that 21 CFR parts 131, 133, 135, and 184 be amended as follows:

PART 131—MILK AND CREAM

■ 1. The authority citation for part 131 continues to read as follows:

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

§§ 131.111 and 131.162 [Removed]

■ 2. Sections 131.111 and 131.162 are removed.

PART 133—CHEESES AND RELATED CHEESE PRODUCTS

■ 3. The authority citation for part 133 continues to read as follows:

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

§§ 133.111, 133.116, 133.121, 133.125, 133.127, 133.134, 133.140, 133.154, 133.164, 133.168, 133.170, 133.174, 133.185, and 133.186 [Removed]

■ 4. Sections 133.111, 133.116, 133.121, 133.125, 133.127, 133.134, 133.140, 133.154, 133.164, 133.168, 133.170, 133.174, 133.185, and 133.186 are removed.

PART 135—FROZEN DESSERTS

■ 5. The authority citation for part 135 continues to read as follows:

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

§§ 135.115 and 135.130 [Removed]

■ 6. Sections 135.115 and 135.130 are removed.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

■ 7. The authority citation for part 184 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, and 371.

§ 184.1157 [Amended]

■ 8. Section 184.1157 is amended by revising paragraph (c)(2) to read as follows:

§ 184.1157 Benzoyl peroxide.

* * * * *

(c) * * *

(2) The ingredient is used in the following foods at levels not to exceed current good manufacturing practice: flour; milk used for production of Asiago fresh and Asiago soft cheese (§ 133.102), Asiago medium cheese (§ 133.103), Asiago old cheese (§ 133.104), Blue cheese (§ 133.106), Gorgonzola cheese (§ 133.141), Parmesan and reggiano cheese (§ 133.165), Provolone cheese (§ 133.181), Romano cheese (§ 133.183), and Swiss and emmentaler cheese (§ 133.195) in part 133 of this chapter; and annatto-colored whey, such that the final bleached product conforms to the descriptions and specifications for whey, concentrated whey, or dried whey in § 184.1979(a)(1), (2), or (3), respectively.

* * * * *

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–13424 Filed 7–16–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 136, 139, 146, 161, and 169

[Docket No. FDA–2025–N–1307]

RIN 0910–AJ12

Proposal To Revoke 23 Standards of Identity for Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to revoke 23 standards of identity for food. FDA is 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. This proposed action would reduce redundant regulatory requirements.

DATES: Submit either electronic or written comments on the proposed rule by September 15, 2025. FDA does not intend to extend the comment period.

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 September 15, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–1307 for ''Proposal to Revoke 23 Standards of Identity for Foods.'' 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, the plain language summary of the proposed rule of not more than 100 words as required by the ''Providing Accountability Through Transparency Act,'' 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 FURTHER 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; Meridith L. Kelsch, Office of Policy, Regulations, and Information, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Proposed Rule

This action proposes to remove 23 standards of identity for food that FDA tentatively concludes are no longer necessary to promote honesty and fair dealing in the interest of consumers.

B. Summary of the Major Provisions of the Proposed Rule

This action proposes to remove the following food standard regulations:

Part 136—Bakery Products

- 136.130 Milk bread, rolls, and buns

Part 139—Macaroni and Noodle Products

- 139.117 Enriched macaroni products with fortified protein
- 139.120 Milk macaroni products
- 139.121 Nonfat milk macaroni products
- 139.122 Enriched nonfat milk macaroni products
- 139.140 Wheat and soy macaroni products
- 139.160 Vegetable noodle products
- 139.165 Enriched vegetable noodle products
- 139.180 Wheat and soy noodle products

Part 146—Canned Fruit Juices

- 146.121 Frozen concentrate for artificially sweetened lemonade
- 146.126 Frozen concentrate for colored lemonade
- 146.137 Frozen orange juice
- 146.148 Reduced acid frozen concentrated orange juice
- 146.150 Canned concentrated orange juice
- 146.151 Orange juice for manufacturing
- 146.152 Orange juice with preservative
- 146.153 Concentrated orange juice for further manufacturing
- 146.154 Concentrated orange juice with preservative

Part 161—Fish and Shellfish

- 161.136 Olympia oysters
- 161.176 Frozen raw lightly breaded shrimp

Part 169—Food Dressings and Flavorings

- 169.180 Vanilla-vanillin extract
- 169.181 Vanilla-vanillin flavoring
- 169.182 Vanilla-vanillin powder

In addition to the removal of these food standards, this action proposes to amend regulations that reference these food standards.

