Guidelines for demonstration of compliance with PFAS requirements under Article 5(5) PPWR

Executive Summary

Regulation (EU) 2025/40 (PPWR) introduces limits for PFAS in food-contact packaging, applicable from 12 August 2026. It is the **manufacturer**[1] that is responsible for the conformity assessment and the **supplier**[2] for providing necessary information and documentation.

There is today no harmonised testing methodology for PFAS in food contact packaging at EU level. The European Commission has therefore proposed[3] a three-step analytical workflow based on state-of-art analytical capacities and a meta-analysis of PFAS testing on food contact packaging materials. This guidance is however non-binding and leaves significant discretion to Member States. As a result, there is a high risk of divergent enforcement approaches across the EU, leading to legal uncertainty for operators and potential disruption of the internal market.

Systematic testing at all stages of the supply chain would create a disproportionate compliance burden and large costs for external testing. There is also not enough testing capacity within EU at time being. In the absence of standardised analytical methodologies testing may not either provide reliable or harmonised compliance outcomes, taking into account the nature of PFAS used in the manufacturing of plastic packaging (e.g. fluoropolymers processed well below degradation temperatures).

Therefore, we propose a **practical, proportionate, and risk-based compliance framework**, based on three key principles:

1. Documentation as the primary element of compliance
2. Targeted, risk-based analytical testing where justified
3. Limited and case-specific use of advanced analytical methods

This approach ensures that legal requirements are met on a feasible way for suppliers and manufacturers, while maintaining a high level of protection of human health and the environment, while safeguarding the functioning of the internal market.

[1] Defined in Article 3(1) point (13)

[2] Defined in Article 3(1) point (16)

[3] European Commission. "Draft Commission Notice on the Guidance Document for Regulation (EU) 2025/40 on Packaging and Packaging Waste." Annex to the Communication to the Commission, C(2026) 2151 final. Brussels: European Commission, March 30, 2026, 18.

Avenue de Cortenbergh 71 - B-1000 Brussels • Phone: +32 (0)2 732 41 24 • Fax: +32 (0)2 732 42 18 info@eupc.org • www.plasticsconverters.eu

1. Regulatory Context

Article 5(5) of Regulation (EU) 2025/40 establishes strict limits for PFAS in food-contact packaging, applicable from 12 August 2026. It states: '(...), food-contact packaging shall not be placed on the market if it contains per- and polyfluorinated alkyl substances (PFAS) in a concentration equal to or above the following limit values to the extent that the placing on the market of packaging containing such a concentration of PFAS is not prohibited pursuant to another Union legal act:

a) 25 ppb for any PFAS as measured with targeted PFAS analysis (polymeric PFAS excluded from quantification);
b) 250 ppb for the sum of PFAS measured as the sum of targeted PFAS analysis, where applicable with prior degradation of precursors (polymeric PFAS excluded from quantification); and
c) 50 ppm for PFASs (including polymeric PFAS); if total fluorine exceeds 50 mg/kg the manufacturer, importer or downstream user as defined respectively in Article 3, points (9), (11) and (13) of Regulation (EC) No 1907/2006 shall, upon request, provide to the manufacturer or the importer as defined respectively in Article 3(1), points (13) and (17), of this Regulation proof of the quantity of fluorine measured as content of either PFAS or non-PFAS in order for them to draw up the technical documentation as referred to in Annex VII to this Regulation.'

Because of the lack of harmonised analytical methods for PFAS testing in food-contact packaging at EU-level, the Commission have proposed a step-by-step testing workflow for enforcement.

- Step 1: Total fluorine screening (TF). If TF is below 50 mg/kg, the sample could be considered compliant. If TF is above 50 mg/kg next step is done.
- Step 2: Methods such as pyrolysis-GC/MS can be used to confirm whether the fluorine is organic (PFAS) or inorganic. If the organic fluorine is below 50 mg/kg, the sample could be considered compliant.
- Step 3: Direct TOP (Total oxidizable Precursors) analysis is recommended to check compliance with the 25 µg/kg and 250 µg/kg concentration limit.

