Alternatives Assessment for PFAS in Food Packaging

Stakeholder Webinar #1

Catherine Rudisill, M.S.
Work Assignment Manager
Chemistry Lead
SRC, Inc.
Syracuse, NY

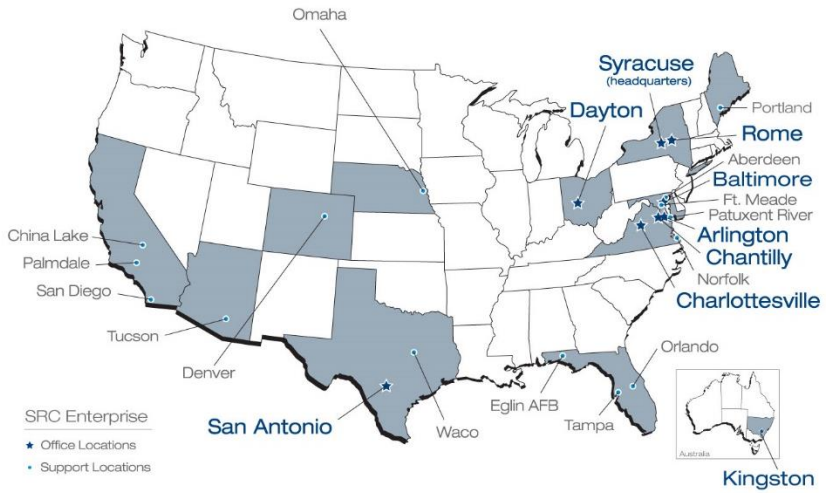
Brian Penttila, Ph.D.
Project Manager
Safer Alternatives Chemist
WA Dept. of Ecology
Olympia, WA

Overview

- Intro & Background
- Stakeholder Engagement
  - Status, progress and next steps
- PFAS Base-case recommendation
- Candidate alternatives (work in progress)
- Product scoping (work in progress)
- AA Module and data needs (work in progress)

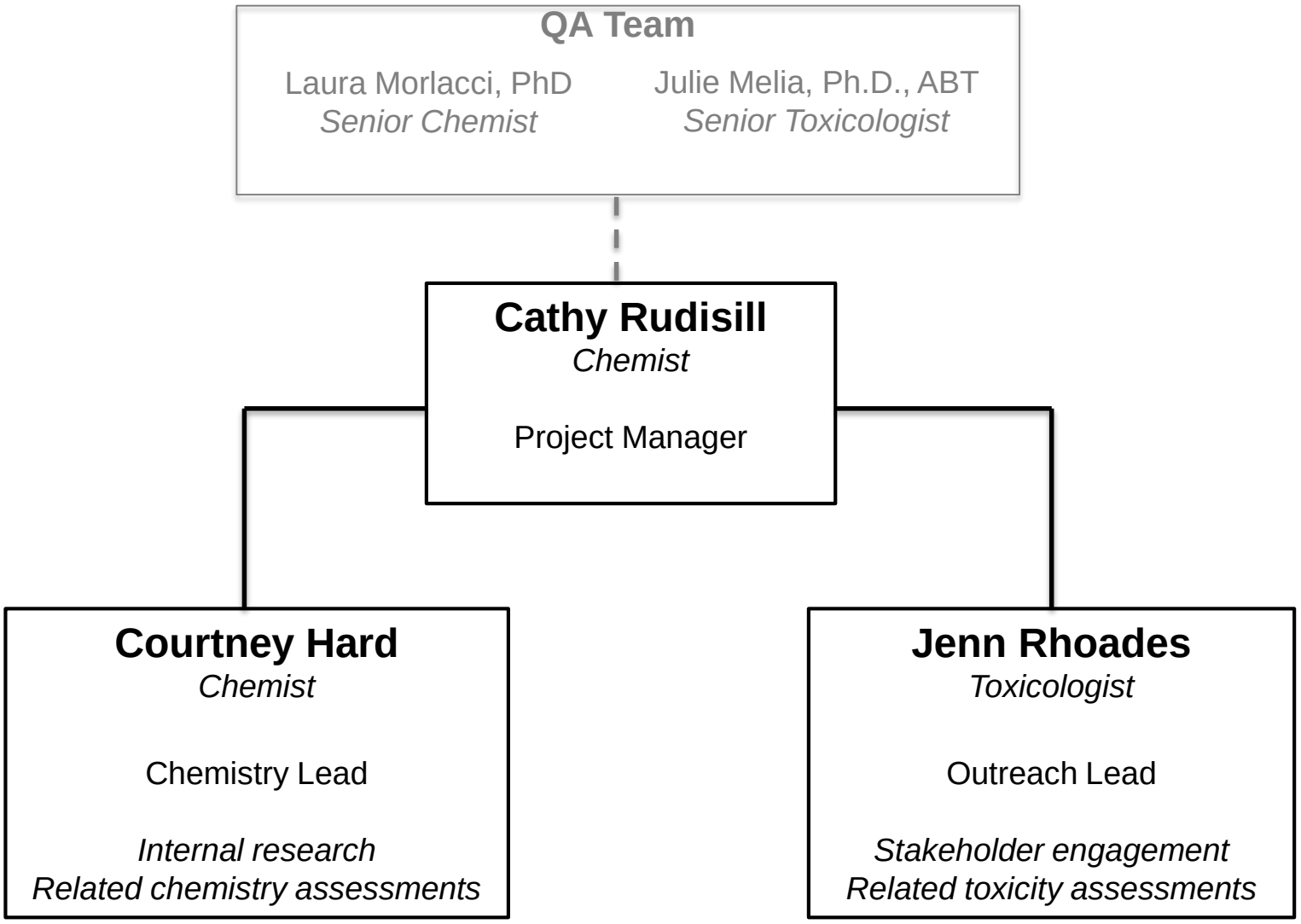
SRC Quick Facts

- Founded in 1957 by Syracuse University
  - Separated in 1976
- Not-for-profit, Research & Development
- >1,000 employees and growing
- PFAS AA team located at HQ in Syracuse, NY
- U.S. EPA
  - New Chemicals Program (PMNs, > 25,000 assessed)
  - Safer Choice (AAs, Labeling Program, and SCIL since their inception)
  - Model development
    - EPISuite™, ECOSAR



