UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Amendment to Add a New Method for the Analysis of Sulfites in Foods

Docket No. FDA-2019-N-0463

PRELIMINARY REGULATORY IMPACT ANALYSIS
INITIAL REGULATORY FLEXIBILITY ANALYSIS
UNFUNDED MANDATES REFORM ACT ANALYSIS

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Executive Summary

This proposed rule, if finalized, would, among other things, amend the regulations that specify the method of analysis that the Food and Drug Administration (FDA) uses to determine the concentration of sulfites in foods. The currently specified method of analysis is the Monier-Williams method as refined by FDA. This is known as the optimized Monier-Williams method (OMW Method). This rule proposes to update the incorporation by reference to replace the reference to the Monier-Williams method and the appendix that refines the methodology with an updated reference to the OMW Method and add a recently developed, accurate, and more efficient analytical method of analysis, referred to as a Liquid Chromatography Tandem Mass Spectrometry Method (LC-MS/MS method). The LC-MS/MS method would serve as the primary method used by the FDA to determine sulfite concentrations in foods if this proposed rule becomes finalized. The benefit of this proposed rule would be the cost savings, in the form of time savings, associated with use of the LC-MS/MS method.[1] We estimate that, at the mean, the present value of the benefits of this proposed rule is $1.0 million using a 3 percent discount rate and $0.9 million using a 7 percent discount rate (2017$). The cost of this proposed rule would consist of both one-time validation costs and materials costs associated with use of the LC-MS/MS method. We estimate that, at the mean, the present value of the costs of this proposed rule would be $0.2 million using either a 3 or a 7 percent discount rate (2017$). At the mean, the estimated present value of the net benefits of this proposed rule would be $0.8 million using a 3 percent discount rate and $0.7 million using a 7 percent discount rate (2017$).

[1] There would be no impact from the update to the incorporation by reference for FDA's current methodology (i.e., the optimized Monier-Williams method) because only the reference would change, not the method.

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I. Introduction and Summary

A. Introduction

We have examined the impacts of this 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 would not be a significant regulatory action as defined by Executive Order 12866 and would be a deregulatory action for purposes of Executive Order 13771.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. This proposed rule would amend the regulations that specify the method of analysis that the FDA uses to determine the concentration of sulfites in foods and would not require other entities to use these methods. Hence, this proposed rule would be limited to the FDA and we therefore propose to certify that this proposed rule would 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 $154 million, using the most current (2018) 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 and Cost Savings of the Proposed Rule

This proposed rule would amend the regulations that specify the method of analysis that FDA uses to determine the concentration of sulfites in foods. The currently specified method of analysis is the same as the OMW Method. This rule proposes to update the incorporated reference to the OMW Method and to add to this a recently developed, accurate, and more efficient analytical method of analysis, referred to as the LC-MS/MS method. The LC-MS/MS method would serve as the primary method used by the FDA to determine sulfite concentrations in foods if this proposed rule becomes finalized.

The benefit of this proposed rule would be the cost savings, in the form of time savings, associated with use of the LC-MS/MS method. Using a standard 10 year time horizon, we estimate that the present value of the benefits of this proposed rule ranges from $0.5 million to $1.7 million, with a mean estimate of $1.0 million, using a 3 percent discount rate, and ranges

from $0.4 million to $1.4 million, with a mean estimate of $0.9 million, using a 7 percent discount rate (2017$). Annualized benefits, which are illustrated below in Table 1, are estimated to range from $0.06 million per year to $0.2 million per year, with a mean estimate of $0.1 million per year, using either a 3 percent or a 7 percent discount rate (2017$).

The cost of this proposed rule would consist of both one-time validation costs and materials costs associated with use of the LC-MS/MS method. Using a standard 10 year time horizon, we estimate that the present value of the total costs of this proposed rule is $0.2 million, using a 3 percent discount rate, and ranges from $0.1 million to $0.2 million, with a mean estimate of $0.2 million, using a 7 percent discount rate (2017$). We estimate that annualized costs, which are presented below in Table 1, are $0.02 million per year, using either a 3 percent or a 7 percent discount rate (2017$).

