

Ultra-Processed Foods and Health Outcomes – Time to Move Beyond Association to Causation

Andrew Bremer, MD, MAS, PhD
Director, Office of Nutrition Research

Concept Clearance: New Common Fund Program

Title: Ultra-Processed Foods (UPFs) and Health Outcomes – Time to Move Beyond Association to Causation

Objectives:

- Support robust multidisciplinary research across the lifespan on mechanisms by which UPFs affect chronic disease
- Provide the evidence base needed to inform dietary guidance, policies, and programs that improve health and promote disease prevention

Funds and Anticipated Number of Awards: \$57-63M per year for 20 meritorious awards (contingent upon funding availability)

Program Co-Chairs: ONR (Bremer), NIDDK (Rodgers), NCCIH (Langevin)

Program Duration: 5 years

Council Action: Vote for concept approval for the UPF research program

Background and Rationale

- Diet-related chronic diseases are the leading cause of death worldwide, with **over one million deaths** in the U.S. per year (>15,000 deaths/week). They contribute to over \$1.1T in direct health care costs and lost productivity per year.
- Epidemiological studies suggest an association between an UPF-rich diet and increased risks for adverse health outcomes. UPFs constitute ~**60 %** of the daily caloric intake in the U.S. (~**66 %** of the daily caloric intake in children) and ~**70 %** of the U.S. food supply.
- UPFs are most often defined by the Nova classification system that assigns food to one of four groups based on the extent and purpose of industrial processing (and does **NOT** consider nutritional profile).
- The 2025 Dietary Guidelines Advisory Committee found limited evidence on the health impact of UPFs across the lifespan and called for further research to examine the effects of UPF dietary patterns and their effects on health outcomes.

Nova groups

Examples

1) Unprocessed or Minimally Processed Foods

Edible parts of plants and animals after separation from nature or preserved by minimal processes (no substances added)



2) Processed Culinary Ingredients

Substances extracted from foods or nature and used to prepare, cook and season Group 1 foods



3) Processed Foods

Group 1 foods modified with the addition of Group 2 ingredients aiming food preservation and/or enhancement of its sensory qualities

