



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 169

[Docket No. FDA-2020-N-1807]

RIN 0910-AI16

French Dressing; Proposed Revocation of a Standard of Identity

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 for French dressing. This action, in part, responds to a citizen petition submitted by the Association for Dressings and Sauces (ADS). We tentatively conclude that this standard no longer promotes honesty and fair dealing in the interest of consumers. Revocation of the standard of identity for French dressing could 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-1807 for “French Dressing; Proposed Revocation of a Standard of Identity.” 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, 240-402-2371.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Proposed Rule

B. Summary of the Major Provisions of the Proposed Rule

C. Legal Authority

D. Costs and Benefits

II. Background

III. ADS Citizen Petition and Grounds

IV. Description of the Proposed Rule

V. Preliminary Economic Analysis of Impacts

VI. Paperwork Reduction Act of 1995

VII. Consultation and Coordination with Indian Tribal Governments

VIII. Federalism

IX. Analysis of Environmental Impact

X. Reference

I. Executive Summary

A. Purpose of the Proposed Rule

This proposed rule, if finalized, would revoke the standard of identity for French dressing. This action, in part, responds to a citizen petition submitted by the Association for Dressings and Sauces (ADS) (petition). We tentatively conclude that the standard of identity for French dressing no longer promotes honesty and fair dealing in the interest of consumers and revoking the standard could provide greater flexibility in the product's manufacture, consistent with comparable, nonstandardized foods available in the marketplace.

B. Summary of the Major Provision of the Proposed Rule

This proposed rule, if finalized, would revoke the standard of identity for French dressing.

C. Legal Authority

We are issuing this proposed rule to revoke the standard of identity for French dressing consistent with our authority under of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 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 dressings for salad, and would not require any of the affected firms within the industry to change their manufacturing practices. Our analysis of current food manufacturing practices and the petition to revoke the standard indicate that revoking the standard of identity could provide benefits in terms of additional flexibility and the opportunity for innovation to manufacturers. The potential for innovation is evidenced by the growing variety of dressings for salads on the market that are formulated to meet consumers' preferences and needs. Therefore, we

tentatively conclude that the proposed rule to revoke the standard of identity for French dressing would, if finalized, provide social benefits at no cost to the respective industries.

II. Background

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

In the *Federal Register* of August 12, 1950 (15 FR 5227), we established a standard of identity for French dressing. We later amended that standard of identity in the *Federal Registers* of May 10, 1961 (26 FR 4012), February 12, 1964 (29 FR 2382), February 1, 1967 (32 FR 1127 at 1128), May 18, 1971 (36 FR 9010), and November 8, 1974 (39 FR 39554) to allow the use of certain ingredients in French dressing. We also re-designated the French dressing standard of identity as 21 CFR 169.115 (42 FR 14481, March 15, 1977).

We received a citizen petition from the ADS asking us, in part, to revoke the standard of identity for French dressing (Citizen Petition from the Association for Dressings and Sauces, dated January 13, 1998, submitted to the Division of Dockets Management, Food and Drug Administration, Docket No. FDA-1998-P-0669 ("petition")). We are issuing this proposed rule, in part, in response to the petitioner's request.

III. ADS Citizen Petition and Grounds

The petition asks us to revoke the standard of identity for French dressing (petition at page 1).

The petition states that there has been a proliferation of nonstandardized pourable dressings for salads with respect to flavors (Italian, Ranch, cheese, fruit, peppercorn, varied vinegars, and other flavoring concepts) and composition (including a wide range of reduced fat, “light,” and fat-free dressings) (petition at page 3). The French dressing standard of identity, according to the petition, no longer serves as a benchmark for other dressings because of the wide variation in composition to meet consumer interests (id.). Instead, the petition claims that the standard of identity has become marginalized and restricts innovation (id.). Therefore, the petition states that the French dressing standard of identity no longer promotes honesty and fair dealing in the interest of consumers (id.).