The Commission concludes that based of the evidence currently available to the Commission, all samples compliant with test (1) are also compliant with tests (2) and (3). Unfortunately, the Commission's recommendation is not binding for the Member States which retain discretion in how compliance is verified.

As a result, economic operators face uncertainty regarding compliance expectations, particularly for products placed on multiple national markets.

Without further clarification, **identical products could be assessed differently across Member States**, undermining the level playing field and the proper functioning of the internal market.

2. Proportionality – the likelihood of PFAS presence

Fluoropolymers have historically been used in the manufacturing of plastics packaging as processing aids in very low concentration. Due to the Universal PFAS restriction process raw material suppliers and converters have been working to find other solutions and to manage the concentration limits of PFAS. According to a broad analysis of 103 packaging samples[4], it was concluded that intentional PFAS use is the primary risk factor for non-compliance. In addition, fluoropolymer additives typically begin to degrade at temperatures around 500 °C[5], whereas standard polyolefin processing temperatures generally range between 180°C and 250°C. Consequently, for many plastic packaging applications, the likelihood of relevant PFAS presence is considered limited and mainly associated with intentional PFAS use.

Therefore, a proportionate compliance approach should primarily rely on documented risk assessments and supply-chain verification to confirm whether fluoropolymers have been intentionally added to the processed material raw materials, rather than on systematic testing as the principal verification tool.

3. Proposed Compliance Framework

Preventive Measures for Non-Intentional PFAS Contamination

Preventive measures should be adopted as a core element of the risk management approach for non-intentionally added PFAS.

Economic operators should identify credible contamination pathways and implement preventive controls proportionate to the material, application, supply-chain complexity and likelihood of PFAS presence. These measures should be documented in the technical file supporting the Declaration of Conformity and reviewed periodically or whenever there is a significant change in supplier, formulation, recycled-content source, process conditions or packaging structure.

Preventive measures may include the following:

- supplier qualification procedures, including PFAS-specific questionnaires and declarations addressing both intentional use and potential contamination;

[4] Skedung, L, et al. "A Harmonized Workflow for PFAS Compliance Testing under EU Packaging and Packaging Waste Regulation and Emerging Universal Restrictions: A Food Contact Packaging Case Study"

[5] Bakker, J., et al. (2021) Per- and Polyfluorinated Substances in Waste Incinerator Flue Gases. Rijksinstituut voor Volksgezondheid en Milieu (RIVM) Report 2021-0143; DOI 10.21945/RIVM-2021-0143

- contractual requirements requiring suppliers to notify changes in formulation, processing aids, recycled feedstock, coatings, inks, adhesives or other inputs that could affect PFAS status;
- procurement restrictions or additional controls for higher-risk input streams, including poorly characterised recycled materials, mixed plastics or materials with uncertain historical use;
- segregation of higher-risk and lower-risk material streams, including appropriate storage, handling and production-line controls where cross-contamination is plausible;
- traceability systems covering relevant raw materials, recycled feedstock, additives, inks, adhesives, coatings and other components;
- good manufacturing practices designed to avoid contamination during production, conversion, storage and transport;
- assessment of water, cleaning agents, processing aids or other ancillary materials where they could represent a credible PFAS contamination pathway;
- periodic reassessment of suppliers and input streams, particularly for recycled content or complex supply chains;
- targeted verification, including representative testing, where preventive controls or documentation do not provide sufficient confidence.

The adoption of preventive measures should not be interpreted as creating a general obligation for systematic testing. Rather, it demonstrates due diligence by reducing the likelihood of non-intentional PFAS contamination before it occurs and by supporting a proportionate, risk-based compliance conclusion.

