Is your food service ware safe?

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Independent Consultant

April 22, 2020

Disclosure

- Clients include public interest organizations, food additives and food service companies
- Co-authored food additive petitions requesting FDA revoke approval for food contact substances such as long-chain perfluoroalkyl substances, perchlorate, ortho-phthalates and carcinogenic flavors

Outline

- What safety means in the context of food contact materials
- The journey to better food packaging and service ware
- Restrictive substances lists alone are not enough to make better products and gain consumers trust

Chemicals

- PFAS
- Styrene
- Lactic acid
- Polyvinyl alcohol
- Phthalates
- Bisphenol A
- Perchlorate
- …….

Food contact substances

- Polymers
- Oligomers
- Catalysts
- Pigments
- Solvents
- Reaction by-products
- Degradation products
- …….

Food contact materials

- Plastic(s)
- Paper
- Cardboard
- Other fibers
- Coating
- Adhesives
- Printing inks
- …..

FOOD CONTACT ARTICLES

[Food ware, service ware, packaging, food manufacturing equipment, etc.]

Chemicals

- PFAS
- Styrene
- Lactic acid
- Polyvinyl alcohol
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- …….

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FOOD CONTACT ARTICLES MUST BE SAFE

The US Food and Drug Administration defines

Safe or *safety* means that there is a **reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use**. (21 CFR § 170.1(i))

- Safety may be determined by scientific procedures or by general recognition of safety.
- It's based in the concept of **risk** which considers exposure and hazard
- Chemicals known to cause cancer in man or animals **must not** be added to food

Requirements to determine safety

In determining safety, the following factors shall be considered:

(1) The probable consumption of the substance and of any substance formed in or on food because of its use.

(2) The cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet.

(3) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as appropriate. (21 CFR § 170.1(i))

The manufacturer determines safety, then…

- U.S. Food and Drug Administration (FDA) approval of food additive petition; publication in Code of Federal Regulation
- FDA review of food contact notifications (FCN) submitted by manufacturer; FDA publishes its opinion in website Inventory of Effective Food Contact Substance Notifications
- Manufacturer self-determination that the use is ‘generally recognized as safe’, or GRAS; bypasses FDA review. Unknown substance, uses and safety

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Department of Health and Human Services
Food and Drug Administration

NOTIFICATION FOR NEW USE OF A FOOD CONTACT SUBSTANCE

FOR NEW USES OF FOOD CONTACT SUBSTANCES

AGENCY USE ONLY

DATE OF RECEIPT

When completed send the form and notification to:

NOTIFICATION CONTROL ASSISTANT
OFFICE OF FOOD ADDITIVE SAFETY
HFS-275
5100 PAINT BRANCH PARKWAY
COLLEGE PARK, MD 20740-3835

Enter the total number of pages in the Premarket Notification:

DATE EFFECTIVE *(if effective)*

FCN NUMBER

GENERAL INSTRUCTIONS

- You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. You should make reasonable estimates if you do not have actual data.
- Before you complete this form, you should read the appropriate guidance for completion of a notification for a food contact substance.

Part I - GENERAL INFORMATION

Only one new food contact substance (FCS) may be the subject of a particular notification. However, new multiple uses maybe combined in a notification. A "new" use is one not otherwise authorized. If authorization is sought for use of multiple FCSs that are food additives, separate notifications should be submitted for each new use. Any accompanying information for a notification may be provided to FDA in a Food Additive Master File and referenced in a notification. Any information referenced in a notification must be submitted to FDA prior to your notification. If you reference information from a third party that is located in other FDA files, provide a letter of authorization for such use, if necessary. Authorization is not necessary to reference publicly available information in FDA's files. If third party authorization is required, provide the name of the authorizing official for the third party and a mailing address.

Completion of this form alone may not constitute a complete notification for a new use of an FCS. A notifier must also submit all data and information that forms the basis of the notifier's safety determination for the use that is the subject of the notification and any data and information required by regulation. Five copies of your complete notification must be submitted, each with a completed and signed original or copy of this form.

Part II - CHEMISTRY INFORMATION

Summarize all pertinent information concerning the FCS that is the subject of the notification. This should include: chemical identity, manufacturing process, physical properties and specifications, conditions of use, intended technical effect, and stability data. In addition to the summary information provided, your notification should include all supporting information or data. Also, include sufficient data to enable FDA to confirm your estimated daily intake resulting from the intended use of the substance. For information on recommendations on migration testing and presentation of the chemistry information see "Guidance for Industry: Preparation of Premarket Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations."

Part III - TOXICOLOGY INFORMATION

Include a list of toxicology studies considered key to the safety decision, discuss the potential mutagenicity and carcinogenicity of the notified substance and its constituents, determine the acceptable daily intake (ADI), as appropriate, and state the basis for your safety decision. This information should be consistent with the discussion in the Safety Narrative, which is described in the "Guidance for Industry: Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations."

