DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Revocation of Methods of Analysis Regulation

Docket No. FDA-2020-N-1383

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

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I. Introduction and Summary

A. Introduction

We have examined the impacts of the proposed 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). 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 this proposed rule does not add any new regulatory burden on the industry, 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 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 $165 million, using the most current (2021) 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 revoke 21 CFR 2.19 methods of analysis, which states that FDA policy is to use the Association of Official Analytical Chemists (AOAC) methods of analysis as published in the 1980 edition of "Official Methods of Analysis of the Association of Analytical Chemists" to analyze samples in FDA enforcement programs when the method of analysis is not prescribed in a regulation. FDA is proposing this action because a general reference to the 1980 edition of the "Official Methods of Analysis of the Association of Analytical Chemists" is unnecessary and because newer, updated methods of analysis may exist. FDA believes it is more appropriate, flexible, and efficient to identify the Agency's preferred methods of analysis in documents such as the Office of Regulatory Affairs (ORA) Laboratory Procedures Manual, FDA compliance programs, and other resources. Thus 21 CFR 2.19 is an unnecessary policy. We expect the economic impact on the FDA resulting from revoking an unnecessary regulation to be minimal.

Table 1 summarizes the estimated benefits and costs of the proposed rule, if finalized. Annualized over 10 years, the estimated benefits (i.e. cost savings) of the proposed rule would be $0 at both the 3 and 7 percent discount rate. The present value of the estimated benefits (i.e., cost savings) of the proposed rule would also be $0 at both the 3 and 7 percent discount rate. The annualized costs of the proposed rule, if finalized, would be $0 at both 3 and 7 percent discount rate. The present value of costs of the proposed rule would also be $0 at both 3 and 7 percent discount rate.

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	2019	7%	10 years	
		$0	$0	$0	2019	3%	10 years	
	Annualized Quantified							
	Qualitative	There would no longer be any inefficiencies due to keeping unnecessary regulations on the books.						
Costs	Annualized Monetized $millions/year	$0	$0	$0	2019	7%	10 years	
		$0	$0	$0	2019	3%	10 years	
	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: None Small Business: None Wages: None Growth: None							

II. Preliminary Economic Analysis of Impacts

A. Background

The Agency uses results obtained from chemical, physical, and biological methods of analysis to test industry compliance with our regulations. In order to standardize the methods of analysis used, ensure reliability and accuracy, and provide information to industry on our practices, 21 CFR 2.19 was enacted in 1972. The Agency has revised the methods of analysis regulation several times, including in 1982 to refer to

the methods of analysis published in the 13th edition of AOAC's "Official Methods of Analysis of the Association of Analytical Chemists." A general reference to the 1980 edition of the "Official Methods of Analysis of the Association of Analytical Chemists" is unnecessary because newer, updated methods of analysis may exist.

B. Market Failure Requiring Federal Regulatory Action

This proposed rule revokes the unnecessary regulation of 21 CFR 2.19 methods of analysis. Unnecessary rules can result in confusions and inefficiencies. By removing the unnecessary policy statement in this regulation, we would reduce inefficiencies related to keeping unnecessary FDA regulations on books.

C. Purpose of the Proposed Rule

If finalized, this proposed rule would revoke 21 CFR 2.19 methods of analysis. The regulation states that it is FDA policy to use the 1980 edition of the AOAC publication's methods of analysis in FDA enforcement programs, when the method is not otherwise specified in a regulation. FDA believes it is more appropriate, flexible, and efficient to identify the Agency's preferred methods of analysis in documents such as the ORA Laboratory Procedures Manual and other resources. Revocation of this regulation would eliminate an unnecessary policy.

D. Baseline Conditions

Baseline conditions refer the methods of analysis in FDA enforcement programs currently used to analyze samples. Current practice among Agency laboratory personnel is to follow FDA's regulations and the recommendations in the Laboratory Procedures Manual and FDA's compliance programs. Based on conversations with FDA subject matter experts, we do not believe revoking 21 CFR 2.19 would change Agency current practice. There is no change from baseline. We request comment on our estimation of the baseline.

E. Benefits of the Proposed Rule

Because revoking the unnecessary regulation would not change Agency current practice, revoking it would not affect the FDA. The regulation to be revoked does not apply to industry. Revoking it would neither increase nor decrease industry flexibility.

There may be qualitative benefits to removing 21 CFR 2.19. There would no longer be any inefficiencies due to keeping unnecessary regulations on the books. The FDA would maintain current practices following the proposed rule. There would be no quantifiable cost savings. FDA requests comments on the benefits of the proposed rule.

F. Costs of the Proposed Rule

We believe there would be no costs to industry from the proposed rule, if finalized, because the regulation it would revoke (21 CFR 2.19 methods of analysis) only applies to Agency personnel.

According to FDA subject matter experts, revocation of 21 CFR 2.19 would not change Agency current practice, and FDA believes it is more appropriate, flexible, and efficient to identify the Agency's preferred methods of analysis in documents such as the ORA Laboratory Procedures Manual and other FDA guidance. We estimate no quantifiable costs. We expect any impact on the FDA to be negligible. FDA requests comments on the costs of the proposed rule.

G. International Effects

We believe that if finalized, this rule would not result in any costs or benefits to either domestic or foreign firms because it would revoke an unnecessary regulation. Therefore, it would not have any effect on foreign or domestic manufacturer practices and we do not expect there to be any significant international effects.

III. Initial 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 rule does not affect the industry, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. This document serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.