The Fluorine Number That Stops a Packaging Line

PFAS compliance, analytical blind spots and the economics of qualifying food-contact packaging after the August 2026 EU deadline

José M. López, BSc, MD, PhD, LLD (C)

November 2026 | Regulatory Affairs / Processing Technologies

Executive abstract

The European Union's packaging legislation has transformed fluorinated chemistry from a predominantly supplier-side concern into a release decision for food manufacturers. Since 12 August 2026, food-contact packaging has been subject to three distinct PFAS concentration thresholds, while the analytical infrastructure needed to establish conformity remains heterogeneous. A November 2026 printing-ink industry briefing highlights the continuing mismatch between binding obligations and harmonised evidence. This article examines how that mismatch propagates through purchasing, laboratory testing, converting, filling and commercial contracts. It distinguishes elemental fluorine from molecular PFAS, packaging composition from migration into food, and supplier declarations from demonstrable conformity. Worked examples expose the consequences of incompatible reporting units, sampling design and measurement uncertainty. Comparative analysis addresses the European Union, Spain, Great Britain and the United States. An industrial qualification framework and a proposed interlaboratory research programme seek to reduce unnecessary stock immobilisation without weakening chemical safety or the legal requirements governing market access.

Keywords: *PFAS; food-contact packaging; total fluorine; measurement uncertainty; conformity assessment; packaging engineering; market surveillance*.

1. A regulation that reaches the filling machine

A food manufacturer may have a warehouse full of packaging that performs exactly as specified, protects the food adequately and has never caused a customer complaint. None of those facts establishes compliance with Article 5(5) of Regulation (EU) 2025/40. The Packaging and Packaging Waste Regulation (PPWR) introduces a composition-based restriction for food-contact packaging from 12 August 2026. Its consequences are therefore not confined to the chemical supplier or converter. They reach the person deciding whether the next production order can be released. [1]

The immediate editorial signal is the European Printing Ink Association's October 2026 presentation, publicly available in November, describing a regulatory obligation already applicable despite incomplete

harmonisation of evidence and testing. The Food and Drink Federation's current implementation guidance identifies similar practical difficulties. [2,3] These are industry interpretations, not legislation. Their significance is that they identify a live operational problem several months after the deadline, rather than a hypothetical future compliance exercise.

The central question is not whether PFAS should be restricted. It is how a company establishes the relevant facts about a finished packaging unit when different laboratories and suppliers describe different chemical quantities. A purchaser may receive a declaration of no intentional addition, a total-fluorine result and a targeted PFAS panel, each apparently favourable. If the documents concern different material revisions, different units or different analytical endpoints, their combination may not establish the proposition required by law.

2. Three limits, three analytical propositions

Article 5(5) prohibits placing food-contact packaging on the market at or above 25 micrograms per kilogram for an individual PFAS measured by targeted analysis, 250 micrograms per kilogram for the sum measured by targeted analysis (with precursor degradation where applicable), and 50 milligrams per kilogram for PFAS including polymeric forms. Polymeric PFAS are excluded from quantification under the first two limbs. The provision also requires evidence concerning the attribution of fluorine when total fluorine exceeds 50 mg/kg, on request, from the relevant chemical manufacturer, importer or downstream user. Other applicable Union prohibitions remain relevant. [1]

These are mass concentrations in packaging, not migration limits in food. The first two thresholds operate at microgram scale: the third at milligram scale. A report that merely states compliance with a 50-ppm screening value does not, as a matter of analytical logic, establish that each individual substance is below 25 ppb. The Commission's interim enforcement approach should be understood separately from that logical distinction.

Consider a hypothetical kilogram of packaging containing 40 micrograms of a single targeted PFAS. The concentration is 40 ppb and therefore exceeds the individual threshold, even though its contribution to total fluorine is far below 50 ppm. The example does not describe an actual sample or an official enforcement decision. It illustrates why the legal endpoints must remain separately visible in a technical dossier, including when a screening procedure is accepted for routine verification.

The distinction between intentional addition and incidental presence is equally important. An ink manufacturer may truthfully declare that no fluorinated ingredient was deliberately incorporated. That declaration does not exclude contamination from recycled feedstock, shared equipment, impurities or another component. Conversely, an elevated elemental fluorine result does not establish that a prohibited PFAS is present. Both errors can lead to commercially expensive decisions.

3. What the laboratory actually measures

3.1 Elemental screening

Combustion followed by ion chromatography can quantify fluorine recovered after destruction of a sample. Other approaches, including particle-induced gamma-ray emission, measure elemental fluorine by different physical principles. Neither technique, by elemental measurement alone, identifies the molecular structure that contained the fluorine. The result depends on sampling, calibration, recovery and matrix effects. Inorganic fluorides and organic fluorinated compounds can contribute to the same number.

