Food Packaging Forum

Addressing the chemical safety of food contact materials (FCMs) in the US: Science-based insights for policymaking

Developed and published by the Food Packaging Forum Foundation in June 2025.

Introduction

Evidence shows that if the chemical safety assessment of food packaging and other food contact materials (FCMs) is founded on **modern scientific knowledge and principles then their safety can be assured**. This includes consideration of:

- low-dose effects/non-monotonic dose responses, as is the case for endocrine-disrupting chemicals (EFSA 2021)
- some population groups are more vulnerable than others (e.g., infants) (Trasande et al. 2018)
- humans are not exposed to single chemicals but rather to mixtures of chemicals that can have cumulative effects (Maffini & Vandenberg, 2024)

Importantly, food contact chemicals cannot **be considered safe if they**:

- **migrate from food contact materials**, implying a very high probability of human exposure
- but have **not been empirically tested** for all relevant hazard properties
- and if **mixture effects of all migrating chemicals** are not being considered**.**

This document provides a non-exhaustive set of **12 science-based insights** to consider for improving the safety of food contact materials including food packaging by policy makers.

1. Comprehensive hazard assessment

To ensure safety, **toxicity testing of FCMs would need to be expanded beyond genotoxicity** to multiple endpoints associated with non-communicable diseases relevant to human health, such as **cardiovascular diseases, brain-related disorders, metabolic and endocrine diseases, as well as immunological and reproductive disorders, and cancers**. This is not being done in the current US regulatory framework, and a framework approach to consider these impacts of chemicals on chronic diseases has been proposed (Muncke et al. 2023). It involves developing and using suitable *in* *vitro* assays as well as utilizing novel approaches such as adverse outcome pathways (AOPs) and the Key Characteristics concept (Smith et al. 2016).

To considerably reduce the time and resources for safety assessments while improving consumer protection, the US could move from a risk-based to a **hazard-based approach** for food contact chemicals management (Zimmermann et al. 2022). A risk-based approach requires both hazard and exposure data, but exposure data are difficult to determine and are missing for many chemicals. A hazard-based approach avoids this limitation and enables proper consideration of chemicals for which no safe levels exist (e.g., carcinogens, mutagens, endocrine disruptors). Another precaution to consider is the introduction of a Mixture Assessment Factor (MAF), as outlined in the EU's Chemical Strategy for Sustainability (EU 2020).

Not to be overlooked are chemicals with **persistence and bioaccumulation** properties. For example, per- and polyfluoroalkyl substances (PFAS) are of high environmental and human health concern in part due to their extreme persistence (Cousins et al., 2020).

For more details, see: Food Packaging Forum's submitted comments *on US FDA Food Additive Petition FDA-2024-N-3609*

2. Food contact chemicals that are Generally Recognized as Safe (GRAS)

For food contact chemicals, the evidence shows value in removing the FDA's voluntary generally recognized as safe (GRAS) notification and replacing it with a mandatory disclosure. In addition, notification letters, including the data used to derive GRAS safety decisions could be made publicly available. This public information could include the chemical's use in a specific food contact material (i.e. paperboard, metal coating, etc.) and an assessment of its migration into different food types.

3. Transparency for FDA's Food Contact Substance Notifications (FCN)

Currently, the FDA's food contact substance notification listing does not provide any information on safety decisions. However, this is important to enable independent, third-party review. Notification letters, including the data used to derive FCN safety decisions could be made publicly available. This could include a chemical's use in a specific food contact material (i.e. paperboard, metal coating, etc.) and an assessment of its migration into different food types.