- Other Government Work
  - NLM/NIH – HSDB
  - ATSDR Toxicological profiles
  - OSHA – PELS
  - State Agencies
  - DoD

SRC Staff


QA Team
Laura Morlacci, PhD
Senior Chemist
Julie Melia, Ph.D., ABT
Senior Toxicologist
Cathy Rudisill
Chemist
Project Manager
Courtney Hard
Chemist
Chemistry Lead
Internal research
Related chemistry assessments
Jenn Rhoades
Toxicologist
Outreach Lead
Stakeholder engagement
Related toxicity assessments

WA State Law RCW 70.95G

- Bans perfluorinated and polyfluorinated substances from food packaging materials
- “**Food package**" means a package or packaging component that is intended for direct food contact and is comprised, in substantial part, of paper, paperboard, or other materials originally derived from plant fibers.”
- “’**Perfluoroalkyl and polyfluoroalkyl substances" or "PFAS chemicals**" means, for the purposes of food packaging, a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom.’”
- Dept of Ecology will conduct an Alternatives Assessment that considers:
  - Chemical hazard
  - Exposure
  - Performance
  - Cost & availability
- If Ecology determines that there are safer alternatives, then ban will take effect (no earlier than 2020)
- If no alternatives, then Ecology will conduct yearly follow-up report

Timeline

January 2019 - SRC Assessment begins

Webinar 1 & 2

SRC Final Report

Peer Review

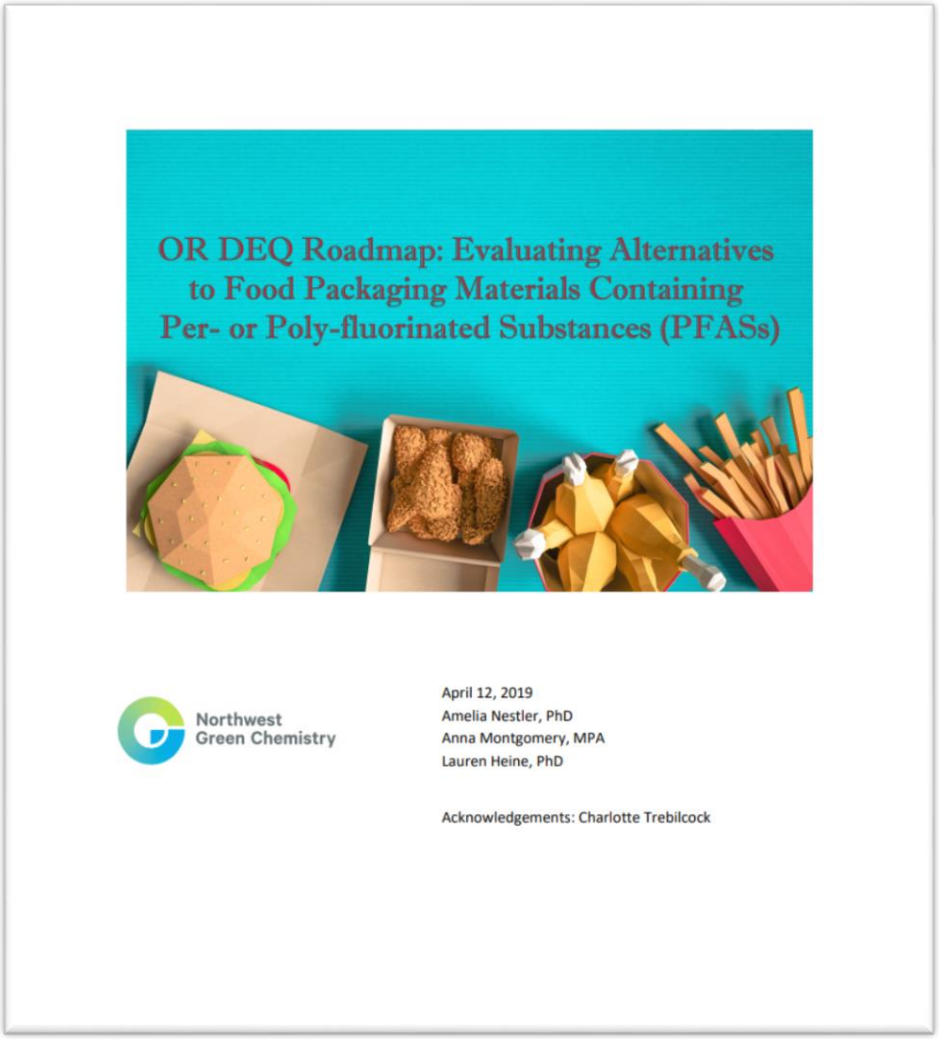
Ecology Recommendation

Previous Work on this Topic

- Center for Environmental Health (CEH). 2018. *Avoiding Hidden Hazards: A Purchaser's Guide to Safer Foodware*. (Accompanying database updated Dec 2018). https://www.ceh.org/wp-content/uploads/CEH-Disposable-Foodware-Report-final-1.31.pdf
- Collaborative Network for a Cancer-Free Economy. 2018. *Purchasing Safer Compostable Food Service Ware*. https://sustainablepackaging.org/wp-content/uploads/2018/07/Purchasing-Safer-Compostable-Food-Service-Ware.pdf.
- Trier X, Taxvig C, Rosenmai AK, Pederson GA. 2017. PFAS in paper and board for food contact – options for risk management of poly- and perfluorinated substances. Copenhagen K, Denmark: Nordic Council of Ministers. TemaNord, 573(2017). Available online at: http://orbit.dtu.dk/files/149769110/Rapport_PFAS_in_paper_and_board_for_food_contact_Options_for_risk_management_of_poly_and_perfluorina.pdf
- Safer Made. *Safer Materials in Food Packaging*. 2019. https://docs.wixstatic.com/ugd/dcb253_151dcf652c6f47aca2d4a571cbd79b30.pdf
- EDF. 2018. PFAS Freedom of Information (FOIA) Food Contact Notification Chemistry Memo. Environmental Defense Fund. Available online at: https://www.edf.org/sites/default/files/EDF-PFAS-FOIA-FCN-Chemistry-Memos.pdf

Goal: Build on this previous work so as to produce an assessment that can inform a regulatory decision

Oregon DEQ Roadmap – April 2019



OR DEQ Roadmap: Evaluating Alternatives to Food Packaging Materials Containing Per- or Poly-fluorinated Substances (PFASs)

