Navigating the PFAS regulatory maze

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Introduction

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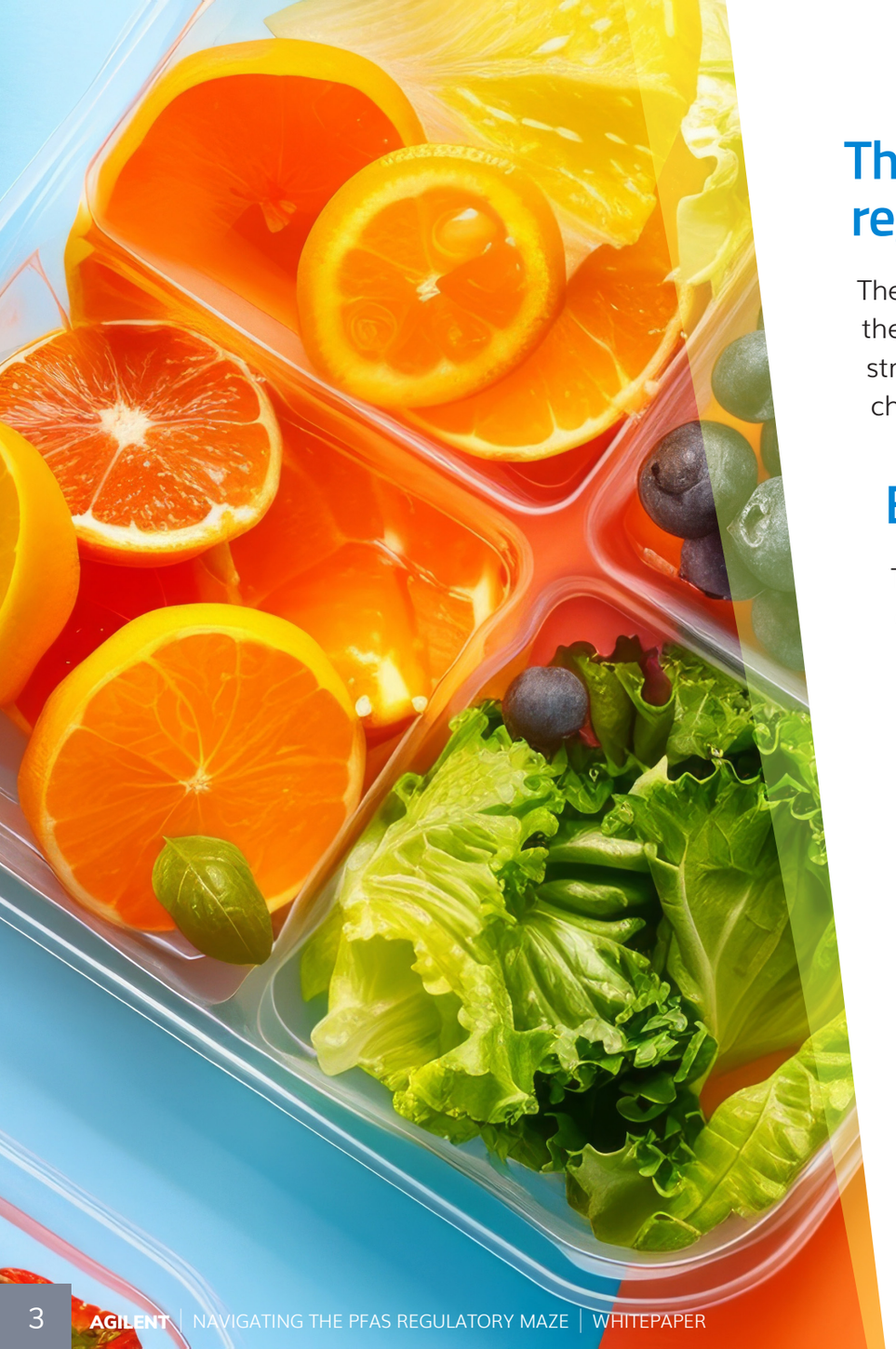
Per- and polyfluoroalkyl substances (PFAS) present a confronting and immediate challenge to the food and beverage industry. Introduced for their versatility and resilience, these substances—and their derivatives—are remarkably stable, even under extreme temperatures, making them nearly impossible to avoid. From non-stick cookware and grease-proof food packaging to their widespread presence in groundwater, drinking water and surface water, PFAS have become deeply embedded in everyday life.

While the ubiquity of 'forever chemicals' in all facets of our environment is not a new occurrence, mounting scientific evidence suggests bioaccumulation of PFAS could lead to serious health risks, with liver damage, kidney and testicular cancer, thyroid disease and reduced fertility among the most concerning outcomes.