4. Bisphenol A (BPA) and other bisphenols in food contact materials

Bisphenol A (BPA) is a widely used food contact chemical such as for aluminum beverage can coatings, in reusable plastic drinking bottles, and in kitchenware. It is a recognized endocrine disrupting chemical by the European Chemicals Agency, and in 2023 the European Food Safety Authority (EFSA) lowered its safe tolerable daily intake (TDI) by a factor of 20,000 after harmful effects were discovered on the immune system. In response, the *European Commission* adopted a ban on the use of BPA and other hazardous bisphenols and derivatives in December 2024 that is applicable across the entire European Union. BPA is still allowed and widely used across food contact materials in the United States and the safe threshold is 25,000 times above the EU's. The available scientific evidence for the harm of BPA and other bisphenols to human health justifies regulatory action.

5. Expanding safe reuse systems for food packaging

Reusable food contact materials are beneficial because they reduce waste, conserve resources, and lower environmental pollution compared to single-use items. However, using plastics for these materials is of concern, as plastic is not inert and can degrade over time and release its complex mixture of (untested) chemicals as well as microplastics into the food. Additionally, plastics can absorb chemicals during their use that may later migrate into food (e.g., detergents used during washing, consumers' repurposing of containers that bring them in contact with non-food chemistry) (Tisler and Christensen 2022). "Traditional" reuse materials, such as ceramics, glass, and metals are highly inert and show less degradation over time and are much easier to sanitize. Therefore, they are highly suitable for reuse systems as they are more hygienic and lead to less migration. Expanding infrastructure to have many collection points and gain support by major companies and governments would facilitate the introduction and scale-up of efficient and convenient reuse systems.

6. Recognizing the limits of plastic recycling

There are many known limitations related to the recycling of plastic food packaging that are important to consider:

- Food packaging often contains hazardous chemicals that need to be removed during recycling to guarantee safety, but suitable processes are not available to adequately achieve this. For this reason, the Chinese government currently does not allow recycled plastic content in food contact materials.
- Many packaging materials cannot be collected and separated into single streams, which prevents efficient and cost-effective recycling processes.
- Food packaging is often contaminated with food residues, which makes the material unrecyclable.
- The quality of plastic polymers decreases with repeated cycles of mechanical recycling – so the addition of primary materials is required.
- Novel methods of plastic recycling often referred to as "advanced recycling" or "chemical recycling" have not been shown to be feasible at scale or economically viable. Many of these approaches require significant amounts of energy to operate, produce large volumes of hazardous waste, or downgrade the material into a fuel for energy (which is then not recycling and does not fit within a circular economy) (Wiesinger 2024).

Therefore, plastic recycling often fails in practice, can pose health risks to workers and consumers, and delays the necessary shift to more sustainable, inert and healthier food packaging that can be reused.

7. FDA's Threshold of Regulation rule

The FDA's Threshold of Regulation (TOR) rule (21 CFR 170.39) allows companies to use chemicals in food contact materials without adequate prior safety assessment. In short, it exempts any toxicological testing on the basis of "the dose makes the poison" assumption, i.e. for very low levels of chemicals migrating into foodstuffs (0.5 ppb), the TOR rule assumes that they cannot be of concern to health. This assumption is, however, incorrect based on three main lines of evidence:

- Some chemicals have known toxicological thresholds well below 0.5 ppb, such as bisphenol A (EFSA 2023).
- Chemicals migrate from food contact materials in mixtures that can cause adverse health effects. Therefore, setting limits for individual food contact chemicals is not appropriate for protecting health. The use of a Mixture Assessment Factor in chemical risk assessments can provide the necessary safety.
- When determining whether a chemical falls under TOR, a pre-market exposure assessment is made which is never reviewed post-market, even though exposures may well change over time and increase, leading effectively to higher exposures than anticipated when a chemical was identified to receive a TOR exemption. This justifies the need for a systematic post-market review of food contact chemicals used under TOR and FCN.

