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Division of Dockets Management  
Food and Drug Administration (FDA)  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Comment on Proposed Rule re: Use of Salt Substitutes to Reduce the Sodium Content in Standardized Foods (Docket No. FDA-2022-N-2226-0001)**

CSPI supports FDA's proposal to "horizontally" amend all standards of identity (SOI) that specify salt as a required or optional ingredient to permit the use of safe and suitable salt substitutes across an array of standardized foods. This proposed rule has the potential to affect 140 foods including cheeses, breads, canned vegetables, and condiments, and is part of a larger effort by FDA to reduce sodium in the U.S. food supply. We agree that reducing sodium in the food supply may help reduce excess sodium intake, which could in turn reduce the prevalence of hypertension and related diseases among people who currently consume excess sodium.

In this comment, CSPI expresses that:

- We support FDA's proposed approach to horizontally amending the SOI to allow the use of salt substitutes, as long as the substitutes effectively replicate the food safety functions of sodium in the food and have been reviewed for safety by FDA.
- Evidence suggests the benefits of replacing sodium with potassium chloride outweigh the risks it may pose to consumers who need to limit their potassium intake, but FDA should assess and mitigate any unintended harm resulting from a potential increase in potassium in the food supply.
- Allowing the use of salt substitutes in standardized foods should be combined with additional steps to reduce dietary intake of sodium, including by setting mid- and long-term voluntary sodium reduction targets for industry, adopting front-of-package labels and menu warnings that identify foods that are high in sodium, and adopting strong sodium limits for products making "healthy" claims (all actions previously requested of FDA by CSPI<sup>1,2,3</sup>).
- FDA should carefully consider the data and theory of change behind its assertion that sodium reduction may help reduce health disparities and partner with other federal agencies to develop meaningful health equity interventions.

**I. CSPI supports FDA's proposal to horizontally amend the SOI to allow the use of salt substitutes.**

CSPI has long advocated in favor of amending food standards to allow for sodium substitution<sup>4,5</sup> and we are excited that FDA is planning to adopt this important policy change. U.S. adults consume, on average,

50% more sodium daily than recommended by the Dietary Guidelines for Americans.<sup>6,7</sup> Most dietary sodium comes from processed and pre-prepared foods, as opposed to salt added while cooking, preparing, or consuming food at home.<sup>8</sup> Therefore, there is substantial potential to reduce dietary sodium intake and improve population health by reducing sodium in processed and prepared foods. One study predicted that reducing the mean population sodium intake by 1,200 milligrams per day (about what is needed to align consumption with the Federal government's recommendations) would save between 44,000 and 92,000 lives each year.<sup>9</sup>

This proposed rule is a crucial part of FDA's broader initiative to spur sodium reduction in the U.S. food supply. Under the proposed rule, FDA would amend SOI that currently list "salt" as a required ingredient to instead list "salt or salt substitute," with "salt substitute" defined as "a safe and suitable ingredient (or combination of ingredients) that is used to replace some or all of the added salt (sodium chloride), to reduce sodium in the food, and that serves the functions of salt in the food." The proposal acknowledges that salt "may serve a variety of functions such as taste, texture, moisture control, and microbial safety" and gives food manufacturers broad flexibility to determine what ingredients constitute salt substitutes. One of FDA's goals in providing this new flexibility is to "allow for innovation in producing healthier standardized foods."

FDA is requesting comments on "potential regulatory alternatives including 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." CSPI agrees with FDA's present approach, with a couple of important caveats. We recognize that there may be specific instances where sodium plays an important food safety role (*e.g.*, moisture control or microbial safety) where specific substitutes with evidence of effectiveness for that function should be recommended to ensure the critical properties are maintained. We therefore ask the agency to ensure that the removal of sodium not have adverse implications for food safety by, for example, recommending preferred substitutes that could serve each of the different food safety functions of salt in food. Also, in general, we do not think FDA is doing enough to prevent unsafe ingredients from entering the food supply, and therefore, as we state in the next section, we urge FDA to prohibit chemicals that enter the food supply through the "secret GRAS" pathway (defined below) from being used as sodium substitutes in standardized foods.