These concerns have intensified regulatory scrutiny, with authorities worldwide tightening limits on PFAS in food packaging, water and consumer goods. Non-compliance not only risks hefty fines but also erodes consumer trust, which can be difficult to rebuild once lost.

The financial and reputational fallout is clear—companies like DuPont and 3M have faced billions in PFAS-related liabilities, and while McDonald's ongoing lawsuit remains unresolved, it serves as a stark warning for food and beverage manufacturers.[1,2,3] To complicate the predicament, global food supply chains are deeply interconnected, yet the regulatory landscape remains fragmented, with varying standards across different regions. This disparity creates compliance challenges, forcing businesses to navigate a patchwork of evolving policies while ensuring product safety and consumer confidence.



The global PFAS regulatory landscape

The European Union and United States are leading the way in PFAS regulation, adopting increasingly stringent measures to address the presence of these chemicals in food and water.

EU regulatory landscape

The EU takes a proactive and comprehensive approach to mitigate the risks posed by PFAS. A proposed ban on a wide range of PFAS, including thousands of the most concerning compounds, has been submitted by five member states and is currently under review by the European Chemicals Agency (ECHA). This initiative aims to minimise risks to consumers, protect brand integrity, and ensure food supply chain safety by setting strict limits and testing requirements.

The European Food Safety Authority (EFSA) has established a tolerable weekly intake (TWI) of 4.4ng per kg of body weight for four specific PFAS compounds: PFOS, PFOA, PFNA and PFHxS.[4] Based on this TWI, the EU has set maximum limits for these compounds in various food categories, including eggs, seafood, meat and edible offal, as stipulated in EU Regulation 2023/915. Additionally, the European Drinking Water Directive includes limits for 20 PFAS compounds, with a total limit of 500 ng/L for all PFAS combined.[5]

Currently, the EU actively monitors and controls PFAS levels in food through various measures:

- **EU REGULATION 2023/915:** establishes maximum levels for certain PFAS in specific food categories.[6]
- **RASFF NOTIFICATIONS:** The Rapid Alert System for Food and Feed (RASFF) monitors and reports food safety issues within the EU. As shown in ***Figure 1***, a search for "PFAS" on the RASFF portal reveals numerous notifications related to PFAS contamination in food products, leading to product recalls and withdrawals.
- **ONGOING MONITORING AND RESEARCH:** The EU continuously assesses PFAS levels in food to inform future regulations.

These measures demonstrate the EU's commitment to addressing PFAS contamination in food and protecting consumer health. Food manufacturers operating in the EU must stay proactive in PFAS management strategies to ensure compliance.

RASFF Window Rapid Alert System for Food Feed

Figure 1

European Commission | **RASFF Window**
Rapid Alert System for Food and Feed

Subject	Date	Origin	Notifying
Presenza di PFOA (acido perfluoro-ottanoico) in Vongole del Pacifico sgusciate cotte - congelate//Presence of PFOA (perfluorooctanoic acid) in frozen cooked shelled Pacific clams	3 JAN 2025	Vietnam	Italy
PFOS in carp (Cyprinus carpio) of undetermined origin (Italy or Spain) via France	6 DEC 2024	---	Belgium
PFOA in frozen cooked bivalve molluscs (Paphia textile) from Vietnam	2 SEP 2024	Vietnam	Italy
Border rejection - PFOA in frozen yellow clam meat cooked from Vietnam	16 JUL 2024	Vietnam	Denmark
Perfluorooctane sulphonic acid (PFOS) (5.5 µg/kg - ppb) in cooked prawns from Belgium	1 JUL 2024	Belgium	Belgium
PFOA in frozen cooked bivalve molluscs (Paphia textile) from Vietnam DL 449	3 JUN 2024	Vietnam	Italy
PFOA in cooked bivalve molluscs (Paphia textile) from Vietnam	8 MAY 2024	Vietnam	Italy
PFOA in bivalve molluscs (paphia undulata).	1 FEB 2024	Thailand	Netherlands
PFOS in skim milk concentrate from the United Kingdom	29 DEC 2023	United Kingdom	Netherlands
PFOS in bovine meat from Belgium	6 DEC 2023	Belgium	Belgium
PFOS in Skim milk concentrate from United Kingdom	29 NOV 2023	United Kingdom	Netherlands
PFOS in bovine meat from Belgium	23 NOV 2023	Belgium	Belgium
PFOA in bivalve molluscs	12 OCT 2023	Vietnam	Netherlands
PFOA in bivalve molluscs	5 OCT 2023	Vietnam	Netherlands
PFNA in dried shrimps from Thailand	2 FEB 2024	Thailand	Norway
PFOA in bivalve molluscs (paphia undulata).	1 FEB 2024	Thailand	Netherlands

RASFF Window – Results, accessed January 6, 2025

US regulatory landscape

The US takes a multi-pronged approach to PFAS regulation, with both federal and state-level regulations playing a significant role, presenting unique challenges for food and beverage companies.