Part VI - LIST OF ATTACHMENTS

Attach additional sheets if there is not enough space to answer a question fully. Label each continuation sheet with the corresponding section heading. List these attachments, any test data or other data, and any optional information included in the notification. Please do not attach information that can be included on the form.

OPTIONAL INFORMATION

You may include any information that you want FDA to consider in evaluating this notification.

CONFIDENTIALITY OF INFORMATION

By submitting a notification under section 409(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(h)), a notifier waives any claim to confidentiality for information necessary to describe the food contact substance and the intended conditions of use that are the subject of the notification. If you are claiming any information in this notification to be confidential you should designate the confidential material in writing, or otherwise mark the confidential material in the notification (e.g. by drawing a line around it), and submit a separate redacted copy of the notification. FDA may disagree regarding the disclosability of information claimed confidential.

Section A: Identification for the FCS
Section B: Manufacture
Section C: Impurities
Section D: Intended use
Section E: Stability of the FCS
Section F: Migration levels into food
Section G: Estimated daily intake

Safety narrative describing scientific basis for safety determination:

- Summarize the chemistry and toxicology information that justify a conclusion
- Address the safety of any mutagenic or carcinogenic constituents
- Supporting documentation should be included

Inventory of Effective Food Contact Substance (FCS) Notifications

results also includes terms not shown on this page, but included in the full record on the detail page.)

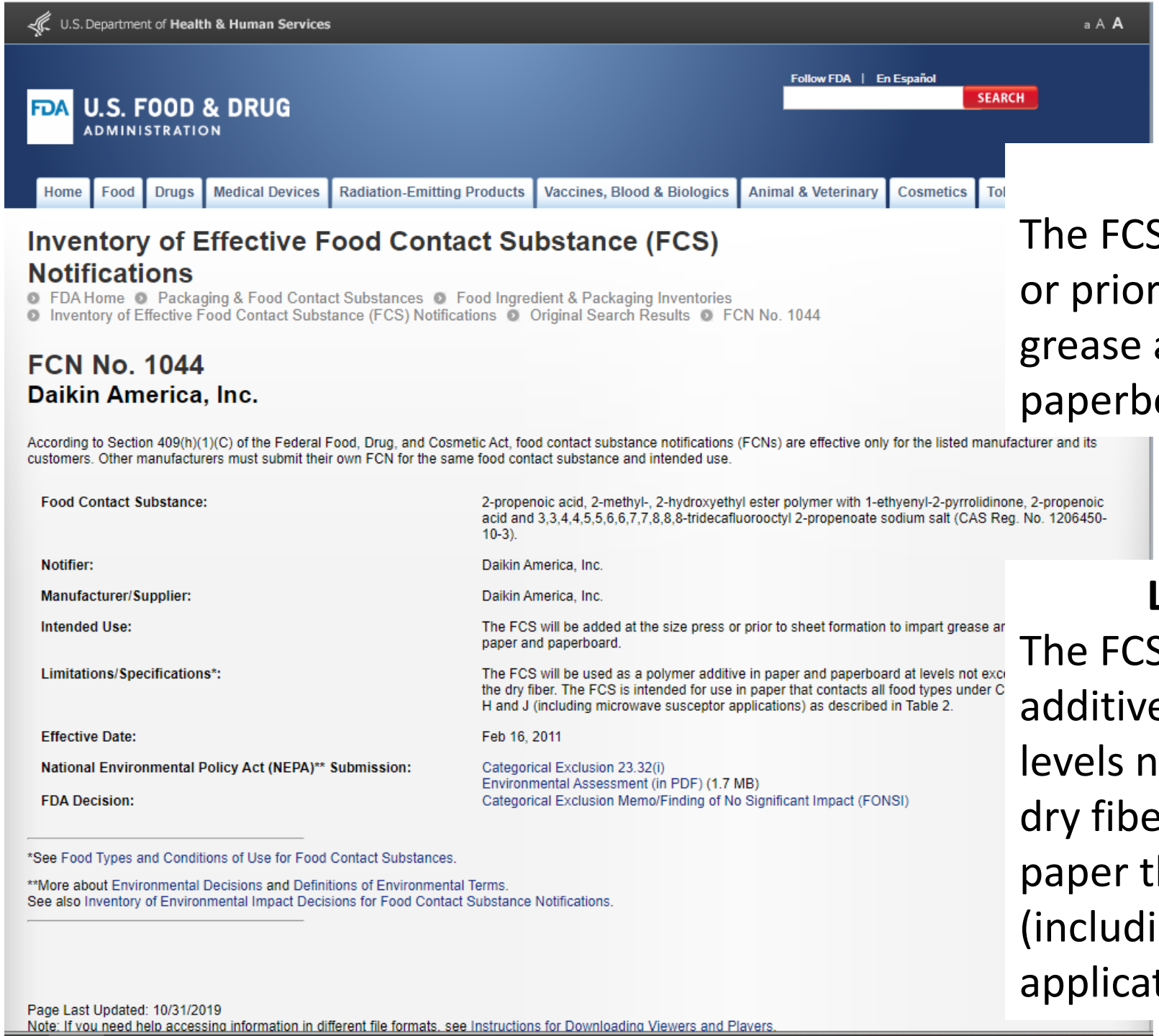
- The search results will return hits of records containing words that include the search term. For example, a search for the color ***red*** will return results that include terms such as *red*uce, ing*red*ient, and manufactu*red*. To limit results to only the searched term, place a space before and after the word in the basic search or in the advanced search "this exact phrase" field.

