Challenges Related to PFAS in Packaging

Thursday, May 11, 2023

Dr. Claire Sand thinks “all food packaging all the time”

Claire’s mission is to enable a more sustainable food system with science and value chain innovations that more sustainably increases food shelf life and prevents food waste

- 35+ years of food packaging experience
- Ranks innovative packaging science and value chain solutions to extend shelf life
- Generates implementation roadmaps and aligns business cases

- IFT Fellow, Riester-Davis-Brody life-time achievement in food packaging award recipient
- Doctorate in Food Science and Nutrition at University of Minnesota
- MS and BS in Packaging at Michigan State University

Adjunct Professor

MICHIGAN STATE UNIVERSITY

CAL POLY SAN LUIS OBISPO

Monthly Columnist

food technology

PACKAGING DIGEST

Current Leadership & Boards

FOOD WASTE

Journal of Food Science — Associate Editor

Food Packaging Division — Executive Board

Comprehensive Reviews in Food Science and Food Safety — Editorial Board

Packaging Technology and Science — Editorial Board

NSF — Reviewer National Science Foundation

Recent Awards

Riester-Davis-Brody Food Packaging Lifetime Achievement Award

IFT Fellow

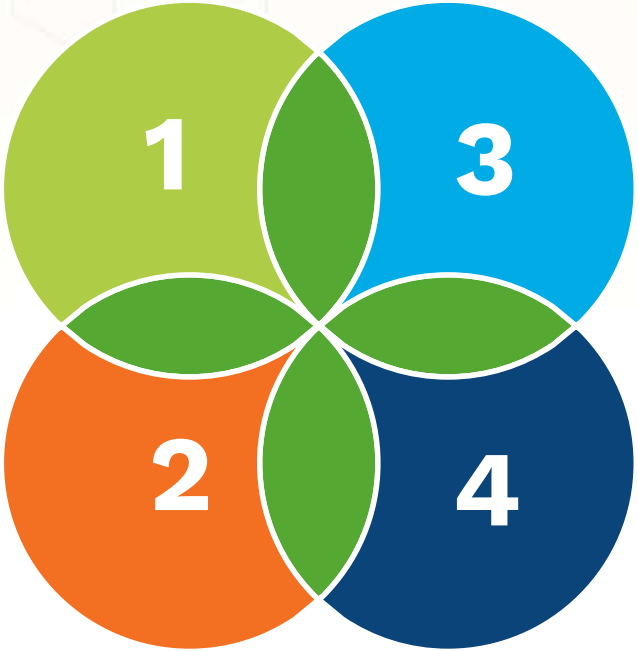
Food Safety Summit — Celebrating 25 Years — Produced by Food Safety

IFT

Key Takeaways

Strong bonds in PFAS extends its existence

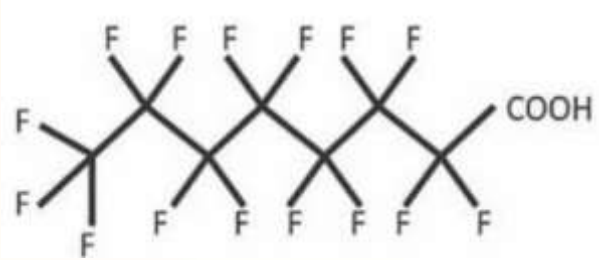
PFAS sources in food are from production, processing and packaging



Industry has worked hard with a fragmented approach and alternatives to PFAS face roadblocks

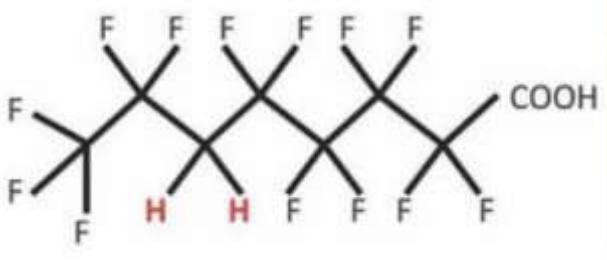
Future Proof Packaging is needed to avoid the pitfalls of a fragmented approach

PFAS Overview



Perfluoroalkyl substances

- All **Hydrogens** attached to **Carbons** are replaced by **Fluorine**
- Few degradation products and stable



Polyfluoroalkyl substances

- Some **Hydrogens** attached to **Carbons** are replaced by **Fluorine**
- Can participate in condensation polymers such as PET, nylon
- Many degradation products

The Long and the Short of PFAS

Long Chain PFAS (LCPFAS)

- Banned in 2016
- Perfluorocarboxylic acids (PFCAs) chain length ≥8
- Includes perfluorooctanoic acid (PFOA)
- Perfluoroalkane sulfonic acids (PFSAs) chain length ≥6
- Includes perfluorohexane sulfonic acid (PFHxS) and perfluorooctane sulfonate (PFOS)

Short Chain PFAS (SCPFAS)

- Approved and became regrettable substitutes
- Perfluorocarboxylic acids (PFCAs) chain length <8
- Perfluoroalkane sulfonic acids (PFSAs) chain length <6

Assistance of Maricel Maffini is appreciated

LCPFAS were phased out in 2016

- **CAS Reg. No. 1071022-26-8**

2-propenoic acid, 2-methyl-, polymer with 2-(diethylamino)ethyl 2-methyl-2-propenoate, 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, acetate

- **CAS Reg. No. 357624-15-8**

Hexane, 1,6-diisocyanato-, homopolymer, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-1-octanol-blocked

- **CAS Reg. No. 1071022-26-8**

2-propenoic acid, 2-methyl-, polymer with 2-(diethylamino)ethyl 2-methyl-2-propenoate, 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, acetate

- **CAS Reg. No. 870465-08-0**

Copolymers of 2-perfluoroalkylethyl acrylate, 2-N,N-diethylaminoethyl methacrylate, glycidyl methacrylate, acrylic acid, and methacrylic acid

- **CAS Reg. No. 479029-28-2**

Copolymer of 2-perfluoroalkylethyl acrylate, 2-(dimethylamino)ethyl methacrylate, and oxidized 2-(dimethylamino)ethyl methacrylate (2)

- **CAS Reg. No. 220459-70-1**

Glycine, N,N-bis[2-hydroxy-3-(2-propenyloxy)propyl]-, monosodium salt, reaction products with ammonium hydroxide and pentafluoroiodoethane-tetrafluoroethylene telomer ().

- **CAS Reg. No. 71608–61–2**

Pentanoic acid, 4,4-bis [(*gamma*-*omega*perfluoro-C8-20-alkyl)thio] derivatives, compounds with diethanolamine

- Perfluoroalkyl substituted phosphate ester acids, ammonium salts formed by the reaction of 2,2-bis[([gamma], [omega]-perfluoro C4-20 alkylthio) methyl]-1,3-propanediol, polyphosphoric acid and ammonium hydroxide.
- Copolymers of 2-perfluoroalkylethyl acrylate, 2-N,N-diethylaminoethyl methacrylate, and glycidyl methacrylate
- 3-cyclohexene-1-carboxylic acid, 6-[(di-2-propenylamino) carbonyl]-, sodium salt, reaction products with pentafluoroiodoethane-tetrafluoroethylene telomer, ammonium salts
- Diethanolamine salts of mono- and bis (1*H*,1*H*,2*H*,2*H* perfluoroalkyl) phosphates where the alkyl group is even-numbered in the range C8–C18 and the salts have a fluorine content of 52.4 percent to 54.4 percent as determined on a solids basis