C. Legal Authority

We are issuing this proposed rule based on our authority under section 401 of the Federal Food, Drug, and Cosmetic Act (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 judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers. This proposed 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

Based on our analysis, we anticipate benefits from some revoked food standards in the form of producer and consumer surplus generated by increased flexibility. We anticipate cost savings from revoking these food standards in the form of eliminating the need for companies to read and understand food standards during product development. We discuss these impacts qualitatively.

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 23 standards of identity 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.

In line with the President's deregulatory agenda and the Secretary's direction, we have initiated a review of food standards to assess which standards are outdated or unnecessary and are good candidates for revocation. This rulemaking is one of several that FDA is planning to streamline its food standard regulations. Throughout this document, we refer to standards of identity for food products as ''standards'' or ''food standards.''

III. Description of the Proposed Rule

FDA issued most food standards regulations before 1980. FDA's initial approach to food standards during the 1940s to 1960s was oriented to maintaining the value of food and preventing economic adulteration. In the absence of premarket safety standards and labeling for ingredients, many early food standards have been described as ''recipe standards,'' prescribing, under a common or usual name for the food, the ingredients that must and could be used, sometimes with a manufacturing process, and many provided very limited flexibility (60 FR 67492, 67494, December 29, 1995). This approach both addressed economic adulteration or debasement and ensured that ingredients in, and the production processes used for, standardized foods were ones that FDA regarded as safe (*id.*).

Since 1938, the FD&C Act has been amended numerous times, including amendments related to ingredient safety, ingredient labeling (including allergen labeling), food packaging, safe food production and manufacturing practices, and nutrition labeling information and claims. The standards in this proposed rule predate many of these amendments. The FD&C Act's amendments, along with developments and changes in nutrition, food science, agriculture, and production/manufacturing, mean these food standards may be unnecessary now. For example, the food industry may have moved away from the standardized food to make different, nonstandardized foods. A standard may be an inappropriate impediment to adopting new technologies or food reformulation that would make a food easier to produce or give consumers more choices, including healthier choices that support the Secretary's Make America Healthy Again priorities. Further, some food standards may be redundant in that they provide for additional ingredients to be added to another standardized food or otherwise apply to a food that could be effectively covered by a broader standard. In other cases, substantial time has passed since the standard was established or last amended, and the standard appears to have less significance. In all these situations, the utility of a standard may be quite diminished, and revocation of a food standard may be appropriate as we would not expect that the standard is necessary to promote honesty and fair dealing in the interest of consumers.

We also note that the history of food standards teaches us that consumer preferences and the food industry sometimes change faster than FDA can issue or update regulations, and we should therefore use food standards judiciously. When a food standard no longer promotes honesty or fair dealing in the interest of consumers, FDA may consider whether it is more appropriate to revoke the standard, rather than to amend the standard or replace it with a new one. In those instances, other provisions of the FD&C Act and its implementing regulations for the food would still apply and may permit more flexibility and innovation. FDA believes that food standards are most appropriate when, for example, they protect against instances of economic adulteration or debasement or standardize foods that are likely targets thereof, standardize foods that are important staples of the U.S. diet (either in their inherent nutrient profile or volume), set enrichment or fortification criteria, or standardize foods that are particularly significant in domestic programs or international trade.

Considering the history and appropriateness of food standards along with the current FD&C Act and its implementing regulations, we have identified some initial categories of standards that describe situations when we may consider revoking a food standard. In this proposed rule, we identify four categories of food standards that we tentatively conclude are no longer necessary ''to promote honesty and fair dealing in the interest of consumers'' (21 U.S.C. 341). As we continue our review of all the food standard regulations, we may identify additional categories for revocation.

Category 1: Standardized Foods With Little to No Market in the U.S.

These are foods for which FDA's initial research (described below) shows little to no evidence of a market in the U.S. Our tentative conclusion is that maintaining a standard for a food that has little to no U.S. market is not necessary to promote honesty and fair dealing in the interest of consumers.