8. Priority hazardous food contact chemicals

The recently developed FCCprio List systematically identifies and prioritizes known food contact chemicals that are hazardous. Out of 15,159 known food contact chemicals, 1,222 were identified as food contact chemicals of high concern. Substances in Tier 1 are known to migrate from food contact materials and have been measured in people. These substances are therefore ideal to be subjected to post-market review and considered for a phase-out from the production of food contact materials. Below is the list of the 94 highest priority food contact chemicals (Tier 1 of the FCCprio List):

Priority Chemical Name (Tier 1 of the FCCprio List)	**CAS Number**
1,1,1-TRICHLOROETHANE	71-55-6
1,4-BENZENEDIAMINE	106-50-3
1,4-DICHLOROBENZENE	106-46-7
1-BUTANESULFONIC ACID, NONAFLUORO-	375-73-5
1-METHYLETHYLBENZENE	98-82-8
2,2',3,4,4',5,5'-HEPTACHLOROBIPHENYL	35065-29-3

2,2',3,4,4',5'-HEXACHLOROBIPHENYL	35065-28-2
2,2',4,5,5'-PENTACHLOROBIPHENYL	37680-73-2
2,2',5,5'-TETRACHLOROBIPHENYL	35693-99-3
2,3,7,8-TETRACHLORODIBENZO-P-DIOXIN	1746-01-6
2,4-DIAMINOTOLUENE	95-80-7
2,6-XYLIDINE	87-62-7
2-HYDROXY-4-METHOXYBENZOPHENONE	131-57-7
2-NAPHTYLAMINE	91-59-8
2-PHENYLPHENOL	90-43-7
4,4'-DIAMINOBIPHENYL METHANE	101-77-9
4,4'-SULFONYLDIPHENOL	80-09-1
4-AMINOBIPHENYL	92-67-1
4-AMINOPHENYL ETHER	101-80-4
4-METHYL-2-PENTANONE	108-10-1
4-TERT-OCTYLPHENOL	140-66-9
6:2 FLUOROTELOMER SULFONIC ACID	27619-97-2
ACRYLONITRILE	107-13-1
ANTIMONY	7440-36-0
ARSENIC	7440-38-2
BENZALDEHYDE	100-52-7
BENZENE	71-43-2
BENZOPHENONE	119-61-9
BENZYL BUTYL PHTHALATE	85-68-7
BERYLLIUM	7440-41-7
BISPHENOL A	80-05-7
BUTYLPARABEN	94-26-8
CADMIUM	7440-43-9
CARBON DISULFIDE	75-15-0
CHLOROFORM	67-66-3
COBALT	7440-48-4
CROTONALDEHYDE	123-73-9
DI(2-ETHYLHEXYL) PHTHALATE	117-81-7
DIBUTYL PHTHALATE	84-74-2
DICYCLOHEXYL PHTHALATE	84-61-7
DIHEXYL PHTHALATE	84-75-3
DIISOBUTYL PHTHALATE	84-69-5
DIISODECYL PHTHALATE	26761-40-0
DIISONONYL PHTHALATE	28553-12-0
DI-N -PENTYL PHTHALATE	131-18-0
DI-N-OCTYL PHTHALATE	117-84-0
ETHER, BIS(PENTABROMOPHENYL)	1163-19-5
ETHYLBENZENE	100-41-4
FORMALDEHYDE	50-00-0
FURAN	110-00-9
LEAD	7439-92-1
MANGANESE	7439-96-5
MERCURY	7439-97-6
MONO-(2-ETHYLHEXYL) PHTHALATE	4376-20-9

