



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 152

[Docket No. FDA-2020-N-1690]

RIN 0910-AI17

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) proposes to revoke the standard of identity and the standard of quality for frozen cherry pie. This action, in part, responds to a citizen petition submitted by the American Bakers Association (ABA). 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.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2020-N-1690 for "Frozen Cherry Pie; Proposed Revocation of a Standard of Identity and a Standard of Quality." Received comments, those filed in a timely manner (see ADDRESSES), will be

placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FUTURE INFORMATION CONTACT: Andrea Krause, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-3719.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Proposed Rule

This proposed rule, if finalized, would revoke the standards of identity and quality for frozen cherry pie. This action, in part, responds to a citizen petition submitted by the American Bakers Association (ABA). We tentatively conclude that the standards of identity and quality for frozen cherry pie are no longer necessary to promote honesty and fair dealing in the interest

of consumers and revoking these standards will provide greater flexibility in the product's manufacture, consistent with comparable, nonstandardized foods available in the marketplace.

B. Summary of the Major Provisions of the Proposed Rule

This proposed rule, if finalized, would revoke the standards of identity and quality for frozen cherry pie.

C. Legal Authority

We are issuing this proposed rule to revoke the standards of identity and quality for frozen cherry pie consistent with our authority under section 401 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 341), which directs the Secretary of Health and Human Services (Secretary) to issue regulations fixing and establishing for any food a reasonable definition and standard of identity, quality, or fill of container whenever, in the Secretary's judgment, such action will promote honesty and fair dealing in the interest of consumers.

D. Costs and Benefits

The proposed rule would affect manufacturers of frozen cherry pie and 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 and the opportunity for innovation to the manufacturers. Therefore, we tentatively conclude that the proposed rule to revoke the standards for frozen cherry pie would, if finalized, provide social benefits at no cost to the respective industries.

II. Background

Section 401 of the FD&C Act directs the Secretary to issue regulations fixing and establishing for any food a reasonable definition and standard of identity, quality, or fill of container whenever, in the Secretary's judgment, such action will promote honesty and fair

dealing in the interest of consumers. The purpose of these standards is to protect consumers against economic adulteration and reflect consumers' expectations about food.

We proposed the standards of identity and quality for frozen cherry pie in the *Federal Register* of November 1, 1967 (32 FR 15116), and finalized them in the *Federal Register* of February 23, 1971 (36 FR 3364); the requirements were codified at 21 CFR 28.1 (“Frozen cherry pie; identity; label statement of optional ingredients”) and 21 CFR 28.2 (“Frozen cherry pie; quality; label statement of substandard quality”). We later amended the standards of identity and quality in the *Federal Register* of June 13, 1973 (38 FR 15504), by removing minimum frozen cherry pie weight requirements, aligning the definition of blemished cherries with that in the United States Department of Agriculture’s U.S. Standards for Grades of Frozen Red Tart Pitted Cherries, and adding clarifying language. We renumbered the two sections in the *Federal Register* of March 15, 1977 (42 FR 14302 at 14449), and combined them into § 152.126 (21 CFR 152.126), with the new section covering both the standards of identity and quality.

FDA received a citizen petition from the ABA asking us, in part, to revoke the frozen cherry pie standards of identity and quality (Citizen Petition from the American Bakers Association, dated August 18, 2005, Docket No. FDA-2005-P-0435 (“petition”). We propose to grant this request; our proposed action is to revoke part 152 (21 CFR part 152 (“Fruit pies”)) in its entirety because the standards for frozen cherry pie are the only standards in part 152.

III. ABA Citizen Petition and Grounds

The petition asks us, in part, to revoke the standards of identity and quality for frozen cherry pie in 21 CFR 152.126 (petition at page 10).

The petition claims that the essential elements of § 152.126 are the requirements that the drained cherry content of frozen cherry pies cannot be less than 25 percent of the weight of the pie and that no more than 15 percent by count of the cherries in the pie can be blemished (*id.* at page 9). The petition asserts that the sole purpose of § 152.126 is to establish a standard of quality, and not a standard of identity, for frozen cherry pie products (*id.*). The petition also

opposes the use of any food standards to establish quality characteristics of foods and asserts that food manufacturers and consumers should determine food quality (id.). Consumers would decide whether they wish to spend more money on higher-quality products or less money on lower-quality products. The petition further states that a product of unacceptably low quality will not survive in the marketplace (id.).

The petition also states that there is no basis for singling out frozen cherry pie for the imposition of standards of identity and quality (id. at page 10). The petition observes that there are no standards of identity and quality for any other types of frozen fruit pies, or for any non-frozen fruit pies, including those filled with cherries (id.). The petition further asserts that nonstandardized fruit pies have been sold throughout the country for many years without any evidence of public confusion (id.).

