



Accelerating commercialization of novel bio-based materials and improving safety by design through public private partnerships

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ENVIRONMENTAL HEALTH AND SAFETY EHS ROADMAP – CELLULOSE NANOMATERIALS EXPOSURE SCENARIOS FOR LIFE-CYCLE RISK ASSESSMENT (LCRA)

Assess occupational, consumer, environmental impacts [ROADMAP]



Develop/adopt standardized EHS methods



Create a data set demonstrating safety



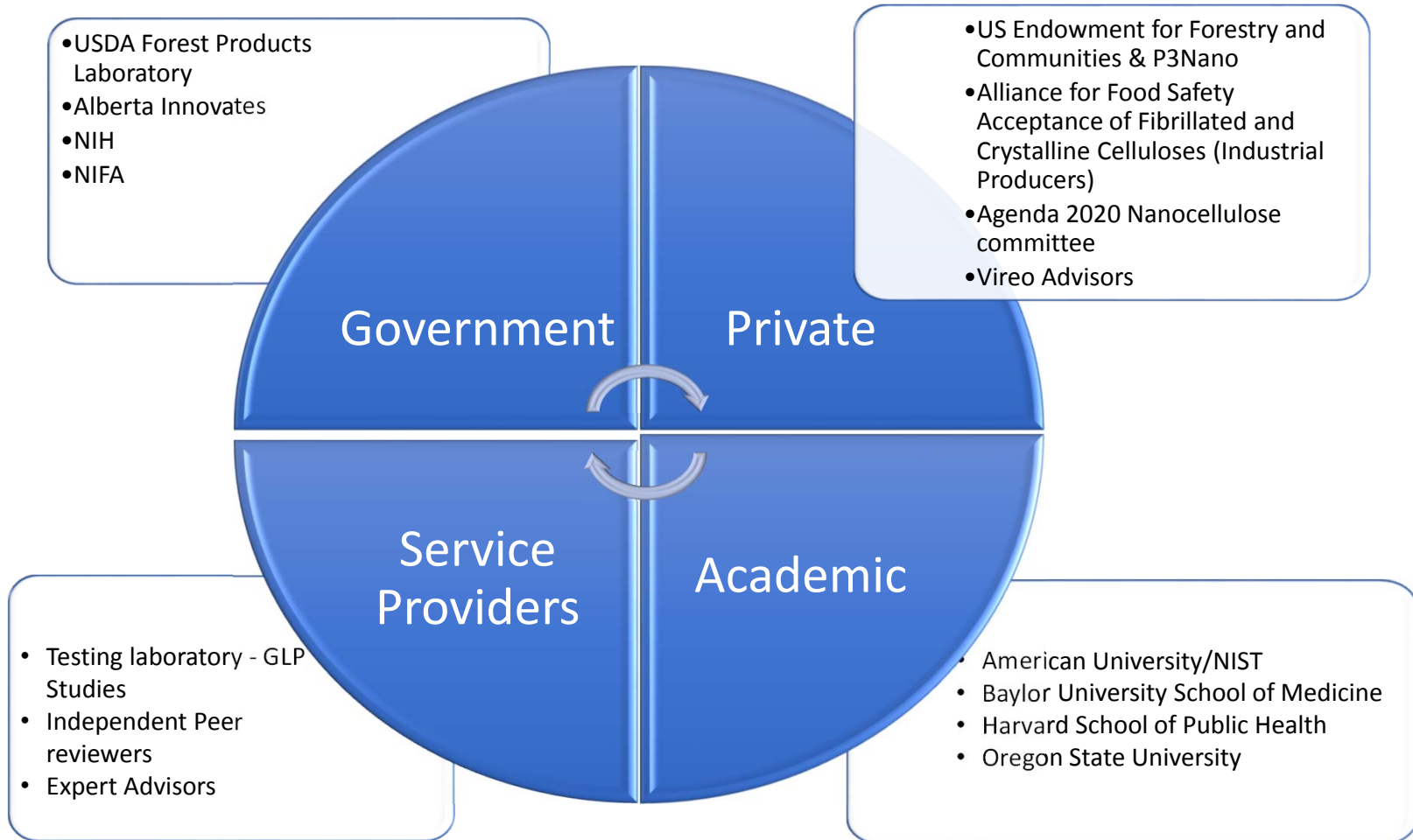
Develop a testing strategy for next-gen materials