A useful screening method is not necessarily a useful confirmatory method. Its purpose may be to triage samples for further investigation, rather than to identify every regulated compound. A report should identify the actual measurand, the mass basis, the limit of quantification, recovery and the scope of the method. A result expressed as fluorine mass cannot automatically be relabelled as PFAS mass.

3.2 Targeted molecular analysis

Liquid chromatography coupled with mass spectrometry can quantify selected PFAS for which the laboratory has suitable reference standards and validated extraction and measurement procedures. The strength of the technique is molecular specificity. Its limitation is coverage: an unlisted compound, poorly extracted species or polymeric material may not be represented in the result. A panel of forty compounds is not a measurement of every compound meeting the legal definition.

The peer-reviewed literature has long demonstrated this distinction. Schaider and colleagues investigated fluorinated substances in US fast-food packaging using elemental screening and molecular analysis; subsequent work comparing total-fluorine methods and targeted analysis further illustrates the challenge of accounting for fluorine in complex packaging matrices. [4,5] These historical studies establish analytical limitations, not the prevalence of non-compliant packaging in November 2026.

3.3 Precursor conversion and mass balance

Oxidative precursor assays can reveal certain substances that are not directly represented in an initial targeted panel by converting them into measurable products. Conversion is method-dependent and incomplete coverage remains possible. The assay should not be described as a universal measurement of all PFAS. Likewise, subtracting inorganic fluorine from total fluorine may narrow the investigation but does not uniquely identify the remaining organic species.

For an identified compound with molecular mass M and n fluorine atoms, its fluorine mass fraction is approximately 19n/M. Thus, the fluorine contribution of a compound is its concentration multiplied by that fraction. A defensible mass balance must put all terms on the same basis before subtraction. A residual difference may reflect unidentified compounds, polymers, extraction losses, analytical uncertainty or differences between sampled material. It is not automatically the concentration of an unknown PFAS.

4. The unit conversion that creates a false certificate

Packaging laboratories frequently use surface-area units, whereas Article 5(5) uses mass concentration. A film with a basis weight of 40 g/m² contains 0.04 kg per square metre. A hypothetical surface loading of 2 micrograms per square metre corresponds to 50 micrograms per kilogram of that film. If the same surface

loading is measured on a 200 g/m² board, the corresponding concentration is 10 micrograms per kilogram. The conversion is elementary, but the material identity is decisive.

A multilayer laminate complicates the calculation. If a coating is 2 g/m² on a 100 g/m² finished structure, a concentration reported per kilogram of coating cannot simply be compared with a result per kilogram of the entire structure. Component data are useful for locating the source and calculating a mass balance, while the conformity assessment must address the applicable packaging unit. The Commission guidance discussed by industry treats the complete unit as relevant, including inks and adhesives. [2,3] Artificially changing the unit of assessment to obtain a favourable concentration would not be a defensible compliance strategy.

A procurement specification should therefore identify whether the laboratory received an intact finished unit, a printed web, an unprinted substrate, a coating or a composite sample. It should require the basis weight and the method used to convert area into mass. A certificate without that information may be impossible to reconcile with another certificate even when both laboratories performed their own measurements correctly.

5. Sampling: the laboratory can be right about the wrong object

A roll of packaging is not necessarily homogeneous. Printing coverage, adhesive application, edge treatment and material changes between production runs can create spatial variability. A sample cut from an unprinted margin may not represent a heavily printed panel. A sample from the beginning of a roll may not represent a later splice. The first task is therefore to define the population about which a conclusion is sought.

Composite sampling can reduce analytical cost and provide information about average composition. It can also obscure differences between units or production lots. Suppose one of ten equal-mass units contains 100 ppb of an individual PFAS and the remaining nine contain none. A composite would average 10 ppb, below the individual threshold, despite the first unit exceeding it. This hypothetical example does not prescribe an official sampling plan. It demonstrates why averaging across distinct units can answer a different question from the legal conformity of each unit.

A qualification plan should identify the material family, supplier site, printing system, coating recipe, lot boundaries and relevant variants. Sampling should be justified against expected heterogeneity. Retained specimens should be protected from contamination and linked to the production order. Laboratories should be informed of the purpose of the investigation, rather than receiving an anonymous piece of film with a generic request for a PFAS test.

