

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Frozen Cherry Pie; Revocation of a Standard of Identity and a Standard of Quality

Docket No. FDA-2020-N-1690

Final Regulatory Impact Analysis
Final Regulatory Flexibility Analysis
Unfunded Mandates Reform Act Analysis

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Executive Summary

The Food and Drug Administration (FDA) is revoking the standard of identity and standard of quality for frozen cherry pie. We conclude that these standards no longer promote honesty and fair dealing in the interest of consumers. Revocation of 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. Revocation of the standards of identity and quality for frozen cherry pie 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 final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104-121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers 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). Rules are “significant” under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they “have an annual effect on the economy of \$200 million or more (adjusted every 3 years by the Administrator of [the Office of Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.” OIRA has determined that this final rule is not a significant regulatory action as defined by Executive Order 12866 Section 3(f)(1).

Because this rule is not likely to result in an annual effect on the economy of \$100 million or more or meets other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does not fall within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we conclude that this final rule would not generate compliance costs, we certify that the final 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 estimates of anticipated impacts, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$183 million, using the most current (2023) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The final 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 petition to revoke the standards indicate that revoking the standards of identity and quality could provide benefits in terms of additional flexibility to manufacturers of frozen cherry pie products.¹ We also 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 respect, place restrictions on the food that are inconsistent with consumers’ expectations. Revocation of the standards

¹ 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.

would allow additional flexibility for, and the opportunity for innovation regarding, frozen cherry pie, providing benefits to both consumers and industry. Therefore, we conclude that the final rule to revoke the standards for frozen cherry pie 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 Final Rule

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized \$millions/year	\$0	\$0	\$0	2023	7%		
						3%		
	Annualized Quantified					7%		
						3%		
	Qualitative	Benefits to manufacturers would be from additional flexibility, and the opportunity for innovation regarding, frozen cherry pie products.						
Costs	Annualized Monetized \$millions/year	\$0	\$0	\$0	2023	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:							

C. Comments on the Preliminary Economic Analysis of Impacts and Our Responses

We received comments on our preliminary regulatory impact analysis (Ref. 1) of the proposed rule (Ref. 2). The number assigned to each comment is purely for

organizational purposes and does not signify the comment's value or the order in which it was received.

(Comment 1) Some comments expressed concern that revoking the standards will allow manufacturers to use cheaper ingredients, such as artificial sweeteners, "unknown additives," or "fillers," to increase profits.

(Response 1) We received no information to support the assertion that manufacturers might use cheaper ingredients to make the product cheaper to produce. Manufacturers must comply with the ingredient labeling requirements in 21 CFR 101.4. In the absence of a standard of identity, manufacturers will have the flexibility to use different ingredients to produce products that meet consumer expectations for frozen cherry pie. For example, revocation of the current standards allows reduced-sugar frozen cherry pie varieties to be sold in the market. Therefore, consumers will still be informed about the ingredients in the frozen cherry pie they purchase, and based on their preference, be able to choose from a variety of frozen cherry pies.

(Comment 2) Some comments mentioned that revocation of the standards will "hurt the consumers" by using cheaper ingredients. Some comments also stated that the revocation may compromise the quality of frozen cherry pie and such action will "put the health of consumers at risk." On the contrary, a few comments supported the revocation that it would allow marketing of low sugar varieties that "some consumers may desire" and viewed artificial sweeteners as "acceptable and sometimes desirable" and "more healthy."

(Response 2) We received no information that indicates that artificial sweeteners pose a "health risk." Under current Good Manufacturing Practices (cGMP), manufacturers must

apply appropriate process controls and use safe and suitable ingredients to ensure that the food is suitable for human consumption (see generally 21 CFR Part 117). Revocation of the current standards will promote flexibility and innovation in product manufacture, consistent with comparable nonstandardized foods available in the market. We disagree that revoking the standard of identity will “put the health of consumers at risk.” The comment did not provide information discussing what the health risks would be, and we are unaware of any evidence that supports this statement.

(Comment 3) Some comments stated that revocation of the standards will allow manufacturers to lower the quality of the frozen cherry pies or add “low quality or rotten cherries” in order to “cut costs.” Several comments also stated that there will be fewer or no actual cherries in the frozen cherry pie products if the proposed rule is finalized.