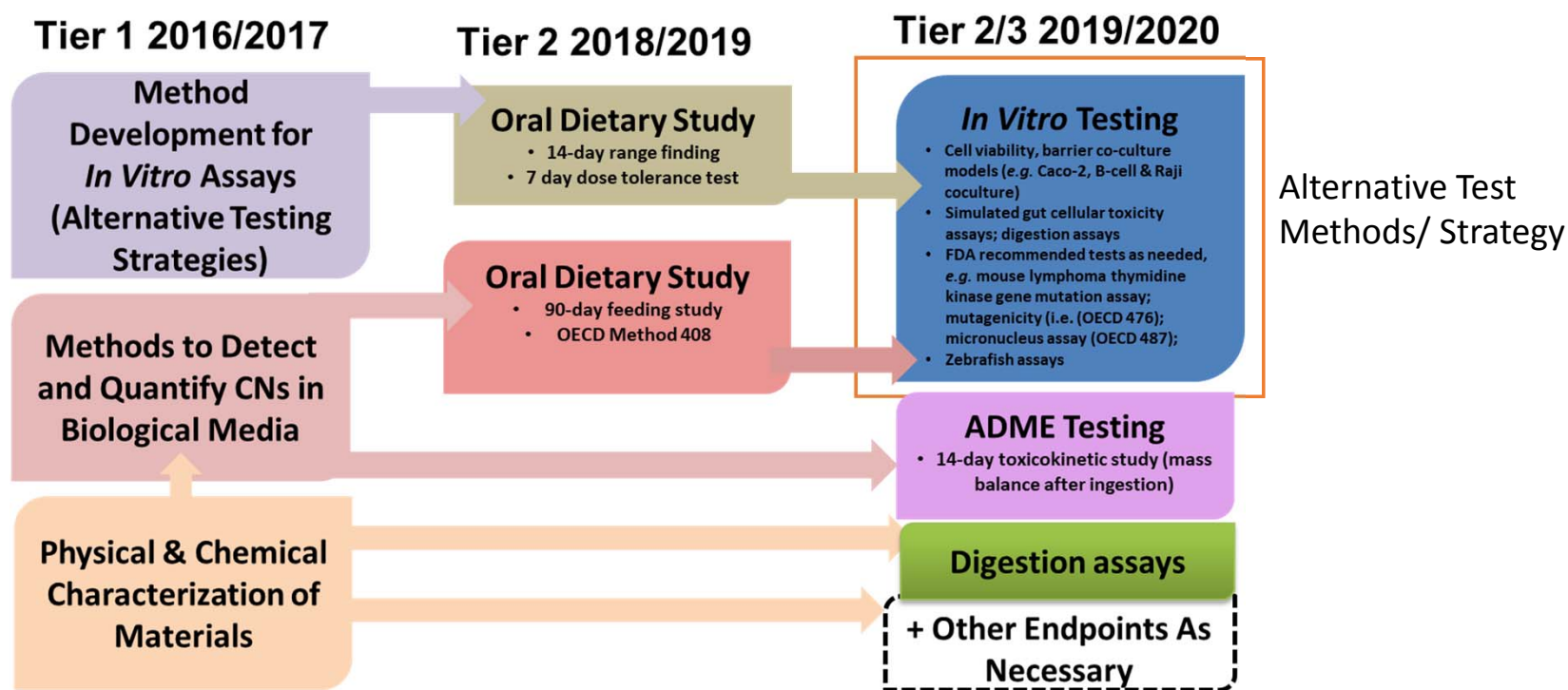
Shatkin, J.A. and B. Kim. (2015) Cellulose Nanomaterials: Life Cycle Risk Assessment, and Environmental Health and Safety Roadmap