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SCPFAS Were Phased Out In 2020

In 2020, The FDA began a 3-year phase out of 11 short-chain PFAS involved in 15 previous FCN approvals by manufacturers (Archroma, Asahi Glass, and Daikin Chemours. This includes:

CAS Reg. No. 1878204-24-0
2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester, polymer with 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, sodium salt

CAS Reg. No. 1440528-04-0
Copolymer of 2-(dimethylamino) ethyl methacrylate with 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate, N-oxide, acetate

CAS Reg. No. 1334473-84-5
2-Propenoic acid, 2-methyl-, 2-(dimethylamino)ethyl ester, polymer with 1-ethenyl-2-pyrrolidinone and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate, acetate

CAS Reg. No. 1345817-52-8
Butanedioic acid, 2-methylene-, polymer with 2-hydroxyethyl, 2-methyl-2-propenoate, 2-methyl-2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, sodium salt

CAS Reg. No. 1206450-10-3
2-propenoic acid, 2-methyl-, 2-hydroxyethyl ester polymer with 1-ethyenyl-2-pyrrolidinone, 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate sodium salt

CAS Reg. No. 1071022-26-8
2-propenoic acid, 2-methyl-, polymer with 2-(diethylamino)ethyl 2-methyl-2-propenoate, 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, acetate

CAS Reg. No. 357624-15-8
Hexane, 1,6-diisocyanato-, homopolymer, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro-1-octanol-blocked

CAS Reg. No. 1158951-86-0
2-propenoic acid, 2-methyl-, polymer with 2-hydroxyethyl 2-methyl-2-propenoate, α-(1-oxo-2-propen-1-yl)-ω-hydroxypoly(oxy-1,2-ethanediyl) and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-propenoate, sodium salt

CAS Reg. No. 1071022-26-8
2-propenoic acid, 2-methyl-, polymer with 2-(diethylamino)ethyl 2-methyl-2-propenoate, 2-propenoic acid and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl 2-methyl-2-propenoate, acetate ()

2-Propenoic acid, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl ester, polymer with α-(1-oxo-2-propen-1-yl)-ω-hydroxypoly(oxy-1,2-ethanediyl CAS Reg. No. 863408-20-2 , (CAS Reg. No. 1225273-44-8
Copolymer of perfluorohexylethyl methacrylate, 2-N,N-diethylaminoethyl methacrylate, 2-hydroxyethyl methacrylate, and 2,2'-ethylenedioxydiethyl dimethacrylate, acetic acid salt () or malic acid salt).

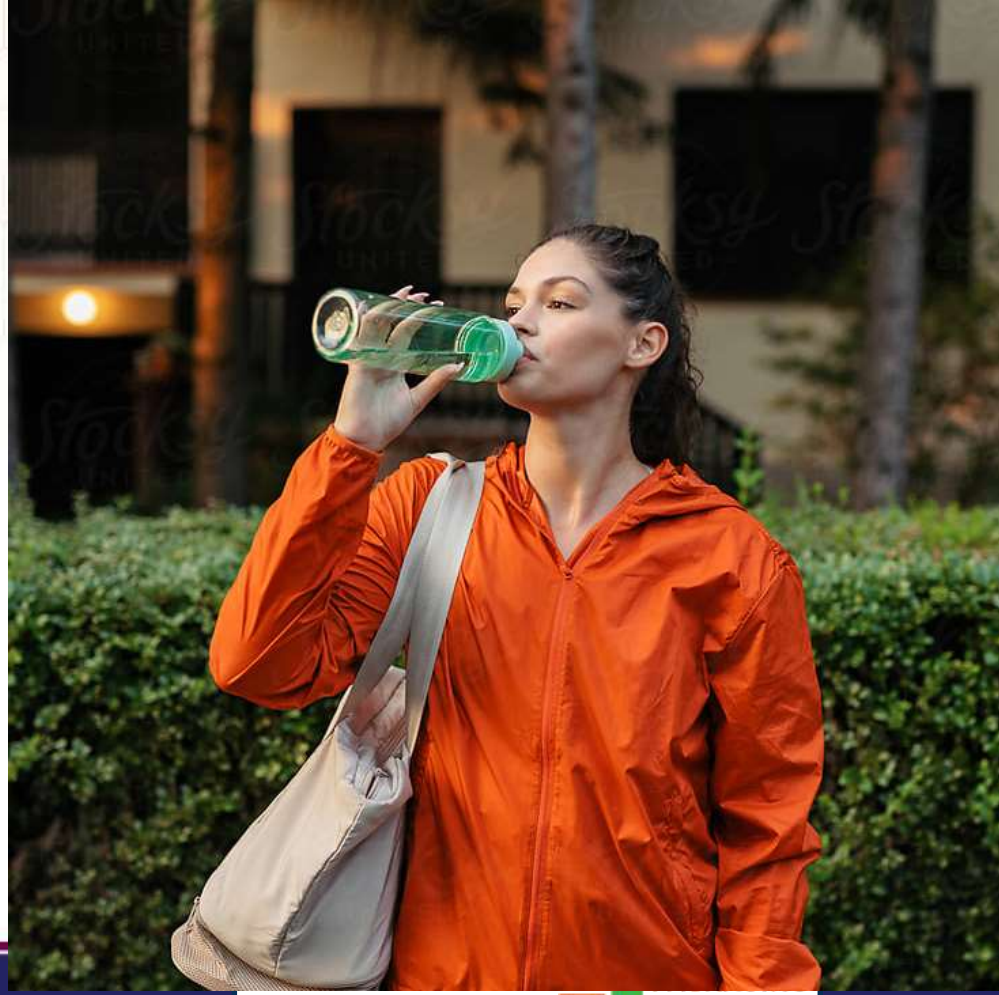
Assistance of Maricel Maffini is appreciated

Insights provided by: Packaging Technology & Research

PFAS Are Not Alone In Packaging

Other Chemicals of Concern Exist:

- Phthalates
- BPAs
- Heavy metals
- Perchlorate



Selected Sources of PFAS in Packaging

Selected Sources of PFAS Primary Packaging

1 Primary Packaging	2 Secondary & Tertiary Packaging	3 Ingredients	4 Production Environment
Impart Improved Barrier Release Agents	**Forming Materials**	**Improving Barriers**	**Providing Grease & Oil Resistance**
For Thermoforming, blowmolding	Wetting and leveling agents, emulsifiers, foaming agents, or dispersants	Flourination of PE was approved in 1983	Dry end coatings on paperboard and corrugated, and paper Lower the surface tension
	Emulsifiers assist in producing Teflon examples include the use of PFOA	Now used during forming of in HPDE, PP, PET blowmolded, thermoformed containers	Wet end use on paperboard
	Bond with functional groups such as acids and alcohols and/or take part in condensation polymerization of Nylon and PET	Primarily Polyfluoroalkyl substances	Coatings on hydroscopic polymers such as PLA, cellulose, starch, ethylenes, etc.
		Polymers fluorinated with hexafluoropropylene (HFP), tetrafluoroethylene (TFE), vinylidene fluoride (VDF) polymers	Packaging for Pet food, bakery, FOH fried foods

Selected Sources of PFAS Tertiary Packaging

1 Primary Packaging | 2 Secondary & Tertiary Packaging | 3 Ingredients | 4 Production Environment

- Packaging containing PFAS can come in contact with and then contaminate other packaging that has direct contact with food
- Migration into food can occur through secondary packaging such as labels, coatings, and cartons into food
- Handling of secondary packaging and then food in second-stage BOH/Production environments can contaminate food