## **II. Only chemicals that consumers can trust to be safe should be allowed as salt substitutes in standardized foods**

SOI for foods were explicitly established to "promote honesty and fair dealing in the interest of consumers,"<sup>10</sup> and they historically served as an early means for the FDA to ensure the safety of new chemicals entering the food supply.<sup>11</sup> For example, when the agency set standards for bread in the 1940s, it allowed specific dough conditioners, but excluded others, and certain emulsifiers were challenged and eventually excluded from the standard out of concerns regarding lack of safety testing and consumer deception.<sup>12</sup>

The FDA moved away from considering food additive safety in food standards with the passage of the Food Additives Amendment of 1958, a statute intended to ensure the safety of all chemicals used in food, regardless of whether they were included in standardized foods.<sup>13</sup> Unfortunately, as CSPI has repeatedly highlighted,<sup>14</sup> FDA's implementation of that statute has left a substantial loophole in the law that allows companies to self-determine that a chemical is safe and introduce that chemical into foods without notifying the FDA or the public.<sup>15</sup> Chemicals that enter the food supply through this pathway are sometimes referred to as "secret GRAS" chemicals.

The FDA's proposal to amend the SOI to allow for sodium substitutes permits any salt substitute that is either an approved food additive or GRAS for its intended use. This definition would allow secret GRAS chemicals to be used as sodium substitutes in standardized foods. Such a move does not promote honesty and fair dealing in the interest of consumers.<sup>16</sup> Accordingly, we ask the FDA to amend its proposal to clarify that a "sodium substitute" cannot include any ingredient that is self-certified as GRAS in secret.<sup>17</sup>

### **III. FDA should assess and mitigate any potential unintended harm resulting from increased use of the salt substitute potassium chloride in the U.S. food supply.**

In this proposed rulemaking, FDA summarizes existing data on the potential population health benefits of sodium reduction but also notes that "to the extent manufacturers choose to use potassium chloride as a salt substitute and consumers choose to consume those products, consumers who may need to limit their potassium intake may see negative health effects that should be accounted for in cost estimates" and requests comments on "evidence that could contribute to a more thorough assessment (including possible quantification) of such costs." CSPI agrees that FDA should assess both the potential benefits and risks of increased potassium in the food supply, and identify ways to mitigate the risks.

While previous research suggests there will be net benefits from replacing sodium with potassium salt in the food supply, some of the same research identifies substantial risks for certain subpopulations. For example, an assessment by the United Kingdom Department of Health's Scientific Advisory Committee on Nutrition and Committee on Toxicology using the Benefit-Risk Analysis for Foods (BRAFO) methodology concluded that, if 15 to 25 percent of sodium in food were replaced with potassium salt, the benefits (reduction in hypertension and number of strokes) would outweigh the risks (increase in cases of hyperkalemia, and resultant arrhythmia, adverse cardiac effects, or death, in individuals with previously undiagnosed chronic renal impairment).<sup>18</sup> However, the risks included a 2.2 fold increase in the number of cases of life-threatening hyperkalemia in the United Kingdom (8,500 additional cases annually, primarily expected to occur among people with undiagnosed chronic kidney disease (CKD) stages 3 to 5).<sup>19</sup> An assessment of the mortality benefits and risks of distributing a potassium-enriched salt substitute in China predicted that the intervention would prevent 461,000 deaths from cardiovascular disease (CVD) annually but cause an estimated 11,000 annual deaths from hyperkalemia in individuals with CKD.<sup>20</sup>

However, these studies are both modelling studies. In a more rigorous randomized trial with 20,995 Chinese adults with a history of stroke or age 60 or older with high blood pressure, where participants

were randomly assigned to either continue their regular salt use or replace it with a salt substitute containing 75% sodium chloride and 25% potassium chloride, there was no significant difference in the rates of serious adverse events attributed to hyperkalemia between the regular salt and salt substitute groups.<sup>21</sup> However, adults with serious kidney disease and those taking medications that could substantially elevate blood potassium were excluded from this study, limiting its generalizability to those at the greatest risk of experiencing unintended harm.

