#### November 19, 2025

The Honorable Dr. Martin A. Makary Commissioner of Food and Drugs U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

### Re: Inclusion of Phosphorus on Nutrition Facts Labels to Improve Health Outcomes

- cc: Kyle Diamantas, Deputy Commissioner for Human Foods, U.S. Food and Drug Administration
- Dr. Donald A. Prater, Principal Deputy Director for Human Foods, U.S. Food and Drug Administration
- Dr. Robin McKinnon, Acting Director, Nutrition Center of Excellence, U.S. Food and Drug Administration
- Kasey Heintz, Interdisciplinary Nutrition Scientist, Nutrition Center of Excellence, U.S. Food and Drug Administration
- Laura Carroll, Senior Advisor for Nutrition Outreach, Human Foods Program, U.S. Food and Drug Administration

### Dear Commissioner Makary:

On behalf of the undersigned organizations, individuals committed to improving public health and nutrition transparency, and Americans seeking more transparency in food and nutritional choices, we urge the U.S. Food and Drug Administration (FDA) to include phosphorus content on Nutrition Facts labels. This simple, evidence-based step would empower millions of Americans to make informed food choices, improve overall health, and prevent adverse health outcomes.

This issue is particularly urgent for populations at higher risk of chronic disease, including individuals with kidney disease, cardiovascular disease, diabetes, and other chronic diseases.

#### A Public Health Imperative for All Americans

While phosphorus labeling is critical for those with chronic diseases, emerging evidence shows that excess phosphorus intake, particularly in the form of phosphate additives, harms the general population as well. Studies demonstrate associations between dietary phosphate intake and increased risk of all-cause mortality and elevated risks for:

- Cardiovascular disease
- Bone loss and fractures

<sup>&</sup>lt;sup>1</sup> See the attached 'Evidence for Concern' Appendix for citations

- Type 2 diabetes
- Lethal prostate cancer
- Breast cancer
- Kidney disease.

Therefore, the widespread use of phosphate additives is a concern for all Americans, not only those with chronic diseases. Its ubiquity in the food supply, particularly in ultraprocessed foods, represents a modifiable driver of population-level disease risk.

# The Problem: Hidden Phosphorus in the Food Supply

Despite the well-established negative impacts of excess dietary phosphorus intake on health, consumers currently have no way to know how much phosphorus is in the foods they eat. Food manufacturers use more than 50 different phosphate additives yet are not required to disclose their quantities. Liberal and unchecked usage of phosphate results in nearly half of the best-selling grocery items containing phosphorus additives.<sup>2</sup> Americans must scour ingredient lists for chemical names such as "pyrophosphate" or "tripolyphosphate," as well as hidden sources of added phosphorus such as lecithin and modified food starch, guessing which foods are safe and which could harm their health.

The use of phosphate additives has increased dramatically over the past several decades. These additives now contribute an estimated 12% to 50% of daily phosphorus intake. Because phosphorus additives are highly bioavailable, meaning they are absorbed at rates approaching 100%, they pose increased risks to individuals with kidney disease and, as mounting evidence suggests, to those with normal kidney function, as well. However, their presence is virtually impossible to quantify, as manufacturers are not required to measure or disclose additive content. Due to their Generally Recognized as Safe (GRAS) status, companies can add virtually any type or amount of phosphate additive without premarket approval. This regulatory gap has led to incomplete and inaccurate phosphorus data in the USDA's FoodData Central database. Direct chemical analyses show that actual phosphorus content in many processed foods is 15–30% higher than database values suggest.<sup>3</sup>

The result is a preventable crisis in consumer transparency. Americans are forced to guess, clinicians lack reliable data to guide nutrition counseling, and the FDA's public health mission, to help empower consumers to build nutritious diets that support health and wellness,<sup>4</sup> remains unfulfilled.

<sup>&</sup>lt;sup>2</sup> León JB, Sullivan CM, Sehgal AR. The prevalence of phosphorus-containing food additives in top-selling foods in grocery stores. J Ren Nutr. 2013;23(4):265-270.e2. doi:10.1053/j.jrn.2012.12.003

<sup>&</sup>lt;sup>3</sup> See the attached 'Evidence for Concern' Appendix for citations

<sup>&</sup>lt;sup>4</sup> https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/fdas-nutrition-initiatives

### The Solution: Add Total and Added Phosphorus to Nutrition Labels

We strongly recommend that FDA mandate disclosure of both total phosphorus and added phosphorus on Nutrition Facts labels.

- Total phosphorus reporting would provide a complete picture of dietary intake, reflecting all natural and additive sources.
- Added phosphorus labeling, modeled after "added sugars," would specifically target industrial phosphate additives, which carry the highest health risk.