Selected Sources of PFAS Ingredients

1 Primary Packaging | 2 Secondary & Tertiary Packaging | 3 Ingredients | 4 Production Environment

Reusable packaging for bulk ingredient transport

- Includes totes, bags, liners, barrels, and bins
- Contamination of reusable totes occurs from prior use of PFAS contaminated ingredients
- Abrasion increases surface area and sites for subsequent migration
- Reuse increases migration due to contact time

Single-use packaging for bulk ingredient transport

- Totes, bags, liners, barrels, and bins

Selected Sources of PFAS Production

1 Primary Packaging	2 Secondary & Tertiary Packaging	3 Ingredients	4 Production Environment

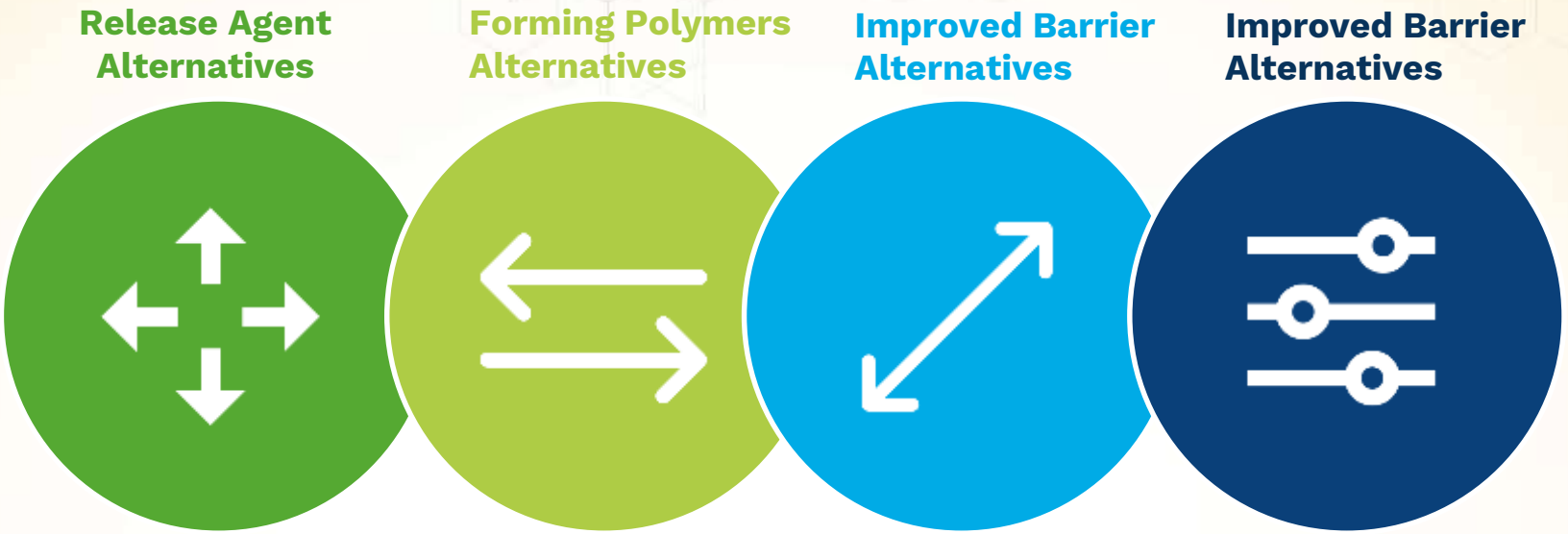
Equipment used to form packaging
• Cartoners, labelers, conveyors, thermoformers, unnesters, unscramblers inhibit sticking and make production line move smoother/faster.

Production equipment used in food processing
• Extruders, ingredient conveyance systems, hoppers, mixers
• PTFE (Teflon-Polytetrafluoroethylene) is use for food processing equipment

Water and CIP cleaning agents

Industry Response has been Fragmented with Drop-in Solutions

Roadblocks hinder many Drop In Solutions



- For many options, there are unintended consequences and/or regrettable alternatives in switching to the still approved SCPFAS

Regrettable Substitutions are a Concern

These include:

- **CAS Reg. No. 9011-17-0**
1-propene,1,1,2,3,3,3-hexafluoro-polymer with 1,1- difluoroethene modified with a halogenated ethylene
- **CAS Reg. No. 25190-89-0**
tetrafluoroethylene-hexafluoropropylenevinylidene fluoride copolymers
- **CAS Reg. No. 9011-17-0**
vinylidene fluoride-hexafluoropropene copolymer
- **CAS Reg. No. 94228-79-2**
2,3,3,4,4,5,5-Heptafluoro-1-pentene polymer with ethene and tetrafluoroethene added in 2016
- **CAS Reg. No. 1279108-20-1**
Hexane, 1,6-diisocyanato-, homopolymer, α-[1-[[[3-[[3 (dimethylamino)propyl]amino]propyl]amino]carbonyl]-1,2,2,2-tetrafluoroethyl]-ω-(1,1,2,2,3,3,3-heptafluoropropoxy)poly[oxy[trifluoro(trifluoromethyl)-1,2-ethanediyl]]-blocked
- **CAS Reg. No. 464178-94-7**
2-propen-1-ol, reaction products with 1,l,1,2,2,3,3,4,4,5,5,6,6-tridecafluoro-6-iodohexane, dehydroiodinated, reaction products with epichlorohydrin and triethylenetetramine as manufactured in accordance with the description in the FCN.
- **CAS Reg. No 464178-90-3**
2-propen-1-ol, reaction products with pentafluoroiodoethane-tetrafluoroethylene telomer, dehydroiodinated, reaction products with epichlorohydrin and triethylenetetramine.
Perfluorohexane sulfonate (PFHxS)
- **CAS Reg. No. 69991-62-4**
Perfluoropolyether dicarboxylic acid, ammonium salt.
- **CAS Reg. No. 200013-65-6**
Diphosphoric acid, polymers with ethoxylated reduced methyl esters of reduced polymerized oxidized tetrafluoroethylene.
- **CAS Reg. No. 162492-15-1**
Diphosphoric acid prepared by reaction of phosphorous pentoxide phosphate esters of ethoxylated perfluoroether diol
- **CAS Reg. No. 1314-56-3**
Diphosphoric acid prepared by reaction of phosphorous pentoxide
- **CAS Reg. No. 2466-09-3**
Diphosphoric acid prepared by reaction of phosphorous pentoxide pyrophosphoric acid.
CAS Reg. No. 328389-91-9
Fluorinated polyurethane anionic resin prepared by reacting perfluoropolyether diol (CAS Reg. No. 88645-29-8), isophorone diisocyanate (CAS Reg. No. 4098-71-9), 2,2-dimethylolpropionic acid (CAS Reg. No. 4767-03-7), and triethylamine (CAS Reg. No. 121-44-8).
- Other compounds that contain flouro-based compounds at wet and dry end paperboard production and in formation of plastics

Assistance of Maricel Maffini is appreciated

Insights provided by: PACKAGING Technology & Research

Roadblocks hinder many Drop In Solutions

Release Agent Alternatives

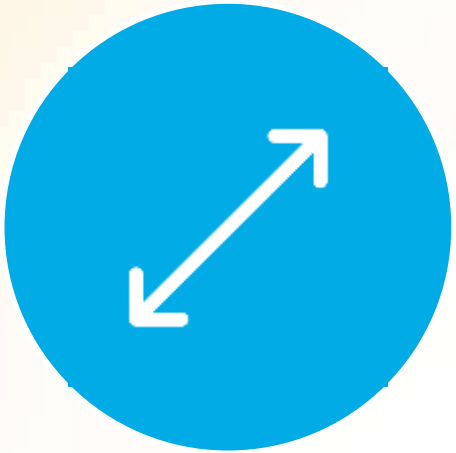
- Silicone resins and elastomers as release agents
- CAS 7473-98-5, 155419-56-0, 2855-27-8, 102782-94-5, 917773-10-5