6. Measurement uncertainty and the administrative decision

A numerical result near a limit is not a perfectly known concentration. Consider a hypothetical targeted result of 24 micrograms per kilogram with an expanded uncertainty of 6 micrograms per kilogram. The reported value is below 25, but the uncertainty interval crosses the threshold. A result of 28 with the same uncertainty also crosses it. The two results do not justify pretending that the underlying concentration is known without ambiguity.

An internal purchasing decision rule can require an appropriate guard band, for example acceptance only where the result plus its stated expanded uncertainty is below the applicable threshold. That is a

conservative commercial rule, not a universal statutory rule for enforcement. The competent authority must apply the applicable legal and procedural framework, including any prescribed treatment of uncertainty. A laboratory should state the decision rule used when issuing a conformity statement. ISO/IEC 17025 and ILAC guidance provide a useful metrological framework. [6,7]

The opposite mistake is to invoke uncertainty as an automatic defence against any adverse result. Uncertainty is evidence about measurement quality; it does not erase a credible finding. Where results are disputed, the parties should first establish whether they tested equivalent specimens and measured the same endpoint. A second test of a different roll is not necessarily a counter-analysis of the first result.

7. The interim enforcement approach and its limits

The Commission's June 2026 guidance, as described in the current FDF implementation material, recommends a staged analytical approach beginning with total fluorine, followed where appropriate by further differentiation and targeted investigation. [3,8] The practical rationale is understandable: comprehensive molecular testing of every packaging variant would consume laboratory capacity and may not be technically feasible. A screening strategy allows attention to be directed towards higher-risk material.

Nevertheless, a guidance-based screening conclusion should not be represented as a mathematical demonstration of all three statutory limits. Guidance informs implementation; it does not amend the thresholds. A credible targeted result indicating an exceedance should not be ignored merely because an earlier elemental screen was favourable. The dossier should record the screening route, its limitations and any additional evidence that changes the assessment.

For a food business, this creates a difficult balance. Testing everything without a risk rationale can generate unnecessary expense and ambiguous results. Testing nothing because a supplier has signed a declaration leaves the manufacturer exposed to gaps in the supply chain. The appropriate response is a documented, material-specific strategy, with explicit triggers for additional investigation.

8. Packaging redesign can create a different food-safety problem

Fluorinated treatments have been used because of their ability to resist oils and water. Removing them may change surface energy, wetting, grease penetration and the behaviour of a package under heat or humidity. [9] The performance of a replacement depends on the substrate, coating, converting conditions and food. A substitute that performs well in a dry laboratory test may fail after exposure to a hot fatty product or prolonged humid storage.

The failure mechanisms are not limited to visible leakage. A barrier change may affect moisture uptake, mechanical strength, seal integrity or oxygen transfer. In dry powders, moisture ingress can cause caking and loss of flowability. In lipid-rich products, oxygen ingress can accelerate oxidation. In chilled foods, a compromised seal may invalidate assumptions used in microbiological shelf-life validation. These are plausible engineering pathways, not claims that PFAS-free materials necessarily perform worse.

Qualification should therefore use the actual food and intended process: filling temperature, seal pressure and dwell time, distribution conditions, stacking, abrasion and storage. Relevant tests may include seal strength, leak integrity, water-vapour and oxygen transmission, grease resistance and sensory stability. The

acceptance criteria should derive from product requirements rather than an arbitrary comparison with the incumbent material. A composition-compliant package that fails its protective function is not an acceptable industrial solution.

9. The purchasing contract as a control measure

The manufacturer needs information that survives changes in the supplier's own purchasing decisions. A declaration tied only to a trade name is weak if the converter can change ink, adhesive or coating without notification. A better agreement identifies the material revision, manufacturing site, relevant composition information, test methods, reporting basis and conditions requiring prior notification.

Commercial confidentiality is a genuine constraint. A food manufacturer may not need the complete proprietary formulation of an ink, but it does need sufficient evidence to discharge its own obligations. Confidential disclosure to an independent laboratory or competent authority, controlled access to technical documentation and appropriately scoped supplier assurances may reconcile these interests. The contract should specify what happens when evidence is incomplete, when a batch is disputed and who bears the costs of investigation or replacement. Contractual allocation does not transfer away statutory responsibility.

The critical procurement distinction is between a promise and a fact. A warranty can allocate financial consequences if a material is non-compliant; it cannot make a non-compliant material lawful. Similarly, a certificate can describe a tested specimen but cannot guarantee that an unnotified subsequent formulation change has no effect. Supplier qualification must therefore be connected to change control and incoming-material identity.

