U.S. FOOD & DRUG ADMINISTRATION

Office of the Commissioner
Office of Policy, Legislation, and International Affairs
Office of Economics and Analysis
Economics Staff

Revocation of Food Standards for 11 Products Not Currently Sold

Docket No. FDA 2025 N-1184

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

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14192, 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 benefits and costs of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits. Rules are economically significant under Executive Order 12866 if they have an annual effect on the economy of $100 million or more; 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, or tribal governments or communities. The Office of Information and Regulatory Affairs (OIRA) has determined that this proposed rule is not a significant regulatory action under Executive Order 12866.

Executive Order 14192 requires that any new incremental 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 ten prior regulations.” This proposed rule, if finalized as proposed, is expected to be deregulatory under Executive Order 14192.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 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 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 1 year.” The current threshold after adjustment for inflation is $187 million, using the most current (2024) 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. Overview of Benefits, Costs, and Transfers

This proposed rule would revoke 11 food standards for products not currently sold. Since no firms are producing these products, we do not anticipate any manufacturers to change their practice. Therefore, we do not anticipate any costs associated with this rule. If a firm were to choose to start producing one of these products again, there could

be benefits in terms of additional flexibility. We do not anticipate that any firms would reenter the market and therefore do not anticipate any benefits of this rule.

Table 1. Summary of the Benefits, Costs, and Distributional Effects of the Proposed Rule (millions of 2024 dollars)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized ($m/year)	$0	$0	$0	2024	7%		
						3%		
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	Annualized Monetized ($m/year)	$0	$0	$0	2024	7%		
						3%		
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized ($m/year)					7%		
						3%		
		From:			To:			
	Other Annualized Monetized ($m/year)					7%		
						3%		
		From:			To:			
Effects	State, Local, or Tribal Government: None Small Business: None Wages: None Growth: None							

Note: Benefits encompass positive and negative benefits. Costs encompass costs and cost savings.

In line with Executive Order 14192, in Table 2 we estimate present and annualized values of costs, cost savings, and net costs over a perpetual time horizon.

Table 2. E.O. 14192 Summary Table (in millions of 2024 dollars, discounted over an infinite time horizon at a 7 percent discount rate)

	Primary Estimate	Low Estimate	High Estimate
Present Value of Costs	$0		
Present Value of Cost Savings	$0		
Present Value of Net Costs	$0		
Annualized Costs	$0		
Annualized Cost Savings	$0		
Annualized Net Costs	$0		

Note: Values in parentheses denote net negative costs (i.e. net cost savings).

II. Preliminary Economic Analysis of Impacts

A. Background

Executive Order 14192, "Unleashing Prosperity Through Deregulation" (90 FR 9065, February 6, 2025) directs agencies to eliminate unnecessary and burdensome regulations. Revoking these 11 standards for foods no longer marketed in the United States is consistent with this directive. It is also consistent with section 6 of Executive Order 13563, "Improving Regulation and Regulatory Review" (76 FR 3821, January 21, 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.

FDA has identified 11 regulations which supply food standards for foods that are no longer marketed. As such, these standards no longer promote honesty and fair dealing in the interest of consumers. Therefore, FDA is rescinding these 11 food standards in a proposed rule. We note that should anyone wish to manufacture and distribute one of the listed products in the United States in the future they may do so under the provisions of the FD&C Act and implementing regulations that apply to nonstandardized foods or foods in general.

B. Need for Federal Regulatory Action

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 is what it purports to be, reducing the search time and cost for the consumer. However, food

standards that are no longer needed to promote honesty and fair dealing in the interest of consumers may create barriers to entry for new products, thus rescinding such standards may encourage innovation within the industry.

The 11 food standards rescinded by this proposed rule are for products that are no longer sold in the U.S. As such, these food standards are no longer needed to promote honesty and fair dealing.

C. Baseline Conditions

FDA identified 11 food standards that have no market presence. We describe these food standards, as found in 21 CFR, in Table 3.

Table 3. List of Standards of Identity Considered in Market Analysis

Location in 21 CFR	Description
145.116	Artificially Sweetened Canned Apricots
145.126	Artificially Sweetened Canned Cherries
145.131	Artificially Sweetened Canned Figs
145.134	Canned Preserved Figs
145.136	Artificially Sweetened Fruit Cocktail
145.140	Canned Seedless Grapes
145.171	Artificially Sweetened Canned Peaches
145.176	Artificially Sweetened Canned Pears
145.181	Artificially Sweetened Canned Pineapple
155.131	Canned Field Corn
155.172	Canned Dry Peas

We conducted a market analysis to assess whether these 11 products were on the market. We rely on point-of-sale data from Circana to identify that the 11 food products were not marketed at multi-outlet and convenience retailers from 2019 through 2024.[1] Circana defines multi-outlet and convenience retailers as brick-and-mortar food, drug, mass-market (including Walmart), club (excluding Costco), dollar, military, and convenience stores. We obtained annual data on dollar sales and unit sales from relevant products at the Universal Product Code (UPC) level.