Roadblocks hinder many Drop In Solutions

Forming Materials Alternatives

- Alternatives to polymers have a host of chemicals of concern beyond PFAs
- Biodegradable alternatives are very problematic

Roadblocks hinder many Drop In Solutions



Improved Barrier Alternatives

- Water barriers - alkyl succinic anhydride (ASA), styrene acrylic emulsion (SAE), alkyl ketene dimer (AKD) and rosin cannot be produced in sufficient volumes and are cost prohibitive now
- Biopolymer PEF is promising

Roadblocks hinder many Drop In Solutions

Impart Grease & Oil Resistance Alternatives

- Increased density with cellulose, carbon nanofibers, starch coatings during calendaring results in 20-30% slower production
- Waxes or Polymer atomization, finishes, coatings may interfere with recycling
- Removable and non-removeable plastic liners are not recyclable w/o SDO

The Value Chain provides the opportunity to *Future Proof Packaging*

Value Chain provides the opportunity to address

Regrettable substitutions exist

- Industry experts know that substitutions may be regrettable
- This is a costly, and time-consuming game of whack-a-mole

Regulations that do not align with safety

- Hidden data
- GRAS status is dubious
- Delayed action continues
- Reliance on voluntary abandonments

Shape-shifting supply chain

- Snapshots do not protect brands or consumers

Hodge-podge of local and retailer bans

Extensive incoming inspection is costly and is not in alignment

Value Chain provides the opportunity to…

Future Proof Packaging

- Proactively Plan for the **Future** - Avoid kicking the can down the road with regrettable substitutions
- Build a more valued **safety-focused** relationship with regulatory agencies
- Build/rebuild **Trust** in all entities of the packaging value chain
- **Align** vs Entrap value chain partners
- **Collective work** builds a better shared future

A *Future Proof* Packaging Approach 4 Key Elements

Adjust to Reward Significance in Relationships

Manage Knowledge

Inspire From The Top

Share Work

A *Future Proof* Packaging Approach Elements

Share Work

- **Collective work** builds a better shared and safe future
- Beyond Taskforces and to actual work
- Build a Chain of Custody to instill confidence
  reduce fraud and add value
- Deliver on shared innovations
- Deliver on joint systems solutions
- Work toward harmonized standards to avoid a 2-tier system in which some citizens are protected for chemicals of concern by regulations and some are not

Case Studies

A *Future Proof* Packaging Approach Case Studies

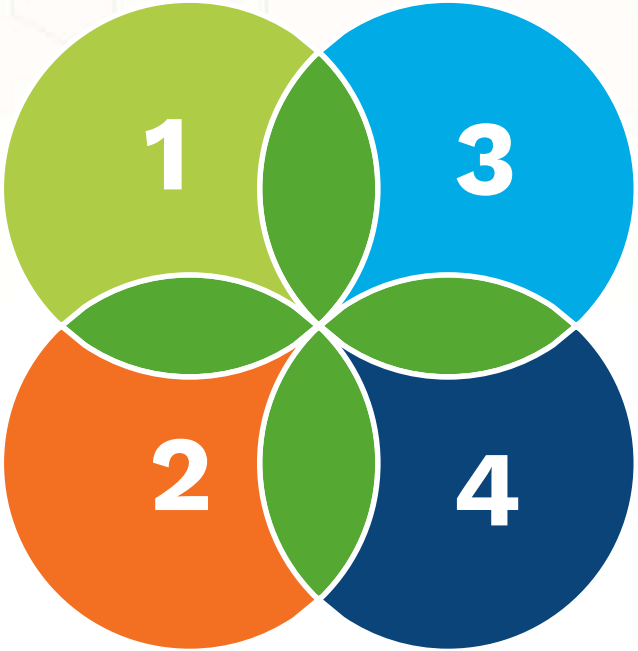
System solutions to replace for oil and grease resistance need in FOH QSR french fry cartons

- **Reduce oil in contact with packaging via a systems approach using one or all of these solutions**
- **Reformulate fries to**
  - Enhanced PME-based oil resistance so that less oil is adsorbed
- **BOH Processing to**
  - Adsorb oil prior to FOH packaging with diatomaceous earth or food grade clays
  - Use a 2-phase system in which oil is drained more extensively at a station before final FOH packaging
- **Non-PFAS plastic (reusable) packaging**
- **Package redesign to**
  - Employ a removeable plastic liner within FOH cartons
  - FOH cartons with a sealed low point with an adsorbent substance
  - FOH cartons dusted with an adsorbent substance
  - PFAS sensors on packaging for value chain use

Key Takeaways

Strong bonds in PFAS extends its existence

PFAS sources in food are from production, processing and packaging



Industry has worked hard with a fragmented approach and alternatives to PFAS face roadblocks

Future Proof Packaging is needed to avoid the pitfalls of a fragmented approach

Challenges Related to PFAS in Food Packaging: Federal and State Regulations

May 11, 2023

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CHALLENGES RELATED TO PFAS IN PACKAGING

Weldon Williams, VP Standards

- Who is tms?
- PFAS Problem in Packaging
- Clean Packaging

WHO IS TMS?

tms unites technology, marketing and sourcing to
drive transformational change for the world's leading brands.

The Power of And

In response, tms has harnessed traditionally siloed services to create something greater.

We are an "and" company, connecting our world-class expertise across Technology and Marketing and Sourcing to create innovative, agile end-to-end solutions that drive customer-centric transformation.

Whether you use all or part of us. Only we can make the inventive connections we do, at the scale that we do, to deliver the impact we do.

Technology

Multiply the value of your marketing or sourcing efforts with a suite of proprietary products and the latest data-informed technology solutions.

Marketing

Craft brand experiences that captivate, engage and ignite demand. Customer-centric transformation that drives transactions builds your brand.

Sourcing

Make complex problems simple. Transform ideas into reality. By connecting data with insights, supply with demand and people with your brand, we design, engineer, source and manage in new innovative and responsible ways.

PFAS Problem

+ *Prevalent*
+ *Pervasive*
+ *Perform*

Global PFAS Regulatory Landscape

NORTH AMERICA

- State Legislation: multiple states have enacted legislation that bans the use of products with intentionally added fluorinated chemicals (New Hampshire, Vermont, Iowa, Illinois, Hawaii, Massachusetts, North Carolina, Oregon & Nevada)
- 2021 United States House Resolution 6026 Keep Food Containers Safe from PFAS Act: The introduction or delivery for introduction into interstate commerce of food packaging containing intentionally added PFAS is prohibited.

EUROPE

- European Chemicals Agency: ECHA published a proposal to restrict the use of PFAS in the entire EU. The market phase-in of non-fluorine based OGRs covers these new restrictions and the future enforcement date.

APMEA

- China: China's MEE (Ministry of Ecology Environment) issued the 'New Pollutant List of Key Control (2023 version)', which came into effect on March 1, 2023, and includes 3 PFAS related chemicals with expectations that the list will expand.
- Australia: APCO (Australian Packaging Covenant Organization) released the reporting template which is associated with the Action Plan to Phase out PFAS in Fiber-based Food Contact Packaging by the end of 2023.