10. Jurisdictional differences and the problem of old stock

10.1 European Union and Spain

Regulation (EU) 2025/40 is directly applicable in Member States, with the Article 5(5) restriction applicable from 12 August 2026. Articles 38 and 39 and Annex VII address conformity assessment and the EU declaration of conformity. The responsible economic operator must be identified from the actual supply arrangement, including private-label and imported packaging. [1] Existing food-contact obligations under Regulation (EC) 1935/2004 and good manufacturing practice under Regulation (EC) 2023/2006 remain independently relevant. [10,11]

In Spain, the EU composition restriction is not dependent on a new Spanish transposition measure. National and autonomous-community authorities exercise their respective food-safety and market-surveillance functions; the competent body depends on the product and nature of the control. An operator should distinguish a packaging conformity issue from a finding of unsafe food, although the same facts can justify investigation under both regimes. Administrative measures should identify the applicable legal basis and factual deficiency. Spanish Law 39/2015 provides the general administrative procedural framework, subject to applicable sector-specific provisions. [12]

The Commission guidance does not provide a general stock-exhaustion exemption. Packaging already placed on the market before the deadline may remain available, but the date of manufacture or warehouse receipt

alone is not necessarily the decisive event. The analysis depends on the first qualifying market placement and the state of manufacture; sales and grouped packaging are generally assessed at filling, with fact-specific exceptions involving completed manufacture and transfer. Imported goods require attention to release for free circulation. [3,8] Companies should preserve transaction records and not rely on a date printed on a roll label.

10.2 Great Britain and Northern Ireland

The PPWR should not be assumed to apply domestically in Great Britain simply because it applies in the EU. British food-contact and packaging rules must be assessed independently, while exporters into the EU must meet the destination requirements. Northern Ireland requires separate treatment under the applicable Windsor Framework arrangements; current FDF guidance treats the relevant PPWR requirements as applicable there. [3] A single UK-wide supplier declaration without territorial scope can therefore be misleading.

10.3 United States

The FDA approach is not a direct equivalent of the EU's three concentration thresholds. On 3 January 2025 FDA announced that 35 food-contact notifications covering fluorinated grease-proofing agents for paper and paperboard would cease to be effective on 6 January, with a limited compliance period ending 30 June 2025 for certain existing articles. [9,13] Other food-contact uses require their own authorisation and safety analysis. State-level restrictions must also be checked for the destination market. An EU-compliant concentration result is not by itself evidence of US authorisation, and an FDA authorisation for a particular use is not a waiver of the EU composition restriction.

11. The economics of a packaging hold

The most immediate financial exposure is often not the cost of the test but the loss of usable production time. Consider a hypothetical plant filling 12,000 units per hour, with a contribution margin of EUR 0.18 per unit. A six-hour stoppage represents EUR 12,960 of potentially foregone contribution if output cannot be recovered. If production can be rescheduled, the relevant cost instead includes overtime, changeover, transport and customer-service effects. These figures are illustrative, not observed industry averages.

Suppose the plant holds 300,000 empty packages at EUR 0.07 each. The inventory value is EUR 21,000. A disputed lot may also immobilise finished food, creating a much larger exposure. A second qualified source may cost more per unit but reduce the probability of an extended interruption. The purchasing decision should compare the incremental annual cost with plausible disruption scenarios, not simply compare the two unit prices.

A rational qualification programme prioritises materials by the combination of chemical uncertainty, annual throughput, lead time, substitutability and consequences of failure. A low-volume speciality coating with no qualified substitute can be more commercially critical than a high-volume standard film. The cost model should remain separate from the legal decision: no favourable financial calculation permits release of known non-compliant packaging.

12. An industrial release architecture

The recommended system begins with a packaging bill of materials that includes the substrate, inks, adhesives, coatings and other relevant elements. Each item should be connected to a supplier revision and the finished packaging specification. The technical team then identifies the legal market, relevant conformity obligations, evidence already available and unresolved analytical questions.

The release decision should distinguish three states: evidence sufficient for the defined use; evidence incomplete and requiring investigation; and confirmed non-conformity requiring containment and corrective action. Incomplete evidence is not necessarily proof of a chemical exceedance, but it is not a basis for an unconditional conformity declaration either. Escalation should be time-bound, with named responsibility and documented reasons.

When a finding arises, the plant should identify affected packaging lots and finished-food orders, preserve representative samples, prevent uncontrolled use and determine whether market action is required under the applicable law. A packaging composition exceedance and an unsafe-food finding are not automatically identical. The assessment must consider the legal obligation, actual distribution and any food exposure evidence, without delaying necessary protective action.