Basic Search | Advanced Search | Field Search

Search: Show Items Clear

Records Found: 1468 Show All **Page 1 of 30**

FCN No. (sorted Z-A)	Food Contact Substance	Manufacturer/Supplier	Effective Date
2034	Copolymers of styrene (CAS Reg. No. 100-42-5), α-methylstyrene (CAS Reg. No. 98-83-9), butyl methacrylate (CAS Reg. No. 97-88-1), 2-ethylhexyl acrylate (CAS Reg. No. 103-11-7), methyl methacrylate (CAS Reg. No. 80-62-6), butyl acrylate (CAS Reg. No. 141-32-2), itaconic acid (CAS Reg. No. 97-65-4), methacrylic acid (CAS Reg. No. 79-41-4), hydroxypropyl acrylate (CAS Reg. No. 999-61-1 and CAS Reg. No. 2918-23-2), sodium methallyl sulfonate (CAS Reg. No. 1561-92-8), and sodium styrene sulfonate (CAS Reg. No. 2695-37-6).	Arakawa Chemical Industries, Ltd.	Mar 31, 2020
2033	An aqueous mixture of peroxyacetic acid (PAA) (CAS Reg. No. 79-21-0), hydrogen peroxide (HP) (CAS Reg. No. 7722-84-1), acetic acid (AA) (CAS Reg. No. 64-19-7), 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) (CAS Reg. No. 2809-21-4), and optionally dipicolinic acid (DPA) (CAS Reg. No. 499-83-2) and/or sodium hydroxide (NaOH) (CAS Reg. No. 1310-73-2). **REPLACES FCN 1426**	Solvay Chemicals, Inc.	Mar 31, 2020
2031	Zinc pyrithione (CAS Reg. No. 13463-41-7).	Symphony Environmental Technologies Plc.	Feb 25, 2020
2028	Polyurethane resins (CAS Reg. No. 89097-02-9) derived from the reaction of diphenylmethane diisocyanate with 1,3-propanediol and polytetramethylene ether glycol.	BASF SE and its affiliates	Feb 12, 2020
2026	Blocked isophorone diisocyanate (IPDI) polymer consisting of trimer, pentamer, heptamer, and nonamer oligomers, with the primary component of interest being the trimer (CAS Reg. No. 103170-26-9). **REPLACES FCN 1039**	The Sherwin-Williams Company	Mar 25, 2020
2025	Cellulose, triacetate (CAS Reg. No. 9012-09-3).	Eastman Chemical Company	Jan 31, 2020
2024	Acetic acid ethenyl ester, polymer with ethene and ethenol (CAS Reg. No. 26221-27-2).	Kuraray Co., Ltd. Kuraray America, Inc. Kuraray Europe GmbH Kuraray Asia Pacific Pte. Ltd.	Jan 28, 2020
2023	A mixture of 35-60 percent hydroxysulfinoacetic acid, disodium salt (CAS Reg. No. 223106-41-0), 10-60 percent hydroxysulfoacetic acid, disodium salt (CAS Reg. No. 29736-24-1), and 0-40 percent sodium sulfite (CAS Reg. No. 7757-83-7).	Brüggemann Chemical US, Inc.	Jan 22, 2020
2022	Microfibrillated cellulose pulp (CAS Reg. No. 65996-61-4).	FIBERLEAN TECHNOLOGIES LIMITED	Jan 14, 2020
2021	Microfibrillated cellulose pulp (CAS Reg. No. 65996-61-4).	Kemira Oyj	Jan 9, 2020
2020	Mixed esters of C_5-C_{12} fatty acids with pentaerythritol, dipentaerythritol, and polypentaerythritol.	LANXESS Solutions US Inc.	Jan 3, 2020
2019	Platinum 5,10,15,20-tetrakis(pentafluorophenyl)porphyrin (CAS Reg. No. 109781-47-7).	GEA Food Solutions Germany GmbH	Jan 2, 2020



U.S. Department of Health & Human Services

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FDA U.S. FOOD & DRUG ADMINISTRATION

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Inventory of Effective Food Contact Substance (FCS) Notifications

FDA Home ● Packaging & Food Contact Substances ● Food Ingredient & Packaging Inventories
Inventory of Effective Food Contact Substance (FCS) Notifications ● Original Search Results ● FCN No. 1044

FCN No. 1044
Daikin America, Inc.

