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RE: Docket No. FDA–2022–N–2226 for “Use of Salt Substitutes to Reduce the Sodium Content in Standardized Foods.”

Submitted online at www.regulations.gov

Dear Commissioner Califf,

The Institute of Food Technologists (IFT) is thankful for the opportunity to comment on the use of salt substitutes in standardized foods. IFT is a global organization of approximately 12,000 members who are committed to advancing the science of food. We believe science is essential to ensure the global food system is equitable, sustainable, safe, and nutritious.

IFT supports the public health goal of reducing sodium consumption and the use of salt substitutes can help achieve this important goal. We commend the FDA on this proposed rule and the horizontal approach to implement these changes, which will allow greater flexibility for the use of salt substitutes in standardized foods and provide consumers with more low sodium options in the marketplace.

The FDA requested comments on “regulatory alternatives allowing the use of only specified salt substitutes, at only specified levels of substitution, for only specified purposes, for only specified products, in conjunction with only specified ancillary formulation changes, or with specified labeling requirements.” IFT would recommend not considering these regulatory alternatives as they are likely to thwart the FDA’s goal to “provide flexibility and facilitate innovation in the production of standardized foods with less sodium.” The use of salt substitutes in foods often requires additional subtle changes in food formulation to ensure safety, quality, and consumer acceptance. As most SOI include a narrow set of criteria for specific foods, further regulatory restrictions, such as the types of salt substitutes, levels of substitution and other formulation changes would likely limit innovation and minimize the introduction of lower sodium foods in the marketplace.

The FDA also requested comments on the cost of the proposed rule; specifically, potential costs of negative health effects for consumers who need to limit potassium intake (assuming

potassium salts are most frequently used as salt substitutes). IFT would recommend that any health cost considerations for potential negative health effects of potassium salts also include considerations of the positive health effects of added potassium in the diet. Approximately 70% of Americans do not achieve adequate daily intake of potassium, while the reverse is true for sodium; 79% of Americans exceed the recommended intake of sodium for Chronic Disease Risk Reduction (2,300 mg/d)¹. Low intake of potassium is considered a public health concern by the Dietary Guidelines for Americans and higher potassium intake is associated with reduced risk of cardiovascular disease and hypertension². Clinical trials with potassium substitutes have shown benefits for blood pressure reduction and individuals with higher sodium intake (i.e., most of the American population) showed larger reductions in blood pressure with greater potassium intake³. A review of clinical trials with salt substitutes also demonstrated benefits for blood pressure reduction, and included other mineral salts in addition to potassium⁴.

These reductions in blood pressure can lead to reduced risk of cardiovascular events and mortality which can substantially reduce health care costs. A recent prospective cohort study demonstrated a >20% reduction in the rate of stroke, major CV events, and total mortality when 25% of sodium chloride in the diet was replaced with potassium chloride over ~5 years⁵. A modeling study in China reported the substitution of discretionary sodium chloride with potassium chloride could prevent almost 500,000 deaths from CVD annually⁶. They also estimate around 10,000 additional deaths related to hyperkalemia in individuals with chronic kidney disease (CKD), but most CKD patients would benefit from the replacement of sodium chloride with potassium chloride. Taken together, this research suggests there would be a net benefit for health and likely health care costs if salt substitutes, including potassium salts, were incorporated into the diet. Thus, the cost savings of these benefits should be considered in addition to costs from potential negative health effects.

¹ Dietary Guidelines Advisory Committee. Scientific Report of the 2020 Dietary Guidelines Advisory Committee: Advisory Report to the Secretary of Agriculture and the Secretary of Health and Human Services. Washington, DC: (2020).

² Jackson SL, Cogswell ME, et al. Association between Urinary Sodium and Potassium Excretion and Blood Pressure Among Adults in the United States: National Health and Nutrition Examination Survey, 2014. *Circulation* (2018) 137(3):237.

Ma Y, He FJ, et al. 24-Hour Urinary Sodium and Potassium Excretion and Cardiovascular Risk. *N Engl J Med* (2022) 386(3):252

Yang Q, Liu T, et al. Sodium and Potassium Intake and Mortality among Us Adults: Prospective Data from the Third National Health and Nutrition Examination Survey. *Archives of Intern Med* (2011) 171(13):1183.

³ Filippini T, Naska A, Kasdagli MI, Torres D, Lopes C, Carvalho C, et al. Potassium Intake and Blood Pressure: A Dose-Response Meta-Analysis of Randomized Controlled Trials. *J Am Heart Assoc* (2020) 9(12): e015719.

⁴ Jafarnejad S, Mirzaei H, et al. The Hypotensive Effect of Salt Substitutes in Stage 2 Hypertension: A Systematic Review and Meta-Analysis. *BMC Cardiovascular Disorders* (2020) 20(1):1

⁵ Neal B, Wu Y, et al. Effect of Salt Substitution on Cardiovascular Events and Death. *N Engl J Med* (2021) 385(12):1067.

⁶ Marklund M, Singh G, et al. Estimated Population Wide Benefits and Risks in China of Lowering Sodium through Potassium Enriched Salt Substitution: Modelling Study. *BMJ* (2020):369.

IFT appreciates the opportunity to provide comments to this proposed rule and supports FDA's efforts to continue to reduce sodium intake in the US population. We thank you for considering our comments. Please contact Anna Rosales, Senior Director Government Affairs and Nutrition (arosales@ift.org) if IFT may be of further assistance.

Sincerely,

Anna Rosales
Senior Director Nutrition and Government Affairs
Institute of Food Technologists