This precedent already exists: FDA requires labeling of sodium, total and added sugars, and various fats (including saturated and trans fats) because of their established links to chronic disease. Phosphorus should be viewed in the same was, given its equally well-documented associations with adverse outcomes, including cardiovascular disease - the nation's leading cause of premature death.

# Diseases Directly Impacted by Phosphorus Intake<sup>5</sup>

Chronic kidney disease (CKD) affects one in seven U.S. adults, a prevalence equivalent to that of diabetes. CKD is a common, costly and serious disease that presents a growing public health concern. For individuals with CKD, the inability to excrete phosphorus efficiently leads to phosphorus overload, which contributes to cardiovascular disease, bone disease, and increased mortality. Cardiovascular disease (CVD) remains the leading cause of death in the United States, affecting nearly half of U.S. adults. It is a common, costly, and serious condition that continues to pose a substantial public health challenge. Excess dietary phosphorus, particularly from highly absorbable phosphate additives, has been associated with vascular calcification, endothelial dysfunction, left ventricular hypertrophy, and increased cardiovascular mortality, underscoring the need for improved transparency in the food supply.

Diabetes affects more than 38 million Americans, with prevalence continuing to rise nationwide. It is a major driver of morbidity and healthcare spending. Elevated dietary phosphorus intake has been linked to insulin resistance, impaired glucose metabolism, and increased risk of type 2 diabetes, suggesting that individuals with or at risk for diabetes may be especially vulnerable to the health impacts of excessive phosphorus exposure.

# **Benefits of Labeling Transparency**

Including total and added phosphorus on Nutrition Facts labels would:

- Empower those with CKD to manage phosphorus intake effectively and improve survival.
- Enable families to make better dietary choices for their loved ones.

<sup>&</sup>lt;sup>5</sup> See the attached 'Evidence for Concern' Appendix for citations

- Support clinicians and dietitians in implementing evidence-based nutritional guidance.
- Improve health equity for communities disproportionately affected by kidney disease.
- Reduce national healthcare costs associated with the management of phosphorusrelated complications.
- Promote better health for all consumers, helping healthy individuals avoid excess phosphorus exposure.

### Partnership and Path Forward

We stand ready to collaborate with FDA's Center for Food Safety and Applied Nutrition, nutrition scientists, and food manufacturers to support implementation of phosphorus labeling requirements. We are well positioned to convene experts in medicine, nutrition, and public health to inform analytical methods, reference standards, and consumer education strategies.

By mandating disclosure of total and added phosphorus, FDA would take a transformative step toward nutrition transparency, public safety, and chronic disease prevention. This action aligns with the agency's broader goal of improving health equity through access to accurate, science-based nutrition information.

For any questions or concerns, please contact Miriam Godwin at the National Kidney Foundation, at <a href="Miriam.Godwin@kidney.org">Miriam.Godwin@kidney.org</a> and Jesse Roach at the National Kidney Foundation, at <a href="Jesse.Roach@kidney.org">Jesse.Roach@kidney.org</a>.

We thank you for your continued leadership and stand ready to assist in advancing this critical public health priority.

### Sincerely,

National Kidney Foundation Academy of Nutrition and Dietetics Alport Syndrome Foundation American Kidney Fund American Society of Nephrology American Society of Pediatric Nephrology Bone Health & Osteoporosis Foundation IGA Nephropathy Foundation Renal Physicians Association

# **Appendix: Evidence for Concern**

While phosphorus labeling is critical for those with chronic diseases, emerging evidence shows that excess phosphorus intake harms the general population as well. Studies demonstrate associations between dietary phosphate intake and increased all-cause mortality<sup>1</sup> and elevated risks for:

- Cardiovascular disease<sup>2,3,4,5,6,7</sup>
- Bone disease, loss, and fractures<sup>8,9,10,11,12</sup>
- Type 2 diabetes<sup>13</sup>
- Lethal prostate cancer<sup>14</sup>
- Breast cancer<sup>15</sup>
- Kidney Disease

The use of phosphate additives has increased dramatically over the past several decades. <sup>16,17,18</sup> These additives now contribute an estimated 12% to 50% of daily phosphorus intake. <sup>19,20</sup> Because phosphorus additives are highly bioavailable, meaning they are absorbed at rates approaching 90%, they pose increased risks to individuals with kidney disease. However, their presence is virtually impossible to quantify, as manufacturers are not required to measure or disclose additive content. Due to their Generally Recognized as Safe (GRAS) status, companies can add virtually any type or amount of phosphate additive without premarket approval. This regulatory gap has led to incomplete and inaccurate phosphorus data in the USDA's FoodData Central database. <sup>21</sup> Direct chemical analyses show that actual phosphorus content in many foods is 15–30% higher than database values suggest. <sup>22,23</sup>