13. Research & Innovation Opportunity

The unresolved question is how to combine inexpensive elemental screening with selective molecular analysis and supplier information without producing unjustified confidence. Existing literature establishes that different analytical techniques capture different fractions of fluorinated material. [4,5] The proposed research is an integration and validation exercise, not a claim to have invented those techniques or established patent novelty.

The hypothesis is that a matrix-specific decision protocol incorporating component identity, sampling variability, fluorine mass balance and targeted confirmation could reduce both missed exceedances and unnecessary holds compared with a single generic screening rule. Its plausibility follows from the complementary information supplied by elemental and molecular measurements. Its performance remains unproven.

A multicentre study should include printed paperboard, coated paper, polymer films and multilayer structures, with representative production variants and appropriately characterised reference materials. Participating laboratories should report recovery, uncertainty, limits of quantification and the exact analytical basis. Blind duplicate specimens would allow separation of within-laboratory variation from between-laboratory differences. The study should compare decisions against independently characterised materials, not simply against agreement between laboratories.

Prespecified outcomes should include false acceptance, false rejection, unresolved classifications, turnaround time and total cost per defensible decision. Particular attention should be paid to low-level targeted exceedances in materials with low total fluorine and to inorganic fluorine in materials with elevated elemental results. A protocol that performs well only on one substrate should not be generalised to all packaging.

The regulatory constraint is fundamental: a research protocol cannot alter statutory limits or bind a competent authority. Any future commercial method would require validation for its intended matrices and transparent documentation of limitations. A patent and freedom-to-operate review would be necessary before asserting proprietary novelty. The potential industrial benefit is a more reliable qualification service for ingredient suppliers, food manufacturers and packaging converters, not a universal certificate of absence.

14. Conclusions

The 2026 packaging restriction is a practical test of industrial evidence management. It requires manufacturers to distinguish what a supplier promises, what a laboratory measures and what the law prohibits. These propositions overlap but are not interchangeable. The most effective response is neither indiscriminate testing nor unquestioning reliance on declarations. It is a traceable, risk-based qualification system that links the actual packaging unit to appropriate analytical evidence and the intended food use.

The commercial opportunity lies in preventing avoidable production interruptions while maintaining chemical safety and product protection. The regulatory opportunity lies in more transparent decision rules and better communication between authorities, laboratories and operators. Neither can be achieved by treating a single fluorine number as a complete description of a complex material.

References and source status

1. Regulation (EU) 2025/40 on packaging and packaging waste, especially Articles 5, 38 and 39 and Annex VII. https://eur-lex.europa.eu/eli/reg/2025/40/oj

2. EuPIA. PPWR: complex, demanding and far from complete. October 2026 presentation, published online November 2026. https://www.eupia.org/wp-content/uploads/2026/11/202610_PPWR-COMPLEX-DEMANDING-AND-FAR-FROM-COMPLETE.pdf

3. Food and Drink Federation. PPWR business guidance. https://www.fdf.org.uk/fdf/business-guidance-hubs/packaging/ppwr-business-guidance-page/

4. Schaider LA et al. Fluorinated compounds in U.S. fast food packaging. Environmental Science & Technology Letters (2017), 4, 105–111. https://doi.org/10.1021/acs.estlett.6b00435

5. Total Fluorine Measurements in Food Packaging: How Do Current Methods Perform? (2019). https://doi.org/10.1021/acs.estlett.8b00700

6. ISO/IEC 17025:2017. General requirements for the competence of testing and calibration laboratories. https://www.iso.org/standard/66912.html

7. ILAC G8:09/2019. Guidelines on decision rules and statements of conformity. https://ilac.org/publications-and-resources/ilac-guidance-series/

8. European Commission. Guidance document for Regulation (EU) 2025/40, June 2026, document 2026/3084. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52026XC03084

9. US FDA. Authorized uses of PFAS in food contact applications. https://www.fda.gov/food/process-contaminants-food/authorized-uses-pfas-food-contact-applications

10. Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food. https://eur-lex.europa.eu/eli/reg/2004/1935/oj

11. Regulation (EC) 2023/2006 on good manufacturing practice for food-contact materials. https://eur-lex.europa.eu/eli/reg/2006/2023/oj

12. Spain. Law 39/2015 on the common administrative procedure of public administrations. https://www.boe.es/eli/es/l/2015/10/01/39/con

13. US FDA. FDA determines authorization for 35 food contact notifications related to PFAS are no longer effective. 3 January 2025. https://www.fda.gov/food/fda-updates-food/fda-determines-authorization-35-food-contact-notifications-related-pfas-are-no-longer-effective

© 2026 José M. López. All rights reserved.