Category 2: Standardized Food That Would Be Covered by 21 CFR 130.10 in the Absence of Its Standard of Identity

Section 130.10 is a cross-cutting standard that covers foods that deviate from a standard of identity due to compliance with an expressed nutrient content claim defined by FDA regulation (21 CFR 130.10(a)). There are several expressed nutrient content claims defined under FDA's regulations in 21 CFR 101.54 through 101.62. These regulations define claims such as ''fat free,'' ''low sodium,'' and ''reduced calorie'' and can be met by reducing nutrients such as fat, salt, and sugar in foods. Manufacturers may wish to reduce nutrients in standardized foods consistent with these claims. In some cases, an additional specific food standard exists to permit reductions in fat, salt, or sugar. These standards tend to predate the establishment of 21 CFR 130.10. Before 21 CFR 130.10 was issued, specific standards that allowed these kinds of products were useful; now, however, we tentatively conclude that, in some instances, they may be redundant. We are not currently aware of any evidence suggesting that separate standards would, in this situation, remain necessary to promote honesty and fair dealing in the interest of consumers.

Category 3: Standardized Foods That Include the Name of Another Standardized Food in Their Names

There are some standardized foods that are similar to other standardized foods except for the addition of certain ingredients (*e.g.,* fruits, vegetables, or meats), which may be accompanied by other very minor modifications to reflect changes resulting from the addition of these ingredients. In such cases, we propose to revoke the standards for the foods with additional ingredients so that they are nonstandardized foods. We note that, after revocation, the nonstandardized food may have a name that includes the common or usual name of the standardized food, along with any additions that may be needed to the name to reflect the new ingredient(s) (see 21 CFR 101.3). As we have previously stated, a nonstandardized food may be labeled with a name that includes the common or usual name of a standardized food, provided that the name of the nonstandardized food is not misleading. The goal of the revocations proposed under category 3 is to avoid redundant standards that are no longer necessary to promote honesty and fair dealing in the interest of consumers.

Category 4: Standardized Foods That Could Be Covered by a Broader Standard

Some standardized foods are covered by the standard specified under their common or usual name and also fit within the description of a broader standard for that category or type of food. In this case, FDA believes the more specific standard may not be needed and the food could instead be covered under the broader standard. FDA may conclude that the specific standard is redundant and unnecessary to promote honesty and fair dealing in the interest of consumers. Once the

specific standard is revoked and the food is covered under the broader standard, section 403(a)(1) of the FD&C Act (relating to false or misleading labeling) may require the continued use of descriptive words already in the labeling of the food, *e.g.,* geographic origins, or description(s) of ingredient quantity. These descriptive words may come from the common or usual name or provisions that were in the specific standard. The goal of the revocations proposed under category 4 is to avoid redundant standards that are no longer necessary to promote honesty and fair dealing in the interest of consumers.

FDA has performed an initial review of Parts 136, 139, 146, 161, and 169, which cover standards for bakery products, macaroni and noodle products, canned fruit juices, fish and shellfish, and food dressings and flavorings, respectively. FDA conducted research to determine the market status of each standardized food listed in these parts to assess likely sales, both in person and online. We searched commercial databases of retail food products to evaluate if the identified food standards 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, we also narrowed the search by food ingredients, food characteristics, and year. We also considered recent sales data using the information from an additional market research company. Because these databases do not capture online sales, we performed internet and online shopping searches using product names. The internet searches helped with assessing the product's name and whether the statement of identity (21 CFR 101.3(b)) generally appears sufficient. As explained above, FDA research was primarily focused on market status. Our review of foods' names was very broad and should not be regarded as a compliance or enforcement review.

Based on these considerations and our market research, we tentatively conclude that 23 food standards should be revoked because they fall into one or more of the categories described above and are not necessary to promote honesty and fair dealing in the interest of consumers. The 23 food standards are listed in Table 1 along with the primary applicable considerations for revocation described above.

TABLE 1—AMENDMENTS TO FOOD STANDARDS

[Parts 136, 139, 146, 161, 169]