Chronic kidney disease (CKD) affects one in seven U.S. adults, a prevalence roughly equivalent to that of diabetes. CKD is a common and serious disease that presents a growing public health concern. For people living with CKD, the inability to excrete phosphorus efficiently leads to phosphorus overload, which contributes to cardiovascular disease, renal osteodystrophy, and increased mortality. <sup>24,25</sup>

Cardiovascular disease (CVD) remains the leading cause of death in the United States, <sup>26</sup> affecting nearly half of U.S. adults. <sup>27</sup> It is a common, costly, and serious condition that continues to pose a substantial public health challenge. Excess dietary phosphorus, particularly from highly absorbable phosphate additives, has been associated with vascular calcification, <sup>28</sup> endothelial dysfunction, <sup>29</sup> left ventricular hypertrophy, <sup>30</sup> and increased cardiovascular mortality, <sup>31</sup> underscoring the need for improved transparency in the food supply.

Diabetes affects more than 38 million Americans, with prevalence continuing to rise nationwide. It is a major driver of morbidity and healthcare spending. <sup>32</sup> Elevated dietary phosphorus intake has been linked to insulin resistance, impaired glucose metabolism, and increased risk of type 2 diabetes, <sup>33</sup> suggesting that individuals with or at risk for diabetes may be especially vulnerable to the health impacts of excessive phosphorus exposure.

<sup>1</sup> Chang AR, Lazo M, Appel LJ, Gutiérrez OM, Grams ME. High dietary phosphorus intake is associated with all-cause mortality: results from NHANES III. *Am J Clin Nutr*. 2014;99(2):320-327. doi:10.3945/ajcn.113.073148

- <sup>3</sup> Calvo MS, Dunford EK, Uribarri J. Industrial Use of Phosphate Food Additives: A Mechanism Linking Ultra-Processed Food Intake to Cardiorenal Disease Risk? *Nutrients*. 2023;15(16):3510. doi:10.3390/nu15163510 <sup>4</sup> Raikou VD. Serum phosphate and chronic kidney and cardiovascular disease: Phosphorus potential implications in general population. *World J Nephrol*. 2021;10(5):76-87. doi:10.5527/wjn.v10.i5.76 <sup>5</sup> Kawamura H, Tanaka S, Ota Y, et al. Dietary intake of inorganic phosphorus has a stronger influence on vascular-endothelium function than organic phosphorus. *J Clin Biochem Nutr*. 2018;62(2):167-173. doi:10.3164/jcbn.17-97
- <sup>6</sup> Itkonen ST, Karp HJ, Kemi VE, et al. Associations among total and food additive phosphorus intake and carotid intima-media thickness--a cross-sectional study in a middle-aged population in Southern Finland. *Nutr J*. 2013;12:94. doi:10.1186/1475-2891-12-94
- <sup>7</sup> Anderson JJB. Potential health concerns of dietary phosphorus: cancer, obesity, and hypertension. *Annals of the NY Academy of Sciences*. 2013;1301(1):1-8. doi:10.1111/nyas.12208
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- <sup>11</sup> Kim YA, Yoo JH. Associations between cola consumption and bone mineral density in Korean adolescents and young adults: a cross-sectional study using data from the Korea National Health and Nutrition Examination Survey, 2008–2011. *Journal of Nutritional Science*. 2020;9:e56. doi:10.1017/jns.2020.49 <sup>12</sup> Calvo MS, Tucker KL. Is phosphorus intake that exceeds dietary requirements a risk factor in bone health? *Annals of the New York Academy of Sciences*. 2013;1301(1):29-35. doi:10.1111/nyas.12300
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- <sup>15</sup> Brown RB, Bigelow P, Dubin JA, Mielke JG. High Dietary Phosphorus Is Associated with Increased Breast Cancer Risk in a U.S. Cohort of Middle-Aged Women. *Nutrients*. 2023;15(17):3735. doi:10.3390/nu15173735 <sup>16</sup> Calvo M, Whiting S. The Regulatory Aspects of Phosphorus Intake: Dietary Guidelines and Labeling. In: *Dietary Phosphorus: Health, Nutrition, and Regulatory Aspects, Uribarri J & Calvo MS, Eds*. CRC Press; 2018:249-266.
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- <sup>26</sup> https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm
- <sup>27</sup> https://www.heart.org/en/-/media/PHD-Files-2/Science-News/2/2025-Heart-and-Stroke-Stat-Update/2025-Statistics-At-A-Glance.pdf
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- 32 https://diabetes.org/about-diabetes/statistics/about-diabetes
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