Environmental Science: Nano, (2):477-499. DOI: 10.1039/C5EN00059A

PUBLIC/PRIVATE PARTNERSHIP MODEL



FOOD SAFETY TESTING STRATEGY



FOOD SAFETY STUDY MATERIALS

ANIMAL TESTS

Novel forms

- UMaine CNF (cake)
- Hardwood CNC (powder)

PCHEM/ALTERNATIVE TESTS

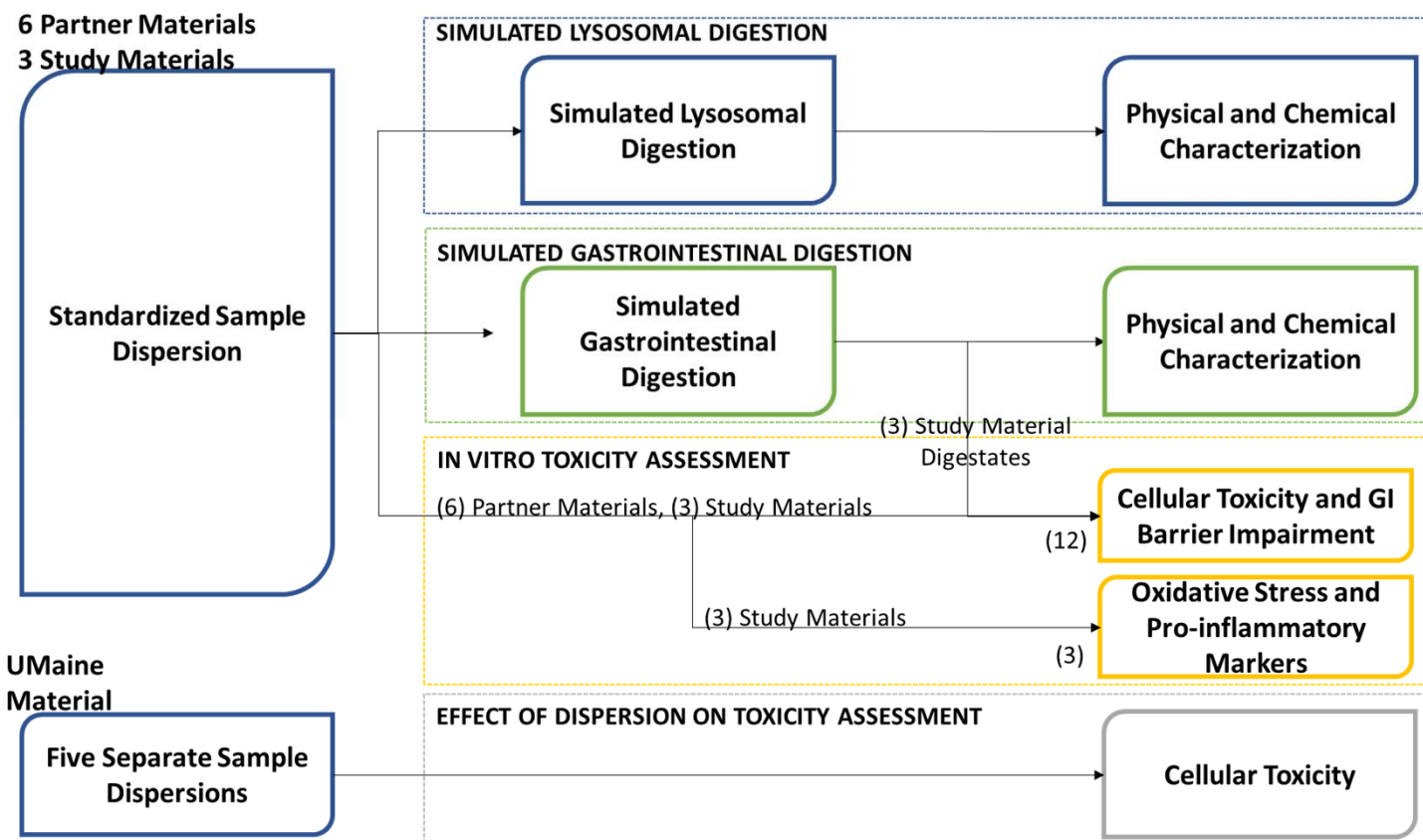
- UMaine CNF
- Hardwood CNC
- 6 industrial CMF/CNF
- Conventional cellulose