What does this mean?

+ Attention regarding fluorinated chemicals is not going to diminish but will continue to increase
+ Manufacturers must strategize now on phasing out their use and identifying acceptable alternatives
+ Testing programs may be required to monitor levels, especially in markets where limit thresholds are being introduced
+ Recycled materials will not be excluded

> Trying to ban individual PFAS is an impossible game of whack-a-mole. As soon as one is addressed, industry comes up with another.

Brian Ronholm

Consumer Reports

Roll of Packaging

+ Protection
+ Conveyance
+ Presentation
+ Brand Ambassador
+ Corporate Values

What is “Clean Packaging”

+ Transparency
+ Simplified Materials
+ Eco-Friendly
+ Regulatory Compliance
+ Enables “Clean Food”

Why ”Clean Packaging” is important?

+ The World is Changing
+ Age of Mistrust
+ Shifting Consumer Expectations

Consumers want packaging that…

+ Does not impact the taste of the food
+ Does not contain unnecessary chemicals
+ Does not negatively impact the environment

Three-Pronged Strategic Approach

+ Compliance & Safety

+ Design Assurance

+ Emerging Issues Management

Compliance & Safety

+ Product Transparency

+ Priority Risk Assessments

+ Regulatory Review

Design Assurance

+ Raw Materials & Substances Review

+ Materials Management

+ Product & Material Testing

Emerging Issues Management

+ Legislation Monitoring

+ Supplier & Industry Collaboration

+ Strategic Alignment

Way Forward

Vigilance  Agility

Thank you

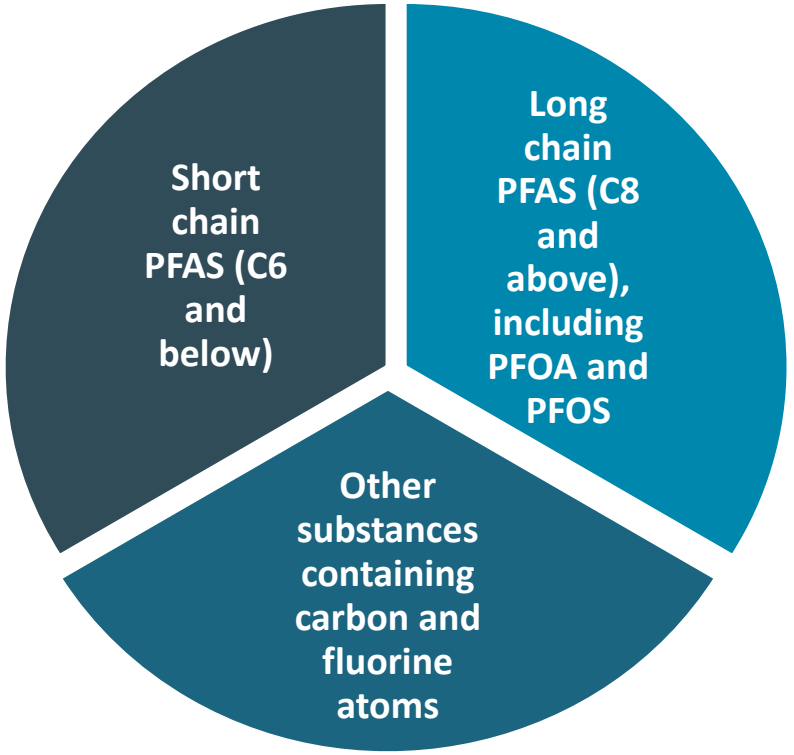
As we transition into our new name and identity, this legal line will soon be updated:

Agenda

- PFAS in food packaging
- Federal PFAS regulations
- State PFAS regulation

What are PFAS?

- **PFAS: per- and poly- fluoroalkyl substances**
  - **Thousands** of chemical compounds
  - **Category** rather than definition
  - **Differing** toxicity profiles!



What are PFAS?

- State laws have consistently defined PFAS as including substances with:

  . . . at least one fully fluorinated carbon atom

- (Still) a broad definition that includes, for example:

Perfluorooctanoic acid (PFOA)

Perfluorooctane sulfonate (PFOS)

Perfluorononanoic acid (PFNA)

Polytetrafluoroethylene (PTFE)

Other Fluoropolymers . . .

Uses of PFAS in Food Packaging and Other Articles Contacting Food

- Additive to impart grease and water resistance to paper
- Processing aids in the production of polyolefin films
- Articles used in food processing equipment (e.g., gaskets, O-rings, tubing, tape)
- Fluorination of polyolefin containers
- Cookware

Federal PFAS Regulations

PFAS Cleared by Food Contact Notifications (FCNs)

Grease proofing agents for paper and paperboard → 35

Repeated-use applications → 24

Processing aids for polymers → 7

PFAS Authorized for Food-Contact Use (1)

- Non-stick cookware
  - FDA: High temps “vaporizes off virtually all the smaller (i.e., migratable) PFAS molecules”. . . Resulting in “a highly polymerized coating bound to the surface of the cookware. Studies show that this coating contains a negligible amount of PFAS capable of migrating to food.” *
- Gaskets, O-Rings, and other parts used in food processing equipment
  - FDA: Polymerization and cross-linking “removes virtually all the smaller (i.e., migratable) PFAS molecules, resulting in a negligible amount of PFAS capable of migrating to food.” *
- Processing aids in the production of food contact polymers
  - FDA: “The amount of PFAS used as processing aids in the manufacture of other food contact polymers is so small that a negligible amount of PFAS is capable of migrating to food from this use.” *

*Authorized Uses of PFAS in Food Contact Applications | FDA, Feb. 24, 2022

PFAS Authorized for Food-Contact Use (2)

- Grease-proofing agents for paper and paperboard food packaging
  - FDA: "Applied to paper at lower temperatures, which are not high enough to remove residual smaller (i.e., migratable) PFAS molecules. Under certain conditions, the smaller PFAS "sidechain" can detach from the polymerized molecule. As a result, there may be potential for PFAS migration to food from this use." *See,* Authorized Uses of PFAS in Food Contact Applications | FDA, Feb. 24, 2022
- Fluorinated PE Containers
  - FDA: "Seeking scientific data and information on current food contact uses of fluorinated polyethylene, consumer dietary exposure that may result from those uses, and safety of certain per- and polyfluoroalkyl substances that may migrate from fluorinated polyethylene food containers." (87 FR 43274, July 20, 2022)

FDA Activities on PFAS Uses (1)

- Grease Proofing Agents
  - FDA worked with manufacturers to voluntarily stop sales of grease-proofing agents containing C8 (long chain) compounds (cleared by FCNs) for use in food contact applications in the U.S. market (see Authorized Uses of PFAS in Food Contact Applications | FDA)
  - FDA revoked the food additive regulations authorizing the remaining uses of long-chain PFAS in food packaging (see 81 FR 5, January 4, 2016 and 81 FR 83672, November 22, 2016)
  - FDA working with manufacturers to voluntarily stop sales of grease-proofing agents containing C6 compounds (cleared by FCNs) for use in food contact applications in the U.S. market
  - FDA monitoring the current use of different PFAS products in the US and assessing possible risks presented by products still permitted for use

FDA Activities on PFAS Uses (2)