In the United States, 14.8 percent of adults have CKD, including 6.6 percent with CKD stage 3 or 4.<sup>22</sup> The relationships between CKD, dietary potassium, and serum potassium are complex and not well understood, but certain late-stage CKD patients are at increased risk for hyperkalemia and may benefit from restricting dietary potassium.<sup>23,24</sup> While the National Academies of Sciences, Engineering, and Medicine (NASEM) recommends that healthy adults consume 2,600 mg/day of potassium (females) to 3,400 mg/day (males), it recommends that patients with CKD should consult with their health care providers about individualized potassium intake recommendations.<sup>25</sup> Meanwhile, many patients with CKD also have hypertension, and patients with hypertension are typically advised to restrict dietary sodium, including by seeking out reduced sodium foods.<sup>26</sup> Under this proposed rule, there may be an increase in the availability of foods with reduced sodium and increased potassium.

Education of patients who are advised to restrict dietary potassium, especially those who are simultaneously advised to restrict dietary sodium, will be critical to mitigating the risks of this policy. Health care providers who are advising a potassium-restricted diet should advise patients to monitor potassium intake, especially in light of this new policy that could increase potassium content in some foods. Fortunately, patients who need to restrict dietary potassium have access to the information they need. As of 2021, all foods are required to bear updated Nutrition Facts labels that include the amount of dietary potassium in milligrams per serving and as a percentage of the Daily Value.<sup>27</sup>

Although only 57 percent of consumers report regularly<sup>a</sup> using the Nutrition Facts label when buying a food product for the first time,<sup>28</sup> patients carefully monitoring their potassium intake may be more likely to do so. However, patients may be less likely to review labels for products they already frequently consume, which may make them less likely to realize that those foods have been reformulated. To ensure that consumers are able to accurately monitor their sodium and potassium intakes, FDA should encourage companies that reformulate existing products with more potassium as a result of this rule to apply a temporary disclosure alerting consumers to the increased potassium content.

#### **IV. FDA should adopt additional policies to reduce dietary intake of sodium.**

In this proposed rulemaking, FDA requests comments on “potential regulatory approaches to reducing salt in food or the dietary intake of salt that do not involve allowing the use of salt substitutes in standardized foods.” We appreciate this opportunity to provide input on other sodium reduction policies.

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<sup>a</sup> “Regularly” defined as responses of “Always” or “Most of the time” (not “Sometimes,” “Rarely,” or “Never”)

In addition to allowing the use of salt substitutes in standardized foods, FDA must monitor and evaluate the food industry's progress toward the short-term (2.5-year) voluntary sodium reduction targets that the agency established in 2021<sup>29</sup>; finalize the long-term (10-year) targets that the agency proposed in 2016<sup>30</sup>; and establish an intermediate (*e.g.*, 5- or 7-year) sodium reduction goal for industry. FDA should also identify particular products that represent the largest contributors to sodium exposure in the American diet and maintain a public database of these products and their nutritional content. CSPI previously requested each of these actions in a citizen petition filed with FDA in April 2023.<sup>31</sup>