According to Section 409(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act, food contact substance notifications (FCNs) are effective only for the listed manufacturer and its customers. Other manufacturers must submit their own FCN for the same food contact substance and intended use.

Food Contact Substance:	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. 1206450-10-3).
Notifier:	Daikin America, Inc.
Manufacturer/Supplier:	Daikin America, Inc.
Intended Use:	The FCS will be added at the size press or prior to sheet formation to impart grease ar paper and paperboard.
Limitations/Specifications*:	The FCS will be used as a polymer additive in paper and paperboard at levels not exc the dry fiber. The FCS is intended for use in paper that contacts all food types under C H and J (including microwave susceptor applications) as described in Table 2.
Effective Date:	Feb 16, 2011
National Environmental Policy Act (NEPA) Submission:**	Categorical Exclusion 23.32(i) Environmental Assessment (in PDF) (1.7 MB)
FDA Decision:	Categorical Exclusion Memo/Finding of No Significant Impact (FONSI)

*See Food Types and Conditions of Use for Food Contact Substances.

**More about Environmental Decisions and Definitions of Environmental Terms.
See also Inventory of Environmental Impact Decisions for Food Contact Substance Notifications.

Page Last Updated: 10/31/2019
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Intended use

The FCS will be added at the size press or prior to sheet formation to impart grease and oil resistance to paper and paperboard

Limitations/Specifications

The FCS will be used as a polymer additive in paper and paperboard at levels not exceeding 1 percent of the dry fiber. The FCS is intended for use in paper that contacts all food types (including microwave susceptor applications)

Journey to a safe product starts here:

SAFETY ASSESSMENT OF RAW MATERIALS AND IMPURITIES

- Hazard
  - Toxicity testing
  - Read across
  - GreenScreen
- Exposure
  - Migration
  - Consumption estimate
- Dose-effect relationship
- Estimated daily intake/Acceptable daily intake <1

Journey to a better product starts here:

MATERIAL DESIGN

Journey to a better product starts here:

MATERIAL DESIGN

Starting materials

- Fiber
  - Virgin
  - Post industrial recycled
  - Post consumer recycled
- Polymer
  - Petrochemical
  - Bio-based
  - Post industrial recycled
  - Post consumer recycled

Journey to a better product starts here:

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Ingredients

- Avoid hazardous chemicals
  - PBT, CMR, EDC
- Consult restricted substances lists
  - Food Safety Alliance for Packaging

Packaging part/component	Substance(s) / Topic(s)	Description	Should not use intentionally (where suitable alternatives exist)	Minimize Use	Additional information/ references
Any packaging component	- *ortho*-Phthalates (aka Phthalates) (non-exhaustive list given below)	- Phthalates should not be used as plasticisers and additives in packaging materials including inks, adhesives, plastics, etc., where suitable alternatives exist.	X		Prop65, SVHC, Consumer Interest
	Di-(2-ethylhexyl)phthalate (117-81-7)	Di-*n*-propyl phthalate (131-16-8)			
	Diisodecylphtalate (26761-40-0)	Dicyclohexyl phthalate (84-61-7)			
	Dibutylphthalate (84-74-2)	Diethyl phthalate (84-66-2)			
	Diisononylphtalate (28553-12-0)	Diisobutyl phthalate (84-69-5)			
	Diisooctylphtalate (27554-26-3)	Diisodecyl phthalate (68515-49-1)			
	Diisobutyl phthalate (84-69-5)	Diisoheptyl phthalate (41451-28-9)			
	Diethyl phthalate (84-66-2)	Diisohexyl phthalate (146-50-9)			
	Benzyl butyl phthalate (85-68-7)	Dimethyl phthalate (131-11-3)			
	Di(*n*-octyl) phthalate (117-84-0)	*n*-Octyl *n*-decyl phthalate (119-07-3)			
	Di-*n*-hexyl phthalate (84-75-3)	Di-*n*-pentyl phthalate (131-18-0)			
Any Packaging components	- Heavy Metals: Cadmium, Chromium VI, Lead, Mercury	- Must not be intentionally used in packaging materials, including inks and pigments/colorants.			Follow CONEG/ TPCH regulations
Any Packaging Component	- SVHC (Substances of Very High Concern) (lists available from ECHA website)	- Applicable to products for sale in Europe, must comply with regulation - see below "REACH comment and links			Follow regulation where applicable
Any Packaging Component	- California Proposition 65	- Applicable to products for sale in California, must comply with regulation - e.g. well below communication limits (MADL, NSRL) or absence.			Follow regulation where applicable
Can coatings and Plastic resins (e.g. polycarbonate) containing Bisphenol A	Bisphenol A (BPA, 80-05-7)	- Bisphenol A based materials should not be used where suitable alternatives exist.	X		Prop65, SVHC, Consumer Interest
Grease-proof coated paper and board	Perfluoro and polyfluoro compounds:				
	- C8 and higher (PFOA and related)	- Must not be used.	X		Not allowed by US-FDA
	- C6 polyfluoro, C2 perfluoro ethers and other polyfluoro and perfluoro compounds	- Can be used but consider alternatives if available.		X	Consumer Interest

