Global PFAS regulations, guidance, and regulatory methods

PFAS Food Legislation Overview

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Introduction

Per- and polyfluoroalkyl substances (PFAS) are a group of synthetic chemicals widely used for their water- and grease-resistant properties. However, their persistence in the environment and potential health risks have led to increasing regulatory scrutiny, including in the food and beverage industry.

Regulating PFAS in food and beverage products is necessary due to their widespread use and potential health impacts. PFAS are persistent in the environment, including throughout our ecosystem and food supply chain. Air, water, soil, and livestock potentially all have PFAS exposure and contamination. PFAS can also migrate from packaging into food, leading to human exposure. Given their persistence and bioaccumulative nature, even low levels of PFAS can pose significant health risks over time.[1] Effective regulation helps mitigate these risks, ensuring consumer safety and maintaining public health standards.

Globally, PFAS legislation varies widely, with significant activity in Europe, North America, and the Asia-Pacific region. Many countries have ratified international agreements such as the Stockholm Convention, which aims to eliminate or restrict the use of persistent organic pollutants, including certain PFAS.[2] As scientific understanding of PFAS evolves, so too does the regulatory framework, with many jurisdictions moving towards stricter controls and phase-outs of these substances.

European Food Safety Authority (EFSA) conclusions on PFAS and human health

In 2020, the EFSA published a scientific opinion on the risks to human health related to the presence of PFAS in food, underscoring the need to effective PFAS testing and regulations.[3] The key points were:

- **Group tolerable weekly intake (TWI):** EFSA set a new safety threshold for PFAS, establishing a group TWI of 4.4 nanograms per kilogram of body weight per week for the sum of four PFAS: PFOA, PFNA, PFHxS, and PFOS.
- **Critical health effects:** The most critical health effect identified was the decreased response to the immune system to vaccination. This is in addition to other effects like increased cholesterol, reduced birth weight, and high serum levels of the liver enzyme alanine transaminase (ALT).
- **Exposure assessment:** EFSA's assessment indicated that a significant portion of the population exceeds the critical serum levels for these PFAS, suggesting a health concern.
- **Recommendations:** EFSA recommended developing approaches for deriving potency factors for PFAS and highlighting the need for further research to better understand their health impacts.

Challenges of keeping up with PFAS regulations

Testing for PFAS in food and beverages is analytically difficult. Methods must be both sensitive and accurate to detect low concentrations of PFAS in complex matrices. The pervasive nature of PFAS compounds also increases the risk of contamination throughout the testing process—from sample collection and preparation to analytical detection. Additionally, the constantly evolving regulatory landscape requires laboratories to continuously update their testing protocols to comply with new standards. Keeping pace with these changes and addressing the technical complexities of PFAS analysis are ongoing challenges for the industry.

Given the dynamic nature of PFAS regulations, it is essential for testing laboratories to stay current with the latest methodologies and regulatory requirements. This ensures they can provide accurate and reliable data, which is critical for compliance and for protecting public health.

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European regulations and methods for PFAS testing in food

Due to their persistence in the environment and potential health risks, the European Union (EU) has established stringent regulations and recommendations to monitor and control PFAS levels in food, beverages, and food contact materials.

Key regulations and recommendations

These regulations and recommendations are used to regulate PFAS in food, beverages, and food packaging materials by setting maximum allowable levels and providing guidelines for monitoring and testing. Food business operators must comply with these limits to ensure their products are safe for consumption. Regular monitoring and testing help identify potential sources of contamination and enable corrective actions to be taken promptly.

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European Commission Regulation (EU) 2023/915

European Commission Regulation (EU) 2023/915 establishes maximum levels for certain contaminants, including PFAS, in food (Table 1).[1] This regulation replaces the previous Regulation (EC) No 1881/2006 and incorporates the latest scientific data to establish strict limits that are achievable through good manufacturing practices. Methods for sampling and analysis PFAS in food are outlined in EU 2022/1428.

Key points of this regulation include:

- **Maximum levels:** The regulation sets maximum levels for PFAS that are as low as reasonably achievable to minimize health risks.
- **Vulnerable populations:** Special attention is given to infants and young children, with stricter maximum levels for food intended for these groups.
- **Market restrictions:** Food containing contaminants exceeding the maximum levels cannot be placed on the market or used as food ingredients.