Northwest Green Chemistry

April 12, 2019

Amelia Nestler, PhD
Anna Montgomery, MPA
Lauren Heine, PhD

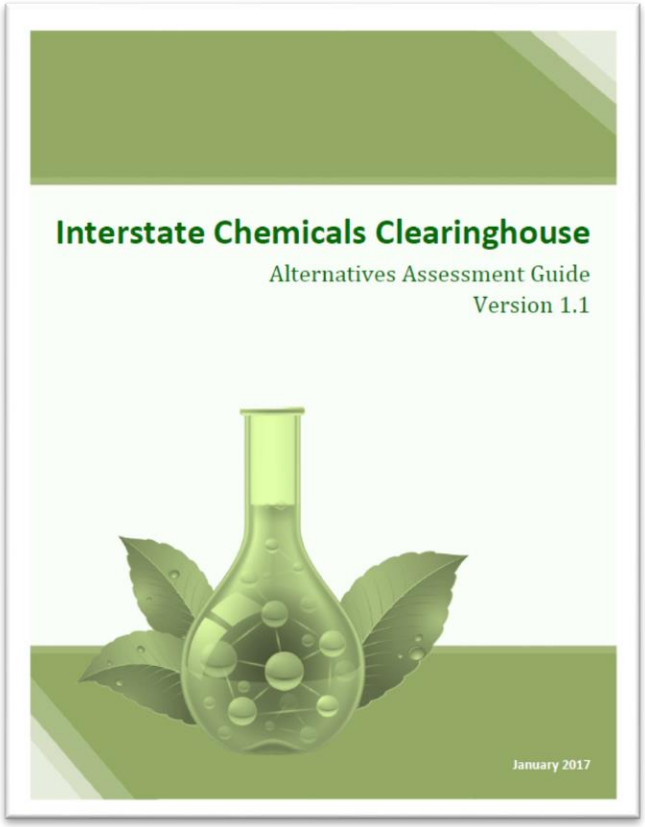
Acknowledgements: Charlotte Trebilcock

https://www.oregon.gov/deq/FilterDocs/toxicsRoadmap.pdf

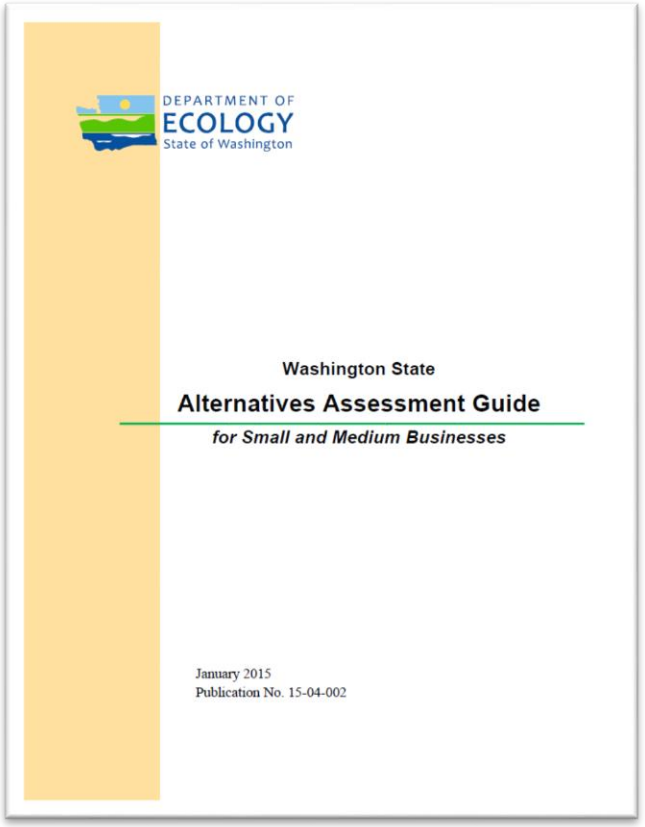
PFAS in Food Packaging

- U.S. Production and import of PFOA phased out as part of EPA PFOA Stewardship Program. Not reported in the 2006 or 2012 CDR.
- By 2016 PFOS/PFOA (C8-based chemistries) phased out of food packaging (Schaider et al, 2017; FDA 2016)
- Current PFAS used in food packaging are focused on C6 and shorter chain chemistries
  - Fluoropolymers, primarily
    - Acrylate/Methacrylate side-chain polymers
    - Polyfluorinated polyethers (PFPEs)