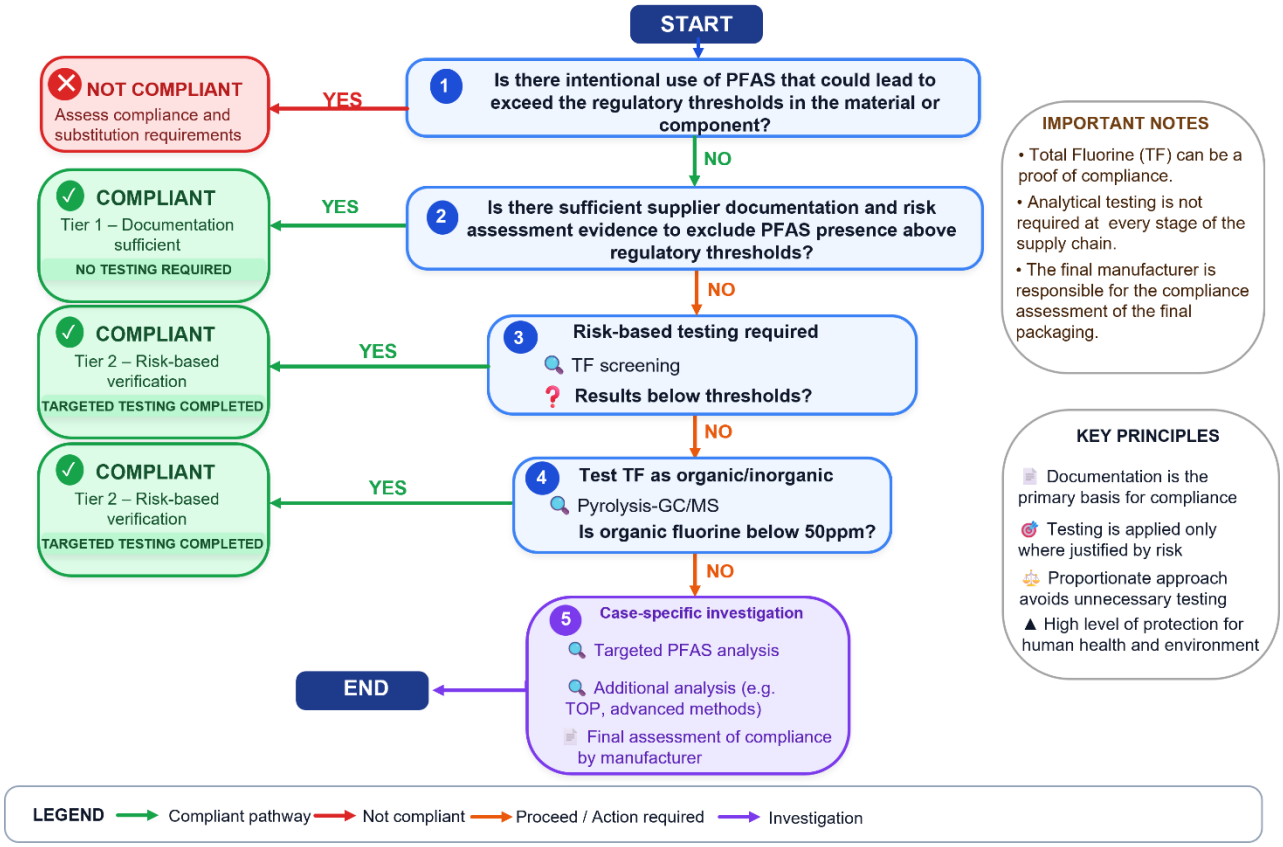
Where preventive measures identify unresolved uncertainty or elevated risk, the economic operator should apply additional verification measures, such as further supplier investigation, review of material history, Total Fluorine screening (and other analysis if needed) interpreted within the overall risk assessment.

Demonstration of compliance

When it comes to testing itself, this document is aligned with the Commission guidance. Accordingly, compliance with Article 5(5) should be based on a **combination of documentation and proportionate verification**, rather than systematic analytical testing. This approach supports the preparation of the EU Declaration of Conformity (Article 39), based on the technical documentation required under Article 38 and Annex VII.