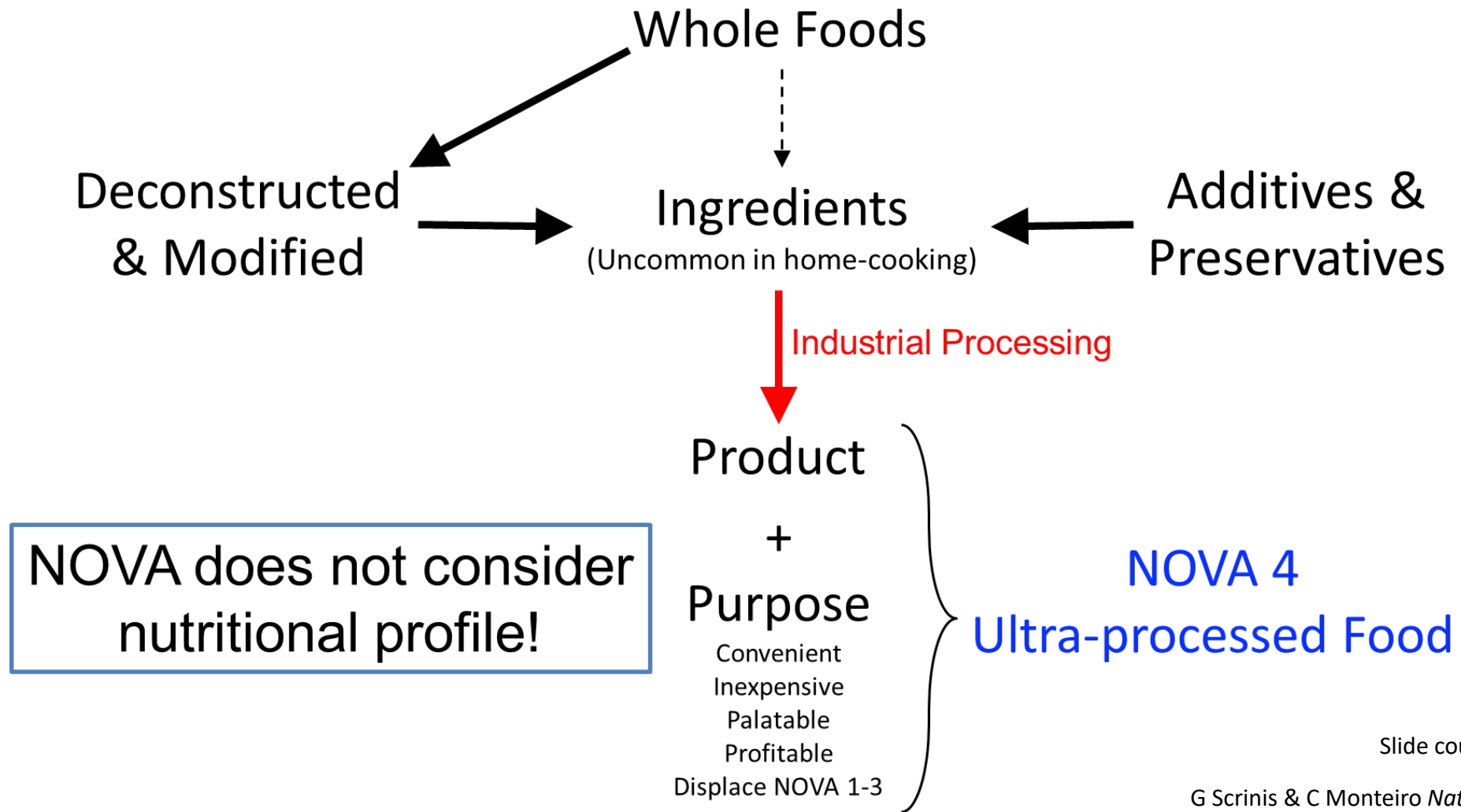


4) Ultra-processed Foods

Formulations of several ingredients that include original or chemically modified food substances obtained with the fractioning of whole foods and additives used to make the final product palatable or hyper-palatable. The aim is to make convenient, tasteful and low-cost products liable to replace all other Nova food groups



Background and Rationale (*cont.*)



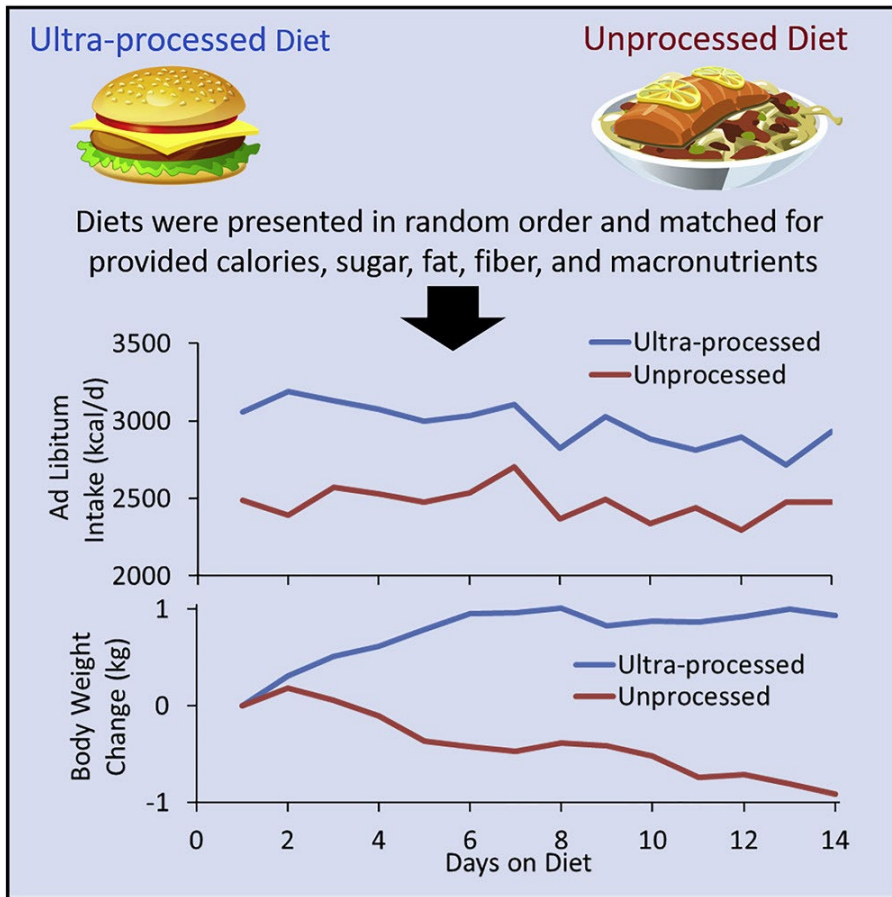
Slide courtesy of Kevin Hall, PhD

G Scrinis & C Monteiro *Nat. Food* 3, 671–673 (2022)

