DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

French Dressing; Revocation of a Standard of Identity

Docket No. FDA-2020-N-1807

Final Regulatory Impact Analysis Final Regulatory Flexibility Analysis Unfunded Mandates Reform Act Analysis

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

Table of Contents

Executive Summary	3
I. Introduction and Summary	4
A. Introduction	4
B. Summary of Costs and Benefits	5
C. Comments on the Preliminary Economic Analysis of Impacts and Our Responses	6
D. Summary of Changes	6
II. Final Economic Analysis of Impacts	6
A. Need for Federal Regulatory Action	6
B. Purpose of the Rule	7
C. Analysis of Regulatory Alternatives of the Final Rule	8
III. Final Small Entity Analysis	0
IV. References	1

Executive Summary

The Food and Drug Administration (FDA) is revoking the standard of identity for French dressing. We conclude that the standard no longer promotes honesty and fair dealing in the interest of consumers. Revocation of the standard of identity for French dressing would provide greater flexibility in the product's manufacture, consistent with comparable, nonstandardized foods available in the marketplace. Revocation of the standard of identity for French dressing would provide social benefits at little to no cost to the respective industries.

I. Introduction and Summary

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, 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). We believe that this final 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 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 an assessment of anticipated costs and benefits, 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 one year." The current threshold after adjustment for inflation is \$158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

The final rule does not require any of the affected firms within the salad dressing 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 of French dressing products¹. 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 conclude that the final rule to revoke the standard of identity for French dressing would provide social benefits at no cost to the respective industries (Table 1).

Category		Primary Estimate	Low Estimate	High Estimate	Units			
					Year	Discount	Period	Notes
					Dollars	Rate	Covered	
Benefits	Annualized	\$0	\$0	\$0	2018	7%		
	Monetized					3%		
	\$millions/year							
	Annualized					7%		
	Quantified					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%		
	Monetized					3%		
	\$millions/year							
00313	Annualized					7%		
	Quantified					3%		
	Qualitative							
Transfers	Federal					7%		
	Annualized					3%		
	Monetized							
	\$millions/year							
	From/To	From:			To:			
	Other					7%		
	Annualized					3%		

 Table 1. Summary of Benefits, Costs and Distributional Effects of Final Rule

¹ We do not quantify benefits because any benefits would be from manufacturers choosing to use the additional flexibility, and we cannot quantify how many manufacturers would choose to use that flexibility or how they might use it. Benefits are discussed qualitatively in Section C. Option 2.

		Duing out	Law	Illah	Units					
Category		Primary Estimate	Low Estimate	High Estimate	Year	Discount	Period	Notes		
					Dollars	Rate	Covered			
	Monetized									
	\$millions/year									
	From/To	From:			To:					
Effects	State, Local or Tribal Government:									
	Small Business:									
	Wages:									
	Growth:									

C. Comments on the Preliminary Economic Analysis of Impacts and Our Responses

The Agency did not receive any comments on the preliminary regulatory impact analysis.

D. Summary of Changes

In 2020, we published the proposed rule "French Dressing; Proposed Revocation of a Standard of Identity" (Ref. [2]). The only differences between the economic analyses of the proposed and final rules are clarifications to language.

II. Final Economic Analysis of Impacts

A. Need for Federal Regulatory Action

FDA proposed to revoke the standard of identity for French dressing at CFR 169.115 (85 FR 82980).

Food standards are intended to promote honesty and fair dealing in the interest of consumers. Food standards establish specifications related to the composition and production of certain food products so that consumers know that a food really is what is purports to be, reducing the search time and cost for the consumer. However, outdated

food standards may discourage innovation within the industry, inhibit the introduction of new products, and benefit one industry over another.

The standard of identity for French dressing as defined in 21 CFR 169.115 describes French dressing as a liquid food prepared from vegetable oil(s), acidifying ingredient(s), and optional ingredients, including seasonings and flavorings. The standard of identity for French dressing also requires that French dressing contain not less than 35 percent by weight of vegetable oil. In addition, the French dressing standard requires the declaration of each ingredient on the label.

B. Purpose of the Rule

When the standard of identity was established in 1950, French dressing was one of three types of dressings FDA identified (15 FR 5227). The French dressing standard allowed for certain flexibility in manufacturers' choices of oil, acidifying ingredient, and seasoning ingredients. Tomatoes or tomato-derived ingredients were among the seasoning ingredients permitted but not required.