Conventional/GRAS

- Commercial Cellulose (SolkaFloc)

Testing strategy allows
“read across” from
animal to alternative
testing

ALTERNATIVE TESTING STRATEGY



CELLULOSE NANOMATERIALS FOOD SAFETY STUDY

Animal Studies		Cell-based Studies	
Study	Result	Endpoint	Result
Acute Oral Rat Toxicity			
7-day Oral Toxicity (OECD TG 407)	NO ADVERSE EFFECTS	Cytotoxicity In Co-Culture Model	NO ADVERSE EFFECTS
14-day Oral Toxicity (OECD TG 407)	NO ADVERSE EFFECTS	Barrier Integrity Over 7-days	NO ADVERSE EFFECTS
Sub-chronic Oral Rat Toxicity		Oxidative Stress	NO ADVERSE EFFECTS
90-day Oral Toxicity (OECD TG 408)	NO ADVERSE EFFECTS	Inflammation	NO ADVERSE EFFECTS

- **Fibrillar/Crystalline Celluloses behave similarly to conventional cellulose and raises no safety concerns when used as a food ingredient at 4% of diet;**
- **Seek GRAS status with FDA allows use in food and food contact applications.**
- **CNs behave similarly to conventional cellulose; supporting evidence for use in food;**
- **Baseline measurements for examining potential impact of future functionalizations on toxicity.**

CN SAFETY STUDIES

Human Health

Endpoint	Result
Inhalation	
Acute Inhalation	
Chronic Inhalation	
Oral	
Acute Oral Toxicity	
Repeated Dose (Acute)	
Repeated Dose (Sub-chronic)	
Dermal	
Skin Irritation/Corrosion	
Skin Sensitization	
Eye Irritation	
Genotoxicity	
Bacterial Assay	
In vitro Genotoxicity	
In vivo Genotoxicity	

Environment

Endpoint	Result
Biodegradation	
Aerobic degradation	
Anaerobic degradation	
Environmental Toxicity	
Aquatic Plants	
Bacteria	
Aquatic Invertebrates (Acute, Chronic)	
Fish (Acute, Chronic)	