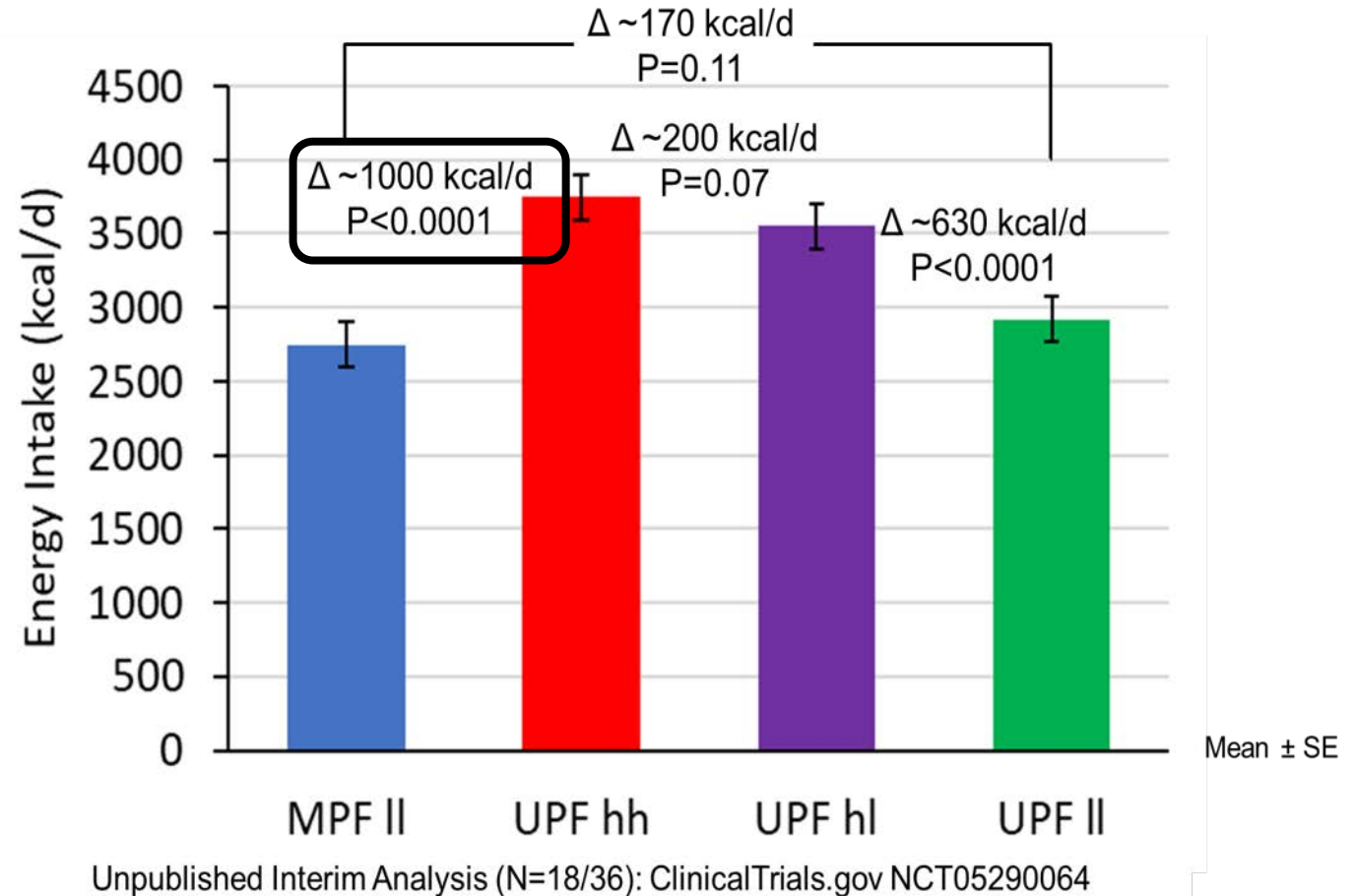
Background and Rationale III

$\Delta EI = 508 \pm 106$ kcal/d; $P=0.0001$