MONOBUTYL PHTHALATE	131-70-4
NAPHTHALENE	91-20-3
NICKEL	7440-02-0
N-NITROSOMORPHOLINE	59-89-2
N-NITROSOPIPERIDINE	100-75-4
O-ANISIDINE	90-04-0
O-TOLUIDINE	95-53-4
PENTACHLOROPHENOL	87-86-5
PERFLUORODECANOIC ACID	335-76-2
PERFLUORODODECANOIC ACID	307-55-1
PERFLUOROHEPTANOIC ACID	375-85-9
PERFLUOROHEXANESULFONIC ACID	355-46-4
PERFLUOROHEXANOIC ACID	307-24-4
PERFLUORONONANOIC ACID	375-95-1
PERFLUOROOCTANESULFONIC ACID	1763-23-1
PERFLUOROOCTANOIC ACID	335-67-1
PERFLUOROPENTANOIC ACID	2706-90-3
PERFLUOROTRIDECANOIC ACID	72629-94-8
PERFLUOROUNDECANOIC ACID	2058-94-8
PHENANTHRENE	85-01-8
PHENOL	108-95-2
PHOSPHORIC ACID, DIBUTYL ESTER	107-66-4
PROPANAL	123-38-6
PROPYLPARABEN	94-13-3
PYRENE	129-00-0
SELENIUM	7782-49-2
SILVER	7440-22-4
STYRENE	100-42-5
TDCIPP	13674-87-8
TETRABROMOBISPHENOL A	79-94-7
TETRAHYDROFURAN	109-99-9
THALLIUM	7440-28-0
TIN	7440-31-5
TOLUENE	108-88-3
TRICLOSAN	3380-34-5
TRIPHENYL PHOSPHATE	115-86-6
TRIS(2-CHLORO-1-METHYLETHYL) PHOSPHATE	13674-84-5
TRIS(2-CHLOROETHYL) PHOSPHATE	115-96-8
URANIUM	7440-61-1
XYLENES	1330-20-7

9. Implementing the recommendations from the US GAO on improving oversight of food contact chemicals by the FDA

Congress tasked the *Government Accountability Office (GAO)* with investigating how the *FDA* could improve "oversight of substances used in manufacturing, packaging, and transporting food." *GAO published their findings* along with two recommendations for change on November 8, 2022. In short, the *GAO* recommends the *FDA* to (i) "request from Congress specific legal authority to compel companies to provide the information needed to reassess the safety of substances and (ii) track the dates of the last reviews for all food contact substances to allow *FDA* to readily identify substances that may warrant post market review."

According to the report, "*FDA* does not have specific legal authority to compel companies to provide information and data on substances' safety and extent of use" particularly when already on the market. Without that critical information, the agency cannot prioritize well when a chemical needs to be reassessed. And while the date of when a chemical or chemical group was approved is available for *FDA* employees to look up, there is no system to inform the agency of when a review might be needed.

10. Considering the findings and recommendations of the PlastChem report

Developed by a team of interdisciplinary and independent scientists, the PlastChem Project's latest report synthesizes the evidence on more than 16,000 chemicals potentially used or present in plastics. It provides a comprehensive overview of the current scientific understanding of the chemicals in plastics, including their properties, hazards, functionalities, uses, production volumes, and regulatory status.

Key findings:

- Plastics are chemically complex: There are at least 16 000 known plastic chemicals that are potentially used or present in plastics.
- Plastic chemicals are a concern: Over 4200 plastic chemicals (25%) are hazardous to human health or the environment.
- Plastics are a major source of exposure: More than 1800 chemicals of concern have a high exposure potential, and each major plastic type can contain at least 400 chemicals of concern.
- Plastics lack transparency: Many plastic chemicals lack public and verifiable information on their identities and structure (25%), functions (50%), presence in plastic (56%), and hazards (66%).
- Global governance gap: Only 6% of all plastic chemicals are regulated internationally, with additional, national regulations applying to 1000 chemicals.

Key recommendations from the report:

- Regulate plastic chemicals comprehensively and efficiently: This can be achieved by implementing a hazard- and group-based approach to identify chemicals of concern and to foster innovation towards safer plastic chemicals.

- Require transparency on plastic chemicals: A unified reporting, disclosure of the chemical composition of plastics, as well as a "no data, no market" approach can facilitate safety assessments and the development of safer plastics.
- Simplify plastics towards safety and sustainability: The chemical complexity of plastics represents a major barrier for governance and circular economy. Simplification encourages the use of fewer and safer chemicals by adopting essential-use and safe-by-design concepts to guide innovation.
- Build capacity to create safer and more sustainable plastics: Technical, institutional, and communication capacity should be built in the public and private sectors. This involves global knowledge exchanges, equal access to technical capabilities, and enhanced institutional resources for an effective management of plastic chemicals.