IV. Description of the Proposed Rule

We have reviewed the petition and tentatively conclude that the standard of identity for French dressing no longer promotes honesty and fair dealing in the interest of consumers. Therefore, we propose to revoke the French dressing standard of identity at 21 CFR 169.115.

When the standard of identity was established in 1950, French dressing was one of three types of dressings we identified (15 FR 5227). We generally characterized the dressings as containing a fat ingredient, an acidifying ingredient, and seasoning ingredients. The French dressing standard allowed for certain flexibility in manufacturers’ choice of oil, acidifying ingredients, and seasoning ingredients. Tomatoes or tomato-derived ingredients were among the seasoning ingredients permitted, but not required. Amendments to the standard since 1950 have permitted the use of additional ingredients, such as any safe and suitable color additives that impart the color traditionally expected (39 FR 39543 at 39554-39555).

Most, if not all, products currently sold under the name “French dressing” contain tomatoes or tomato-derived ingredients and have a characteristic red or reddish-orange color. They also tend to have a sweet taste. Consumers appear to expect these

characteristics when purchasing products represented as French dressing. Thus, it appears that, since the establishment of the standard of identity, French dressing has become a narrower category of products than prescribed by the standard. These products maintain the above characteristics without a standard of identity specifically requiring them.

Additionally, French dressing products are manufactured and sold in lower-fat varieties that contain less than the minimum amount of vegetable oil (35% by weight) required by 21 CFR 169.115(a). We are unaware of any evidence that consumers are deceived or misled by the reduction in vegetable oil when these varieties are sold under names including terms such as “fat free” or “low-fat.” By contrast, these varieties appear to accommodate consumer preferences and dietary restrictions.

Therefore, after considering the petition and related information, we tentatively conclude that the standard of identity for French dressing no longer promotes 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 French dressing and whether the specifications in § 169.115 are necessary to ensure that French dressing meets these expectations.

In addition, our proposal to revoke the standard of identity for French dressing 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. The 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 dressings for salad. Our review of supermarket scanner data for the year 2018 shows that a total of 227 distinct pourable products sold as “French dressing” that year were manufactured by 53 firms. The proposed rule would not require any of the affected firms to change their manufacturing practices. Our analysis of current food manufacturing practices and the petition to revoke the standard indicate that revoking the standard of identity could provide benefits in terms of additional flexibility to the manufacturers of French dressing products. Revoking the standard of identity could provide an opportunity for innovation and the introduction of new French dressing products, providing benefits to both consumers and industry. Therefore, we tentatively conclude that the proposed rule, if finalized, would provide social benefits at little to no cost to the respective industries (Table 1).

Table 1: Summary of Benefits, Costs and Distributional Effects of 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%		
	Qualitative							Benefits to manufacturers would be from additional flexibility, and the opportunity for innovation regarding, French dressing products.
Costs	Annualized	\$0	\$0	\$0	2018	7%		
						3%		

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes	
					Year Dollars	Discount Rate	Period Covered		
	Monetized Millions/year								
	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 lack of costs, this proposed rule would be considered a deregulatory action under EO 13771.

Table 2. EO 13771 Summary Table (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. 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.

VII. 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 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 solicit comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

VIII. 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.

IX. 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.

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 address, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. French Dressing; Proposed Revocation of a Standard of Identity: Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis, available at:
<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

List of Subjects

21 CFR Part 169

Food grades and standards.

Therefore, under the Federal Food, Drug, and Cosmetic Act, it is proposed that 21 CFR part 169 be amended as follows:

PART 169--FOOD DRESSINGS AND FLAVORINGS

1. The authority citation for 21 CFR part 169 continues to read as follows:

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

§ 169.115 [Removed]

2. Remove § 169.115.

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.

[FR Doc. 2020-27822 Filed: 12/18/2020 8:45 am; Publication Date: 12/21/2020]