FSAP
FOOD SAFETY ALLIANCE FOR PACKAGING

Institute of PACKAGING PROFESSIONALS

Food Packaging Chemicals of Concern and Quality Considerations:

- Legal requirements must first be followed for food contact materials, then the below best practices can be considered
- The below considerations in many cases go beyond regulations, if there is a conflict, regulations must be followed. Packaging applications, which have a higher risk due to use (e.g., ovenable, microwavable, etc.) or sensitive target consumer (e.g., infant/toddler food, etc.), should have additional safety assessments and possibly more stringent requirements to be considered when developing.

https://www.iopp.org/files/Food%20Packaging%20Product%20Stewardship%20Considerations%20FSAP-IoPP%20v1_0.pdf

Journey to a better product starts here:

MATERIAL DESIGN

Starting materials

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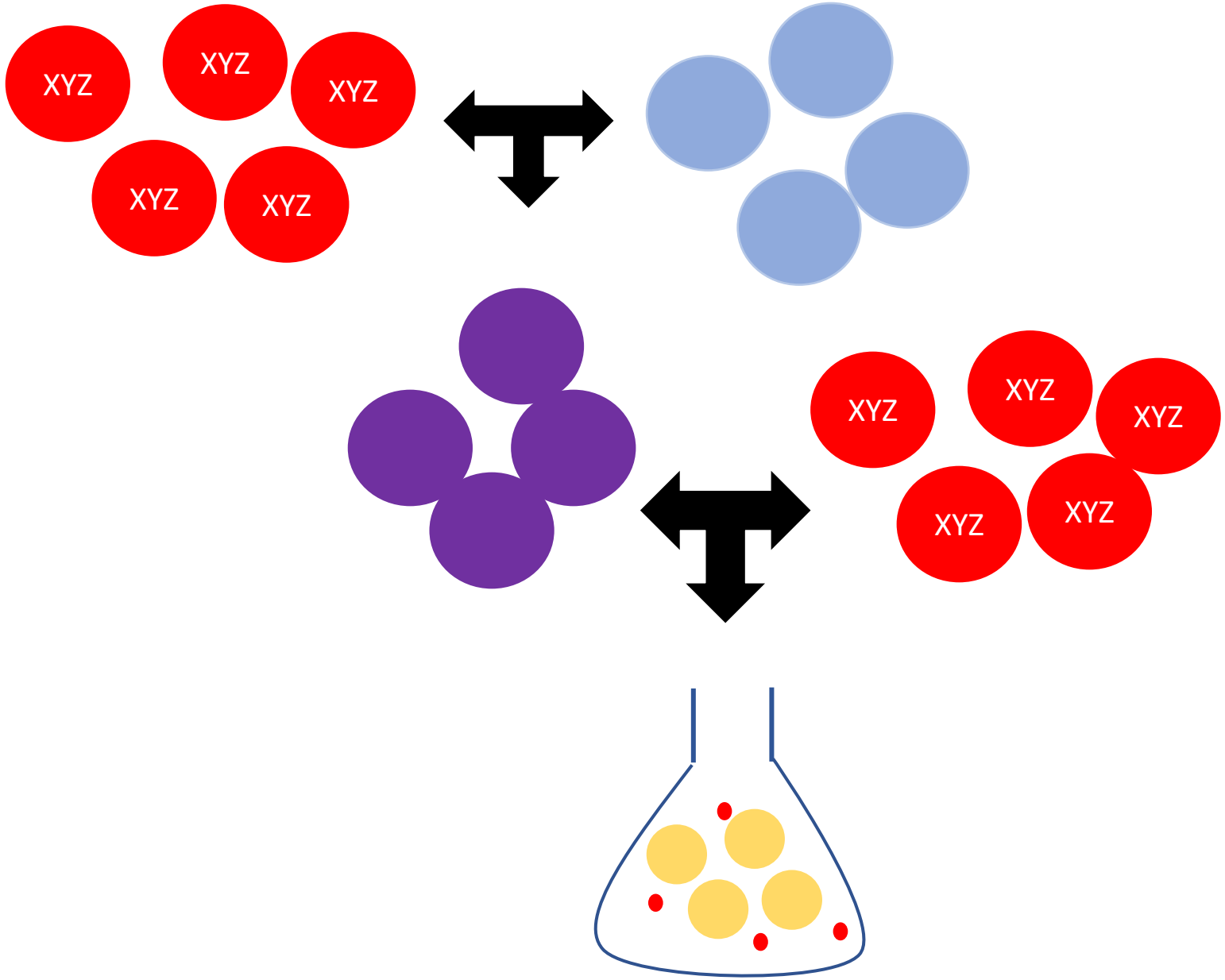
- Polymer
  - Petrochemical
  - Bio-based
  - Post industrial recycled
  - Post consumer recycled