To identify standardized food products, we used the following methods:

1. We identified the standards of identity for each food based on the text of the food standard in 21 CFR Part 145 or 155.
2. We manually reviewed the Circana data to identify descriptive variables that determine whether a product is subject to the food standard.

[1] Food and Drug Administration custom research definitions based on Circana, LLC (fka Information Resources Inc.) data 2019 to 2024, dollar sales, unit sales, product name, and descriptive label variables, Total Multi Outlet with Convenience.

3. We developed search terms for each food standard to systematically identify relevant products.
4. We reviewed the search results for accuracy and quality control.

The Circana data does not cover all distribution channels for food products. Notably, the data does not include online sales and sales from specialty retailers. To supplement our analysis of the Circana data, we also conducted an internet search to identify products for sale online or sold exclusively in specialty stores. We only concluded that a food standard has no marketed products if we found no relevant products through both our market data analysis and our internet search.

Using this method, we identified 11 food standards with no relevant products on the market. As shown in Table 3, these food standards include:

1. Artificially sweetened canned apricots,
2. Artificially sweetened canned cherries,
3. Artificially sweetened canned figs,
4. Canned preserved figs,
5. Artificially sweetened fruit cocktail,
6. Canned seedless grapes,
7. Artificially sweetened canned peaches,
8. Artificially sweetened canned pears,
9. Artificially sweetened canned pineapple,
10. Canned field corn, and
11. Canned dry peas.

We note that the food standards for artificially sweetened canned fruit in this rulemaking only include the sweeteners saccharin and sodium saccharin. Other reduced sugar canned fruits are not affected by this proposed rule. The data available in Circana identified the sweeteners used for any artificially sweetened canned apricots, cherries, figs, fruit cocktail, and pineapple and confirmed that all available products are not subject to these food standards. However, we were unable to confirm the nonnutritive sweeteners used in some reduced sugar canned peaches and pears.

To confirm the sweeteners used in these products, we used Mintel data to cross reference the statement of identity with the ingredient list. This data provides product details including the principal display panel with the statement of identity and ingredient lists but does not provide sales data like Circana. In our search of the Mintel data, we only identified reduced sugar canned peaches and pears sweetened with sucralose or acesulfame potassium. Therefore, we did not identify any products subject to these food standards.

D. Benefits of the Proposed Rule

There are currently no marketed products from these 11 categories. Therefore, we do not anticipate any benefits from revoking these 11 food standards. Revoking these food

standards could provide flexibility and the opportunity for the introduction of new products previously covered under these 11 food standards. It is possible that firms may choose to reenter these markets, however, we do not have sufficient information to predict if firms may choose to do so. If a firm were to choose to start producing one of these products again, there could be benefits in terms of additional flexibility and possible innovation, leading to changes in consumer and producer surplus.

E. Costs of the Proposed Rule

Food standards are intended to promote honesty and fair dealing in the interest of consumers. Since these 11 products do not exist on the market there is no cost to consumers. Additionally, since there are no products currently on the market, it appears that consumers do not have preference for these product categories. For firms to reenter these markets they would need to create new, consumer preferred products to be competitive.

F. Analysis of Regulatory Alternatives to the Proposed Rule

1. Regulatory Alternative 1: Update the Food Standards for Canned Fruits to Include Additional Nonnutritive Sweeteners

For the seven artificially sweetened canned fruits, the only products available on the market do not fall within the food standard since they use sweeteners not included in the food standard definition. One alternative to revoking these seven food standards would be to update these food standards such that the products on the market would be covered under the food standard. However, that could reduce flexibility relative to the proposed rule.

2. Regulatory Alternative 2: Develop 11 Rulemakings to Revoke these 11 Food Standards

One alternative to this single action would be to develop rulemakings to revoke each of these 11 food standards individually. Eleven individual actions would create government inefficiencies in the form of additional paperwork and staff time to write and review the 11 rulemakings but would have the same end result for these food standards. Therefore, we choose to revoke these 11 food standards in a single action.

G. International Effects

We do not anticipate any international effects of this proposed regulation.

III. Initial 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 we do not estimate any cost to any business, we propose to certify that the proposed 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 and the Preamble of the proposed rule, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

This rule only impacts products that are not currently marketed. Therefore, this rule has no costs to any small businesses. If a small business chooses to begin marketing one of the covered products they may realize benefits of additional flexibility in the product development.