CFR section	Title	Primary reason(s) for revocation
136.130	Milk bread, rolls, and buns	Category 1: Standardized foods with little to no market in the U.S.
139.117	Enriched macaroni products with fortified protein	Category 1: Standardized foods with little to no market in the U.S.
139.120	Milk macaroni products	Category 1: Standardized foods with little to no market in the U.S.
139.121	Nonfat milk macaroni products	Category 1: Standardized foods with little to no market in the U.S.
139.122	Enriched nonfat milk macaroni products	Category 1: Standardized foods with little to no market in the U.S.
139.140	Wheat and soy macaroni products	Category 1: Standardized foods with little to no market in the U.S.
139.160	Vegetable noodle products	Category 1: Standardized foods with little to no market in the U.S.
139.165	Enriched vegetable noodle products	Category 1: Standardized foods with little to no market in the U.S.
139.180	Wheat and soy noodle products	Category 1: Standardized foods with little to no market in the U.S.
146.121	Frozen concentrate for artificially sweetened lemonade	Category 1: Standardized food with little to no market in the U.S.
146.126	Frozen concentrate for colored lemonade	Category 3: Standardized food that includes the name of another standardized food in its name.
146.137	Frozen orange juice	Category 1: Standardized food with little to no market in the U.S.
146.148	Reduced acid frozen concentrated orange juice	Category 1: Standardized food with little to no market in the U.S.
146.150	Canned concentrated orange juice	Category 1: Standardized food with little to no market in the U.S.
146.151	Orange juice for manufacturing	Category 1: Standardized food with little to no market in the U.S.
146.152	Orange juice with preservative	Category 1: Standardized food with little to no market in the U.S.
146.153	Concentrated orange juice for further manufacturing	Category 1: Standardized food with little to no market in the U.S.
146.154	Concentrated orange juice with preservative	Category 1: Standardized food with little to no market in the U.S.
161.136	Olympia oysters	Category 4: Standardized food that could be covered by a broader standard.
161.176	Frozen raw lightly breaded shrimp	Category 4: Standardized food that could be covered by a broader standard.
169.180	Vanilla-vanillin extract	Category 1: Standardized food with little to no market in the U.S.
169.181	Vanilla-vanillin flavoring	Category 1: Standardized food with little to no market in the U.S.
169.182	Vanilla-vanillin powder	Category 1: Standardized food with little to no market in the U.S.

Additionally, because we are proposing to remove these standards from the regulations, we are also proposing to amend the following regulations that reference these standards to reflect their removal from the regulations:

- 21 CFR 136.110(c)(6), to remove reference to § 136.130;
- 21 CFR 146.140(a) and (b), to remove reference to § 146.153;
- 21 CFR 146.141(a), to remove reference to § 146.137;
- 21 CFR 146.145(a), to remove reference to §§ 146.137, 146.151, and 146.153; and
- 21 CFR 146.146(a), to remove reference to §§ 146.150 and 146.153.

These proposed amendments would not alter the substantive requirements in the regulations, rather, they would remove refences to the regulations we propose to revoke.

IV. Proposed Effective Date

FDA proposes to make these revocations effective 60 days after publication of a final rule.

V. Preliminary Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866 (''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993)), Executive Order 13563,

Executive Order 14192, the Regulatory Flexibility Act, 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 on 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 do not estimate this rule would have any costs to businesses, 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 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 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 23 food standards that are no longer necessary to promote honesty and fair dealing in the interest of consumers. We anticipate benefits from some revoked food standards in the form of producer and consumer surplus generated by increased flexibility. We anticipate cost savings from revoking these food standards in the form of eliminating the need for companies to read and understand food standards during product development. We do not anticipate any costs to consumers as these food standards are no longer necessary to promote honesty and fair dealing in the interest of consumers. We discuss these impacts qualitatively and summarize the impacts in Table 1.

TABLE 1—SUMMARY OF 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	$0	$0	$0	2024	7		
Monetized ($millions/year)	0	0	0	2024	3		
Annualized					7		
Quantified					3		
Qualitative	Revoking these food standards may lead to increases in producer and consumer surplus generated by increased flexibility.						
Costs:							
Annualized	0	0	0	2024	7		
Monetized ($millions/year)	0	0	0	2024	3		
Annualized					7		
Quantified					3		
Qualitative	Revoking these food standards may lead to cost savings in product development from removing the need for companies to read and understand the food standards.						
Transfers:							
Federal					7		
Annualized					3		
Monetized ($millions/year)	From:			To:			
Other					7		
Annualized					3		
Monetized ($millions/year)	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).

We have developed a Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full analysis of economic impacts is available in the docket for this proposed rule and at *https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria.*

VI. Analysis of Environmental Impact

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

VII. Paperwork Reduction Act of 1995

This proposed rule contains no new or revised collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

VIII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132, ''Federalism'' (64 FR 43255, August 10, 1999). We have determined that this 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.

IX. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175, ''Consultation and Coordination with Indian Tribal'' (65 FR 67249, November 9, 2000). 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 proposed action.

List of Subjects

21 CFR Part 136

Bakery products, Food grades and standards.

21 CFR Part 139

Food grades and standards.

21 CFR Part 146

Food grades and standards, Fruit juices.

21 CFR Part 161

Food grades and standards, Frozen foods, Seafood.

21 CFR Part 169

Food grades and standards, Oils and fats, Spices and flavorings.

