

March 18, 2021

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

**Re: FDA-2020-N-1690; Frozen Cherry Pie;
Proposed Revocation of a Standard of Identity and a Standard of Quality**

The Center for Science in the Public Interest (CSPI) respectfully submits the comments below on the proposed revocation of a standard of identity and standard of quality for frozen cherry pie.

FDA is proposing to revoke the standard of identity (SOI) for frozen cherry pie in response to a petition from the American Bakers Association. FDA asserts that revoking this SOI will provide for greater flexibility in the manufacture of frozen cherry pies, and that the SOI is no longer necessary to promote honesty and fair dealing in the interest of consumers.

CSPI believes this is a poor expenditure of the agency's scant resources and submits this comment to urge FDA to instead direct its efforts towards priorities aligned with the goals of the agency's Nutrition Innovation Strategy.¹

To the extent that FDA directs resources towards changes to any of its SOIs, these changes should provide clear benefits to public health. Accordingly, rather than expending agency resources on revoking the SOI for cherry pie, we urge the agency to instead prioritize a horizontal amendment to all SOIs to allow for the use of sodium substitutes such as potassium chloride (potassium salt).

I. Revoking the SOI for frozen cherry pie would not provide clear benefits for consumers.

The current SOI and quality standards for frozen cherry pie state that at least 25 percent of the weight of the pie must be from cherries, no more than 15 percent of the cherries may be blemished, and artificial sweeteners are not suitable ingredients.² CSPI is unaware of any calls from consumers for more variety in the frozen cherry pie aisle nor complaints that frozen cherry pies currently have too high a proportion of cherries, much less unblemished ones.

By setting a minimum fruit content, the SOI protects consumers of frozen cherry pie from misleading labeling practices referencing fruit often found on non-standardized packaged products with little or no real fruit. When consumers buy frozen cherry pie today, they can trust they are getting real cherries because of the current SOI. While cherry pie is not an especially healthy source of daily servings of fruit,

¹ U.S. Food and Drug Administration. FDA Public Meeting: FDA's Comprehensive, Multi-Year Nutrition Innovation Strategy—Facilitated Breakout Session: Modernizing Standards of Identity & Ingredients Lists on Labels. 2018. <https://www.fda.gov/media/114860/download>. Accessed March 9, 2021.
² 21 CFR § 152.126.

it is important from a transparency and fairness standpoint that consumers are not misled to believe a product contains more real fruit than it actually does.

FDA also asserts that, “[i]f the [SOI] for frozen cherry pie is revoked, manufacturers could use artificial sweeteners to make unbaked, frozen cherry pie products, consistent with other reduced-sugar fruit pies available in the marketplace,” thereby reducing the caloric content of frozen cherry pie products.³ Even assuming a consumer market exists for reduced-sugar frozen cherry pie products, the SOI do not serve as a barrier to creating such. Pie manufacturers can currently sell reduced-sugar frozen cherry pie by using a natural sweetener (e.g., Stevia) or by using artificial sweeteners and a coined name (e.g., “reduced-sugar frozen cherry dessert”).⁴

Moreover, a policy aimed at promoting the use of artificial sweeteners presents potential risks to consumers, as described in CSPI’s resource *Chemical Cuisine*.⁵ Before deliberately encouraging reformulation that would increase population exposure to artificial sweeteners, FDA should conduct a much more comprehensive reassessment of the safety of specific artificial sweeteners.

Overall, it is not clear that revoking the standard for cherry pie is in the interest of consumers and the action may, in fact, harm consumers. This makes revocation of the SOI for cherry pie a poor use of the agency’s regulatory resources.

II. FDA should focus its scant resources on changes to SOIs that will benefit consumers, like allowing sodium substitution.

Most Americans exceed recommendations for dietary sodium,⁶ and there is strong evidence that reducing sodium intake benefits health.⁷ As discussed in CSPI’s past comments to FDA on modernization of SOIs, permitting the use of sodium substitutes, such as potassium salt, in bread, cheese, and other standardized foods would benefit the overall health of the American public.⁸

FDA appears to agree that substitution of potassium salt for sodium chloride would be beneficial for public health, as the agency noted in a recent guidance that, “[f]rom a nutrition and public health perspective, the substitution of potassium chloride for sodium chloride is advantageous due to the over-consumption of sodium and under-consumption of potassium at the population level compared to federal recommendations.”⁹

3 Docket No. FDA-2020-N-1690; 85 Fed. Reg. 244 (December 18, 2020). Frozen Cherry Pie; Proposed Revocation of a Standard of Identity and a Standard of Quality.

4 21 C.F.R. §§ 152.126(a)(2), 102.5.

5 Center for Science in the Public Interest. *Chemical Cuisine*. n.d. <https://www.cspinet.org/eating-healthy/chemical-cuisine>. Accessed March 15, 2021.

6 Brouillard AM, Kraja AT, Rich MW. Trends in dietary sodium intake in the United States and the impact of USDA guidelines: NHANES 1999-2016. *Am J Med*. 2019; 132(10):1199-1206.e5.

7 National Academies of Sciences, Engineering, and Medicine. *Dietary Reference Intakes for Sodium and Potassium*. 2019. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25353>.

8 Center for Science in the Public Interest. Comments Re: Re: FDA-1995-N-0062; Food Standards; General Principles and Food Standards Modernization; Reopening of the Comment Period. July 20, 2020. https://cspinet.org/sites/default/files/attachment/CSPI_SOI_comment_7.20.20.pdf. Accessed March 16, 2021.

9 U.S. Food and Drug Administration. *The Use of an Alternate Name for Potassium Chloride in Food Labeling: Guidance for Industry*. December 2020. <https://www.fda.gov/media/125081/download>. Accessed March 9, 2021.

While SOIs provide numerous benefits to consumers, they may act as a barrier to sodium substitution in many foods for which sodium is part of the SOI, to the extent that standards do not permit such substitutions (outside the context of “reduced sodium” products). FDA could remove this barrier by creating a new “horizontal” regulation allowing sodium substitution across all standardized foods.

We therefore urge that, rather than championing changes to SOIs that serve the interests of industry but have little or no positive value to consumers, FDA shift to focusing its limited resources on amending the SOIs to allow for sodium substitution across standardized foods. In general, FDA’s work on SOIs should be re-focused on changes to SOIs that offer clear and substantial public health benefits.

Sincerely,

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