DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

French Dressing; Proposed Revocation of a Standard of Identity

Docket No. FDA-2020-N-1807

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

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Table of Contents

Executive Summary

The Food and Drug Administration (FDA) is proposing to revoke the standard of identity for French dressing. We are taking this action because we tentatively conclude that this standard no longer promotes honesty and fair dealing in the interest of consumers. We also tentatively conclude that revoking the standard could provide greater flexibility in the product's manufacture, consistent with comparable, nonstandardized foods available in the marketplace. We tentatively conclude that this proposed rule to revoke the standard of identity for French dressing, if finalized, would provide social benefits at little to no cost to the respective industries.

I. <u>Introduction and Summary</u>

A. Introduction

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 (Public Law 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 cost 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 that this proposed rule would not generate compliance costs, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes 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, $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.

B. Summary of Costs and Benefits

The proposed rule would not require firms within the salad dressing industry to change their manufacturing practices. Our analysis of current food manufacturing practices and the proposal 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.[1] The proposed rule could promote innovation regarding French dressing products, providing benefits to both consumers and industry. Therefore, we tentatively conclude that the proposed rule to revoke the standard of identity for French dressing, 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,

[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.

Category		Primary Estimate	Low Estimate	High Estimate	Units: Year Dollars	Units: Discount Rate	Units: Period Covered	Notes
								and the opportunity for innovation regarding, French dressing products.
Costs	Annualized Monetized $millions/year	$0	$0	$0	2018	7%		
						3%		
	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 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

II. Preliminary Economic Analysis of Impacts

A. Need for Federal Regulatory Action

FDA is proposing to revoke the standard of identity for French dressing as prescribed in 21 CFR 169.115.

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 it 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 flavoring. 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 Proposed 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' choice of oil, acidifying ingredients, 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, French dressing has become a narrower product 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 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 to the Proposed Rule

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

Option 1. Take no action;

Option 2. Take the proposed 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 Proposed 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 firms.[2] We request comment on the number of manufacturers and products that would be affected by the revocation of the standard of identity.

If finalized, 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 proposal 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 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 some or 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 proposed action, would result in additional benefits with no additional costs to industry or consumers.

III. Initial Small Entity Analysis

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposed rule does not generate compliance costs, we propose to certify that this proposed rule will not have a significant economic impact on a substantial number of small entities.

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

We do not classify as costs of this proposed 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 proposed rule.