$\Delta \text{Weight} = 0.9 \pm 0.3$ kg; $P<0.001$

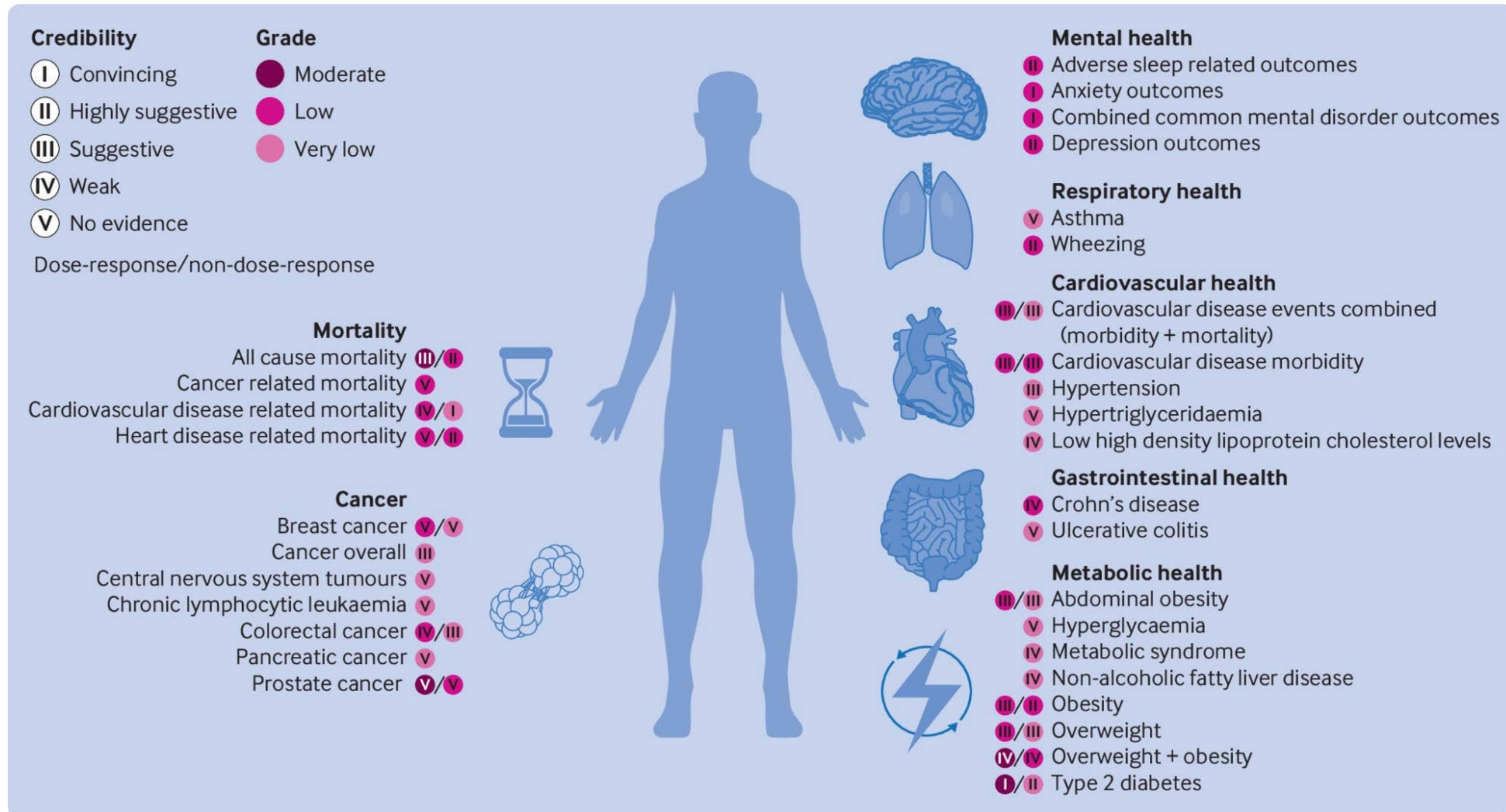


Hall KD et al. Cell Metab 2019;30:1-11.