11. Addressing conflicts of interest within regulatory processes

To ensure evidence-based and effective decision-making, regulators and the public need access to unbiased information that is free of conflicts-of-interest. Policymakers in the chemicals space can consider the take aways from the peer-reviewed feature article on conflicts of interest in the assessment of chemicals, waste and pollution written by over forty science-policy experts in the space (Schäffer et al., 2023).

A conflict of interest occurs when an individual has "a 'direct and material gain' in a certain outcome of an activity, consultation, etc." or "for nonfinancial reasons such as institutional affiliations, political worldviews, or personal relationships (friendships or enmities)." Within the chemicals regulatory space, concerns about conflicts of interest most arise with "for-profit entities, such as the chemical industry, associated industry groups and trade associations (even if registered as not-for-profit organizations), and consultancies working for them." Actors with conflicts of interest have long been known to intentionally generate doubt about the certainty of scientific evidence and misinformation in order to sway public or policymakers' opinions and prevent action.

To address conflicts of interest, the article's authors recommend that regulatory bodies:

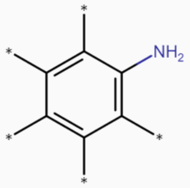
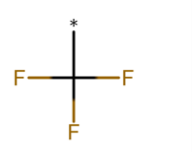
1. Provide clear and strict provisions on conflicts of interest as it pertains to experts involved in regulatory processes. Actors with clear conflicts of interest should not be allowed to participate in the decision-making process or core work of the body.
2. Do not confuse conflicts of financial or political competing interests with legitimate interests or biases.
3. Install regular audits of the regulatory body's work by an independent team to ensure rules on conflicts of interest are being followed, recommend corrective actions, as well as audit the body's outputs to ensure they are transparent, impartial, credible, and scientifically robust.

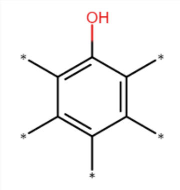
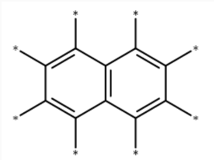
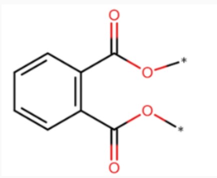
4. Secure as many elements of transparency as possible including following the FAIR and CARE principles for scientific data management and stewardship.

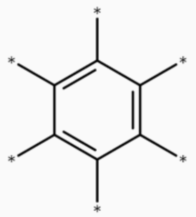
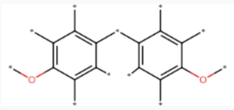
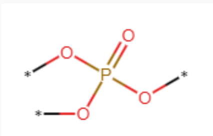
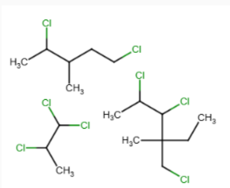
12. The benefits of a grouping approach within chemicals regulation

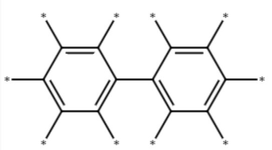
Group-based regulations have been shown to be a quick and effective approach in protecting human health and the environment from harmful chemicals (Wohlleben, 2022). Examples include the convention on chemical weapons and in the Stockholm Convention by swiftly removing groups of harmful chemicals from the market. Today the more than 15,000 known food contact chemicals are primarily being regulated one-by-one, which can require decades just to address individual chemicals due to the complexity of regulatory processes. Applying a group-based approach to food contact chemicals could help by reducing the regulatory processes needed and speed up action on known hazardous chemicals to protect public health sooner.

