While some chemistries might offer a similar performance to fluoropolymers for a particular parameter or property, it is the unique combination of properties that sets fluoropolymers apart and makes them vital to the sectors and industries they serve. Their unique combination of properties makes them durable, efficient, reliable, versatile, and ultimately fundamental to the products they enable. As it will take years or decades to develop alternatives – if possible – a phase-out of fluoropolymers will result in a significant gap in capabilities for innovation, products, and industries.
- **Environmental & Human Health and Safety:** Fluoropolymers are safe when used in their intended ways. A substantial body of scientific data demonstrates that fluoropolymers do not pose a significant risk to human health or the environment because of their unique characteristics:
 - Fluoropolymers' persistency equates to unmatched performance in key product applications and durability that drives ongoing contributions to sustainability.
 - All available data demonstrate that fluoropolymers are NOT bio-available, toxic or even mobile.

- Fluoropolymers do NOT dissolve in or contaminate water or generate microplastics and CANNOT enter or accumulate in a person’s bloodstream
- Fluoropolymers meet the OECD’s criteria for “polymers of low concern” as they do NOT present significant toxicity concerns and do NOT degrade into other PFAS.
- **Responsible manufacturing:** We completely understand the concerns voiced about the potential long-standing environmental impact of PFAS. Responsible manufacturing is an essential requirement for the sustainable production of fluoropolymers. Manufacturers abide by the broad range of requirements and regulations to manage the lifecycle of fluoropolymers, including:
 - Capture, recovery, and recycling efforts during manufacturing and processing
 - Making products more durable and long-lasting as form of emission control and added-value
 - End-of-life recovery and recycling of fluoropolymers in products, wherever possible
 - Robust existing regulation in place for waste management
- **Chemours remains committed and pushes the limits of technology:** Chemours takes very seriously our obligation to manage the PFAS compounds in our manufacturing processes in a responsible manner. Chemours has committed itself to take industry-leading steps to eliminate at least 99% of PFAS air and water emissions from our manufacturing processes by 2030. Chemours is heavily invested in responsible manufacturing and pushing the limits of technology to detect, abate, and remediate emissions.



What’s next in the regulatory process?

The restriction and process of banning fluoropolymers will take several years to come into effect. However, as the timeline progresses, changing the course of action becomes far more difficult. Engagement with decision-makers should ramp up now in the public consultation phase as this allows critical stakeholders to provide more meaningful input to adjust the scope of the final restriction.



- RAC will publish its opinion within nine months after the Dossier’s publication on whether the proposed restriction is appropriate to reducing risk to human health and the environment.
- SEAC will also draft an opinion on the socio-economic impact of the proposed restrictions. After SEAC’s draft opinion is published, **interested parties are invited to comment within 60 days. Considering these comments**, SEAC will adopt its final opinion.
- RAC and SEAC opinions are typically finalized within 12 months after the start of the first consultation. However, a delay is expected, given the complexity and scope of the proposal, beyond March 2024.
- Final RAC and SEAC opinions will be sent to the European Commission, which will submit a

legislative proposal to the EU Member States for voting. This also highlights why it is crucial to act now - as the whole process will get more political (and less scientific) the further down the road you go. **The final restriction is not expected before 2025.**

→ **We encourage everyone to participate** in the broader discussion and bring the implications of this universal PFAS restriction to the attention of policymakers and regulators at all levels; be it local, federal or EU.

Appendix:



Fluoropolymers and the EU Green Deal

Chemours' fluoropolymer technologies play a critical role in achieving the objectives outlined in the EU's Green Deal and the United Nation's Sustainable Development Goals (SDGs). Beyond enabling modern life, these innovative technologies promote and secure European competitiveness and allow for continued investment in jobs and skills.

1. Decarbonization

Chemours' fluoropolymer technologies facilitate the decarbonization of energy and make food production more sustainable. They contribute to reaching the EU's current greenhouse gas (GHG) emission reduction goal of 40% by 2030, as well as net carbon neutrality by 2050.