The estimated net benefits of this proposed rule are defined as the difference between the estimated benefits and the estimated costs of the rule. Using a standard 10 year time horizon, we estimate that the present value of the net benefits of this proposed rule ranges from $0.3 million to $1.5 million, with a mean estimate of $0.8 million, using a 3 percent discount rate, and ranges from $0.3 million to $1.2 million, with a mean estimate of $0.7 million, using a 7 percent discount rate (2017$). Annualized net benefits are estimated to range from $0.04 million per year to $0.18 million per year, with a mean estimate of $0.09 million per year, using a 3 percent discount rate, and from $0.04 million per year to $0.17 million per year, with a mean estimate of $0.10 million per year, using a 7 percent discount rate (2017$).

Table 1. Summary of Benefits, Costs, and Distributional Effects of the Proposed Rule (millions of 2017$)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	**Annualized Monetized $millions/year**	$0.10	$0.06	$0.20	2017	7%	10 Years	Are cost savings
		$0.10	$0.06	$0.20	2017	3%	10 Years	Are cost savings
	Annualized Quantified					7%		
						3%		
	Qualitative							
Costs	**Annualized Monetized $millions/year**	$0.02	$0.02	$0.02	2017	7%	10 Years	
		$0.02	$0.02	$0.02	2017	3%	10 Years	
	Annualized Quantified					7%		
						3%		
	Qualitative							
Transfers	**Federal Annualized Monetized $millions/year**					7%		
						3%		
	From/ To	From:			To:			
	Other Annualized					7%		
						3%		

Table 1. Summary of Benefits, Costs, and Distributional Effects of the Proposed Rule (millions of 2017$)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	Monetized $millions/year							
	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 these cost savings, this proposed rule would be considered a deregulatory action under Executive Order 13771.

Table 2. Executive Order 13771 Summary Table (Millions of 2016$, Over an Infinite Time Horizon)

Item	Primary Estimate (7%)	Lower Estimate (7%)	Upper Estimate (7%)	Primary Estimate (3%)	Lower Estimate (3%)	Upper Estimate (3%)
Present Value of Costs	$0.2	$0.2	$0.2	$0.6	$0.6	$0.6
Present Value of Cost Savings	$1.4	$0.7	$2.2	$3.6	$1.9	$5.8
Present Value of Net Costs	($1.2)	($0.5)	($2.0)	($3.0)	($1.3)	($5.2)
Annualized Costs	$0.02	$0.02	$0.02	$0.02	$0.02	$0.02
Annualized Cost Savings	$0.10	$0.05	$0.20	$0.10	$0.06	$0.20
Annualized Net Costs	($0.08)	($0.04)	($0.14)	($0.09)	($0.04)	($0.16)

Notes: All amounts are in 2016$ and have been discounted relative to year 2016 from year 2019, the latter which is the estimated year in which the proposed rule would become effective if finalized.

II. Preliminary Regulatory Impact Analysis

A. Background

This proposed rule would amend the regulations that specify the method of analysis that

FDA uses to determine the concentration of sulfites in foods to replace the incorporated reference and corresponding appendix with a reference to the OMW Method and include the LC-MS/MS method.[2] If this proposed rule becomes finalized, the LC-MS/MS method would serve as the primary method used by the FDA to determine sulfite concentrations in foods.

B. Market Failure Requiring Federal Regulatory Action

Because the currently specified method of analysis that the FDA uses to determine the concentration of sulfites in foods, the optimized Monier-Williams method, is explicitly mentioned in the Code of Federal Regulations (CFR) (21 CFR 101.100(a)(4) and 130.9 and 21 CFR part 101 Appendix A), it is necessary to amend the appropriate regulations to update the incorporation by reference and also to allow for the use of the new, accurate, and more efficient method of analysis, the LC-MS/MS method.

C. Purpose of the Proposed Rule

This proposed rule would modernize the regulations that specify the method of analysis that the FDA uses to determine the concentration of sulfites in foods by updating the incorporated reference and amending the regulation to include the LC-MS/MS method. The proposed update to the incorporated reference would update the cited reference only. The new reference is the same as FDA's current practice (i.e., the Monier-Williams method as refined by 21 CFR part 101 Appendix A) and this update would not impact FDA's current practices. The LC-MS/MS method is a new, accurate, and more efficient analytical method to determine sulfite concentrations in foods and would serve as the primary method used by the FDA to determine sulfite concentrations in foods if this proposed rule is finalized.