Hall KD et al. Unpublished data.

Background and Rationale IV



Lane MM et al. BMJ 2024;384:bmj-2023-077310



Public Health Researchers Say UPFs are Bad News! (even after adjusting for nutritional profile)

“The observational data shows that there’s a pretty clear association between ultra-processed food and a lot of bad health outcomes. Before FDA can do anything with that, we’re going to need a lot more research.”

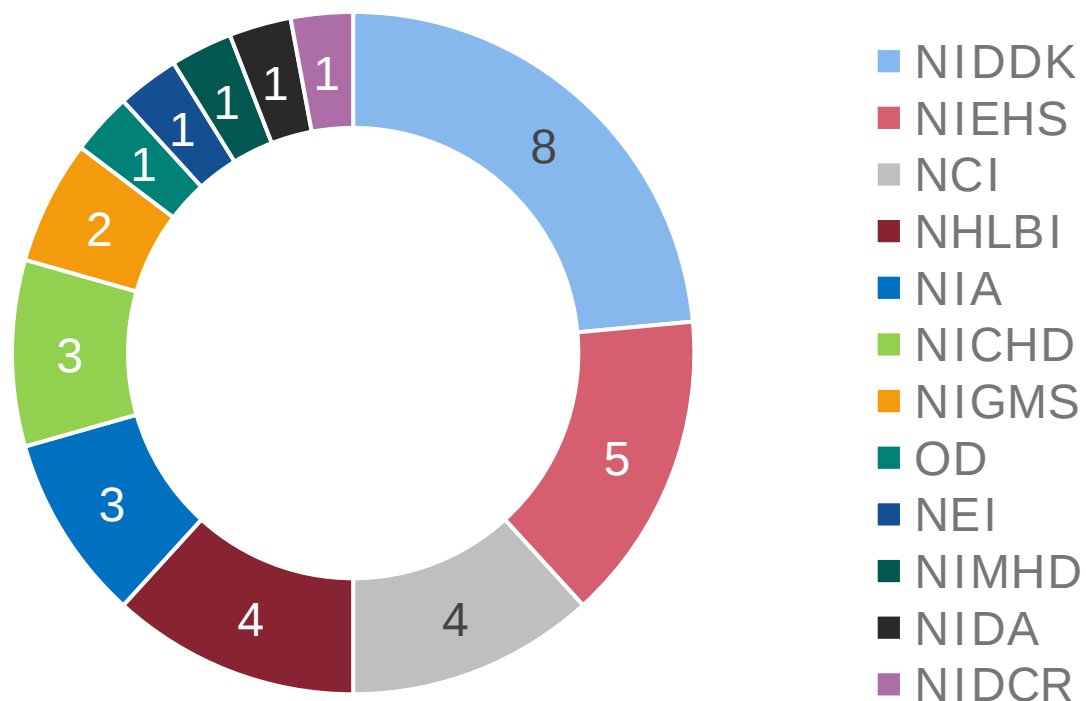
FDA Commissioner Robert Califf, Jan 31, 2024

Why a UPF Common Fund Program?

- Urgent national interest for expansive and comprehensive UPF-related research
- Epidemiological studies have identified associations between UPF consumption and poor health outcomes
- Need to identify and validate new methods, measures, and tools to better understand the biological and behavioral mechanisms by which UPFs impact health
- Need for research to guide reformulation efforts in the food system and to inform programs, practices, and policies
- Need for intervention research to help mitigate current trends in unhealthy UPF consumption and guide future dietary recommendations
- UPF research is relevant to myriad of NIH Institutes/Centers/Offices; there is an existing NIH-wide UPF Working Group to help guide the Common Fund Program

Planning Activities Conducted

NIH UPF Portfolio Analysis Summary



*Portfolio Analysis, FY19-23:

- Extramural and intramural projects
- Two NIH tools: *iSearch* and QVR
- Manually coded projects for health outcomes and study designs
- 12 NIH Institutes/Centers/Offices
- 34 projects

Note: an updated portfolio analysis is underway

*Portfolio analysis provided by:
Libby Walton (ODP), Brama Kowtha (ODP), and Nick Jury (ONR)

Additional Synergies

- **NIH-FDA**

- o This proposed Common Fund UPF program will support research that will bolster the efforts of the new [NIH-FDA Nutrition Regulatory Science Program](#) to answer questions such as:
 - How and why UPFs impact people's health?
 - How might certain food additives and preservatives affect metabolic health and possibly contribute to chronic disease?