No adverse effects found;
standardized testing



No adverse effects found in initial studies;
additional testing required



No data

NEXT STEPS

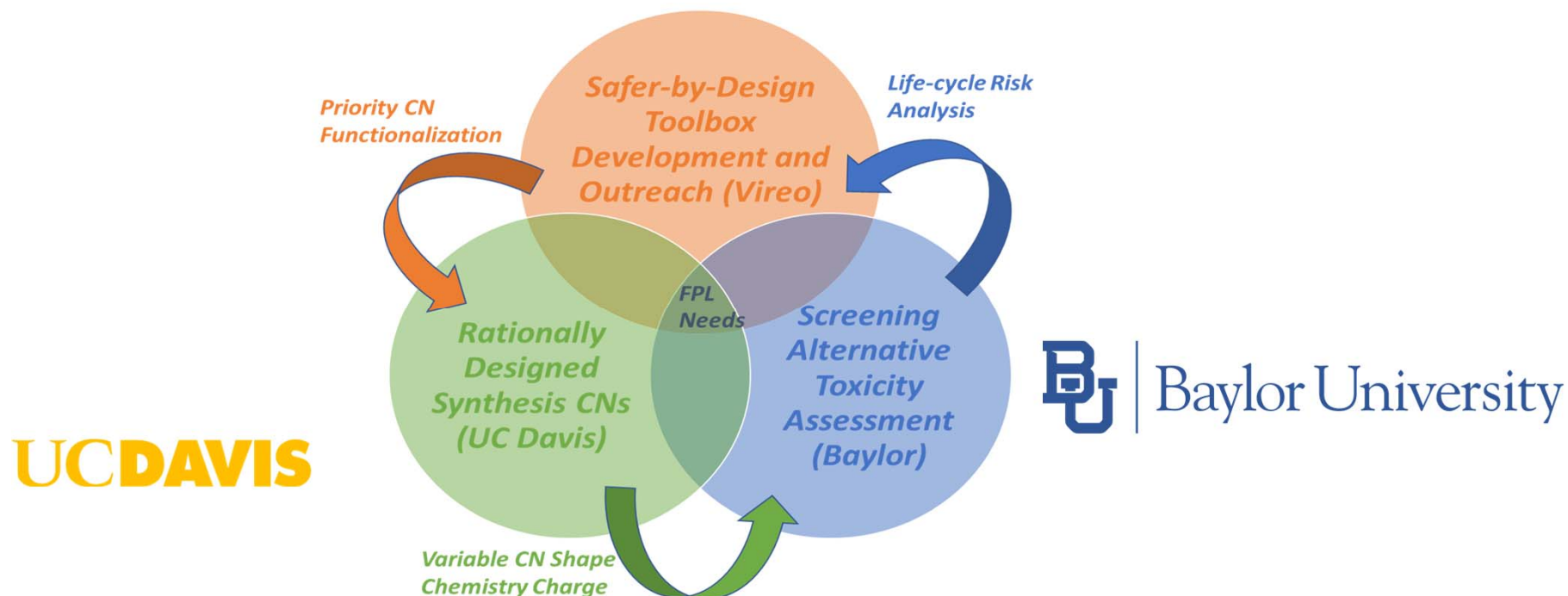
1. Safer-By-Design Manufacturing Toolbox

- *Survey of surface modifications*
- *Select target functionalizations*
- Methods development
- Alternative testing strategy
- Read across to toxicity data for unmodified materials
- Develop data sets/share
- Standardize methods for next generation