IV. Description of the Proposed Rule

We disagree with the petition's opposition to using standards to establish quality characteristics of foods. Congress has given us the authority to promulgate regulations establishing a reasonable standard of quality for any food. We may exercise this authority to promote honesty and fair dealing in the interest of consumers. Congress has placed few limitations on the foods for which standards of quality may be established, excluding only fresh or dried fruits, fresh or dried vegetables, and butter. Frozen cherry pie is not among these foods, and therefore, we have the authority to establish a standard of quality for frozen cherry pie if doing so promotes honesty and fair dealing in the interest of consumers.

However, we tentatively conclude that the frozen cherry pie standards of identity and quality are no longer needed to promote honesty and fair dealing in the interest of consumers. Consequently, the proposed rule would revoke part 152 ("Fruit pies") in its entirety because the standards for frozen cherry pie are the only standards in part 152.

As the petition notes, frozen cherry pie is the only fruit pie, either frozen or non-frozen, that is subject to standards of identity and quality. This means that:

- other cherry pies (i.e., baked, frozen cherry pie, which § 152.126(a)(1) expressly excludes from the standards, and baked, non-frozen cherry pie) are not subject to standards of identity or quality and
- other fruit pies are not subject to standards of identity or quality.

We are not aware of any evidence suggesting that consumers have different expectations for unbaked, frozen cherry pies than for other cherry pies. At the same time, no other cherry pies are subject to a standard of identity or a standard of quality, and we are aware of no evidence indicating that such standards are necessary to promote honesty and fair dealing in the interest of consumers or to ensure that those cherry pies meet consumer expectations. Similarly, other fruit pies are not subject to standards of identity or quality, and we are aware of no evidence indicating that such standards are necessary to promote honesty and fair dealing in the interest of consumers or to ensure that the pies meet consumer expectations.

Additionally, we tentatively conclude that the prohibition of artificial sweeteners in § 152.126(a)(2) does not promote honesty and fair dealing in the interest of consumers. 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. If the standard of identity 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.

Therefore, after considering the petition and related information, we tentatively conclude that the standards of identity and quality for frozen cherry pie are no longer needed to promote honesty and fair dealing in the interest of consumers consistent with section 401 of the FD&C Act. We are interested in any information, including data and studies, on consumer expectations

regarding unbaked, frozen cherry pies and whether the specifications in § 152.126 are necessary to ensure that frozen cherry pie meets these expectations.

In addition, our proposal to revoke the standards of identity and quality for frozen cherry pie is consistent with Executive Order 13771, “Reducing Regulation and Controlling Regulatory Costs” (January 30, 2017), and Executive Order 13777, “Enforcing the Regulatory Reform Agenda” (February 24, 2017). Executive Order 13771 and Executive Order 13777, taken together, direct agencies to offset the number and cost of new regulations by identifying prior regulations that can be eliminated because, for example, they are outdated, unnecessary, or ineffective. Our proposed revocation also is consistent with section 6 of Executive Order 13563, “Improving Regulation and Regulatory Review” (January 18, 2011), which requires agencies to periodically conduct retrospective analyses of existing regulations to identify those “that might be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them” accordingly.

V. Preliminary Economic Analysis of Impacts

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 costs 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, as set forth below, that this rule would not generate significant 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, of \$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.

The proposed rule would affect manufacturers of unbaked, 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. The proposed rule would not require any 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. The proposed rule would promote innovation and the introduction of new unbaked, 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 would, if finalized, 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%		

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	Qualitative							Benefits to manufacturers would be from additional 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%		
	Qualitative							
Transfers	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 2 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.--Executive Order 13771 Summary (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

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is

available in the docket for this proposed rule (Ref. 1) and at

<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

VI. Analysis of Environmental Impact

We have tentatively determined under 21 CFR part 25.32(a) that this action, if finalized, is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Consultation and Coordination with Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively concluded that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we tentatively conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

IX. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies

that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

X. Reference

The following reference is on display at the Dockets Management Staff (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. Frozen Cherry Pie; Proposed Revocation of a Standard of Identity and a Standard of Quality: Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis. Available at: <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

List of Subjects in 21 CFR Part 152

Bakery products, Food grades and standards, Frozen foods, Fruits.

PART 152—[REMOVED]

Therefore, consistent with our authority under 21 U.S.C. 321, 341, 343, 348, 371, and 379e, under the Federal Food, Drug, and Cosmetic Act, it is proposed that 21 CFR part 152 be removed.

Dated: December 2, 2020

Stephen M. Hahn,

Commissioner of Food and Drugs.

Dated: December 14, 2020

Alex M. Azar II,
Secretary,
Department of Health and Human Services.

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