Another action the agency should take is adopt mandatory front-of-package nutrition labels for all packaged foods. CSPI submitted a citizen petition to FDA in August 2022 calling for an easy-to-understand, standardized, mandatory labeling system that would be 1) mandatory, 2) nutrient-specific, 3) include calories, and be 4) interpretive with respect to the levels of added sugars, sodium, and saturated fat per serving.<sup>32</sup> FDA is currently conducting research to identify a label design that will “help consumers quickly and easily identify foods that can help them build a healthy eating pattern, with a focus on the nutrients that the Dietary Guidelines for Americans (Dietary Guidelines) have identified as nutrients to limit” (including sodium).<sup>33</sup> Several of the label designs that FDA is testing aim to help consumers identify products that are high in sodium.<sup>34</sup> A variety of well-powered experimental studies, summarized in a meta-analysis by Croker et al, suggest that front-of-package labels can reduce the amount of sodium in the foods that consumers purchase or select.<sup>35</sup> And observational data from Chile, which adopted front-of-package nutrient warning labels for high sodium products in 2016, found a statistically significant 4.7 percent decline in per capita milligrams of sodium purchased per day ( $p < 0.0035$ ).<sup>36</sup> This reduction in dietary sodium was driven at least in part by sodium reduction in the food supply. Between 2015 and 2017, there was a significant decline in the proportion of foods (savory spreads, cheeses, ready-to-eat meals, soups, and sausages) in Chile that were high in sodium (*i.e.*, exceeded 800 milligrams of sodium per 100 grams of food), from 74 percent [95% CI 69-78] down to 27 percent [20-35].<sup>37</sup> These findings from Chile point to front-of-package labels that identify foods as “high in sodium” as an effective intervention to reduce dietary intake of sodium and the amount of sodium in the food supply.

FDA could also consider requiring safety warning icons on restaurant menus next to menu items with excessively high amounts of sodium. The average default combination meal (*e.g.*, hamburger, fries, and soda) at a fast food restaurant in the U.S. contains 2,110 milligrams of sodium,<sup>38</sup> approaching the recommended limit for an entire day's worth of dietary sodium (2,300 milligrams).<sup>39</sup> Some experimental studies have found that sodium warnings on restaurant menus lead to lower-sodium purchases,<sup>40,41,42</sup> and in New York City—where sodium warning icons were required on chain restaurant menus starting in 2016—there was a significant decrease in mean sodium content of purchases from two full-service chains (but no change in mean sodium content of purchases from two quick-service chains).<sup>43</sup> The selective effects in full-service chains are unsurprising, given that nearly 41% of items offered in New York City full-service restaurant chains contained more than a day's worth of sodium in 2015, versus only 7% of items in the quick-service chains surveyed by researchers.<sup>44</sup> An assessment of the sodium content of menu items in New York City chain restaurants found no change from 2015 to 2017, but the authors note that the relatively short follow-up window may not have allowed restaurants enough time to reformulate and roll out new, lower-sodium items, and reductions in sodium may yet occur.<sup>45</sup>

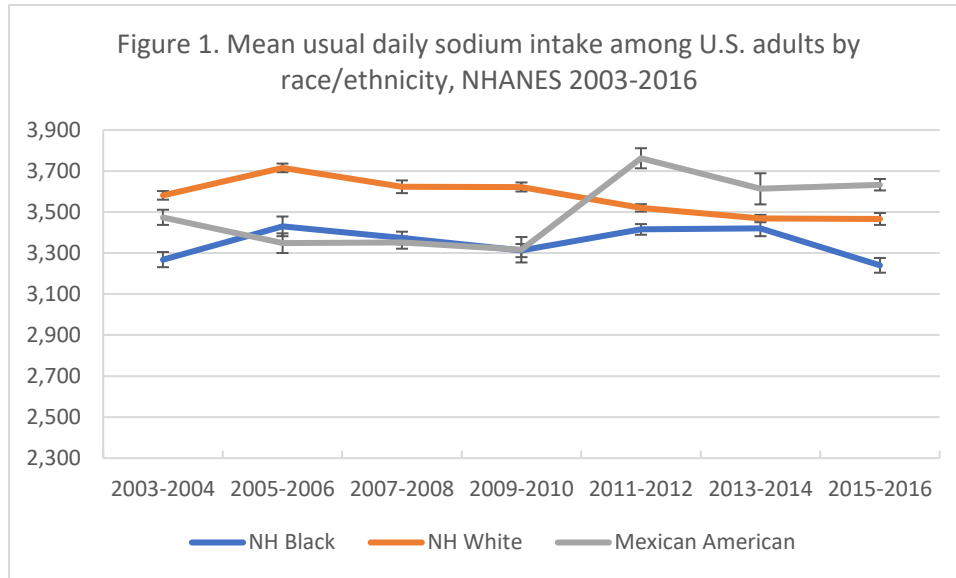
Next, as FDA issues a final rule to redefine the nutrient content claim “healthy,” the agency must maintain strong limits for sodium. In its proposed rule published in September 2022, FDA set a baseline limit of 10 percent Daily Value per Reference Amount Customarily Consumed for sodium in individual foods labeled “healthy,” with some adjustments for certain food groups.<sup>46</sup> In our comments on that proposal, CSPI expressed its support for the proposed baseline limit, but opposed an increase in the amount of sodium allowed in meal products making “healthy” claims from 600 milligrams per serving (the limit under current healthy claim regulations) to 690 milligrams per serving (the limit in FDA’s proposed rule).<sup>47</sup> Increasing the limit for sodium in meal products using “healthy” claims would run counter to FDA’s sodium reduction goals.