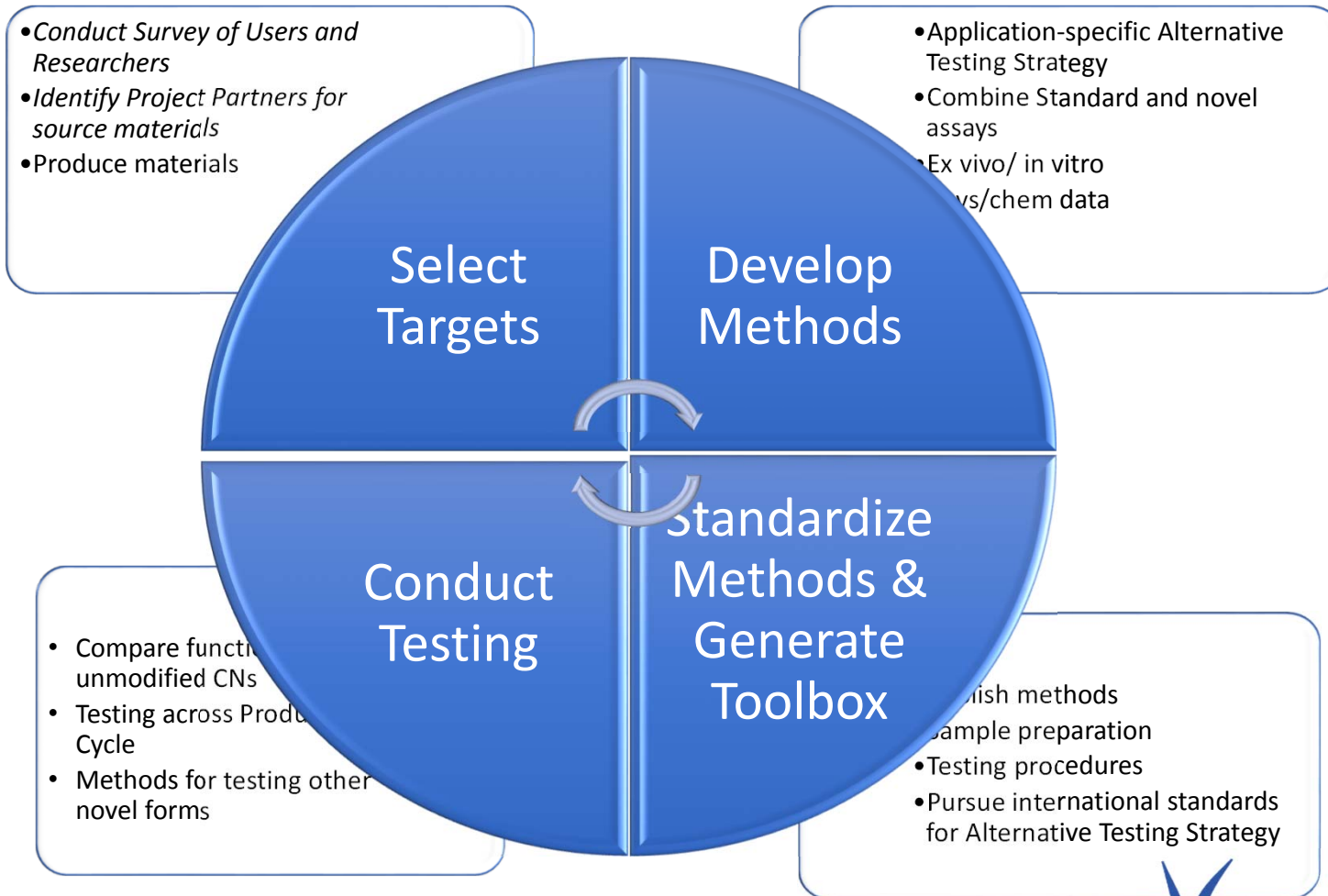


INTERDISCIPLINARY APPROACH TO SAFER BY DESIGN TOOLBOX

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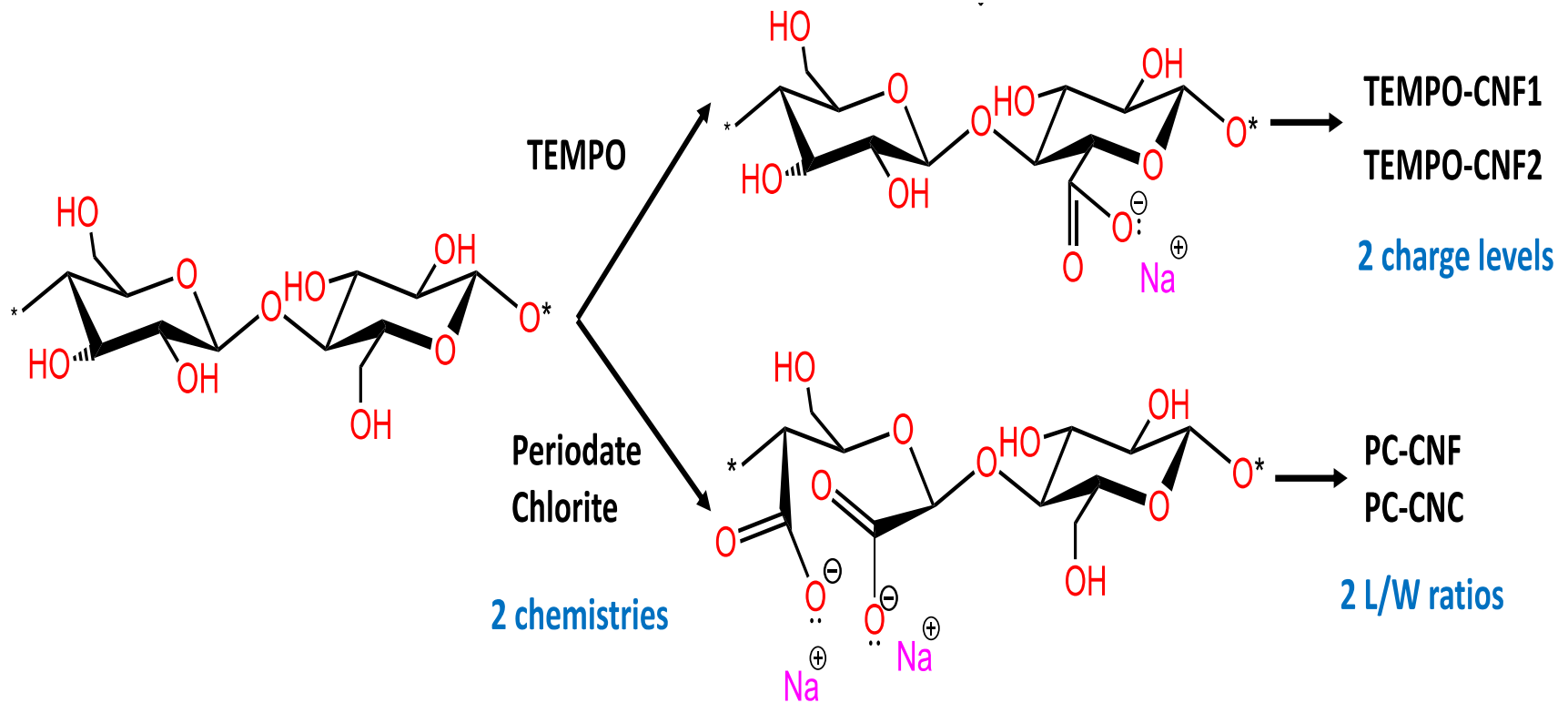
SAFER MANUFACTURING TOOLBOX STRATEGY