General Approach



http://theic2.org/article/download-pdf/file_name/IC2_AA_Guide_Version_1.1.pdf



https://fortress.wa.gov/ecy/publications/documents/1504002.pdf

Stakeholder Engagement: Progress and Next Steps

Stakeholder Engagement

- **Stakeholder engagement seeks to gather information and feedback on:**

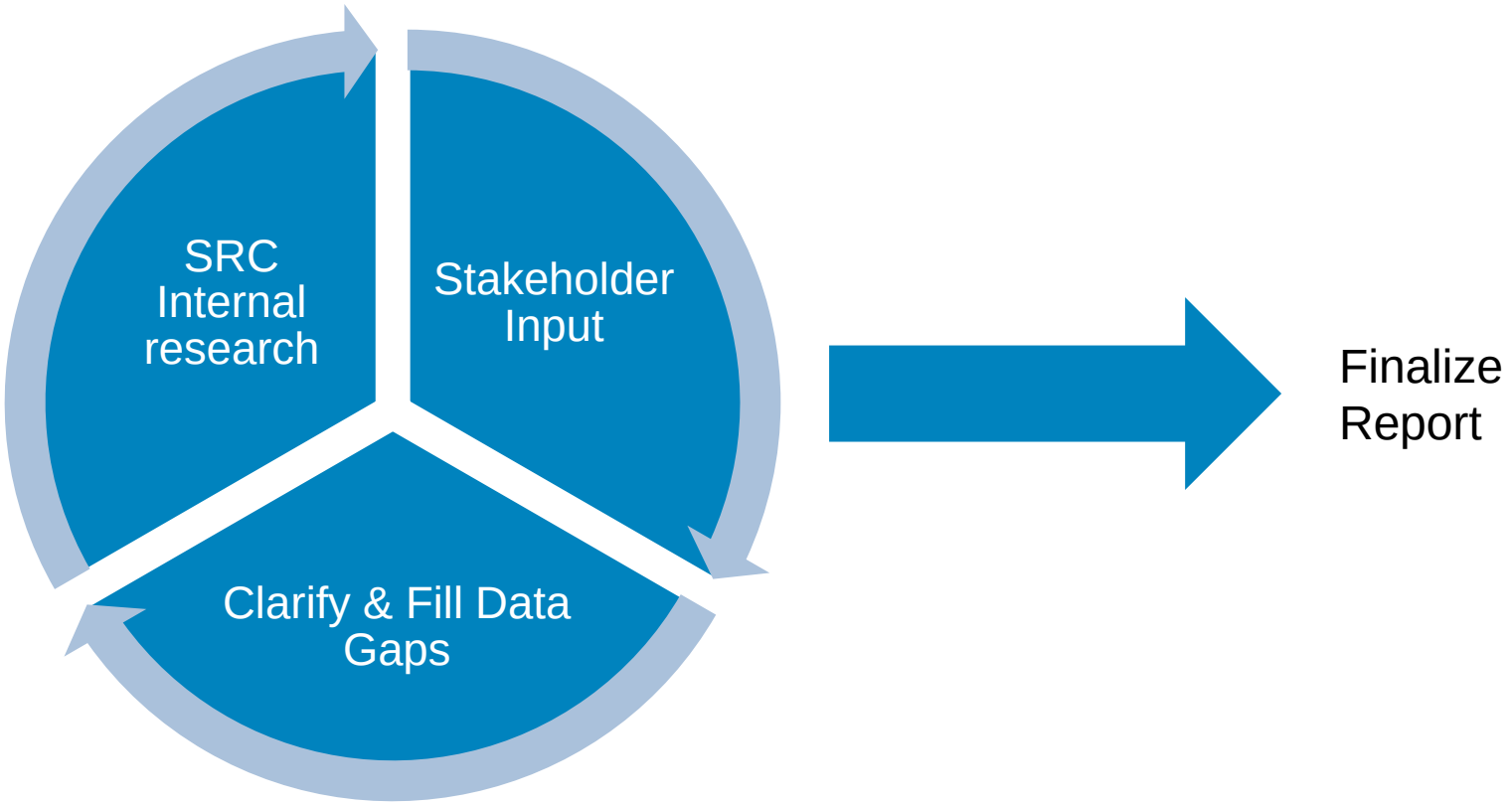
  - **Alternative candidates and processes** (chemical and non-chemical)
    - Prioritization of specific substances for assessment
    - Product scope
    - Performance
      - Define performance criteria for different uses
        - Performance measurements (standard industry test methods, product-specific performance tests, and qualitative assessments)
      - Identify alternatives that can be practicably substituted.
      - Availability
      - Cost

  - **Base-case candidate**

Stakeholder Engagement

- How Stakeholder Input Fits into the Process

Level 2 Stakeholder Engagement – Soliciting information



Stakeholder Engagement

Identify and recruit Stakeholders (open)

- Survey and suggested contacts released on February 13, 2019
  - **Basic primary contact information**
  - **Stakeholder types:**
    - Product manufacturer (B2B)
    - Supplier
    - NGO
    - Industry trade organization
    - Retailer
    - Product manufacturer (consumer facing)
    - Chemical manufacturer/processor/importer
    - Academia/research groups
    - Government representatives
    - Other (composters, recyclers, waste management)
  - **Data type:**
    - Chemical substance identification
    - Chemical hazard data
    - Performance testing
    - Manufacturing considerations
    - Non-chemical or process-related alternatives
    - Exposure related information
    - Consumer advocacy
    - Other

Stakeholder Engagement

Stakeholder Survey Summary

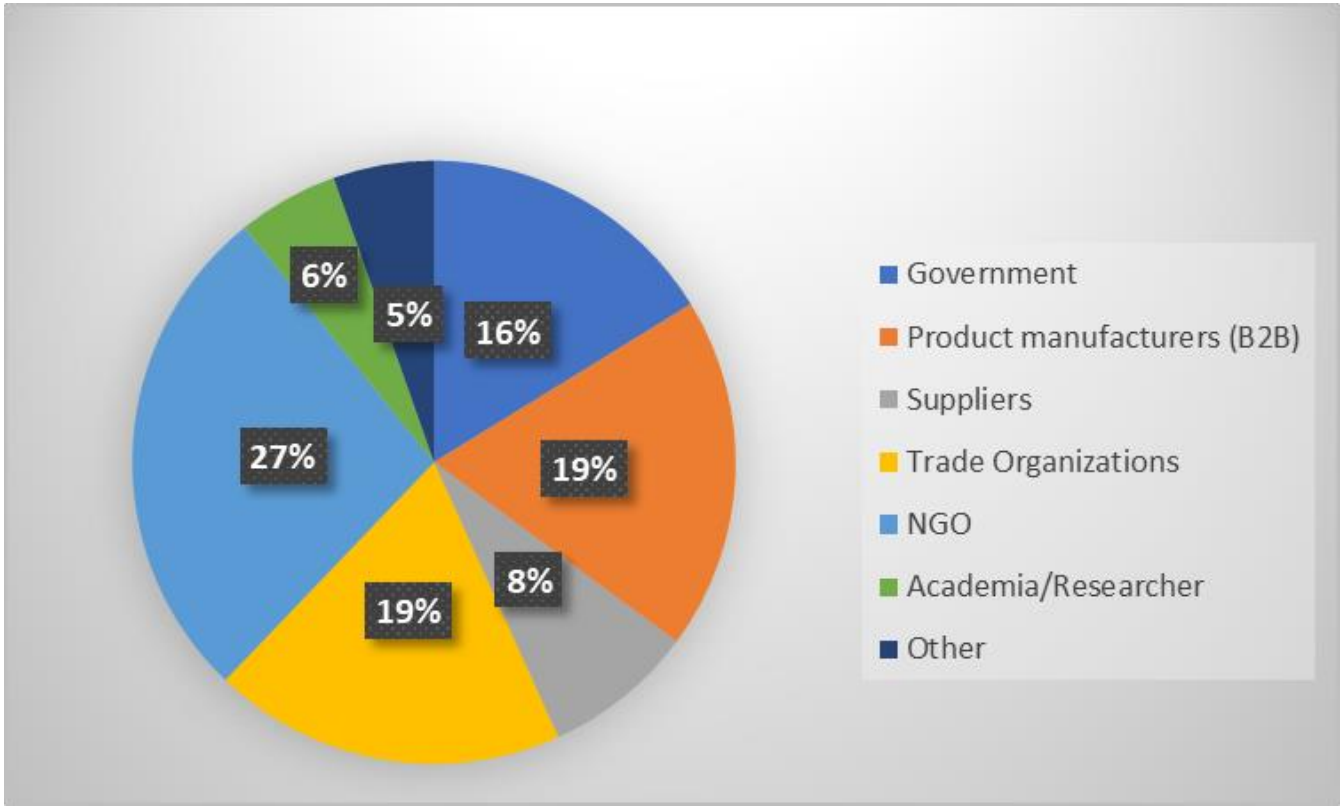
***https://www.surveygizmo.com/s3/4834537/PFAS-AA-Questionnaire* (released on February 13, 2019)**