Therefore, under the Federal Food, Drug, and Cosmetic Act, we propose that 21 CFR parts 136, 139, 146, 161, and 169 be amended as follows:

PART 136—BAKERY PRODUCTS

■ 1. The authority citation for part 136 continues to read as follows:

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

§ 136.110 [Amended]

■ 2. Section 136.110 is amended by revising paragraph (c)(6) to read as follows:

§ 136.110 Bread, rolls, and buns.

* * * * *

(c) * * *

(6) Milk and/or other dairy products: Whenever nonfat milk solids in any form are used, carrageenan or salts of carrageenan complying with the provisions of part 172 of this chapter may be used in a quantity not in excess of 0.8 percent by weight of such nonfat milk solids.

* * * * *

§ 136.130 [Removed]

■ 3. Section 136.130 is removed.

PART 139—MACARONI AND NOODLE PRODUCTS

■ 4. The authority citation for part 139 continues to read as follows:

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

§§ 139.117, 139.120, 139.121, 139.122, 139.140, 139.160, 139.165, and 139.180 [Removed]

■ 5. Sections 139.117, 139.120, 139.121, 139.122, 139.140, 139.160, 139.165, and 139.180 are removed.

PART 146—CANNED FRUIT JUICES

■ 6. The authority citation for part 146 continues to read as follows:

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

§§ 146.121, 146.126, and 146.137 [Removed]

■ 7. Sections 146.121, 146.126, and 146.137 are removed.

§ 146.140 [Amended]

■ 8. Section 146.140 is amended by revising paragraphs (a) and (b) to read as follows:

§ 146.140 Pasteurized orange juice.

* * * * *

(a) Pasteurized orange juice is the food prepared from unfermented juice obtained from mature oranges as specified in § 146.135, to which may be added not more that 10 percent by volume of the unfermented juice obtained from mature oranges of the species *Citrus reticulata* or *Citrus reticulata* hybrids (except that this limitation shall not apply to the hybrid

species described in § 146.135). Seeds (except embryonic seeds and small fragments of seeds that cannot be separated by good manufacturing practice) are removed, and pulp and orange oil may be adjusted in accordance with good manufacturing practice. If the adjustment involves the addition of pulp, then such pulp shall not be of the washed or spent type. The solids may be adjusted by the addition of the optional concentrated orange juice ingredient specified in paragraph (b) of this section. One or more of the optional sweetening ingredients listed in paragraph (c) of this section may be added in a quantity reasonably necessary to raise the Brix or the Brix-acid ratio to any point within the normal range usually found in unfermented juice obtained from mature oranges as specified in § 146.135. The orange juice is so treated by heat as to reduce substantially the enzymatic activity and the number of viable microorganisms. Either before or after such heat treatment, all or a part of the product may be frozen. The finished pasteurized orange juice contains not less than 10.5 percent by weight of orange juice soluble solids, exclusive of the solids of any added optional sweetening ingredients, and the ratio of the Brix hydrometer reading to the grams of anhydrous citric acid per 100 milliliters of juice is not less than 10 to 1.

(b) The optional concentrated orange juice ingredient referred to in paragraph (a) of this section is frozen concentrated orange juice as specified in § 146.146; but the quantity of such concentrated orange juice ingredient added shall not contribute more than one-fourth of the total orange juice solids in the finished pasteurized orange juice.

* * * * *

§ 146.141 [Amended]

■ 9. Section 146.141 is amended by revising paragraph (a) to read as follows:

§ 146.141 Canned orange juice.

(a) Canned orange juice is the food prepared from orange juice as specified in § 146.135, to which may be added not more than 10 percent by volume of the unfermented juice obtained from mature oranges of the species *Citrus reticulata* or *Citrus reticulata* hybrids (except that this limitation shall not apply to the hybrid species described in § 146.135). Seeds (except embryonic seeds and small fragments of seeds that cannot be separated by good manufacturing practice) are removed. Orange oil and pulp may be adjusted in accordance with good manufacturing practice. The adjustment of pulp referred to in this paragraph does not permit the addition of washed or spent pulp. Liquid condensate recovered from the deoiling operation may be added back. One or more of the optional sweetening ingredients named in paragraph (b) of this section may be added, in a quantity reasonably necessary to raise the Brix or the Brix-acid ratio to any point within the normal range usually found in unfermented juice obtained from mature oranges as specified in § 146.135. The food is sealed in containers and so processed by heat, either before or after sealing, as to prevent spoilage. The finished canned orange juice tests not less than 10° Brix, and the ratio of the Brix hydrometer reading to the grams of anhydrous citric acid per 100 milliliters of juice is not less than 9 to 1.