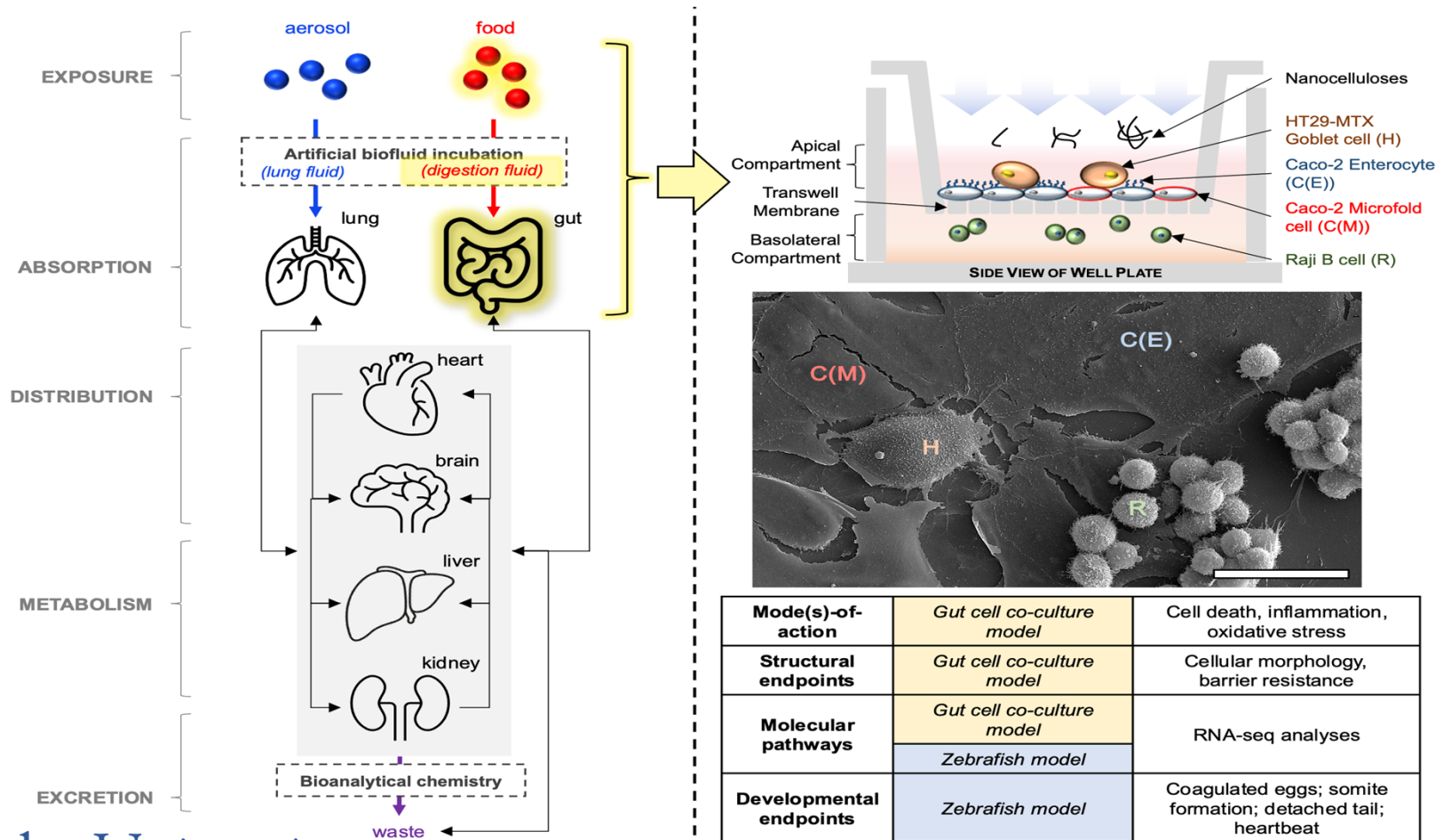
2020 VIREO SURVEY – WHICH FUNCTIONALIZED FORMS LIKELY TO BE COMMERCIAL IN 3 YEARS?