Ingredients

- Avoid hazardous chemicals
  - PBT, CMR, EDC
- Consult restricted substances lists
  - Food Safety Alliance for Packaging

Manufacturing

- Ensure total reactivity
- Control impurities
- Encourage simple processes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Impurities listed in safety assessment of PFAS used to grease-proof paper in contact with food

Table 2: Exposure Estimates for Impurities in the FCS

Impurity	Typical residual (dry basis, mg/kg)	Basis of Exposure	DC (ppb) FCN 518	EDI (ug/p/d) FCN 518	EDI (µg/p/d) FCN 487	EDI (ug/p/d) FCN 314
FCS oligomers		From Microwave use	0.2	0.6	1.5	1.5
C_6-C_{18} Fluorinated telomer iodides (FTI)	<184(total)	100% of residual	0.0048	0.014	0.69	<0.008
Allyl alcohol	1853	LOD of method	0.05	0.15	0.81	0.021
C_6-C_{18} Fluorinated iodohydrins (FI)	<61 (total)	100% of residual	0.0016	0.005	0.23	<0.003
Tetramethyl succinonitrile (TMSN) Breakdown product from AIBN	171		-	AIBN Regulated in § 176.170		
C_6-C_{18} Fluorinated epoxides (FE)	<61 (total)	100% of residual	0.0016	0.005	0.23	<0.003
C_6-C_{18} Fluorinated alcohols (FA)	2989	Migration results FCN 518	0.1	0.3	0.17	0.12
ECH	2.3	100% of residual	0.00006	0.0002	0.009	0.0001
2,3-Dichloro-1-propanol (2,3-DCP)	8.2	100% of residual	0.00021	0.0006	0.03	0.0003
1,3-Dichloro-1-propanol (1,3-DCP)	9484	Migration results from FCN 518	0.0088	0.03	0.012	0.004
3-Chloro-1,2-propanediol (3-CPD)	3355	Migration results from FCN 518	0.014	0.04	0.13	0.03
TETA	<84	Residual level from 518	0.0022	0.007	0.15	0.08
Perfluorooctanoic acid (PFOA)	57	100% of residual	0.0015	0.005	0.2	Not determined
Perfluoroacid congeners	114	2 x PFOA residual level	0.003	0.009	0.4	Not determined
Perfluorinated alkanes		Migration Results FCN 518	0.1	0.3	-	-
Sodium hypophosphite monohydrate				Essentially zero	Essentially zero	Essentially zero
Sodium metabisulfite				Essentially zero	Essentially zero	Essentially zero
Sodium sulfate				Essentially zero	Essentially zero	Essentially zero

Food contact substance (FCS) 2-propen-1-ol, reaction products with pentafluoroiodoethane-tetrafluoroethylene telomer, dehydroiodinated, reaction products with epichlorohydrin and triethylenetetramine (CAS Reg. No 464178-90-3). Food Contact Notification 518

Journey to a better product starts here:

MATERIAL DESIGN

Starting materials

- Fiber
  - Virgin
  - Post industrial recycled
  - Post consumer recycled
- Polymer
  - Petrochemical
  - Bio-based
  - Post industrial recycled
  - Post consumer recycled

Final product

- Is it safe?