Table 1. European Commission Regulation (EU) 2023/915 covers a wide range of contaminants to ensure food safety. It includes natural toxins such as mycotoxins (e.g., aflatoxins and ochratoxin A) and alkaloids (e.g., pyrrolizidine alkaloids). Environmental contaminants like heavy metals (e.g., lead, cadmium, mercury) and persistent organic pollutants (e.g., dioxins, PCBs) are also regulated. Additionally, process contaminants such as acrylamide and polycyclic aromatic hydrocarbons (PAHs) are covered. Other contaminants include melamine and erucic acid. Shown in this table are the included PFAS compounds and their established maximum levels.

EU 2023/915 Regulation	Maximum Levels (µg/kg)				
Perfluoroalkyl substances	**PFOS**	**PFOA**	**PFNA**	**PFHxS**	**Sum**
Meat and Edible Offal					
Meat: bovine, pig, poultry	0.3	0.8	0.2	0.2	1.3
Meat: sheep	1	0.2	0.2	0.2	1.6
Offal: bovine, sheep, pig, poultry	6	0.7	0.4	0.5	8
Meat: game except bear	5	3.5	1.5	0.6	9
Offal: game except bear	50	25	45	3	50
Fishery Products and Bivalve Mollusks					
Muscle meat: fish except below	2	0.2	0.5	0.2	2
Muscle meat*: Baltic herring, bonito, burbot, European sprat, flounder, grey mullet, horse mackerel, sea lamprey, tench, vendance, silverly lightfish, wild salmon and wild trout, wolf fish	7	1	2.5	0.2	8
Muscle meat*: anchovy, babel, bream, char, eel, pike-perch, perch, roach, smelt, whitefish	35	8	8	1.5	45
Crustations and bivalve mollusks	3	0.7	1	1.5	5
Eggs	**1**	**0.3**	**0.7**	**0.3**	**1.7**

**except for infants and young children*

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European Commission Regulation (EU) 2022/1431

European Commission Recommendation (EU) 2022/1431 advises member states to monitor the presence of specific PFAS compounds in food.[2] This recommendation highlights the importance of gathering comprehensive data on PFAS levels in various foodstuffs to better understand human exposure and inform future regulatory actions.

Key aspects of this recommendation include:

- **Data collection:** Member states are encouraged to collect data on PFAS levels in a wide range of foods to assess human exposure.
- **Analytical methods:** The recommendation emphasizes the use of sensitive analytical methods to detect low concentrations of PFAS.
- **Risk assessment:** The data collected will support risk assessments and help refine regulatory measures to protect public health.

EURL POPs: Guidance document on PFAS analysis

Developed by the European Union Reference Laboratory (EURL) for halogenated persistent organic pollutants (POP), the EURL POPs: Guidance document on PFAS analysis provides detailed instructions for laboratories on the analytical parameters and methodologies for detecting PFAS in food and feed.[3]

Key elements of this guidance document include:

- **Analytical parameters:** Detailed guidelines on the analytical parameters for PFAS detection, including sample preparation, extraction, and cleanup procedures.
- **Method validation:** Recommendations for validating analytical methods to ensure accuracy and reliability.
- **Harmonization** Efforts to harmonize PFAS testing methods across European to facilitate consistent and comparable results.

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EU food packaging regulations

The upcoming Regulation 2025/40 (Packaging and Packaging Waste Regulation, or PPWR), effective 12 August 2026, will impose strict limits on PFAS in food packaging within the European Union. This regulation aims to monitor and control nonintentionally added substances, including PFAS, and their migration into food. Specifically, the regulation sets the following limits for PFAS in food-contact packaging: 25 parts per billion (ppb) for any single PFAS, and 250 ppb for the sum of all PFAS.[4]

Additionally, food packaging will be included in updates to REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Regulation and the Persistent Organic Pollutant (POP) Regulations, which will restrict the use of certain persistent organic pollutants such as perfluorooctane sulfonic acid (PFOS), perfluorooctanoic acid (PFOA), and perfluorohexane sulfonic acid (PFHxS) in food packaging.

Methodology and instrumentation

The methodology for PFAS testing in Europe involves analytical techniques such as liquid chromatography coupled with tandem mass spectrometry (LC/MS/MS). This method is highly sensitive and capable of detecting trace levels of PFAS in complex food matrices. Sample preparation typically includes extraction and cleanup steps to isolate PFAS from the food matrix before analysis. These LC/MS/MS workflows achieve the necessary levels of detection for PFAS compounds: parts-per-billion (for European Commission Regulation (EU) 2023/915) or parts-per-trillion (for European Commission Recommendation (EU) 2022/1431).

