DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Revocation of Methods of Analysis Regulation

Docket No. FDA-2020-N-1383

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

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Executive Summary

This final rule will 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. There may be qualitative benefits to removing 21 CFR 2.19 because there will no longer be any inefficiencies due to retaining unnecessary regulations. Revocation of 21 CFR 2.19 will not change Agency current practice; therefore, there are no costs. Annualized over 10 years, the estimated benefits (i.e., cost savings) of the final rule will be $0 at both the 3 and 7 percent discount rate. The annualized costs of the final rule will be $0 at both 3 and 7 percent discount rate.

I. Introduction and Summary

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14192, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104-121), 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 or 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 final 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 10 prior regulations." This final rule is an Executive Order 14192 deregulatory action because it eliminates an unnecessary regulation.

Because this rule is not likely to result in an annual effect on the economy of $100 million or more or to meet other criteria specified in the Congressional Review Act/Small

Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does not fall within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule does not add any new regulatory burden on the industry, 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 estimates of anticipated impacts, 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 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 final rule will not result in an expenditure in any year that meets or exceeds this amount.

B. Overview of Benefits, Costs, and Transfers

The final rule will 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 final rule. Annualized over 10 years, the estimated benefits (i.e., cost savings) of the final rule will be $0 at both the 3 and 7 percent discount rate. The present value of the estimated benefits (i.e., cost savings) of the final rule will also be $0 at both the 3 and 7 percent discount rate. The annualized costs of the final rule will be $0 at both the 3 and 7 percent discount rate. The present value of costs of the final rule will also be $0 at both the 3 and 7 percent discount rate.

Table 1: Summary of Benefits, Costs and Distributional Effects of Final Rule (millions of 2024 dollars)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized $millions/year	$0	$0	$0	2024	7%	10 years	
		$0	$0	$0	2024	3%	10 years	
	Annualized Quantified							
	Qualitative	There will no longer be any inefficiencies due to keeping unnecessary regulations on the books.						
Costs	Annualized Monetized $millions/year	$0	$0	$0	2024	7%	10 years	
		$0	$0	$0	2024	3%	10 years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	Federal Annualized					7%		
						3%		

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	Monetized $millions/year							
	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							

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. We estimate that this rule will generate $0 million in annualized net costs at a 7 percent discount rate, discounted relative to year 2024 over a perpetual time horizon.

Table 1. Executive Order 14192 Summary Table (millions of 2024 dollars, discounted over a perpetual time horizon relative to year 2024 at a 7 percent discount rate)

	Primary Estimate	Low Estimate	High Estimate
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

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

FDA's proposed rule "Revocation of Methods of Analysis Regulation" (87 FR 42398; hereinafter the proposed rule) was published on July 15, 2022, and its

comment period ended September 28, 2022. Only two comments addressed our preliminary regulatory impact analysis (PRIA). We describe and respond to the comments we received on the PRIA in the paragraphs that follow. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

(Comment 1) We received one comment that worries the proposed revisions will affect the internal workforce or harm jobs for workers. The commenter also wants to know what measures have been taken to mitigate that.

(Response 1) Revoking 21 CFR 2.19 will not end the use of AOAC methods of analysis. Currently the CFR gives a blanket requirement to use AOAC even in program areas not covered by the AOAC. This may lead to confusion and inefficiencies, particularly if there are different preferred methods of analysis in enforcement documents. FDA will instead publish their preferred methods of analysis only in enforcement documents in order to provide greater clarity. AOAC methods will remain the Agency's preferred methods of analysis for certain enforcement programs.

(Comment 2) One commenter suggests the loss of AOAC as a federal partner would be very expensive and add a large economic burden to the federal government.

(Response 2) The commenter does not provide any evidence of the rule being expensive. The Methods of Analysis rule applies to program areas not covered by the AOAC. By keeping our preferred methods of analysis in enforcement documents tailored to each program area we will provide greater clarity. AOAC methods will continue to be used as the preferred methods of analysis in program areas where those methods are deemed relevant.

D. Summary of Changes

There are no substantive changes between this final Regulatory Impact Analysis and the preliminary Regulatory Impact Analysis.

II. Final 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 established 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. Need for Federal Regulatory Action

This final 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 will reduce inefficiencies related to retaining unnecessary FDA regulations.

C. Purpose of the Final Rule

This final rule will 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 will 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 will change Agency current practice. There is no change from baseline.

E. Benefits of the Final Rule

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

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

F. Costs of the Final Rule

We believe there will be no costs to industry from the final rule because the regulation it will 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 will 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.

G. International Effects

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

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