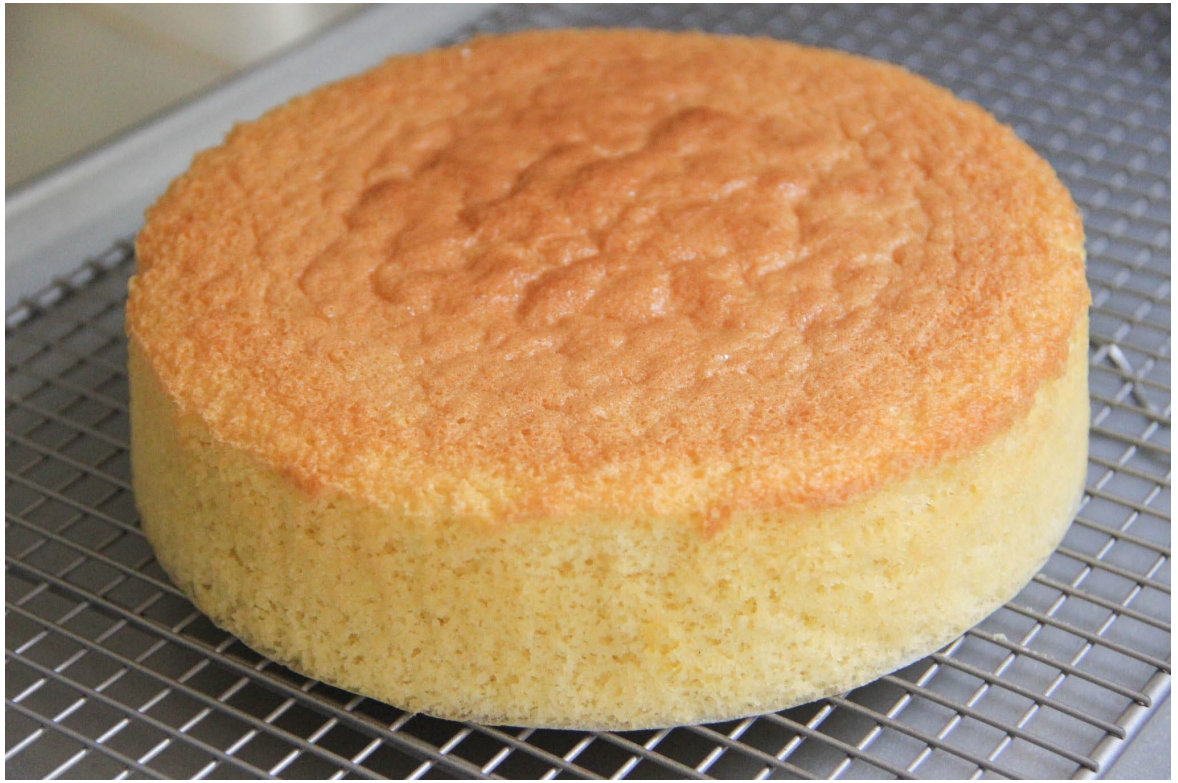
Ingredients

- Avoid hazardous chemicals
  - PBT, CMR, EDC
- Consult restricted substances lists
  - Food Safety Alliance for Packaging

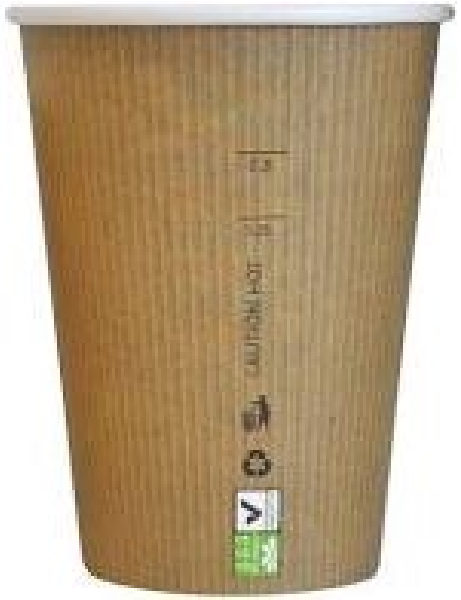
Manufacturing

- Ensure total reactivity
- Control impurities
- Encourage simple processes

Ingredients ≠ final product



IS THE PRODUCT IN CONTACT WITH FOOD SAFE?



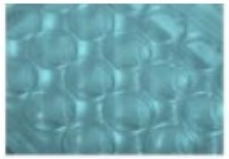
Testing final product vs. testing ingredients