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.

Moreover, French dressing is available in varieties that deviate from the standard of identity. For example, French dressing is available in lower-fat varieties that contain less than the minimum amount of vegetable oil the standard requires. Revoking the

7

French dressing standard of identity will potentially provide an opportunity for more innovation and the introduction of new products within the salad dressing industry. Demand for French dressing with different attributes will be determined in the marketplace by consumers as is currently the case for other dressing products. Consumers would benefit from the introduction of new products that have different attributes. Furthermore, additional revenue from new products would constitute a benefit to the salad dressing industry and would promote innovation.

C. Analysis of Regulatory Alternatives of the Final Rule

We considered the following regulatory options for the French dressing standard of identity:

Option 1. Take no action;

Option 2. Take the final action;

Option 3. Amend the standard of identity so that the requirements are specific to what is currently represented as "French dressing."

Option 1: Take No Action

By convention, we treat the option of taking no new regulatory action as the baseline for determining the costs and benefits of the other options. There are neither costs nor benefits associated with this option. The consequences of taking no action are relative to the costs and benefits of options 2 and 3.

Option 2: Take the Final Action

Revoking § 169.115 would affect the manufacturers of products sold as "French dressing." 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 farms.²

The final rule would not require any of the affected firms to change their manufacturing practices. Our analysis of current food manufacturing practices and the revocation of 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 conclude that the final rule would provide social benefits at no cost to industry.

Option 3: Amend the standard of identity so that the requirements are specific to what is currently represented as "French dressing"

Another option is to amend the standard of identity for French dressing. This approach would further narrow the requirements in 21 CFR 169.115 to reflect what is currently represented to consumers as "French dressing" and could increase costs on all manufacturers of French dressing, affecting about 53 manufacturers, including manufacturers of French dressing varieties that deviate from the standard of identity.

However, we anticipate that few manufacturers of these products would spend resources to ensure compliance with the amended standard and that costs would be negligible. For manufacturers whose products do not already meet the requirements, this

² We analyzed supermarket scanner data to determine the number of manufacturers in the U.S. of pourable French salad dressing products sold in the year 2018. Supermarket scanner data capture the actual sales of individual food and dietary supplement products by supermarkets, drug stores, mass merchandisers, and convenience stores in the U.S. We obtained the scanner data from an independent, third-party contractor. We are contractually prohibited from releasing the proprietary scanner data to the public.

option would require manufacturers to modify their products to meet the narrower requirements of the amended standard of identity. However, we are aware of no evidence indicating that such amendments are needed to protect consumers against economic adulteration or ensure that the dressings reflect consumers' expectations. The benefits of a narrower standard of identity (e.g., consumer confidence and shorter search cost) are uncertain and likely to be very small.

Option 3 would result in negligible costs to manufacturers of products that already meet the requirements in the amended standard and some costs to manufacturers of products that do not meet the requirements. The option would also result in little or no social benefits. Conversely, Option 2, the final action, would result in additional benefits with no additional costs to industry or consumers.

We analyzed the regulatory alternatives options in the Preliminary Regulatory Impact Analysis (Ref. [2]), and no changes were made without any relevant comments.

III. Final 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 this final rule does not generate compliance costs, we certify that the final 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, serves as the Final Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

This final rule revokes the standard of identity of French dressing. Revocation of this standard could increase flexibility to small firms, which could also allow for technological advances in the production of French dressing.

10

We do not classify as costs of this final rule any voluntary expenses that some small firms might incur because they choose to change their manufacturing practices in

ways that would be newly permitted by the final rule.

IV. References

[1] Food and Drug Administration (2021). "Regulatory Impact Analysis: French Dressing; Proposed Revocation of a Standard of Identity (Final Rule)." Silver Spring, MD: U.S. Food and Drug Administration. <u>https://www.fda.gov/aboutfda/reports/economic-impact-analyses-fda-regulations</u>

[2] Food and Drug Administration (2020). "French Dressing; Proposed Revocation of a Standard of Identity (Proposed Rule) Preliminary Regulatory Impact Analysis (PRIA)." Silver Spring, MD: U.S. Food and Drug Administration. <u>https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations</u>