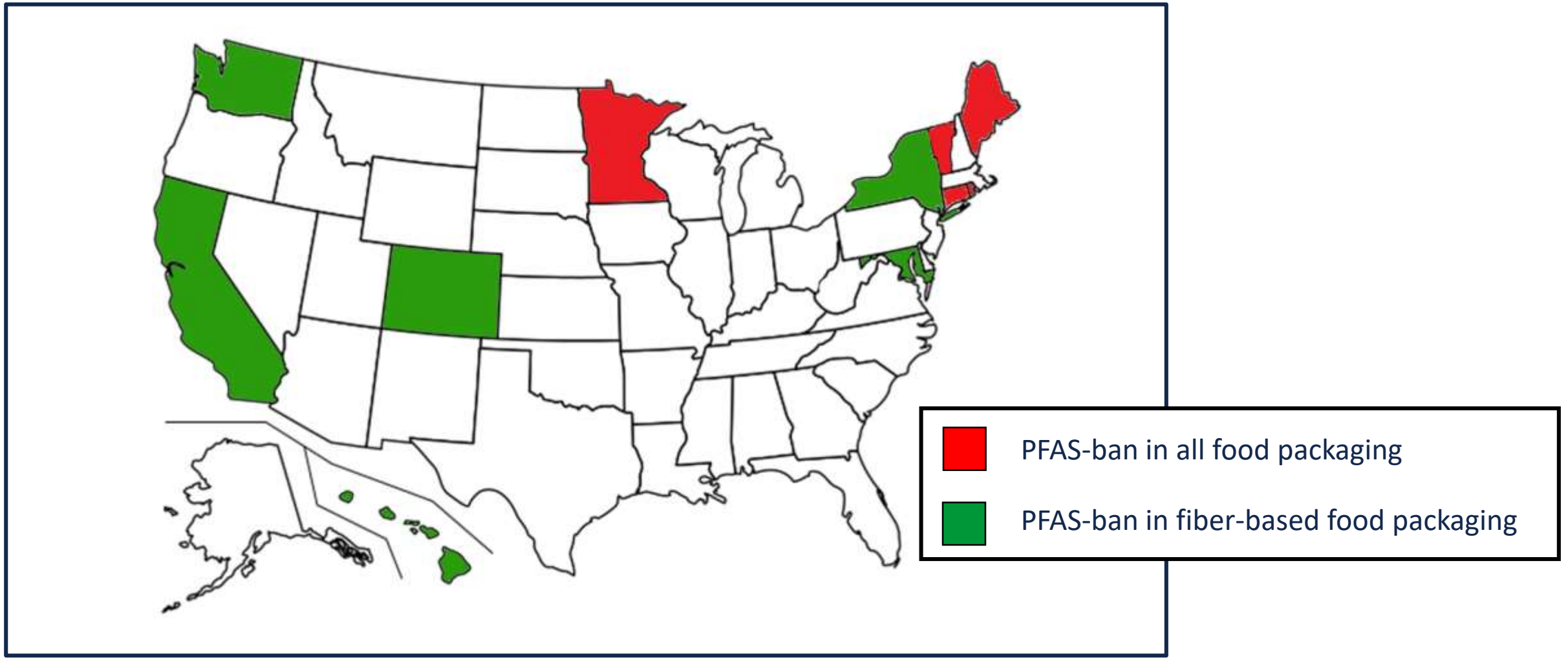
- Fluorinated HDPE Articles
  - Produced by modifying the surface of polyethylene articles through action of fluorine gas in combination with gaseous nitrogen as an inert diluent (21 C.F. R. § 177.1615)
  - HDPE substrate must conform to the specifications and use limitations in § 177.1520
- EPA and FDA are investigating potential C8 PFAS formation and its migration from the containers upon use
  - EPA questions compliance with TSCA SNUR and has brought a legal action to prevent further processing of such containers by one company
  - FDA questioning whether methods other than specified in the regulation are being used to fluorinate containers (i.e., using gasses other than nitrogen), which would place the products out of compliance

What is a safe level of PFAS?

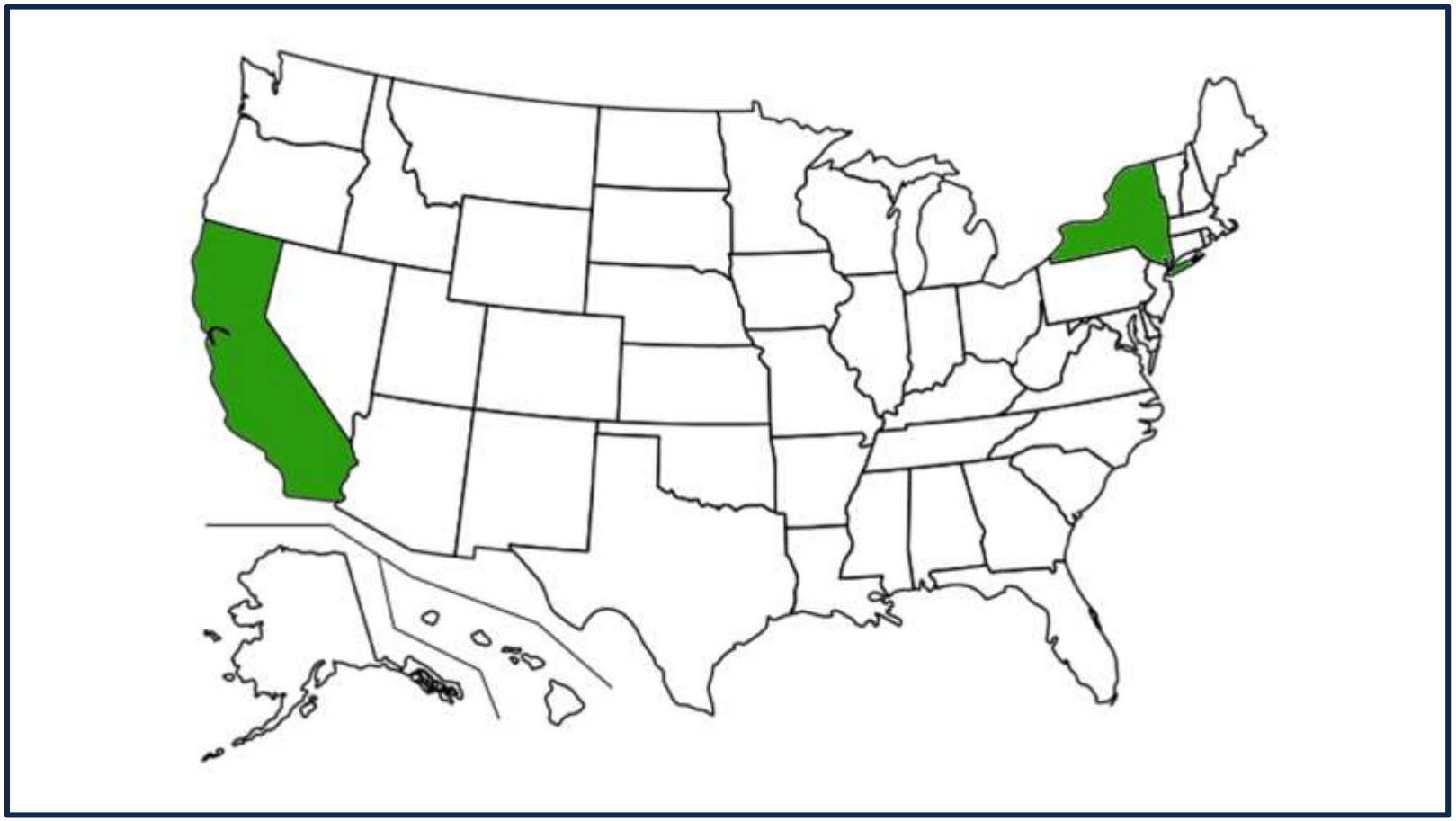
- There is no final determination or guidance from FDA on the issue
- FDA's concern focuses on –
  - bioaccumulation potential of C8 and C6 metabolites and the need for additional toxicity studies to support safe use
  - For new uses of existing substances, FDA generally wants dietary exposures to be less than 0.05 ppb (i.e., 50 ppt)
    - That could be adjusted downward
- EPA concern is likewise related to –
  - bioaccumulation as well as environmental persistence
  - EPA proposed in March 2023 a MCL of 4 ppt in drinking water for PFOA and PFOS and 1.0 ppt for HFPO-DA (commonly referred to as GenX Chemicals) (See Per- and Polyfluoroalkyl Substances (PFAS) | US EPA

