



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 145 and 155

[Docket No. FDA-2025-N-1184]

RIN 0910-AJ06

Revocation of Food Standards for 11 Products Not Currently Sold

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA or we) revokes 11 food standards for foods that are no longer sold in the United States. FDA is taking this action as these standards are no longer necessary to promote honesty and fair dealing in the interest of consumers. This action will remove obsolete rules to reduce unnecessary regulatory requirements.

DATES: This rule is effective [INSERT DATE 65 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], unless significant adverse comment is received by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. If FDA receives significant adverse comments, it will publish a timely withdrawal in the Federal Register informing the public that this rule or a portion thereof will not take effect.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 30 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-2025-N-1184 for "Revocation of Food Standards for 11 Products Not Currently Sold." 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 FUTHER INFORMATION CONTACT: Claudine Kavanaugh, Office of Nutrition and Food Labeling, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371; Meadow Platt, Office of Policy, Regulations, and

Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

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I. Executive Summary

A. Purpose of the Direct Final Rule

This action removes regulations that FDA believes are obsolete and no longer necessary to promote honesty and fair dealing in the interest of consumers. We are also publishing elsewhere in this issue of the *Federal Register* a companion proposed rule proposing to take the actions described in this direct final rule. The companion proposed rule provides a procedural framework within which the rule may be finalized if the direct final rule is withdrawn because of any significant adverse comments. The comment period for the

direct final rule runs concurrently with the companion proposed rule. Any comments received in response to the companion proposed rule will be considered as comments regarding the direct final rule.

B. Summary of the Major Provisions of the Direct Final Rule

This direct final rule revokes:

Part 145 – Canned Fruits

- 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 canned 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

The revocation of the standards for artificially sweetened canned fruit applies only to canned fruit made with saccharin and/or sodium saccharin since these are the only products covered under these standards. The revocation does not apply to any other reduced sugar canned fruit products.

Part 155 – Canned Vegetables

- 155.131: Canned field corn
- 155.172: Canned dry peas

C. Legal Authority

We are issuing this direct final rule to revoke the standards for the listed products based on 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. This direct final rule is also issued upon the Secretary's authority under section 701(a) of the FD&C Act (21 U.S.C. 371) for the efficient enforcement of the FD&C Act.

D. Costs and Benefits

Our analysis of the current market indicates that there are no products currently marketed under the standards of identity listed above. Therefore, we conclude that the direct final rule to revoke the standards would result in zero benefits and zero costs to consumers and industry.

II. Background

President Trump has directed the heads of executive departments and agencies to eliminate unnecessary and burdensome regulations (Executive Order 14192, *Unleashing Prosperity Through Deregulation* (90 FR 9065, February 6, 2025; signed January 31, 2025)). Independently, Secretary Kennedy has expressed support for deregulatory initiatives across all HHS components to focus on the core mission to Make America Healthy Again. *See Request for Information (RFI): Ensuring Lawful Regulation and Unleashing Innovation to Make America Healthy Again* (90 FR 20478, May 14, 2025). Revoking these 11 standards for foods no longer marketed in the U.S. is consistent with these directives. 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.

Section 401 of the FD&C Act (21 U.S.C. 341) 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. FDA has initially identified 11 standards for foods that are no longer sold. As such, these standards are no longer necessary to promote honesty and fair dealing in the interest of consumers. Therefore, in this direct final rule, FDA revokes those 11 standards.

III. Description of the Direct Final Rule

FDA is revoking 11 food standards because FDA is aware of no evidence that such foods are currently being sold in the United States. To assess the U.S. market for these foods, FDA reviewed supermarket scanner data on consumer purchases, as well as data from commercial databases for food products, and conducted Internet searches.¹ This data displayed no purchases for the 11 standardized foods that are the subject of this direct final rule. As such, FDA is not aware of any evidence indicating that these standards “promote honesty and fair dealing in the interest of consumers.” *See* 21 U.S.C. 341. Therefore, such regulations are no longer necessary. Moreover, 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.²

In the event of a stay or invalidation of any of the standards identified for removal, the remaining standards identified in this rule would be unaffected. In addition, if a significant adverse comment applies to a part of the direct final rule and that part can be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of the significant adverse comment.

