

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

# **Frozen Cherry Pie; Proposed Revocation of a Standard of Identity and a Standard of Quality**

Docket No. FDA-2020-N-1690

Preliminary Regulatory Impact Analysis  
Initial Regulatory Flexibility Analysis  
Unfunded Mandates Reform Act Analysis

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## **Executive Summary**

The Food and Drug Administration (FDA) is proposing to revoke the standard of identity and standard of quality for frozen cherry pie. We are taking this action because we tentatively conclude that these standards are no longer necessary to promote honesty and fair dealing in the interest of consumers. We also tentatively conclude that revoking the standards of identity and quality for frozen cherry pie would provide greater flexibility in the product's manufacture, consistent with comparable, nonstandardized foods available in the marketplace. We tentatively conclude that this proposed rule to revoke the standards for frozen cherry pie, if finalized, would provide social benefits at little to no cost to the respective industries.

## **I. Introduction and Summary**

### **A. Introduction**

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 13771 requires that the cost associated with significant new regulations “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.” We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we have tentatively concluded that this proposed rule would not generate compliance costs, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by private sector, \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$156 million, using the most current (2019) Implicit Price Deflator for the Gross

Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

**B. Summary of Costs and Benefits**

The proposed rule would not require firms within the frozen cherry pie industry to change their manufacturing practices. Our analysis of current food manufacturing practices and the proposal to revoke the standards indicate that the proposed rule would provide benefits in terms of additional flexibility to the manufacturers of frozen cherry pie products.<sup>1</sup> We also tentatively conclude that these standards are obsolete because the requirements are not necessary to ensure that frozen cherry pie meets consumers’ expectations about the food and, in some respects, place restrictions on the food that are inconsistent with consumers’ expectations. The proposed rule would allow additional flexibility for, and the opportunity for innovation regarding, frozen cherry pie products, providing benefits to both consumers and industry. Therefore, we tentatively conclude that the proposed rule to revoke the standards for frozen cherry pie, if finalized, would provide social benefits at little to no cost to the respective industries (Table 1).

**Table 1: Summary of Benefits, Costs and Distributional Effects of Proposed Rule**

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized \$millions/year	\$0	\$0	\$0	2018	7%		
						3%		
	Annualized Quantified					7%		
						3%		
	Qualitative							Benefits to manufacturers would be from additional

<sup>1</sup> We do not quantify benefits because any benefits would be from manufacturers choosing to use the additional flexibility, and we cannot quantify how many manufacturers would choose to use that flexibility or how they might use it. Benefits are discussed qualitatively in Section C. Option 2.

Category	Primary Estimate	Low Estimate	High Estimate	Units			Notes
				Year Dollars	Discount Rate	Period Covered	
							flexibility for, and the opportunity for innovation regarding, frozen cherry pie products.
Costs	Annualized Monetized \$millions/year	\$0	\$0	\$0	2018	7%	
						3%	
	Annualized Quantified					7%	
						3%	
Transfers	Qualitative						
	Federal Annualized Monetized \$millions/year					7%	
						3%	
	From/ To	From:			To:		
	Other Annualized Monetized \$millions/year					7%	
					3%		
	From/To	From:			To:		
Effects	State, Local or Tribal Government:						
	Small Business: Wages: Growth:						

**In line with Executive Order 13771, in**  
 Table we estimate present and annualized values of costs and cost savings over an infinite time horizon. Based on these cost savings, this proposed rule, if finalized, would be considered a deregulatory action under EO 13771.

**Table 2. EO 13771 Summary Table (in \$ Millions 2016 Dollars, Over an Infinite Time Horizon)**

Item	Primary Estimate (7%)	Lower Estimate (7%)	Upper Estimate (7%)
Present Value of Costs	\$0	\$0	\$0

Present Value of Cost Savings	\$0	\$0	\$0
Present Value of Net Costs	\$0	\$0	\$0
Annualized Costs	\$0	\$0	\$0
Annualized Cost Savings	\$0	\$0	\$0
Annualized Net Costs	\$0	\$0	\$0

**II. Preliminary Economic Analysis of Impacts**

**A. Need for Federal Regulatory Action**

FDA is proposing to revoke the standards of identity and quality for frozen cherry pie as prescribed in 21 CFR 152.126.

Food standards are intended to promote honesty and fair dealing in the interest of consumers by protecting consumers’ expectations about food and preventing economic adulteration. Food standards establish specifications related to the composition and production of certain food products so that consumers know that a food really is what it purports to be, reducing the search time and cost for the consumer. However, overuse of food standards discourages innovation within the industry, inhibits the introduction of new products, and may lead to favoring one industry over another.

The standard of identity for frozen cherry pie as defined in 21 CFR 152.126 describes frozen cherry pie (excluding baked and then frozen cherry pie) as a food containing pastry shell, cherries, filling, and certain optional ingredients. The frozen cherry pie standard of identity also states that “artificial sweeteners are not suitable ingredients of frozen cherry pie.” However,

baked, frozen cherry pie and baked, non-frozen cherry pie may be made with artificial sweeteners to produce reduced-sugar varieties to accommodate consumer preferences and dietary restrictions. Other types of fruit pies are manufactured with artificial sweeteners to produce reduced-sugar varieties. These varieties appear to cater to consumer preferences and needs, and we are aware of no evidence that they create confusion or circumvent consumer expectations.

The standard of quality prescribes the amount of cherry content and the maximum amount of blemished cherries that may be used. The frozen cherry pie standards also establish the name of the food, require that each ingredient used in the product be declared on the label, and compel a general statement of substandard quality if products fall below the standard of quality. Revoking the frozen cherry pie standards of identity and quality will potentially provide new opportunities for innovation and the introduction of new products within the frozen cherry pie industry.