State PFAS Initiatives

Restrictions on PFAS in Food Packaging (1)

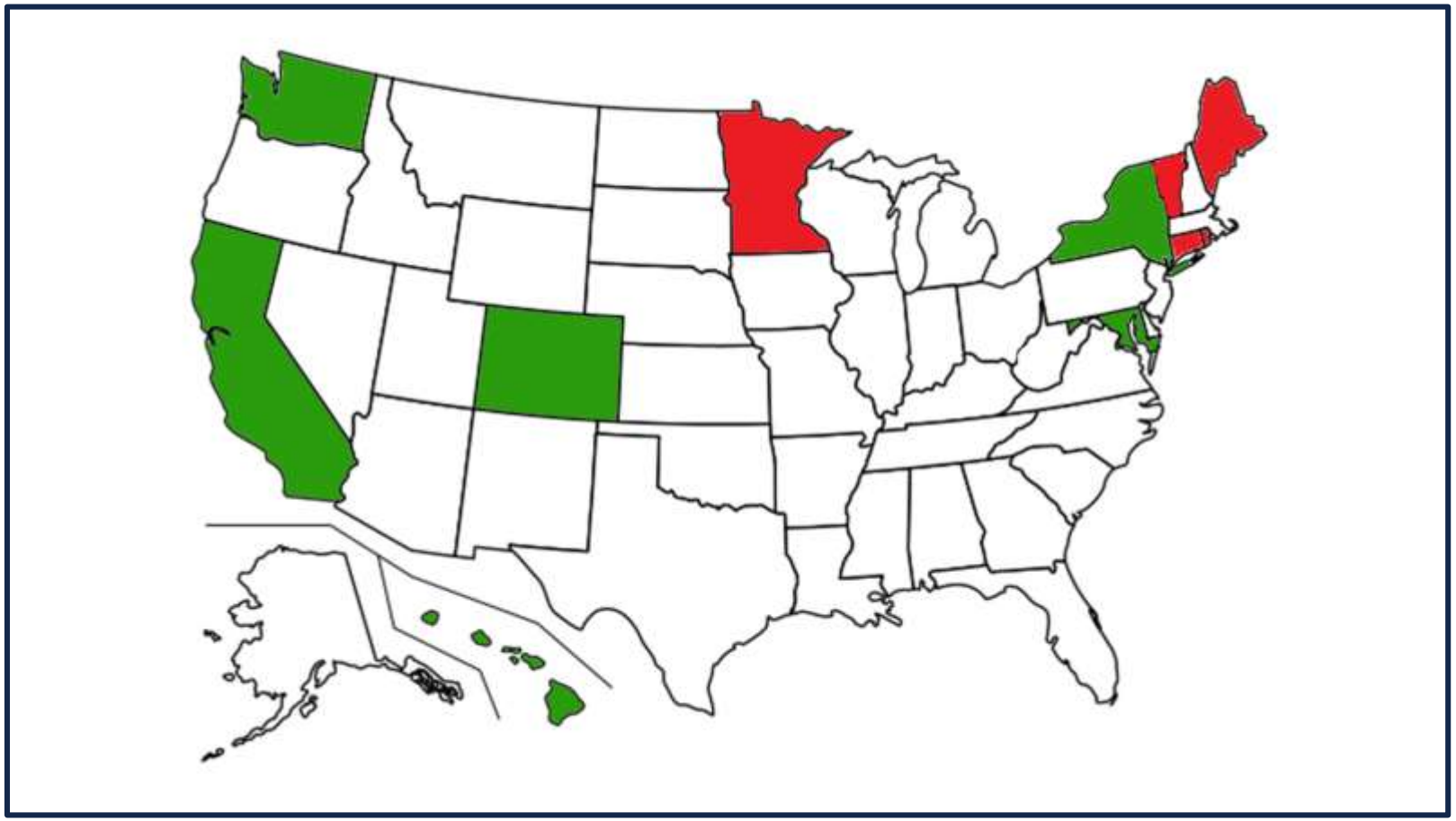


Restrictions on PFAS in Food Packaging



January 2023

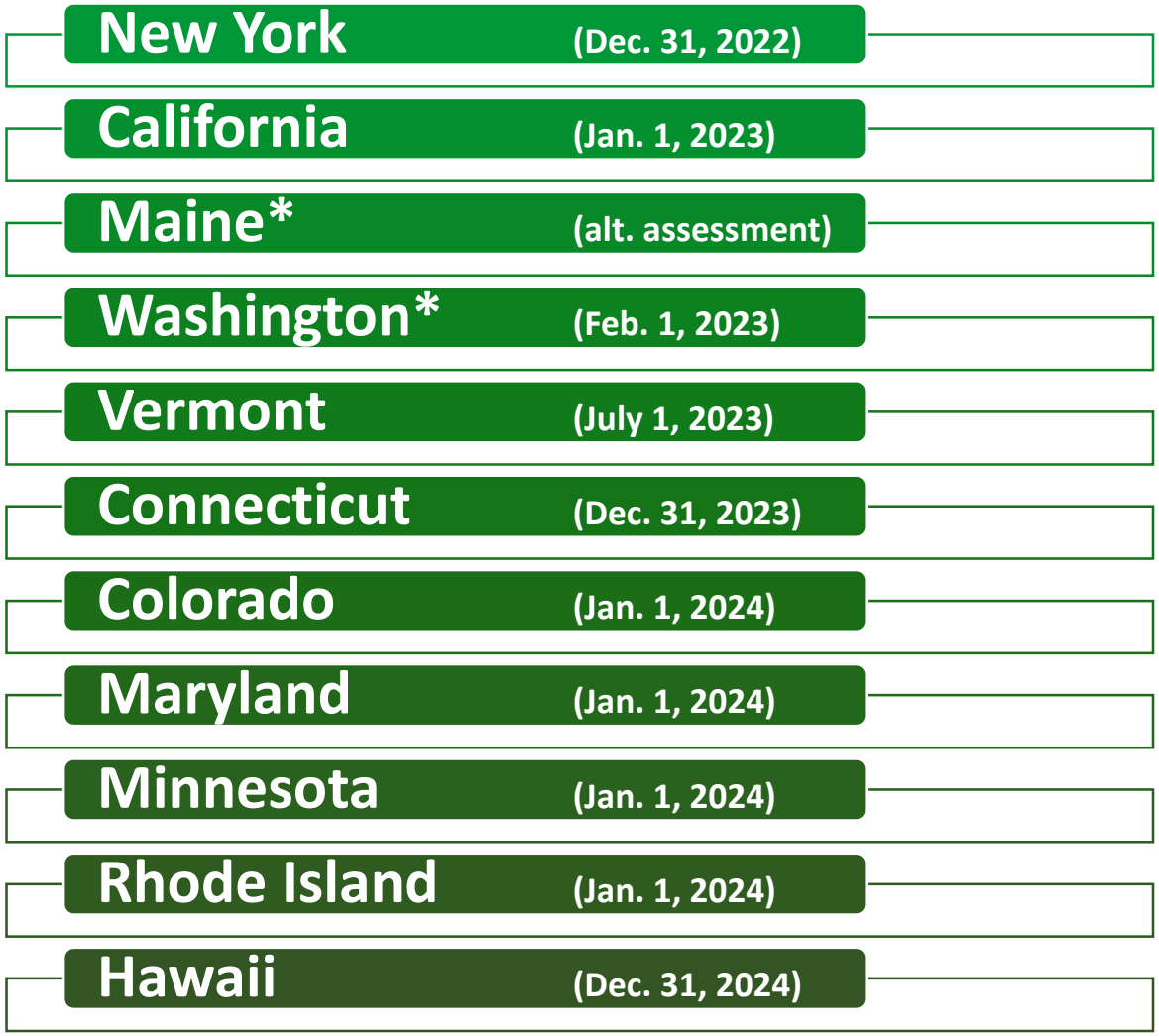
Restrictions on PFAS in Food Packaging



January 2025

***Note: Maine will need to publish an alternatives assessment**

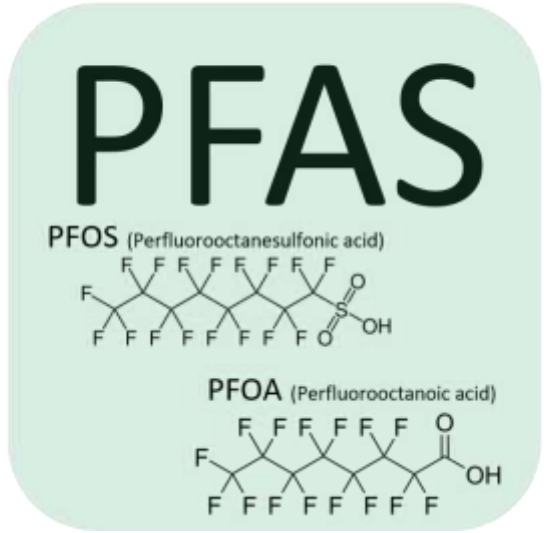
Restrictions on PFAS in Food Packaging (4)



- **Similarities**
  - Definition of "PFAS"
- **Differences**
  - Effective dates
  - Definition of "food packaging"
  - Scope of "intentionally added"
  - Some require alternatives assessments
- **States with proposed legislation:**
  - CO, GA, MA, NH, NJ, NC, PA, TN
  - Also, NY and WA considering expanding their existing laws

How is PFAS Defined by State Laws?

- "Perfluoroalkyl and polyfluoroalkyl substances" or "PFAS" means substances that include any member of the class of fluorinated organic chemicals containing *at least one fully fluorinated carbon atom*.
  - Definition encompasses much more than just fluorinated oil and grease resistant coatings
  - Covers fluorinated extrusion aids, PTFE powder, fluorinated non-stick coatings for cookware, fluoroelastomers, polyvinylidene-based coatings, etc.



State PFAS Laws: Comparison (1)

- **Definition of "food packaging"**
  - Some states define **broadly** (CT, ME, MN, VT, RI)
  - Some states limit to **paper, paperboard, or fiber,** including some which specify packaging types, i.e., wraps, liners plates (CA, NY, WA, MD, CO, HI)
- **Alternatives assessment requirements**
  - Some states require safer alternatives to be identified ***before*** ban takes effect (WA, ME)
  - Washington published two alternatives assessment reports
    - Effective February 2023: Wraps and liners, plates, food boats, pizza boxes
    - Effective May 2024: Bags and sleeves, bowls, flat service ware, open-top containers, closed containers

State PFAS Laws: Comparison (2)

- **Definition of "intentionally added"**
  - Most states ban "intentionally added PFAS" in any amount
    - Typically defined to include deliberate use where continued presence is desired to provide a specific characteristic or effect in product
  - California includes an added twist –
    - Bans "intentionally added" PFAS in paper in any amount
    - Also bans the incidental presence of PFAS (i.e., not tied to intentional use) at levels exceeding 100 ppm
      - as measured by total organic fluorine
  - Processing aids? Release agents?
    - Depends on the state law

Rhode Island PFAS Law

- **Effective date**: January 1, 2024
- **Scope**: “Food package” defined as any package or packaging component that is applied to or in direct contact with any food or beverage
- **Prohibition (food packaging)**:
  - No food package to which PFAS have been intentionally introduced during manufacturing or distribution in any amount shall be offered for sale or for promotional purposes by its manufacturer or distributor in the state
- “**Intentional introduction**” includes use as a processing agent, mold release agent, or intermediate where presence is detected in final package or packaging component