- **HHS, FDA, and USDA**

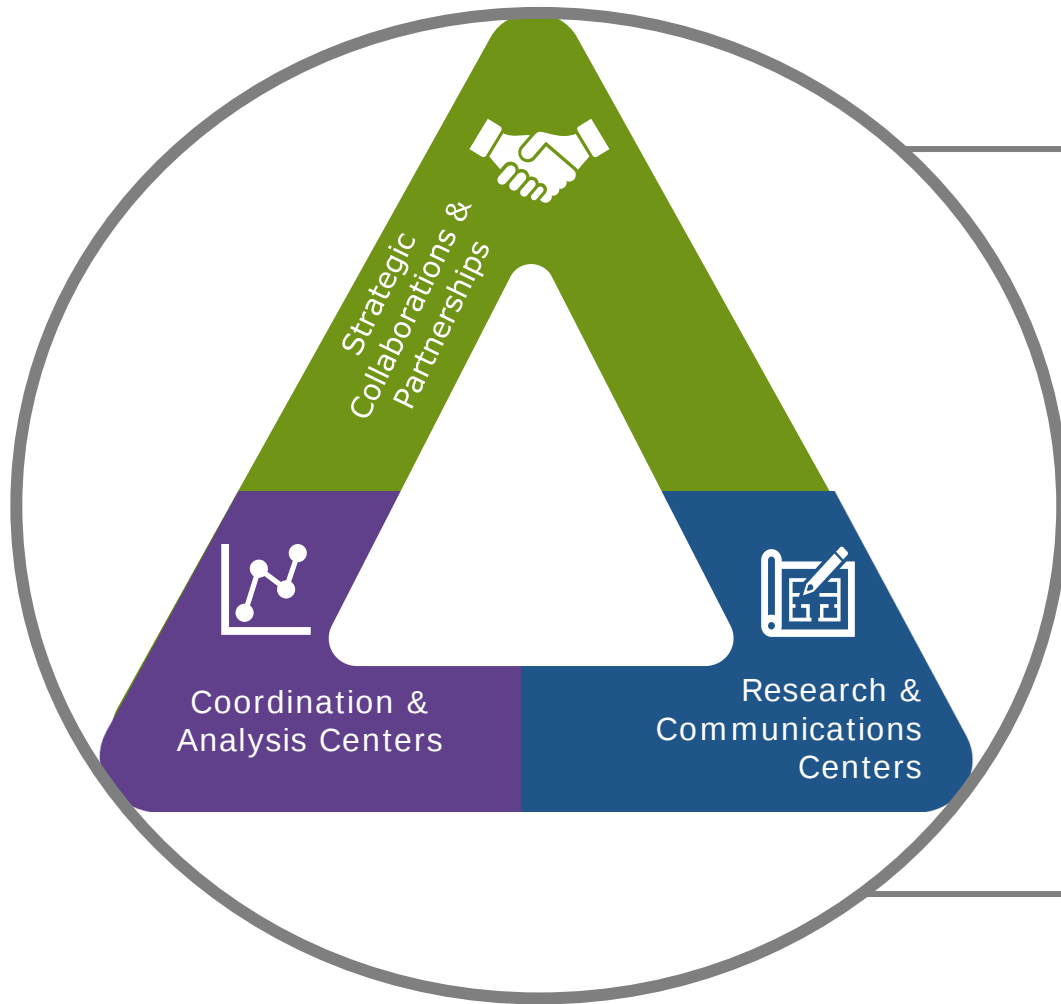
- o [Request for Information](#): Interagency request for data and information to help develop a uniform definition of UPF for human food products in the U.S. food supply. Comments are due by September 23, 2025.