The most common structural groups of known hazardous food contact chemicals include: Primary aromatic amines (PAAs), PFAS, alkyl phenols, polycyclic aromatic hydrocarbon (PAH), toxic metals or metalloids, ortho-phthalates, benzoids, bisphenols, organophosphates, chlorinated alkanes, and polychlorinated biphenyls. Some of these groups are used in products beyond just food contact materials. The table below outlines these groups as examples.

Group	Definition	Structure	Examples of priority chemicals
Primary aromatic amines (PAAs)	Primary amine attached to aromatic carbon ring		ANILINE (CAS: 62-53-3); 4,4'-METHYLENEDIANILINE (CAS: 101-77-9); 2,4-TOLUENEDIAMINE (CAS: 95-80-7); …
PFAS	fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it)	 * = not Cl/Br	PFOA (CAS: 335-67-1); PERFLUOROHEXANOIC ACID (CAS: 307-24-4); 6:2 FLUOROTELOMER SULFONIC ACID (CAS: 27619-97-2);

		 * = not H/Cl/Br	8:2/8:2 DIPAP (CAS: 678-41-1); ...
Alkyl phenols	One or several alkyl groups attached to a single phenol	 * = alkyl group	4-TERT-OCTYLPHENOL (CAS: 140-66-9); 2,4-DIMETHYLPHENOL (CAS: 105-67-9); 4-NONYLPHENOL (CAS: 104-40-5); ...
Polycyclic aromatic hydrocarbon (PAH)	Hydrocarbon compounds composed of multiple fused aromatic rings	 * = hydrocarbons	NAPHTHALENE (CAS: 91-20-3); PHENANTHRENE (CAS: 85-01-8); PYRENE (CAS: 129-00-0); ...
Toxic metals or metalloids			ANTIMONY; TIN; ARSENIC; CADMIUM; COBALT; NICKEL; MANGANESE; SILVER; LEAD; ...
Ortho-phthalates	Esters of phthalic acid (see structure)		DI(2-ETHYLHEXYL) PHTHALATE (CAS: 117-81-7); DIBUTYL PHTHALATE (CAS: 84-74-2); BENZYL BUTYL PHTHALATE (CAS: 85-68-7); ...

Benzoids	Benzene ring(s) with hydrocarbon substituents	 * = hydrocarbons	ALPHA-METHYLSTYRENE (CAS: 98-83-9); P-XYLENE (CAS: 106-42-3); STYRENE (CAS: 100-42-5); ETHYLBENZENE (CAS: 100-41-4); …
Bisphenols	Chemicals with two phenols connected by one atom or a benzene ring		BISPHENOL A (CAS: 80-05-7); BISPHENOL B (CAS: 77-40-7); BISPHENOL M (CAS: 13595-25-0); BISPHENOL S (CAS: 80-09-1); …
Organophosphates	Organophosphorus compounds with the general structure O=P(OR)3, R can be H	 * = hydrocarbons	TRIPHENYL PHOSPHATE (CAS: 115-86-6); 2-ETHYLHEXYL DIPHENYL PHOSPHATE (CAS: 1241-94-7); TRIBUTYL PHOSPHATE (CAS: 126-73-8); …
Chlorinated alkanes	Saturated hydrocarbons with varying degrees of chlorination		DICHLOROMETHANE (CAS: 75-09-2); 1-CHLOROBUTANE (CAS: 109-69-3);

			SHORT-CHAIN CHLORINATED PARAFFINS (SCCPS, CAS: 85535-84-8); MEDIUM CHAIN CHLORINATED PARAFFINS (MCCPS, CAS: 85535-85-9); …
Polychlorinated biphenyls	organochlorine compounds with the following structure	 * = H, Cl	2,2',6-TRICHLOROBIPHENYL (CAS: 35693-92-6); 4,4'-DICHLOROBIPHENYL (CAS: 2050-68-2); 2,2',3,4,4',5'-HEXACHLOROBIPHENYL (CAS: 35065-28-2); …