1

FP extraction

2

Effect-directed analysis

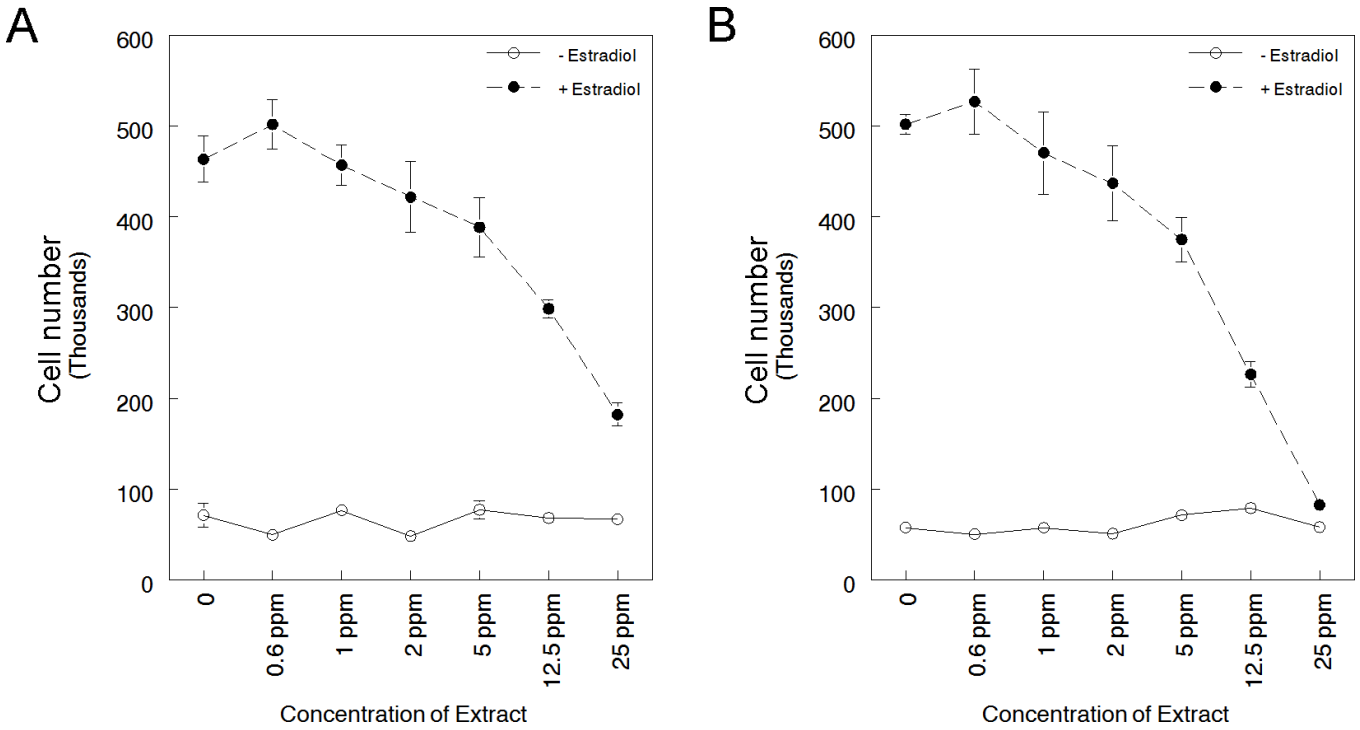


ASSAYS
ER
AR
AhR
GR
RAR
PPARγ
Nrf2
p53
Ames

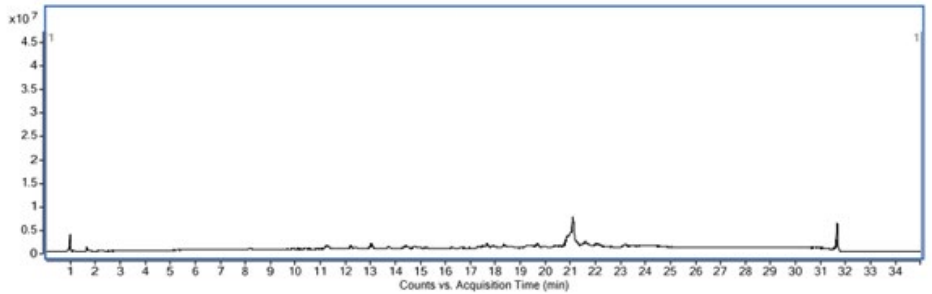
	AR ↑	AR ↓	ER	AhR	PPARγ	RAR	Nrf2	p53	Ames
Sandwich wrapper									
Muffin forms									
Baking paper									
Flour bag									
Pizza box									
White pizza box									
Microwave pizza box									
Popcorn bag 1									
Popcorn bag 2									
Sausage tray									
Fish tray									
Tomato tray									
Cereal box									
Nordic paper									
Basis paper									
Chinese paper 1									
Chinese paper 2									
Board w UV print									
Board w watersol print									
Board w offset print									

Rosenmai et al. Food & Chem Tox 2017

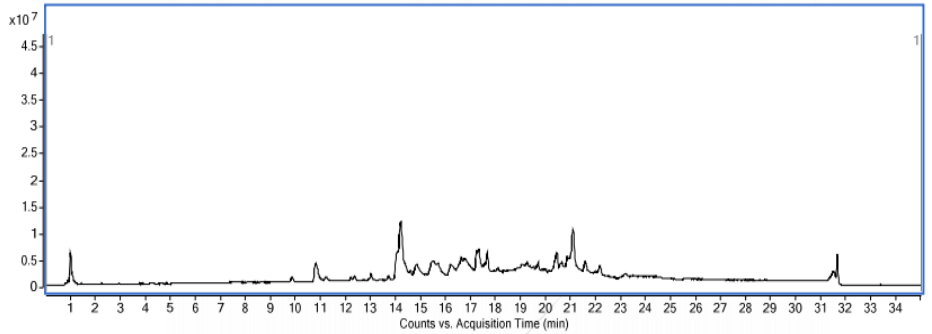
Testing final product vs. testing ingredients



Procedural blank (50% ethanol)



50% ethanol exposed to V7-coated metal



Soto et al. Env Sci & Technology, 2017

In summary

- Chemical constituents of food contact material in general and food service ware in particular migrate into food potentially posing a risk to human health and environmental contamination
- Selection of low-hazard food contact chemicals could help improving materials' safety
- But, understand that what migrates into food may be very different from the starting materials, with very diferent human health


THANK YOU!
drmvma@gmail.com