- Invited interested parties identified through our initial screen
- Survey disseminated through the PFAS CAP website
- Sent to additional contacts suggested by stakeholders

Summary of Survey Response	
Completed survey	33
Current stakeholders	37
Additional contacts	14

Survey Results

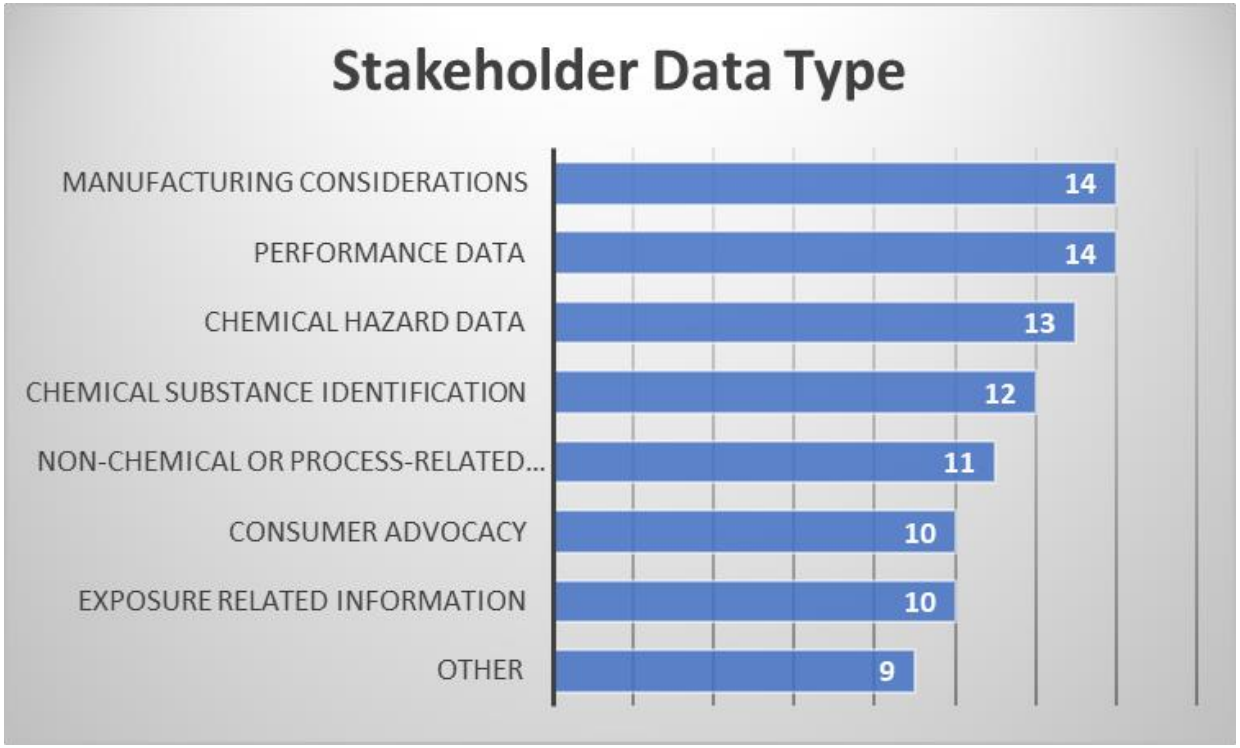
Current Stakeholder Representation



- Areas needing more representation:
  - Purchasers
  - Retailers
  - Chemical manufacturers

Stakeholder Engagement

Current Data Type Representation (Self-Identified)



*Other: compostability, lifecycle, recycling, product testing, regulations, 3rd party certifications, socio-economic considerations, general

Stakeholder Engagement

- Initial Stakeholder Discussions

General Approach:

- Build a rapport
- Map out knowledge-base and interests
- Obtain input/information to support upcoming milestones
  - Base-case
  - Alternatives candidates
  - Scoping
  - Assessment

Status:

Initial contact emails sent to request discussions

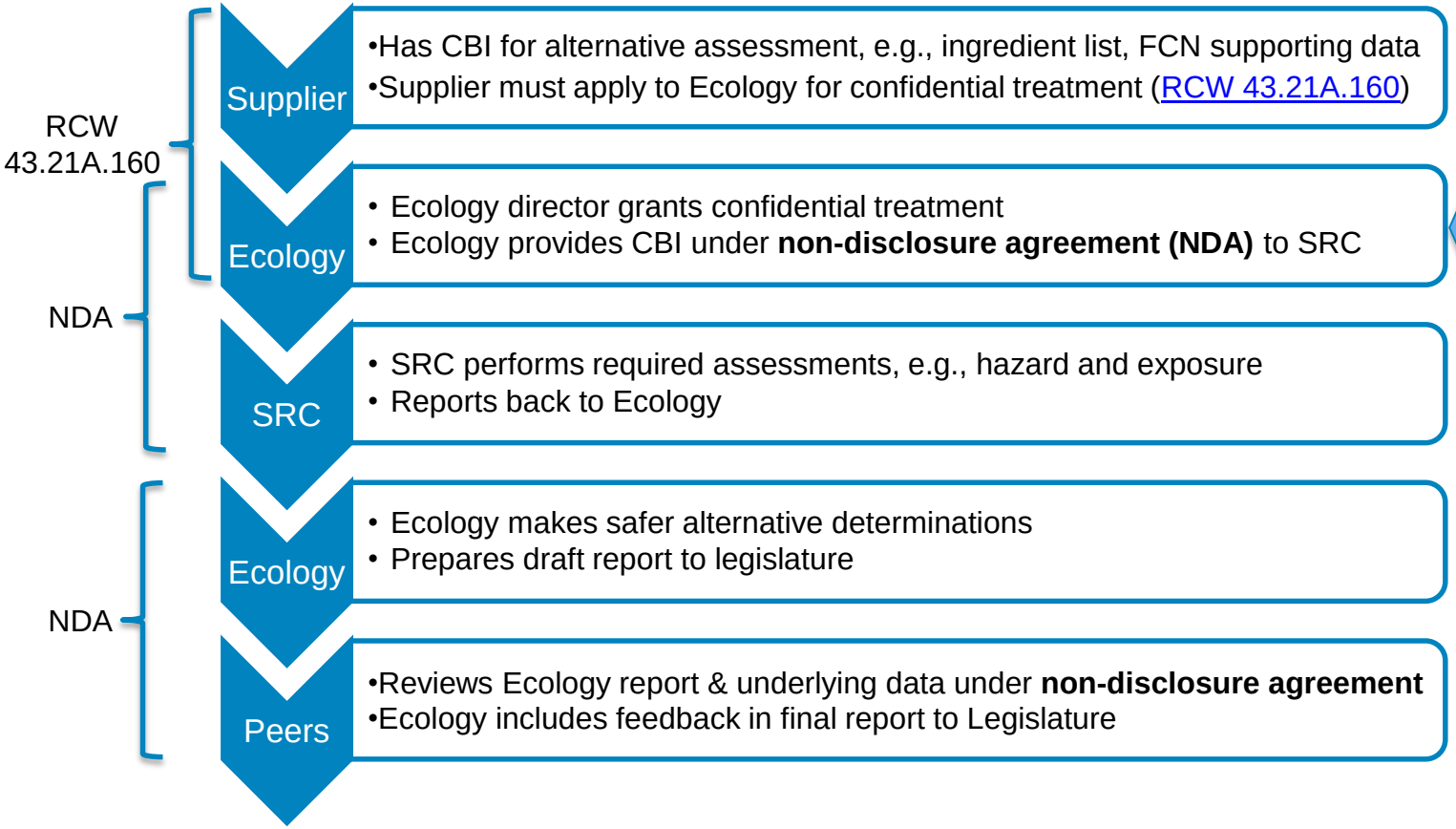
Initial stakeholder discussions continue

Stakeholder Engagement

- Next steps
  - Continue reaching out for initial and follow-up engagement
    - Engage contacts suggested by current stakeholders
    - Open stakeholder recruiting – anticipate adding more stakeholders and further input
  - Targeted discussions for scoping, performance, costing
    - Organize group calls where it makes sense
  - Feedback on proposed base-case
  - Focus on product scoping
  - Gather information on alternatives candidates
  - CBI protocol
    - Initial feedback from stakeholders make clear the need for CBI protocols in order to obtain necessary information

CBI Protections and Submissions

CBI = Confidential Business Information



Manufacturer/Supplier must agree to allow SRC and Peer Reviewers to view all supplied confidential business information under NDA.

Redefining possible®

PFAS Base-Case

Identification

Purpose of the Base-Case

Representative PFAS Food Contact Material (FCM)

- Specified in the Statement of Work
- Sets the standard for comparing alternatives
- Needed to make an informed alternative assessment
- Must be FDA compliant
- Assessment modules
  - Hazard and exposure
  - Performance
  - Cost & Availability

Base-Case Approach

- Mapped U.S. Food Contact Notifications (FCN's)
- Reviewed published monitoring studies
- Incorporated stakeholder input

Base-Case – Mapping FCN's

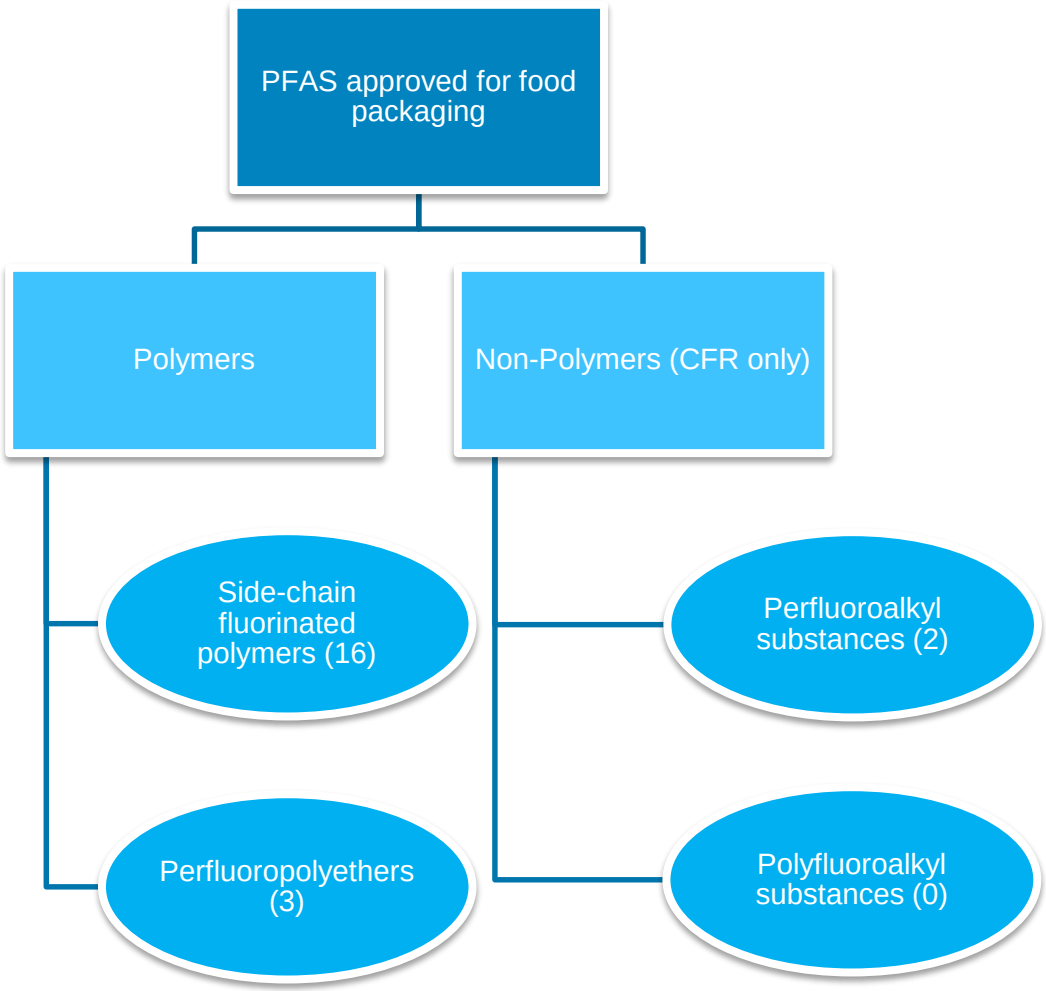
- Identified all PFAS substances used as food contact materials (FCM's)
  - Used for direct food contact paper, paperboard, and other plant-based fiber materials packaging
  - Used to impart oil, grease, and/or water resistance
  - U.S. FDA Food Contact Notifications (FCN's)
    - 31 FCN's for 19 PFAS compounds
  - U.S. FDA's Code of Federal Regulations (CFR) List (indirect additives)
    - 2 approved PFAS compounds (evidence suggests these are no longer used)
  - Accessed via Shraider et al. 2017[1], Neltner 2018[2], and FCN Database[3]
- Obtained representative structures for these substances
  - Categorized and compared chemical structures

