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Dockets Management Staff (HFA-305) U.S. Food and Drug Administration 5630 Fishers Lane, Rm. 1061 Rockville, MD 20852

Comment on Ultra-Processed Foods; Request for Information (Docket No. FDA-2025-N-1793)

The University of California (UC) Research Consortium on Food, Beverages and Health respectfully submits the following comment to the U.S. Food and Drug Administration, U.S. Department of Agriculture and U.S. Department of Health and Human Services on the topic of ultra-processed foods. We strongly support the federal effort to develop a uniform definition of 'ultra-processed foods' for policy and regulatory purposes.

Formed in 2018, the Consortium's primary focus is work to decrease consumption of sugary beverages and to increase consumption of healthy alternatives such as water, throughout the UC system as well as at state and national levels. Our ad hoc group, consisting of faculty across the UC campuses who are nationally prominent in diverse disciplines, conducts and disseminates cutting edge research in areas relevant to the discussion on ultra-processed foods.

This letter represents a consensus comment garnered from the collective experience and wisdom of our university faculty members, which we believe will assist in informing the dialogue on defining ultra-processed foods (UPFs). We add a bibliography of notable peer-reviewed papers on the subject matter.

- 1. It is important to initiate processes necessary to take prompt regulatory action on UPFs, that are the dominant source of harmful nutrient profiles in the U.S. diet.
- 2. The development of a regulatory definition of ultra-processed food is an essential first step to create policies that will reduce the impact of harmful UPFs on the dietary quality and health of the population. At the same time, the science on UPFs is still emerging and industry has a track record of reformulating products, so any definition should have the flexibility to maintain alignment with evolving scientific evidence and to capture new industrial formulations.
- 3. The risk of UPFs to human health is multifaceted. Ultra-processed food and its risk to human health cannot be defined or explained solely by the presence of a handful

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Submitted by: University of California Research Consortium on Food, Beverages and Health

Contact: Christina Hecht, ceahecht@ucanr.edu

of ingredients -- as some states have tried to do. Rather, we recommend that the definition of UPFs must include each of 4 elements that evidence finds are associated with serious risk to human health. We begin with two characteristics that can be inadvertently ignored when considering industrial food manufacturing.

3a. PROCESSING. The amount and the kind of food processing must be considered in defining UPFs. Industrial methods typically used for ultra-processed foods include the use of very high heat and physical alteration of component ingredients. These can alter the food matrix in harmful ways, for example, by creating hydrogenated fats or by methods such as extrusion that can impact metabolism.

- 3b. FOOD PACKAGING. Food packaging should be included as a potential additional characteristic of UPFs. Chemicals and toxic contaminants used in the packaging have been identified that degrade and leach into packaged foods. For example, the plastics used in high-speed asceptic packaging and applied modified atmospheric packaging migrate into food, causing human exposures to microplastics and to the chemicals (e.g., the Per- and Polyfluoroalkyl Substances (PFAS) family of "forever chemicals") used in plastics.
- 3c. INGREDIENTS. Any definition of UPFs must allow for the wide range of industrial ingredients used in the food industry, including new compounds yet to be developed and/or used. Ingredient lists include all manner of chemicals including dyes, flavorants, artificial sweeteners, preservatives, stabilizers, foaming agents, caking agents, emulsifiers, and genetically-modified organisms, some with identified risks to health. The NOVA framework, commonly used to define UPFs, provides a strategy for classifying foods, including those with industrial ingredients, but does not fully address the other three additional characteristics of UPFs.
- 3d. NUTRIENT COMPOSITION. The nutrient composition of foods has a clear impact on health. UPFs are frequently high in energy density, sodium, added sugars, and/or saturated fat. Nutrient composition should also account for what is *missing* from ultra-processed foods: the industrial refining of grains and proteins strips beneficial fiber and micronutrients from the food matrix, depleting the dietary quality of ultra-processed foods. The NOVA framework does not provide a strategy for dealing with the varied risks of nutrient composition. It should be noted that existing international guidelines, such as those promulgated by the Pan-American Health Organization, and FDA's definition of "healthy" provide evidence-based limits on key macronutrients in ultra-processed foods.
- 4. The policy goal of developing a science-based regulatory definition should be to identify characteristics or attributes of ultra-processed foods and beverages that the evolving scientific evidence shows are clearly linked to negative impacts on health and well-being. A new definition can serve as the basis for government

policies to help people limit these foods and beverages in their diets and promote healthier food choices.