The proposed approach is summarised in the following decision framework.

Figure 1: Risk-based decision framework for demonstration of compliance with Article 5(5)



A documented risk assessment should always be conducted, including assessment of possible non-intentional PFAS presence arising from contamination, recycled feedstock, processing aids or supply-chain complexity.

- **3.1 Tier 1 – Documentation (Default Approach)**

Compliance should primarily be demonstrated through:

- supplier declarations
- confirmation of absence of intentional PFAS use
- supply chain information

Where:

- no intentional use of PFAS is identified or intentional usage below regulatory thresholds,
- complete and accurate documentation is available, and
- risk assessment excludes PFAS presence above regulatory thresholds

No systematic analytical testing should be required. Where appropriate, representative analytical data may be used to support documentation, without implying any requirement for systematic or routine testing. In this context, compliance verification should primarily rely on documented risk assessment and supply-chain communication, and suppliers should not be expected to systematically generate or provide analytical test reports where no identified risk justifies such testing.

This approach:

- aligns with Article 15 and 16 of PPWR
- reflects established practices in food-contact legislation
- ensures proportionality

- **3.2 Tier 2 – Risk-Based Testing**

Analytical testing may be used **as a complementary tool**, where justified by specific risk factors such as:

- lack of complete and accurate supplier information
- specific applications with higher likelihood of PFAS presence e.g. complex supply chain, possible contamination

Testing should:

- be applied in a **risk-based manner**

Total Fluorine:

- Can be used to **demonstrate compliance** when proving absence or levels below the regulatory thresholds of PFAS
- If the TF screening result exceeds 50 ppm, and document-based evidence of inorganic or non-PFAS fluorine origin exists, an analysis can be performed to determine whether the fluorine is organic (PFAS) or inorganic, using methods such as pyrolysis-GC/MS.

- **3.3 Tier 3 – Case-Specific Investigation**

Advanced analytical methods (e.g. TOP):

- should be used only:
    - in case of suspected non-compliance

- in enforcement contexts

They should:

- not be systematically required
- not form part of routine compliance demonstration

Such testing should remain proportionate and limited, and should not be interpreted as a general obligation applicable to all packaging.

4. Testing: Key Implementation challenges

- **4.1 Limitations of Total Fluorine (TF)**

Total Fluorine is quantifying the total fluorine content present in a sample, regardless of its source or chemical form.

- Advantage
  - Combustion is done directly on a piece of the sample to be analysed (no extraction step).
  - When measured value falls below the thresholds established by the regulation, it can be used to indicate compliance with PFAS regulations, serving as a straightforward screening tool.
- Disadvantages
  - Since it does not distinguish between PFAS and other non-PFAS fluorinated substances, it has to be complemented with another method such as pyrolysis-GC/MS to confirm whether the fluorine is organic (PFAS) or inorganic if the TF shows a concentration above 50 mg/kg.

TF screening may support a conclusion of low likelihood of relevant PFAS presence when interpreted together with supplier documentation and documented risk assessment, but should not constitute standalone proof of non-compliance.

- **4.2 Limitations of targeted PFAS analysis**

Targeted PFAS analysis:

- Covers only a maximum of 80 substances.
- Cannot detect the full range of PFAS falling under the regulatory definition. Polymeric PFAS cannot be quantified using conventional targeted methods.

As a result, targeted analysis **alone cannot provide a complete or accurate assessment of compliance**.

- **4.3 Supply chain complexity**

Packaging typically consists of multiple components:

- polymers, additives, inks, adhesives, coatings

Each component may originate from different suppliers.

Requiring testing at each stage of the supply chain would:

- create duplication
- increase costs significantly
- be operationally unfeasible
- undermine the value of Declarations of Compliance, as each stage would be required to test regardless, rendering them redundant.