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United States regulations and methods for PFAS testing in food

In the United States, the combination of federal methods (FDA and USDA), state regulations, and AOAC standards creates a regulatory framework for PFAS in food, beverages and food packaging materials. These regulations and methods are used to monitor and control PFAS levels, ensuring that they do not pose a health risk to consumers.

United States Department of Agriculture (USDA) method CLG-PFAS 2.04

The USDA CLG-PFAS 2.04 method screens, determines, and confirms PFAS residues in animal tissues including bovine (cattle), porcine (swine), poultry, and Siluriformes muscle, as well as bovine plasma.[1] Ultrahigh-performance liquid chromatography/tandem mass spectrometry (UHPLC/MS/MS) is used to detect 16 PFAS compounds in these matrices. This method ensures meat products are free from harmful PFAS levels with detection limits in the low parts per-trillion (ppt) range. The process involves homogenizing and extracting samples, cleaning up extracts to remove fats and proteins and analyzing them with UHPLC/MS/MS.

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Food and Drug Administration (FDA) method C-010.03

The FDA method C-010.03 uses liquid chromatography/tandem mass spectrometry (LC/MS/MS) to detect 30 PFAS compounds in food and feed.[2] It ensures PFAS levels are within safe limits through detailed protocols for sample preparation, extraction, and analysis. Key steps include homogenizing and extracting samples, cleaning extracts with solid phase extraction (SPE), and analyzing them with LC/MS/MS. This method is highly sensitive, with detection limits in the low-ppt range. This standardized method provides a robust framework for accurate PFAS detection in food and feed, ensuring safety and compliance with regulatory standards.

Association of Official Analytical Collaboration (AOAC) International standard method performance requirement (SMPR 2023.003)

AOAC SMPRs set the minimum recommended performance characteristics to be used for method validation. AOAC SMPR 2023.003 sets performance requirements for PFAS testing in produce, beverages, dairy products, eggs, seafood, meat products, and feed, evaluating the same 30 PFAS compounds as FDA method C-010.03.[3] It ensures reliable and reproducible testing methods for compliance monitoring, emphasizing method validation for accuracy, precision, and reproducibility, and the use of techniques like LC/MS/MS and UHPLC/MS/MS. This standard helps laboratories maintain high-quality testing procedures to meet regulatory requirements.

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State-level Regulations

In the absence of federal regulations, Maine has taken steps to regulate PFAS in food at the state level. The state has established specific action levels for PFOS in certain food products, setting the limit at 3.4 parts per billion (ppb) for beef and 210 parts per trillion (ppt) for milk.[4] Additionally, Maine prohibits the use of PFAS in food packaging materials.[5]

Beyond Maine, 12 other states have enacted regulations targeting PFAS in food packaging, such as fast food wrappers, microwave popcorn bags, and pizza boxes. As a 2024, these states include California, Connecticut, Minnesota, New York, Vermont, Washington, Maryland, Hawaii, Rhode Island, Oregon, Colorado, and Nevada. [6]

Currently, there are several additional proposed bills pending in various states aiming to regulate PFAS in food packaging, reflecting growing concerns about the health risks associated with these compounds.

Methodology and instrumentation

The primary methodologies for PFAS testing in the U.S. involve liquid chromatography coupled with mass spectrometry. These techniques are highly sensitive and can detect PFAS compounds at ppt levels. The FDA method C-010.03 and USDA CLG-PFAS 2.04 both utilize these techniques to ensure accurate and reliable results.

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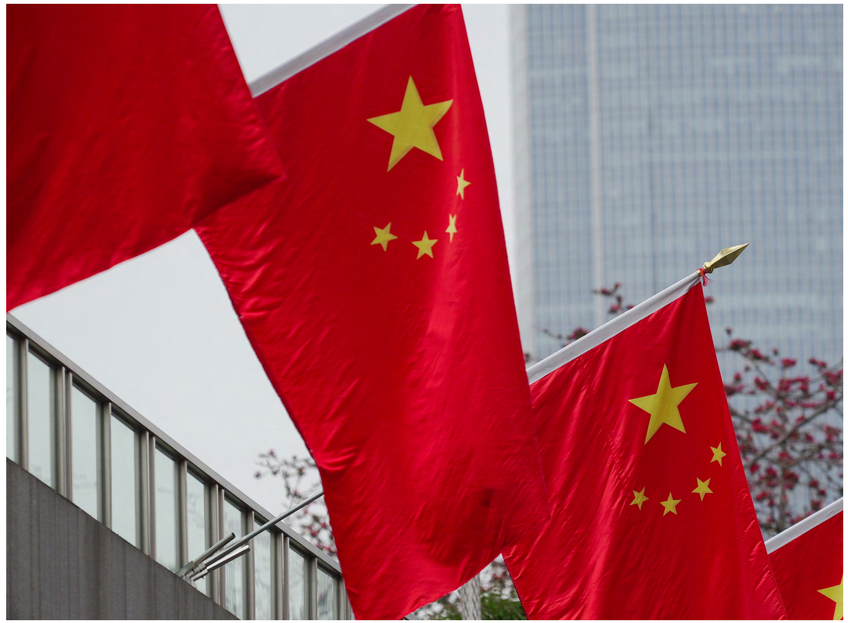
Chinese regulations and methods for PFAS testing in food