Overarching Program Goals

This program will:

- Support robust multidisciplinary research across the lifespan on the mechanisms by which ultra-processed food (UPF) affects chronic disease
- Provide the evidence base needed to inform dietary guidance, policies, and programs that **improve health and promote disease prevention**

UPF Program Components



Strategic Collaborations & Partnerships

Support opportunities for collaborative partnerships with food scientists and other relevant stakeholders to transform the food supply in the U.S. to optimize effective reformulation strategies to create healthier UPF options.

Research & Communications Centers

Mechanistic: Support research to understand the metabolic, biological, and behavioral mechanisms by which components and combinations of UPF exposure may impact health outcomes across the lifespan.

Intervention: Leverage existing and new data to inform the design of intervention studies, using policy, systems, and environmental approaches and behavioral strategies in various populations to reduce the consumption of UPFs associated with adverse health outcomes/chronic diseases.

Translational Communications: Translate findings from first 3 years of the program into solution-oriented and actionable public health strategies.

Coordination & Analysis Centers

Nutrient Database & Dietary Analysis: Collect/integrate UPF ingredients and level of processing from existing databases to develop a new UPF database for consumers/healthcare professionals/researchers and develop novel tools to evaluate UPF intake (including modification of existing tools) to improve rigor/reproducibility of measurements/studies.

Data & Study Coordination: Coordinate/integrate activities of all the Centers, the Nutrient Database, and the Strategic Collaborations and Partnerships.

Proposed UPF CF Program Budget*

Initiatives	Lead IC(s)	FY2027	FY2028	FY2029	FY2030	FY2031	Total
NIH RMS/Program Management	WG/ICOs	\$1,000	\$1,000	\$1,000	\$1,000	\$1,000	\$5,000
Coordination and Analysis Centers	TBD	\$14,000	\$14,000	\$14,000	\$14,000	\$14,000	\$70,000
Research and Communication Centers	TBD	\$32,000	\$33,000	\$34,000	\$38,000	\$38,000	\$175,000
Strategic Collaborations & Partnerships	TBD	\$10,000	\$10,000	\$10,000	\$10,000	\$10,000	\$50,000
Totals	—	\$57,000	\$58,000	\$59,000	\$63,000	\$63,000	\$300,000

(Numbers are in thousands of dollars)

* And availability of funds

Alignment with Common Fund Criteria



Transformative: Inform the development of tools to help consumers make healthy choices, contribute towards disease prevention, and improve public health.



Catalytic: Influence dietary guidance in clinical and community practice, consumer behavior, and food policies. Moreover, inform industry on best practices towards reformulation of UPF to create healthier options.



Goal-Driven: Improve nutrition policies in federal programs, update nutrition facts and ingredient labels, and inform restrictions on UPF marketing to children and populations experiencing health disparities.



Synergistic: Identify biomarkers associated with UPF consumption, targeted experimental studies to understand the effects of various additives, flavor enhancers, preservatives with health outcomes, SDOH, and more.



Novel: Inform food engineering/processing techniques/technologies to create healthier palatable food options.

Anticipated Impact

Deliverables

- A better understanding of the mechanisms through which UPF consumption affects risks for chronic diseases
- Biomarkers for UPF consumption
- Publicly available processed food database module and tools to determine the level of processing and UPF ingredients
- Data to inform interventions specific to UPF consumption and prevention of diseases
- Data to inform FDA regulatory decisions on UPFs, UPF ingredients, and manufacturing processes
- Materials to educate the public and health care professionals

NIH UPF WG & Common Fund UPF Program Co-Chairs

Office of Nutrition Research

Andrew Bremer, Co-Chair

Nicholas Jury, Coordinator

Samantha Adas

Office of Disease Prevention

Bramaramba Kowtha, Coordinator

David Murray

Office of Strategic Coordination

Maurice Davis

Salsawi Kebede

Malgorzata Ochocinska

LeShawndra Price

Jason Shockey

Natalie Vineyard

National Center for Advancing Translational Sciences

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Adam Hartman

National Institute of Nursing Research

Lauren Oliveira Hashiguchi

Sylvia Long

Nadra Tyus

Office of Dietary Supplements

Madison Haise

Edwina Wambogo

Council Action:

Vote for Approval of the Concept:

Ultra-Processed Foods and Health Outcomes – Time to Move Beyond Association to Causation



commonfund.nih.gov



National Institutes of Health
Office of Strategic Coordination – The Common Fund