1. Schaider, Laurel A et al. "Fluorinated Compounds in U.S. Fast Food Packaging" Environmental science & technology letters vol. 4,3 (2017): 105-111. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6104644/#SD1
2. Neltner, T. *Paper mills a significant source of PFAS contamination, but who's watching?* May 21, 2018. http://blogs.edf.org/health/2018/05/21/pfas-paper-mills/
3. https://www.fda.gov/food/packaging-food-contact-substances-fcs/inventory-effective-food-contact-substance-fcs-notifications

Base-Case U.S. FCM's (FCN & CFR)

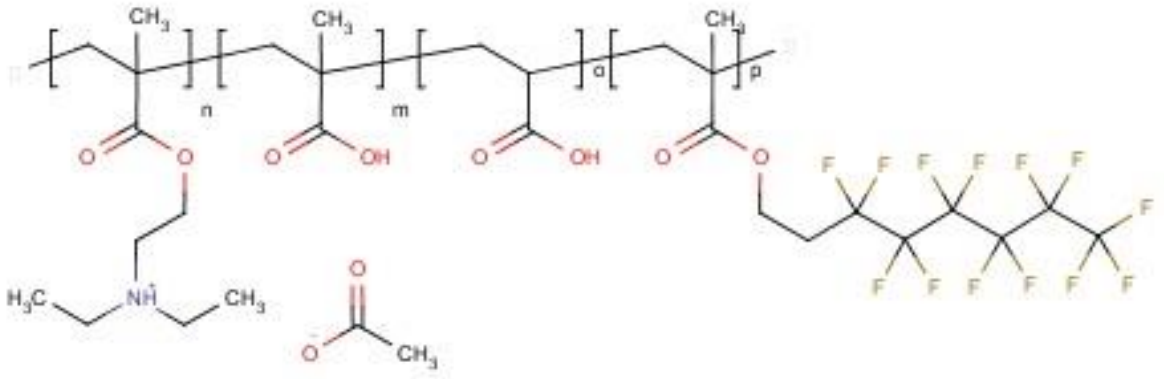
PFAS FCM's

- Polymeric
  - All approved FCN's for fluorinated substances are polymers
- Non-Polymeric
  - There are no approved FCN's
  - 2 CFR's are still approved, but are for substances not likely in use
  - DiPAPs of any chain length not approved



Proposed Base-Case

- Methacrylic acid copolymer with acrylic acid, 2-(diethylamino)ethyl methacrylate, and 2-(perfluorohexyl)ethyl methacrylate, acetate
  - CASRN 1071022-26-8
  - Producer: The Chemours Company
  - Food Contact Notifications 885 and 1027
  - Representative Structure



Base-Case Justification

- What is currently being used in the U.S. Market[1]?
  - C6 Polyfluorinated chemistries
    - Based on independent research and initial stakeholder comments
    - Longer chain PFAS (C8 or greater) have been phased out and the FDA has rescinded approval for FCN's
      - DiPAPs (polyfluoroalkyl phosphoric acid diesters) have been of particular concern for migration into food from food contact paper and its metabolism in the human body to perfluorinated carboxylic acids[4]. These chemicals are no longer approved by the FDA for FCM's.
    - 6:2 Fluorotelomer alcohols dominate the detectable fluorinated compounds found in FCM's in the U.S. [2,3]
      - Consistent with stakeholder statements suggesting that C6 side-chain polymers are used most.
      - Represents a worst-case with regards to exposure
      - Polyfluorinated polyethers not detected (but is also likely a limitation of the current test methods)

[1]Foreign markets, such as Asian regions, are outside the scope of this assessment

[2]Schaider LA, Balan SA, Blum A, Andrews DQ, Strynar MJ, Dickinson ME, Lunderberg DM, Lang JR, Peaslee GF. 2017b. Supporting Information. Fluorinated Compounds in U.S. Fast Food Packaging.

[3]Yuan G, Peng H, Huang C, Hu J. 2016. Ubiquitous Occurrence of Fluorotelomer Alcohols in Eco-Friendly Paper-Made Food-Contact Materials and Their Implication for Human Exposure. Environ Sci Technol. 50(2): 942-950.

[4]DEPA. 2015. Short-chain Polyfluoroalkyl Substances (PFAS). A literature review on information on human health effects and environmental fate and effect aspects of short-chain PFAS. Danish Ministry of the Environment. Environmental Protection Agency.

Base-Case Justification contd.