In China, the regulation and testing of PFAS in food, beverages, and food packaging materials are governed by the following standards and legislative measures. These regulations are constantly changing and evolving to address new scientific finds and emerging health concerns.



China GB 5009.253 and PFAS regulations

China GB 5009.253-2016 is a national food safety standard that outlines the determination of perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) in animal-derived foods using isotope dilution liquid chromatography/tandem mass spectrometry (LC/MS/MS).[1] The maximum allowable concentrations for PFOS and PFOA are set at 0.01 ug/kg and 0.1 ug/kg, respectively, in these foods. In 2025, China proposed a draft to replace GB 5009.253-2016, expanding the scope to include 30 PFAS compounds, including PFOS and PFOA isomers, with allowable concentrations of 0.02 to 0.1 µg/kg. The proposed standard covers other food such as vegetables, fruits, fish, meat, shellfish, and liquid milk.

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China GB 5009.253 and PFAS regulations (continued)

This standard is part of China's broader regulatory framework aimed at controlling the presence of PFAS. The Ministry of Ecology and Environment, along with other ministries, has issued regulations prohibiting the production, distribution, and use of certain PFAS compounds, including PFOS, PFOA, and PFHxS, with specific exceptions for applications such as photo imaging, semiconductor manufacturing, aviation hydraulic oil, and firefighting foam.

The information provided by GB 5009.253-2016 is important for ensuring compliance with PFAS regulations in China. By establishing standardized testing methods, this regulation helps monitor and control PFAS levels in food products, thereby protecting public health. The regulatory framework also includes bans on the production and use of specific PFAS compounds, requirements for environmental management, and guidelines for safe disposal.

Methodology and instrumentation

In China, the testing of PFAS in food, beverages, and food packaging materials primarily involves analytical techniques such as LC/MS/MS. This method allows for the precise quantification of PFOS and PFOA in complex matrices. The isotope dilution technique enhances accuracy by compensating for matrix effects and instrumental variations. Laboratories equipped with high-performance LC/MS/MS systems can detect PFAS at very low concentrations (in the low parts-per-trillion range), ensuring compliance with stringent regulatory limits.

References

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Solutions for PFAS testing in food

PFAS pose a significant risk to consumers, suppliers, manufacturers, and food cultivators. Contamination can occur unintentionally or through agricultural practices. Effective and efficient analytical testing is key for managing exposure, ensuring product safety, and maintaining process control. Given the complexity of regulations and testing requirements, a simplified and scalable solution is essential–allowing for adjustments in the compounds analyzed, detections limits required, and the number of samples tested.

Agilent offers PFAS food testing workflows designed for various sample types, providing rapid and simplified analyses that reduce the risk of false positives.

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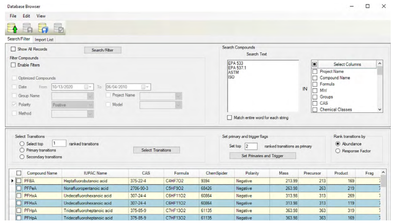

Accelerate method development with verified methodologies tailored to EPA, EU, and ASTM standards, along with a curated PFAS MRM database.

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Solutions for PFAS testing in food

PFAS pose a significant risk to consumers, suppliers, manufacturers, and food cultivators. Contamination can occur unintentionally or through agricultural practices. Effective and efficient analytical testing is key for managing exposure, ensuring product safety, and maintaining process control. Given the complexity of regulations and testing requirements, a simplified and scalable solution is essential–allowing for adjustments in the compounds analyzed, detections limits required, and the number of samples tested.

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