- **Fluoropolymers are used in various components of renewable energy installations and are instrumental in meeting the EU's target of 32% renewable energy consumption by 2030.**
 - Fluoropolymers provide insulation, improved durability, efficiency, and safety in products such as lithium batteries and fuel cells for energy storage. This facilitates sustainable renewable installations in greater numbers and new locations.
 - Fluoropolymers are critical for renewable power generation. They are used in coatings for solar thermal installations as protective armor from harsh environmental conditions, including extreme heat and moisture. They also provide electrical insulation in the wiring of many critical components contained within solar panels, extending the lifetime of solar panels by up to 25 years.
 - Flow batteries are also a storage method enabled by fluoropolymers. These batteries can support large-scale grids, help match supply and demand, and utilize membrane technology made of fluoropolymers.
- **Fluoropolymers also help enable the EU Hydrogen Strategy, which envisages a drastic expansion of hydrogen production and infrastructure, and sets a 13-20% target for clean 'green' hydrogen in the energy mix by 2050.**
 - Hydrogen produced through water electrolysis is one of the green hydrogen production options. Using fluoropolymer-made Nafion™ ion exchange membranes in electrochemical cells offers an environmentally safe way to generate large amounts of hydrogen without emitting CO₂.
 - Fuel cells, another Nafion™ membrane application, convert hydrogen to electricity which is crucial to reach the hydrogen energy target. The availability and use of Nafion™ have allowed

the development of lighter-weight, low-maintenance, robust fuel cells used in the transportation industry.

- The Nafion™ Proton Exchange Membrane (PEM) technology, built with fluoropolymers, is at the heart of hydrogen power storage, production, and usage, including fuel cells and electrolyzers.
- **The food and drink industry needs chemically inert, exceptionally pure, high-performance materials to make food production safe, innovative, and sustainable**
 - Wherever high purity is required, fluoropolymers play an irreplaceable role, as they are present in water filtration systems and food processing systems to guarantee adequate sanitary conditions and avoid contamination that could otherwise reach consumers.
 - Fluoropolymers improve food processing by dealing with issues like plugging, corrosion, and sticking, which can contaminate the product and jeopardize efficiency.
 - Fluoropolymers offer nearly universal chemical resistance and produce a smooth, low-surface energy layer that resists biofilm build-up, meaning higher production efficiency.

2. Mobility

Chemours' fluoropolymer technologies used in automobile applications promote the Green Deal's Smart and Sustainable Mobility Strategy and its goal of reducing GHG emissions in transport by 90% by 2050 while contributing to SDGs 9, 12, and 13.

- **Fluoropolymers are utilized in automobile components such as fuel lines, fuel hoses, O-rings, turbocharger hoses, and hoses in hydraulic systems, as well as electric vehicles, for their unique combination of properties. They help prevent leaks and breakdowns while contributing to fuel efficiency and reducing GHG emissions – significant important given Euro 7 emission standards expected to be implemented in 2025.**
 - Fluoropolymers are used as seals in fuel containment systems and injectors. They are also used in air intake manifolds and cylinder head gaskets to provide essential heat and stress resistance to sealant beads, preventing gas and other liquid leakages.
 - Fluoropolymers are utilized in newer fuel cells and batteries in electric vehicles, providing extra safety while maintaining high voltages.
 - Greenhouse emission controls: Fluoropolymers are used to lower exhaust emissions, which reduces a vehicle's carbon footprint.

3. Digitization

Chemours' fluoropolymer technologies are critical to facilitating the next generation of technology and are a driving force for the EU's Digital Transformation and industrial competitiveness in Europe.

- **Fluoropolymers are essential in enabling 5G data transfer speeds and digitalization – necessary to making the EU a world leader for fully automated and connected mobility systems, as outlined in the European Commission's Digital Strategy.**
 - Fluoropolymers can handle high-purity chemicals and high temperatures, helping semiconductors perform faster, more efficiently, and with fewer defects.
 - Fluoropolymers are used as insulation in cables and wires for the aerospace and autonomous car industries to improve signal quality for critical data transmission and increase durability.
 - Fluoropolymers are also used in cell phones, laptops, tablets, and 5G infrastructure, as wires, semiconductors, and circuit boards power all of these products. .

- Other uses of fluoropolymers in digital applications include semiconductor piping as well as display and touchscreen panels and coatings.

4. Construction

Chemours' fluoropolymers technologies are critical components of common construction materials, enabling the building and renovation of EU homes in an energy and resource-efficient way. They also contribute to SDGs 9 and 11 by making homes more climate-resilient and sustainable.

- **Fluoropolymers have essential uses in construction materials, which will continue to offer critical contributions to building and infrastructure renovation efforts across the EU.**
 - Fluoropolymer-based paints maintain color and shine, prevent mold and moss growth, and are fire resistant.
 - Fluoropolymer-coated glass fabric roofs and laminated coatings resist UV radiation, water, oil, dirt, corrosion, and impermeability to gasses, making them excellent for outdoor and large buildings.
 - By adding a further layer of insulation, fluoropolymer coatings help to make buildings more energy efficient.
 - Fluoropolymer coatings used on steel and concrete bridges have an effective life exceeding 50 years.
 - Fluoropolymers are critical for installing cables in floor and ceiling spaces without using metal conduits, bonding adhesives, sealants, and caulks used on surfaces in buildings.