- **FEDERAL REGULATIONS:** The US Food and Drug Administration (FDA) monitors and regulates PFAS in food. In 2024, the US Environmental Protection Agency (EPA) established strict limits for PFOA, PFOS, PFHxS, PFNA and HFPO-DA in drinking water under the National Primary Drinking Water Regulation.7 Recent FDA actions include:

  - **Product recalls:** The FDA has issued several recalls of food products due to PFAS contamination, including recalls of smoked clams and various frozen food items that were found to be contaminated through production water. The most

> The EU takes a proactive and comprehensive approach to mitigate the risks posed by PFAS

significant PFAS seafood recalls involved canned clams from China, wherein in 2022, the FDA detected high levels of PFOA in samples of canned clams from two different brands, leading to voluntary recalls by Bumble Bee and Crown Prince.[8,9] The FDA estimated that consuming more than 10 ounces of these clams per month could pose a health risk for adults, while children should limit consumption to two ounces per month. These recalls were significant because they were the first major recalls related to PFAS contamination in seafood, highlighting the potential for PFAS to accumulate in fish and shellfish and raising concerns about the safety of these imported products.

- **Import Alert 99-48:** Issued on 31 December 2024, this alert allows the FDA to detain imported food products suspected of harmful chemical contamination, including PFAS. This applies to a broad range of foods and highlights the importance of rigorous testing and analysis to ensure compliance and avoid potential disruptions to import operations.[10]
- **State-level regulations:** In the absence of comprehensive federal regulations for PFAS in food, several states have taken the initiative to implement their own, often stricter, regulations. For example, Maine took decisive action, having established maximum permissible levels for PFAS in certain food products, including milk, beef and fish.[11] Similarly, states like New Hampshire, New York and Michigan have implemented regulations to monitor and limit PFAS concentrations in their water supplies. These state-level initiatives reflect a growing movement towards comprehensive national standards to address PFAS contamination across the country. This trend is mirrored globally, with countries increasingly adopting restrictions on PFAS, particularly in areas like agriculture and food production, recognising the need for a coordinated response to this widespread issue.

The proposed EU PFAS ban: progress and implications

As of February 2025, the proposed EU-wide restriction on PFAS is undergoing evaluation by ECHA's scientific committees, with public consultation expected in late 2025. However, the proposed ban may face legal challenges from various industry groups arguing that

it is too broad, lacks sufficient scientific justification, or imposes disproportionate economic impacts. These potential challenges could influence the timeline for implementation and create uncertainty within the food industry.

The ban aligns with the Packaging and Packaging Waste Regulation (PPWR), which aims for all EU packaging to be reusable or recyclable by 2030.[12] This creates challenges in finding suitable alternatives to PFAS-based materials. Given the complexity of the ban and potential legal challenges, the implementation timeline remains uncertain, with the earliest possible implementation date estimated to be late 2026 or early 2027. The ban includes some specific exemptions for essential uses of PFAS, and derogations may be granted for specific food contact materials or packaging where suitable alternatives are not yet available.

Regulations in other regions

While the EU and US lead in PFAS regulation, other regions are also acting. China and Japan have implemented standards for PFAS in certain applications, while Canada and Australia are conducting research and developing national management plans.

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The complexity of PFAS

The PFAS issue is complicated by the sheer number of different compounds involved. The Organisation for Economic Co-operation and Development (OECD) Global Database lists 4,729 PFAS compounds, but estimates suggest there are 5,000 to 10,000, with many lacking analytical standards.

- The EU focuses on C4-C13 perfluorocarboxylic and sulphonic acids.[13]
- The US EPA Method 537.1 for drinking water includes HFPO-DA, 11Cl-PF3OUdS, 9Cl-PF3ONS, and ADONA.[14]

The toxicological profiles and bioaccumulation potential of PFAS compounds vary significantly. For example, 9Cl-PF3ONS, a major component of F-53B, is a persistent PFAS used primarily in China, particularly in metal plating applications. In studies examining food contact materials, fluorotelomer alcohols (FTOHs) and fluorotelomer sulphonates (FTSs) are among the most frequently detected PFAS, as they serve as precursors to other perfluorinated compounds.