#### B. Purpose of the Proposed Rule

There are currently no standards of identity or quality for non-frozen cherry pie; frozen, baked cherry pie; or any other frozen or non-frozen fruit pies. These other frozen and non-frozen fruit pies have been formulated to satisfy consumers' varying tastes and sold throughout the country for many years without, to our knowledge, any evidence of public confusion. Revoking the frozen cherry pie standards of identity and quality will potentially provide an opportunity for innovation and the introduction of new products within the frozen cherry pie industry. Revoking the standards would allow frozen cherry pie manufacturers to produce unbaked, frozen cherry pies that include a wider variety of attributes that are outside the current standards of identity and quality. Demand for frozen cherry pie with different attributes will be determined in the marketplace by consumers' decisions in the same way as choosing other frozen and non-frozen



fruit pies. Consumers would benefit from the introduction of new products that have different attributes or are sold at a lower price than could be sold under the current frozen cherry pie standards of identity and quality. Furthermore, additional revenue from new products that would not have been possible under the current frozen cherry pie standards would constitute a benefit to the frozen cherry pie industry and would promote innovation.

### C. Analysis of Regulatory Alternatives to the Proposed Rule

We considered the following regulatory options for the frozen cherry pie standards of identity and quality:

Option 1. Take no action;

Option 2. Take the proposed action;

Option 3. Regulate other products, through standards of identity and quality, within the frozen fruit pie industry.

#### Option 1: Take No Action

By convention, we treat the option of taking no new regulatory action as the baseline for determining the costs and benefits of the other options. There are neither costs nor benefits associated with this option. The consequences of taking no action are relative to the costs and benefits of options 2 and 3.

#### Option 2: Take the Proposed Action

Our analysis of existing standards and the proposal to revoke the standards of identity and quality suggests that this proposed rule provides additional flexibility to firms beyond that available under current requirements. For example, all fruit pies other than unbaked, frozen cherry pie may be made with artificial sweeteners to produce reduced-sugar varieties to

accommodate consumer preferences and dietary restrictions. However, the frozen cherry pie standard of identity prohibits the use of such artificial sweeteners in unbaked, frozen cherry pie. By revoking the standard of identity for frozen cherry pie, artificial sweeteners could be used to make unbaked, frozen cherry pie, consistent with other reduced-sugar fruit pies available in the marketplace.

The proposed regulation to revoke § 152.156 would affect manufacturers of frozen cherry pie. Our review of supermarket scanner data for the year 2018 shows that a total of 40 distinct frozen cherry pie products sold that year were manufactured by 20 firms.<sup>2</sup> We request comment on the number of frozen cherry pie manufacturers that would be affected by the proposed rule.

The proposed rule does not require firms within the frozen cherry pie industry to change their manufacturing practices; hence, we do not consider these firms to be burdened by any costs as a result of the proposed rule. Our analysis of the current food manufacturing practices and the proposal to revoke the standards indicate that the proposed rule provides benefits in terms of additional flexibility to the manufacturers of frozen cherry pie. The proposed rule would provide an opportunity for innovation and introduction of new frozen cherry pie products, providing benefits to both consumers and industry. Therefore, the proposed rule to revoke the standards for frozen cherry pie provides social benefits at no cost to their respective industries.

### Option 3: Regulate other products, through standards of identity and quality, within the frozen fruit pie industry

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<sup>2</sup> We analyzed supermarket scanner data to determine the number of manufacturers in the U.S. of frozen cherry pie products sold in the year 2018. Supermarket scanner data capture the actual sales of individual food and dietary supplement products by supermarkets, drug stores, mass merchandisers and convenience stores in the U.S. We obtained the scanner data from an independent, third-party contractor. We are contractually prohibited from releasing the proprietary scanner data to the public.

Another option is to establish standards of identity and quality for other frozen fruit pies in addition to the frozen cherry pie standard. This approach would result in regulations on standards of identity and quality on all frozen fruit pie products, including, but not limited to, apple, apricot, blackberry, blueberry, cherry, cranberry, cushaw, guava, huckleberry, lemon, nectarine, peach, pear, prune, pumpkin, raisin, raspberry, orange, strawberry, watermelon, and/or a mixed variety of the above fruits.

This option would result in significant costs due to modification of manufacturing practices, product re-formulation, and labeling changes by firms that manufacture frozen fruit pies that do not comply with the new standards. Furthermore, we are aware of no evidence indicating that such standards are needed to protect consumers against economic adulteration or ensure that the pies reflect consumers' expectations. The benefits of standardization (e.g., consumer confidence and shorter search cost) are uncertain and likely to be very small.

Option 3 would result in prohibitively high costs to industry and consumers, as increased costs to industry would result in higher prices for consumers. Option 2, the proposed rule, compared to Option 3 would result in no additional costs to industry or consumers. Option 3 would result in little or no social benefit.

### **III. Initial Regulatory Flexibility Analysis**

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule does not generate compliance costs, we propose to certify that this proposed rule will not have a significant economic impact on a substantial number of small entities.

This proposed rule, if finalized, would revoke the standards of identity and quality for frozen cherry pie. The revocation of these standards would permit flexibility to small firms and

would also provide for technological advances in the production of frozen cherry pie, while allowing for production consistent with consumers' expectations and preferences.

We do not classify as costs of this proposed rule any voluntary expenses that some small firms might incur because they choose to change their manufacturing practices in ways that would be newly permitted by the proposed rule.