(Response 3) We received no information to support the assertion that revocation of the standards may lower the quality of frozen cherry pies or allow manufacturers to use low quality ingredients such as “rotten cherries” or “blemished cherries” in order to cut costs. We are also aware of no evidence that revocation of the standards may result in “less cherries,” or no “actual cherries” in the frozen cherry pies in the market. Manufacturers must comply with the quality control operations requirements set forth in cGMP regulations, and violations of such requirements are subject to regulatory action. Revocation of the current standards will not change any of the regulations that ensure the production of a safe and quality product. Ingredients also must be listed by their common or usual name, in descending order of predominance by weight under the Federal Food, Drug & Cosmetic Act (FD&C Act). Therefore, consumers will be able to determine whether frozen cherry pies actually contain cherries.

(Comment 4) A few comments disagreed with the preliminary regulatory impact analysis that the revocation would provide social benefits at little to no cost. A comment argued that the benefits should be measured for consumers' benefit, not for the respective industries. Another comment stated that we did not address the social benefits in the proposed regulatory impact analysis. A comment stated that the industry would "cut corners for the sake of the health and wellbeing of consumers," which is not a social benefit.

(Response 4) We disagree with the comments. In the proposed regulatory impact analysis, we note that the revocation of the standards will provide benefits to both consumers and the industry. Revoking the standards allows manufacturers flexibility and the opportunity to innovate and introduce new frozen cherry pie products, thus allowing consumers to choose from numerous frozen cherry pie products in the market. The comments did not provide any additional information to revise our original discussion.

(Comment 5) A comment mentioned that "the dollar cost of all perishable products that are not purchased by consumers may be considered as an economic factor." The comment recommended that the regulatory impact analysis consider the "cost of disposal of unused products because of what is and what is not on the label."

(Response 5) We do not anticipate revocation of the standards will induce disposal of frozen cherry pie products, and this is not an assumption of the rule. This rule does not require manufacturers to change their products but gives flexibility and innovation for using different ingredients in the frozen cherry pie products. We received no information that the revocation of the standards may induce disposal of frozen cherry pie products that are not purchased by consumers. The comment also did not provide any quantitative

information related to the potential disposal of the products. We decline to make any changes in response to this comment.

D. Summary of Changes

The only differences between the economic analyses of the proposed and final rules are clarifications to language.

II. Final Economic Analysis of Impacts

A. Need for Federal Regulatory Action

FDA proposed to revoke the standards of identity and quality for frozen cherry pie at 21 CFR 152.126 (85 FR 82395).

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, food standards that do not promote honesty and fair dealing in the interest of consumers may discourage innovation within the industry, inhibit 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 not aware of 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 of identity and quality. Revocation of the frozen cherry pie standards will provide new opportunities for innovation and the introduction of new products within the frozen cherry pie industry.

B. Purpose of the 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 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 of the Final 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 final action;

Option 3. Regulate other products, through standards of identity and quality, within the frozen cherry 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 Final Action

Our analysis of existing standards and revoking the standards of identity and quality suggests that this final 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.

Revoking § 152.156 would affect the 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.²

The final rule would 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 final rule. Our analysis of current food manufacturing practices and the revocation of the standard indicate that revoking the standard of identity could provide benefits in terms of additional flexibility to the manufacturers of frozen cherry pie. Revoking the standard of identity could provide an opportunity for innovation and the introduction of new frozen cherry pie products, providing benefits to both consumers and industry. Therefore, we conclude that the final rule to revoke the standards for frozen cherry pie would provide 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

² 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 standards. This approach would result in regulations on standards of identity and quality of 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 manufacturer frozen fruit pies that do not comply with the new standards. Furthermore, we are not aware of 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 final action, compared to Option 3 would result in no additional costs to industry or consumers. Option 3 would result in little or no social benefit.

We analyzed the regulatory alternatives options in the Preliminary Regulatory Impact Analysis (Ref. 1), and no changes were made without any relevant comments.

III. Final Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule does not generate compliance costs, we certify that the final rule will not have a

significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

This final rule revokes the standards of identity and quality of frozen cherry pie. The revocation of these standards would permit flexibility to small firms and also allowing for production consistent with consumers' expectations and preferences.

We do not classify as costs of this final 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 final rule.

IV. References

[1] Food and Drug Administration (2020). "Frozen Cherry Pie; Proposed Revocation of a Standard of Identity and a Standard of Quality (Proposed Rule) Preliminary Regulatory Impact Analysis (PRIA)." Silver Spring, MD: U.S. Food and Drug Administration. <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>

[2] Food and Drug Administration (2020). "Frozen Cherry Pie; Proposed Revocation of a Standard of Identity and a Standard of Quality (Proposed Rule)." Silver Spring, MD: U.S. Food and Drug Administration. <https://www.federalregister.gov/documents/2020/12/18/2020-27823/frozen-cherry-pie-proposed-revocation-of-a-standard-of-identity-and-a-standard-of-quality>