Impact and challenges for the industry

The proposed EU PFAS ban will significantly impact food contact materials and food packaging, potentially requiring manufacturers to reformulate products and find alternative materials. This raises pressing issues for the food and beverage industry, including adapting products and processes, accurately identifying and quantifying PFAS, finding suitable alternatives, and ensuring water used in production is free from PFAS contamination.

Beyond compliance: building a proactive PFAS management strategy

A proactive approach to PFAS management goes beyond simply meeting regulatory requirements. It necessitates a comprehensive strategy that anticipates future challenges and minimises risks throughout the supply chain. This can be achieved through several key actions:

- **RISK ASSESSMENT:** Begin by conducting thorough risk assessments to identify potential sources of PFAS contamination in raw materials, ingredients, processing and packaging. This involves evaluating potential pathways of exposure and assessing the likelihood of contamination at each stage.
- **SUPPLY CHAIN CONTROL:** Once potential sources are identified, implement strict supplier qualification programmes and traceability systems to ensure the integrity of the supply chain. This helps minimise the risk of PFAS contamination from external sources.
- **TESTING AND MONITORING:** To further ensure safety, invest in advanced testing technologies and establish a robust monitoring programme to detect PFAS levels. This allows for early detection and prompt action in case of contamination.
- **STAYING AHEAD OF EVOLVING REGULATIONS**: The PFAS regulatory landscape is constantly evolving. Food and beverage companies must stay informed about new and upcoming regulations, proposed changes, and emerging scientific findings to ensure ongoing compliance. This includes considering broader regulations that intersect with PFAS concerns, such as PPWR's aim for all packaging to be reusable or recyclable by 2030. Aligning PFAS management strategies with these broader sustainability goals can provide a competitive advantage and demonstrate environmental responsibility. However, ensuring compliance with these evolving regulations can be a significant challenge, especially given the lack of standardised testing methods for PFAS, which poses difficulties for accurate and reliable analysis.
- **COLLABORATION AND KNOWLEDGE SHARING:** Finally, collaborate with industry partners, research institutions and technology providers to develop innovative solutions for PFAS mitigation and remediation. Sharing knowledge and best practices across the industry can help accelerate progress and improve overall safety.

Risks in PFAS management

Managing the risks associated with PFAS contamination requires a comprehensive approach. Food and beverage companies must be aware of the potential consequences of non-compliance, as well as the challenges in identifying, monitoring and controlling PFAS throughout the supply chain.

Challenges:

- **SUPPLY CHAIN RISK:** PFAS can enter the supply chain through raw materials, packaging and processing. Supplier audits and traceability systems will help mitigate risks.
- **LOCATION RISK:** The geographical area in which plants are grown and animals raised is a major risk factor for PFAS contamination. High-quality contamination maps aid risk assessment in regions like the US, China and Europe.
- **FOOD TYPE RISK:** Animal-based foods generally have higher PFAS levels than plant-based foods. Fish, game meat and liver may also contain elevated levels of PFAS.

Risks of PFAS non-compliance:

- **BRAND AND CONSUMER RISK:** PFAS contamination poses significant health risks to consumers, thus non-compliance can have equally damaging repercussions for brand reputation, eroding consumer trust. Companies must implement robust testing programmes, transparent communication and swift action in case of contamination, as well as adhere to regulations.
- **FINANCIAL PENALTIES:** Non-compliance can result in hefty fines under laws like the US Clean Water Act and Toxic Substances Control Act.
- **PRODUCT RECALLS:** PFAS contamination can lead to costly recalls and reputational damage.
- **HEALTH RISKS:** Studies link PFAS exposure to various health issues. Food and beverage companies must prioritise consumer safety.

MEASURING TO MANAGE PFAS IN FOOD - PARTNERING WITH AGILENT

Increasingly, food and ingredient manufacturers are concerned about the impact of per- and poly fluoroalkyl substances (PFAS), and the respective regulatory drive, on consumer and product safety.

The proposals to limit use of PFAS and impose stricter management of dietary exposure could mean a dramatic increase in testing for food companies to ensure PFAS is below prescribed limits.

PFAS can enter food through use of water in crop and ingredient production or via bioaccumulation in livestock, including their feed, silage and grass

grown on sludge-fertilised fields. The impact on the supply chain of raw materials and ingredients, as well as on processing and packaging, is so large it is difficult to quantify. Consider the effect on consumer confidence as more litigation and media interest increase visibility of the potential (but not fully understood) impact. Management of the problem is critical, and to manage it effectively, we must measure the impacts and the sources of concerns.