* * * * *

§ 146.145 [Amended]

■ 10. Section 146.145 is amended by revising paragraph (a) to read as follows:

§ 146.145 Orange juice from concentrate.

(a) Orange juice from concentrate is the food prepared by mixing water with frozen concentrated orange juice as defined in § 146.146. To such mixture may be added orange juice as defined in § 146.135, pasteurized orange juice as defined in § 146.140, orange oil, orange pulp, and one or more of the sweetening ingredients listed in paragraph (b) of this section. The finished orange juice from concentrate contains not less than 11.8 percent orange juice soluble solids, exclusive of solids of any added optional sweetening ingredients. It may be so treated by heat as to reduce substantially the enzymatic activity and the number of viable microorganisms.

* * * * *

§ 146.146 [Amended]

■ 11. Section 146.146 is amended by revising paragraph (a) to read as follows:

§ 146.146 Frozen concentrated orange juice.

(a) Frozen concentrated orange juice is the food prepared by removing water from the juice of mature oranges as provided in § 146.135, to which may be added unfermented juice obtained from mature oranges of the species *Citrus reticulata,* other *Citrus reticulata* hybrids, or of *Citrus aurantium,* or both. However, in the unconcentrated blend, the volume of juice from *Citrus reticulata* or *Citrus reticulata* hybrids shall not exceed 10 percent (except that this limitation shall not apply to the hybrid species described in § 146.135) and from *Citrus aurantium* shall not exceed 5 percent. The concentrate so obtained is frozen. In its preparation, seeds (except embryonic seeds and small fragments of seeds that cannot be separated by good manufacturing practice) and excess pulp are removed, and a properly prepared water extract of the excess pulp so removed may be added. Orange oil, orange pulp, orange essence (obtained from orange juice), orange juice and other orange juice concentrate as provided in this section, water, and one or more of the optional sweetening ingredients specified in paragraph (b) of this section may be added to adjust the final composition. The juice of *Citrus reticulata* and *Citrus aurantium,* as permitted by this paragraph, may be added in single strength or concentrated form prior to concentration of the *Citrus sinensis* juice, or in concentrated form during adjustment of the composition of the finished food. The addition of concentrated juice from *Citrus reticulata* or *Citrus aurantium,* or both, shall not exceed, on a single-strength basis, the 10 percent maximum for *Citrus reticulata* and the 5 percent maximum for *Citrus aurantium* prescribed by this paragraph. Any of the ingredients of the finished concentrate may have been so treated by heat as to reduce substantially the enzymatic activity and the number of viable microorganisms. The finished food is of such concentration that when diluted according to label directions the diluted article will contain not less than 11.8 percent by weight of orange juice soluble solids, exclusive of the solids of any added optional sweetening ingredients. The dilution ratio shall be not less than 3 plus 1. For the purposes of this section, the term ''dilution ratio'' means the whole number of volumes of water per volume of frozen concentrate required to produce orange juice from concentrate having orange juice soluble solids of not less than 11.8 percent by weight exclusive of the solids of any added optional sweetening ingredients.

* * * * *

§§ 146.148, 146.150, 146.151, 146.152, 146.153, and 146.154 [Removed]

■ 12. Sections 146.148, 146.150, 146.151, 146.152, 146.153, and 146.154 are removed.

PART 161—FISH AND SHELLFISH

■ 13. The authority citation for part 161 continues to read as follows:

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

§§ 161.136 and 161.176 [Removed]

■ 14. Sections 161.136 and 161.176 are removed.

PART 169—FOOD DRESSINGS AND FLAVORINGS

■ 15. The authority citation for part 169 continues to read as follows:

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

§§ 169.180, 169.181, and 169.182 [Removed]

■ 16. Sections 169.180, 169.181, and 169.182 are removed.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–13420 Filed 7–16–25; 8:45 am]

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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: Proposed rule.

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

DATES: Either electronic or written comments on the proposed rule or its companion direct final rule must be submitted by August 18, 2025. If FDA receives any timely significant adverse comments on the direct final rule with which this proposed rule is associated, we will publish a document withdrawing the direct final rule within 30 days after the comment period ends, and we will then proceed to respond to comments under this proposed rule using the usual notice and comment procedures.

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 August 18, 2025. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 18, 2025. 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 FURTHER 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.

SUPPLEMENTARY INFORMATION:

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