It is the opinion of our Consortium members that a comprehensive and science-based regulatory definition for ultra-processed foods will lay the groundwork for policies that will improve diet quality and related health outcomes.

Sincerely,

The University of California Research Consortium on Beverages and Health (affiliations provided for informational purposes only):

Paul Brown, PhD

Professor of Health Economics and Public Health University of California, Merced

David A. Cleveland, PhD, MS

Research Professor Environmental Studies Program, and Department of Geography University of California, Santa Barbara

Pat Crawford, DrPH, RD

Adjunct Professor - Emerita University of California, Agriculture and Natural Resources

Jennifer Falbe, ScD, MPH

Associate Professor of Nutrition and Human Development Department of Human Ecology University of California, Davis

Christina Hecht, PhD

Senior Policy Advisor Nutrition Policy Institute University of California, Agriculture and Natural Resources

Kenneth Hecht, LLB

Director of Policy Nutrition Policy Institute University of California, Agriculture and Natural Resources

Jessica Jones-Smith, PhD, MPH

Professor

Department of Health, Society, & Behavior
Joe C. Wen School of Population & Public Health
University of California, Irvine

Cristin Kearns, DDS, MBA

Department of Preventive and Restorative Dental Sciences and Philip R. Lee Institute for Health Policy Studies

Assistant Professor, Division of Oral Epidemiology & Dental Public Health and Philip R. Lee Institute for Health Policy Studies School of Dentistry University of California, San Francisco

Robert Lustig, MD, MSL

Emeritus Professor, Department of Pediatrics University of California, San Francisco

Kristine Madsen, MD, MPH

Professor, Joint Medical Program & Public Health Nutrition School of Public Health University of California, Berkeley

Isaac Martin, PhD

Professor, Urban Studies and Planning University of California, San Diego

Mehdi Nemati, PhD

Assistant Professor of CE in Water Resource Economics and Policy School of Public Policy University of California, Riverside

Denise D. Payán, PhD, MPP

Associate Professor Department of Health, Society, & Behavior Joe C. Wen School of Population & Public Health University of California, Irvine

Francisco Ramos-Gomez, DDS, MS, MPH

Professor, Section of Pediatric Dentistry School of Dentistry University of California, Los Angeles

Laura A. Schmidt, PhD, MSW, MPH

Professor, Philip R. Lee Institute for Health Policy Studies and Department of Anthropology, History and Social Medicine School of Medicine University of California, San Francisco

Wendelin Slusser, MD, MS, FAAP

Associate Vice Provost
Semel Healthy Campus Initiative Center
University of California, Los Angeles
Clinical Professor
Schools of Medicine and Public Health
University of California, Los Angeles

Karen Sokal-Gutierrez, MD, MPH

Clinical Professor UC Berkeley-UC San Francisco Joint Medical Program UC Berkeley Interdisciplinary MPH Program School of Public Health University of California, Berkeley

Kimber L. Stanhope, PhD, MS, RD

Research Nutritional Biologist Department of Molecular Biosciences School of Veterinary Medicine University of California, Davis

Petra Wilder-Smith, DDS, DMD, PhD

Professor and Director of Dentistry Beckman Laser Institute Senior Fellow, Chao Family Comprehensive Cancer Center University of California, Irvine

Cherie Wink, BS, RDHMP

Assistant Research Specialist Beckman Laser Institute University of California, Irvine

Diana Winters, MA, PhD, JD

Deputy Director, Resnick Center for Food Law and Policy University of California, Los Angeles

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