- Why this specific methacrylate polymer?
  - C6 Side-chain polyfluorinated
  - Approved for use in a wide range of food types and conditions
  - Approved for use prior to or after sheet formation
  - Cationic polymer
    - Generally problematic from the perspective of aquatic toxicity
  - Published data are available for this substance, its monomers, and known degradation products.
    - Substance identity
    - Persistence
    - Production process
    - Disposal
    - Hazard

Base-Case: Next Steps

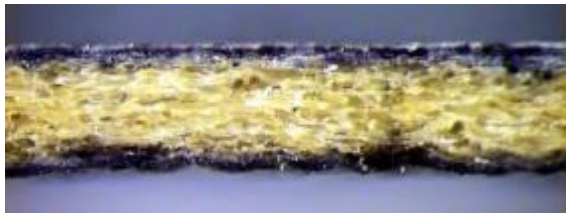
- Moving forward on the base-case
  - Stakeholder comments and feedback
  - Initiate assessment for hazard, performance, exposure, and cost analysis

Candidate Alternatives (In progress)

Packaging Products and Chemicals

Typical Process Treatments for Paper

- Dry end (surface) coatings
  - Size press application
  - Extruded
- Wet end
  - Application to pulp
- Mechanical densification (non-chemical)



Surface sized paper

Photo credit: https://www.theseus.fi/bitstream/handle/10024/117763/Savage_Nicholas.pdf?sequence=2&isAllowed=y

- Considering 3 levels function for alternatives (Tickner et al. 2014)
  1. Chemical function (change in coating)
  2. End use function (change in material)
  3. Function as a service (change in system)

Tickner J; Schifano J; Blake A; Rudisill C; Mulvihill M. (2014) *Advancing safer alternatives through functional substitution*. Environ Sci Technol 49:742-749

Coating Alternatives (not comprehensive)

- Bio-based
  - Plastics
    - Polylactic acid (PLA)
  - Lignin and glycerol-based
  - Waxes
    - Beeswax
- Clay
- Plastics
  - Acrylics
  - Polyvinyl alcohols
  - Polyethylene terephthalate
- Proprietary

More detailed overview of potential alternatives:
Oregon DEQ Roadmap
Figures 4a-c:
https://www.oregon.gov/deq/FilterDocs/toxicsRoadmap.pdf

Base Material Alternatives

- Bio-based materials
  - Plant fiber
    - e.g. Bamboo, palm leaf, sugarcane, nanocellulose, cotton
  - Plastics
    - PLA
- Plastics
  - Polystyrene
  - High density polyethylene
  - Polyethylene terephthalate
  - Polypropylene
- Metal
  - Aluminum

System Alternatives

- Re-usable Foodware
  - Plastics
  - Washable food wraps

  - Sources available that discuss related costs for transition:
    - Wie, S et al. A Decision Tree for Selecting the Most Cost-Effective Waste Disposal Strategy in Foodservice Operations. *J. Am Diet Assoc.* 2003; 103: 475-482.
    - Clean Water Action. Rethink Disposable. http://www.rethinkdisposable.org/

Alternatives: Next Steps

- Finding a reasonable approach given the timeframe and budget
- Product Scoping
  - Scope by product sector?
    - ex. Institutional vs quick-service restaurants
  - Scope by end product?
    - ex. Paper wrappers, molded fibers, liners, bags, trays
  - Other?
- Adjust assessment approach based on alternative type?
- **Key item for stakeholder input**
  - Information on substance identity and formulation
  - Scoping
  - Any input to inform the assessment

AA Modules and Data Needs
(Work in progress)

Hazard Assessment

- IC2 Guideline Level 2
- GreenScreen® or equivalent methodology
- Polymers dominate alternatives
- Difficult substances to evaluate:
  - Data poor
  - ID's poorly described in the public domain

Public domain →

Critical Data Needs:

- **CAS Number/Name**
- $MW_{avg,}$ MW_n
- %MW <500
- %MW <1,000
- Monomer ratios

} Proprietary

Need to Consider the Formula

- Most current GreenScreen on Polymers v1.3:

All constituents intentionally added or impurities ≥100 ppm in formula:

Chemical	CAS	% by Weight	Benchmark	Benchmark by %
Polymer	XXX-XX-X	95.0	U	95.0
Functional Additive	XXX-XX-X	0.00001	2	3.0
Processing Aid	XXX-XX-X	1.4	2	
Processing Aid	XXX-XX-X	1.6	2	
Monomer	XXX-XX-X	2.0	1	2.0

Proprietary

https://www.greenscreenchemicals.org/images/ee_images/uploads/resources/GreenScreen_Version_1.4_Technical_Webinar_02282018_final.pdf

Exposure Assessment

- IC2 Level 1 Basic Comparative Exposure Assessment
- Qualitative approach, not quantitative
- Focusing on p-chem properties and other high-level indicators:
  - Exposure pathways, monitoring studies, manufacturing considerations, and lifecycle thinking
- Greggs W. et al. Qualitative Approach to Comparative Exposure in Alternatives Assessment. *IEAM* 2018: 1-15. https://setac.onlinelibrary.wiley.com/doi/epdf/10.1002/ieam.4070
  - Approach that directly addresses NAS, 2014 recommendations on incorporating exposure into AA

Performance Assessment

- IC2 Level 1 Basic Performance Evaluation
- “Identifies a few, very basic questions about whether the alternative performs the required function in the product.”
- Initial research on testing methods and approaches, will be incorporated into approach
- Testing methods may not be suitable for all substances
- How do we verify performance level without relying solely on company marketing information?
- **Proprietary information**

Critical Stakeholder Information

Cost & Availability

- IC2 Level 1 Basic Cost & Availability Evaluation
- "..asks a few, very basic questions about whether the alternative is being used in cost competitive products. If yes, the alternative is considered feasible."
- Useful resources:
  - **Stakeholders!!**
  - CEH purchaser's guide
  - Procuring a marketing resource
    - Freedonia. *Foodservice Single-Use Products in the US by Product and Market: https://www.freedoniagroup.com/industry-study/foodservice-single-use-products-in-the-us-by-product-and-market-3543.htm*
    - *Costly, but will be helpful in supporting the assessment*

Summary & Conclusions

- Stakeholder engagement
  - Initial stakeholders recruited and contacted
  - Recruitment is ongoing and open to anyone of interest
  - Identified stakeholder groups needing representation
  - Move on to next round of discussions
- Base-case proposed
  - Stakeholder feedback needed
- Initial candidate alternatives identified
- Next steps:
  - Continue ongoing internal research
  - Initiate next round of stakeholder engagement, focusing on base-case, product scope, and
  - Finalize alternatives and product scope
  - Finalize approaches for exposure, performance, cost & availability modules

Thank you!

- Cathy Rudisill – Rudisill@srcinc.com; 315-452-8453
- Questions?