Commercial potential within 3 years								
Materials	24	%	Functional groups	30	%	Applications	23	%
CNF	11	46%	TEMPO oxidized	8	27%	Packaging (barrier, film)	8	35%
CNC	11	46%	Carboxylated	6	20%	Polymer and Composites	6	26%
Hairy cellulose	1	4%	Alkylated	4	13%	Metal ion absorbant	3	13%
Chitin	1	4%	Cationic	3	10%	Coatings	2	9%
			Sulfated	3	10%	Similar to cationic starch	2	9%
			Carboxymethylated	2	7%	Drilling mud	1	4%
			Neutral hydroxyl	1	3%	Cosmetics	1	4%
			PEG	1	3%			
			Phosphorylated	1	3%			
			CN-NCO or CN-R-C=	1	3%			

Surface Functionalization Variables



Safer Manufacturing Alternative Testing Strategy



PUBLICATIONS TO DATE

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AFSAC partners

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Dr. Christie Sayes and the team at Baylor

Jeff Gilman, Jeremiah Woodcock, NIST

Douglas Fox, American University

The Vireo Team

THE TEAM AT VIREO



Dr. Jo Anne Shatkin is an expert in novel product safety and environmental and health policy issues, with over 20 years experience leading projects in risk analysis, safety and regulatory policy work including numerous publications.

She is founder and president of Vireo Advisors in Boston, Massachusetts.



Dr. James D. Ede is a toxicologist experienced in testing strategies for novel materials, including molecular, biochemical and cellular techniques, and is experienced in life cycle risk assessment.



Dr. Kimberly J. Ong is a biologist and environmental scientist. Dr. Ong is an expert in developing protocols specific for novel material testing to improve reliability for risk and exposure assessment and is experienced in regulatory analysis for novel products.



Dr. Shaun Clancy is a chemist with over 30 years experience in the chemicals industry, directing programs in health, safety, and regulatory affairs in major corporations. He is ANSI Co-Chair and participates in ISO TC229 and other international safety committees.



Patricia Hodgkinson is Vireo's research consultant with a background in Food Policy law.



Leslie Hockman has industry experience working for a commercial manufacturer of cellulose nanomaterials and is Vireo's administrator.



Jerry Liu and Megan Roberts are interns and Ph.D. Students at the University of Toronto



Ana Diges is an intern and recent UW-Madison Graduate in Materials Science and Engineering

WE'RE ALWAYS LOOKING FOR NEW TALENT TO JOIN OUR TEAM!!

 **Vireo Advisors, LLC**

THANK YOU!

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