- **4.4 Recycled materials**

When considering the possible presence of PFAS in recycled plastics, it is important to recognise that the likelihood varies significantly depending on the material type. For many recycled materials, the risk of PFAS contamination is inherently low, as PFAS compounds are not employed as additives during their original manufacturing process. Among plastic types, polyolefins, such as polyethylene (PE) and polypropylene (PP), may have traces of PFAS that have historically been used in their processing as lubricants, surface treatments or additives, although in low quantities and the industry is moving away from such practices. For other materials where PFAS are not a manufacturing input, their presence would most likely result from accidental contamination or exposure to PFAS-containing water during use or collection. In the case of PET, the impurity level is generally very low, meaning the likelihood of PFAS contamination remains limited. Mixed plastics, however, present a higher risk profile, as the heterogeneous nature of the material makes it difficult to trace the origin and history of each component, increasing the probability of incidental PFAS contamination.

Given that PFAS contamination cannot be fully excluded from recycled plastics, a precautionary approach must be adopted. This includes systematic traceability, material-specific risk assessment and testing where contamination is considered probable.

5. Roles and Responsibilities in the Supply Chain

In line with Article 15 and 16 of PPWR:

- Suppliers:
    - Issue statements on the conformity of the packaging and packaging materials with the PFAS limit values. These may take the form of statements on the absence of intentional PFAS or on their use below the applicable regulatory threshold, including statements based on supplier documentation confirming the absence of intentional PFAS in the raw materials used.
    - Provide manufacturers with the information and documentation necessary to demonstrate conformity with the PFAS limit values. Testing is only required where justified; where it has been carried out, suppliers are not obliged to provide original or comprehensive test reports. Concise summaries are acceptable.
    - Where commercially sensitive information is involved, put in place confidentiality arrangements, such as NDAs, with the manufacturer, to protect information while ensuring the manufacturer receives all documentation necessary to fulfil its obligations under Article 15 and Annex VII.
- Manufacturers:
    - Compile supply chain information and documentation received from suppliers.
    - Assess the compliance of the final packaging with the PFAS limit values.
    - Prepare the required technical documentation.
    - Issue an EU Declaration of Conformity.

Testing should not be required at every stage of the supply chain, but only where justified. Compliance is assessed at the level of the final packaging, in line with the Declaration of Conformity framework, avoiding unnecessary duplication of testing. The level of detail expected in the technical documentation may be subject to revision as further guidance, implementing acts or FAQs are published.

6. Recommendations for enforcement

To ensure effective and harmonised implementation of Article 5(5) we recommend that the Commission and Member States should:

- **Explicitly recognise that compliance may be demonstrated through documentation, where no indication of PFAS use exceeding the regulatory threshold exists**

- **Avoid systematic or routine analytical testing requirements across the supply chain**
- **Ensure that analytical testing is applied only on a risk-based and proportionate basis**
- **Provide clear guidance to Member States to avoid divergent enforcement approaches**
- **Introduce a transitional approach until harmonised analytical methods are available**
- **Prioritise the development of harmonised analytical methods and protocols**

7. Conclusion

The implementation of PFAS restrictions under Article 5(5) PPWR requires a **pragmatic and proportionate approach**, taking into account:

- the absence of harmonised analytical methods
- the limitations of current testing techniques
- the complexity of supply chains

A risk-based compliance framework, combining documentation, preventive risk management measures and targeted verification, is essential to:

- ensure legal certainty
- avoid disproportionate burdens on industry
- prevent fragmentation of the internal market
- support circular economy objectives

Without such an approach, there is a significant risk of inconsistent enforcement across Member States, leading to fragmentation of the internal market.

About CFREP:

The Contact Sensitive and Food Contact Plastics Regulatory Expert Panel (CFREP), represents manufacturers and users of plastics for food contact and other contact-sensitive applications. Established in 2010 as an expert network for companies and associations specifically focused on plastic food contact materials regulations, CFREP expanded its mission in 2024 by becoming a sector group of European Plastics Converters (EuPC) and broadening its scope to include a wider range of contact-sensitive plastics.