  - No detection limit specified!
- **Exemption** for recycled content, **but it sunsets in 2027**

Maine Notification Law (1)

- **January 1, 2023** – Manufacturers of PFAS-containing product must submit notification that includes:
  - Description of product (and product code)
  - Estimated annual sales volume in state
  - Chemical identity and CASRN of each PFAS, function, and "exact quantity determined using commercially available analytical method"
  - Name and address of reporting manufacturer
- Extension for providing notice can be requested
  - Over 2,000 requests for extension granted
- Online notification system not yet in place
  - Reports currently accepted via email
- Proposed rule released February 14, 2023
  - Public hearing: April 20, 2023
  - Comment deadline: **May 19, 2023**

Maine Notification Law (2)

- Sale of any product containing intentionally added PFAS is banned in Maine, unless manufacturer has complied with notification requirement
- Statutory exemption for "products subject to" Toxics in Packaging and Chemicals of High Concern laws
  - Packaging exempt *when used as food packaging* (per proposed rule):

    "[E]xemptions apply only when items are actually used as packaging, packing components, or food packing, intended for marketing, handling, or protection of products."

2023 State Trends

- States with existing fiber-based PFAS bans are considering expanding that ban to encompass all food packaging
  - Hawaii (HB 748 / SB 504)
  - New York's FY 2023 Executive Budget

- Other states with pending bills on food packaging:
  - Illinois (SB 88): fiber-based
  - New Hampshire (HB 242): applies to "food service businesses"

- Over 20 states are considering prohibiting PFAS in other products (i.e., personal care, cosmetics, apparel, firefighting foam)
  - May be amended to include food packaging

Toxics in Packaging Clearinghouse "CONEG"

- Coalition of U.S. states developed model legislation to develop laws prohibiting "toxics" in packaging
  - Adopted by 19 states so far
  - Originally covered heavy metals in packaging
- **2021 model law updated with PFAS as regulated chemical**
  - Prohibits intentional use of PFAS in all packaging
  - Covers deliberate use where its continued presence is desired in the final package or packaging component to provide a specific characteristic, appearance, or quality

Takeaway

- Thousands of PFAS chemicals can be found for a wide variety of uses in different consumer, commercial, and industrial products
- **Not all PFAS are of the same chemistry or necessarily show similar toxicological characteristics**
  - Challenging to assess potential human health and environmental risks
- Precipitous decisions may result in the premature retirement of many of PFAS products and product applications without adequate consideration of (1) the actual risk presented by individual products, (2) the existence of substitutes, and (3) the health and safety benefits that may be lost

Thank You

Any questions?

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