Finally, FDA should evaluate the impact of each of its sodium reduction policies on sodium intake and presence in the U.S. food supply. This includes evaluating the impact of the final guidance issued in December 2020 titled “Use of an Alternative Name for Potassium Chloride in Food Labeling” which allowed potassium chloride to be listed as “potassium salt” in a food’s ingredients list,<sup>48</sup> a move supported by CSPI.<sup>49</sup>

**V. FDA should carefully consider if sodium reduction has the potential to reduce health disparities and partner with other agencies to develop meaningful health equity interventions.**

This proposed rule states that “there may be potential health equity effects to any regulation that generates or facilitates reduced intake of sodium.” The agency specifically supposes that sodium reduction “has the potential to contribute to better health outcomes and reduce preventable death and disease related to poor nutrition; many of which are experienced at higher rates by certain racial and ethnic groups.” The text goes on to cite statistics demonstrating elevated rates of hypertension among African American women compared to non-Hispanic White women and higher likelihood of death from coronary heart disease among African American adults compared to non-Hispanic White adults, concluding that, “The proposed rule’s likely effect on increasing the availability of lower sodium products may contribute to governmentwide efforts to reduce health disparities.”

We agree that data clearly show African Americans face substantially higher rates of hypertension and CVD-related death compared to other racial and ethnic groups.<sup>50,51</sup> However, African Americans do not, on average, consume more sodium than other racial and ethnic groups (Figure 1).<sup>52</sup> In fact, if anything, they consume less. In the most recent year of data analyzed (2015-2016), non-Hispanic Black adults consumed an average of 3,240 milligrams of sodium per day (standard error=36 mg) compared with 3,466 (29) milligrams per day among non-Hispanic White adults and 3,633 (28) milligrams per day among Mexican American adults.<sup>53</sup> Additionally, NASEM has concluded that evidence does not suggest increased sensitivity to sodium among African Americans.<sup>54</sup> This suggests that factors other than sodium explain the excess risk of hypertension and CVD-related death among African Americans. It is possible that a targeted intervention that disproportionately reduces sodium intake for a particular group could reduce rates of hypertension within that group. But the proposed rule is not such an intervention. It is therefore unclear how sodium reduction across the food supply would represent a targeted intervention specifically intended to improve the diets of African Americans or reduce racial disparities in CVD rates, as all groups would benefit from the FDA’s proposals.



Source: Clarke LS, Overwyk K, Bates M, et al. Temporal Trends in Dietary Sodium Intake Among Adults Aged ≥ 19 Years—United States, 2003-2016. *MMWR*. 2021;70(42):1478-1482. doi:10.15585/mmwr.mm7042a4.

Unless FDA can identify how this proposal would help reduce racial health disparities, we recommend the agency refrain from making this claim. We also recommend that the agency develop and support additional interventions to address factors situated in the causal pathway linking anti-Black structural racism and poor cardiovascular health.<sup>55</sup> While some of these factors (e.g., toxic stress, poor housing conditions, poorly funded schools, poor access to capital, police violence, and racism)<sup>56,57,58,59</sup> fall outside FDA’s jurisdiction, we encourage the agency to think creatively and strategically about how it can partner with other agencies to advance health equity.

Thank you for the opportunity to comment on this proposal, and for the agency’s commitment to reducing sodium in the food supply.

Sincerely,

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