IV. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14192, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5

¹ Mintel is a commercial database of retail food products that we searched to evaluate if the identified foods are currently on the market. The advanced search tool was used to limit results with the following parameters: product name, food product category, and region where sold (U.S.). If necessary for the product, the search was also narrowed by food ingredients, food characteristics, and year. Recent sales data was also considered using the information from an additional market research company. We note these databases do not capture online sales. We therefore further performed internet searches using product names and also did not find evidence of online sales.

² We are aware that other kinds of reduced sugar canned fruits other than those sweetened with saccharin are on the market, including those sweetened with fruit juice, light syrup, other non-nutritive sweeteners, or a combination of these. However, because these products are not sweetened with saccharin, they are not covered under the standards being revoked. We note that if, in the future, manufacturers produce the artificially sweetened fruits in the standards revoked in this rulemaking, such foods would appear to be covered under 21 CFR 130.10, provided that the corresponding standard for the non-artificially sweetened version (i.e., canned apricots, canned cherries, canned figs, canned fruit cocktail, canned peaches, canned pears, canned pineapple) remains standardized.

U.S.C. 801, Pub. L. 104-121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866 and 13563 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. 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.” Rules are “economically significant” under Executive Order 12866 Section 3(f)(1) 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 final rule is not a significant regulatory action under Executive Order 12866.

Because this rule is not likely to result in an annual effect on the economy of \$100 million or more or to meet 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 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 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

\$187 million, using the most current (2024) 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. *Overview of Benefits, Costs, and Transfers*

The final rule will 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 expect any firms to reenter the market and therefore do not anticipate any benefits of this rule.

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

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized (\$millions/year)	\$0	\$0	\$0	2024	7%		
						3%		
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	Annualized Monetized (\$millions/year)	\$0	\$0	\$0	2024	7%		
						3%		
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized Monetized (\$millions/year)					7%		
						3%		
	Other Annualized Monetized (\$millions/year)	From:			To:			
						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. This final rule is considered deregulatory under E.O. 14192. Details on the estimated cost savings of this rule can be found in the rule’s economic analysis.

Table 2. Executive Order 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).

We have developed an Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this direct final rule at <https://www.fda.gov/economics-staff/regulatory-impact-analyses-ria>.

V. Analysis of Environmental Impact

We have determined under 21 CFR 25.32(a) that this action 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.

VI. Paperwork Reduction Act of 1995

FDA concludes that this direct final 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.

VII. Federalism

We have analyzed this direct final rule in accordance with the principles set forth in Executive Order 13132. We have determined that this direct final 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.

VIII. Consultation and Coordination with Indian Tribal Governments

We have analyzed this direct final rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect 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. We invite comments from tribal officials on any potential impact on Indian Tribes from this direct final action.

List of Subjects

21 CFR Part 145

Canned fruits, Food grades and standards.

21 CFR Part 155

Canned vegetables, Food grades and standards.

Therefore, under the Federal Food, Drug, and Cosmetic Act, 21 CFR parts 145 and 155 are amended as follows:

PART 145 – CANNED FRUITS

1. The authority citation for part 145 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

§§ 145.116, 145.126, 145.131, 145.134, 145.136, 145.140, 145.171, 145.176, and 145.181

[Removed]

2. Sections 145.116, 145.126, 145.131, 145.134, 145.136, 145.140, 145.171, 145.176, and 145.181 are removed.

PART 155 – CANNED VEGETABLES

3. The authority citation for part 155 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

§§ 155.131 and 155.172 [Removed]

4. Sections 155.131 and 155.172 are removed.

Robert F. Kennedy, Jr.,

Secretary,

Department of Health and Human Services.

[FR Doc. 2025-13421 Filed: 7/16/2025 8:45 am; Publication Date: 7/17/2025]