As a supplier of testing solutions, Agilent is committed to delivering intentionally designed analytical workflows, specifically for the needs of food manufacturers and safety testing labs to suit their unique needs and pressures.

We deliver right-first-time efficiency and confidence, - helping to ensure safe foods. Simplified sample prep provides faster, reduced cost-per-sample data to manage manufacturing and certification. Sample workflows and analytical pathways manufactured, tested and certified PFAS-free reduce the risk of lab-introduced false positives – all in a method designed by Agilent experts to be easy to implement and scalable to increase capacity or scope as the regulatory and risk management landscape changes. ■

Click here to find out more

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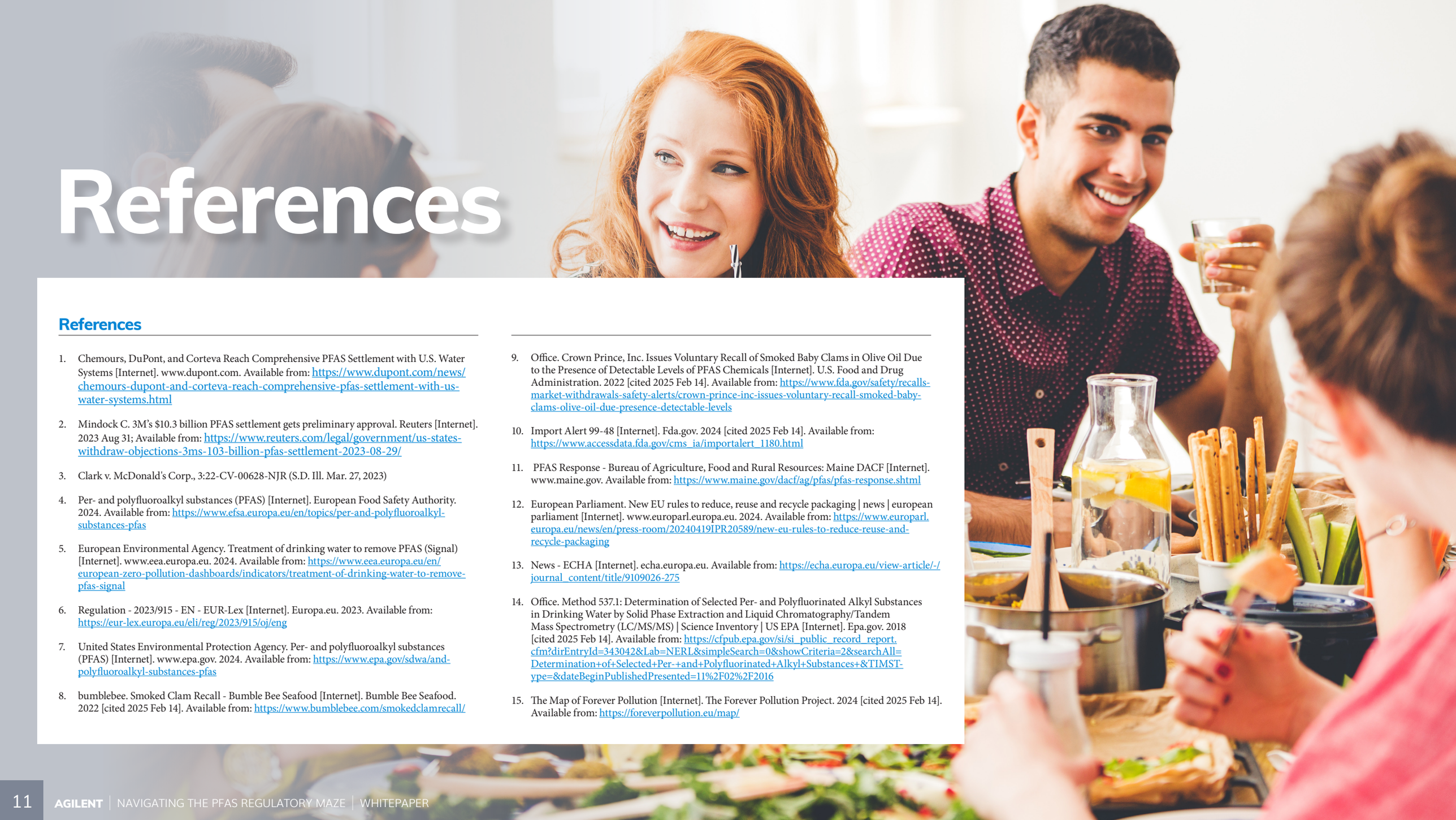

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