D. Baseline Conditions

The baseline condition is the status quo (the current state of the world), in which the currently specified method of analysis that the FDA uses to determine the concentration of sulfites in foods is the optimized Monier-Williams method, and also in which the optimized Monier-Williams method is explicitly mentioned in the Code of Federal Regulations (21 CFR 101.100(a)(4) and 130.9 and 21 CFR part 101 Appendix A). We define costs and benefits relative to this baseline. By definition, the baseline has no costs and no benefits.

E. Benefits of the Proposed Rule

The benefit of this proposed rule would be the cost savings, in the form of time savings, associated with use of the LC-MS/MS method.[3] We estimate that FDA conducts about 774 analyses per year of sulfite concentrations in foods, and that relative to using its current OMW

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[2] This proposed rule would not require other entities to use these methods. Other entities would be free to determine the correlation between the official FDA-designated methods and the entity's method of choice for determining sulfite concentrations in foods and to use their method of choice as they see fit. We do not know of any data sources that would allow us to estimate the distribution of entities across different sulfite-determining methods.

[3] There would be no impact from the update to the incorporation by reference for FDA's current methodology (i.e., the optimized Monier-Williams method) because only the reference would change, not the method.

Method, using the LC-MS/MS method would save roughly 2 hours of time per analysis, for a total time savings of roughly 1,548 hours per year associated with using the LC-MS/MS method. According to Bureau of Labor Statistics Occupational Employment Statistics, the hourly wage of a Chemist ranges from $20.66 per hour at the 10th percentile to $62.77 per hour at the 90th percentile with a mean estimate of $39.36 per hour (2017$). Increasing these hourly wages by 100 percent to account for benefits and overhead, we estimate that the total cost of a Chemist's time ranges from $41.32 per hour to $125.54 per hour with a mean estimate of $78.72 per hour (2017$). Hence, our estimate of the cost savings associated with this proposed rule ranges from $63,963 per year to $194,336 per year with a mean estimate of $121,859 per year (2017$).

Using a standard 10 year time horizon, and illustrated below in Table 3, we estimate that the present value of the benefits associated with this proposed rule ranges from $0.5 million to $1.7 million, with a mean estimate of $1.0 million, using a 3 percent discount rate, and ranges from $0.4 million to $1.4 million, with a mean estimate of $0.9 million, using a 7 percent discount rate (2017$). Annualized benefits, which are also illustrated below in Table 3, are estimated to range from $0.06 million per year to $0.2 million per year, with a mean estimate of $0.1 million per year, using either a 3 percent or a 7 percent discount rate (2017$).

Table 3. Summary of the Benefits of this Proposed Rule (millions of 2017$)

	Low	Mean	High
Present Value			
3%	$0.5	$1.0	$1.7
7%	$0.4	$0.9	$1.4
Annualized Amount			
3%	$0.06	$0.10	$0.20
7%	$0.06	$0.10	$0.20

Notes: Present value and annualized amounts estimated using a 10 year time horizon (t =1 through t = 10).

F. Costs of the Proposed Rule

The cost of this proposed rule would consist of both one-time validation costs and materials costs associated with use of the LC-MS/MS method.[4]

One-Time Validation Costs

We estimate that 3 FDA laboratories spent about 80 hours apiece on the validation process, for a total of 240 hours spent by FDA on the validation process. As stated above, according to Bureau of Labor Statistics Occupational Employment Statistics, the hourly wage of a Chemist ranges from $20.66 per hour at the 10th percentile to $62.77 per hour at the 90th percentile with a mean estimate of $39.36 per hour (2017$). Increasing these hourly wages by 100 percent to account for benefits and overhead, we estimate that the total cost of a Chemist's time ranges from $41.32 per hour to $125.54 per hour with a mean estimate of $78.72 per hour (2017$). Hence, our estimate of the one-time validation costs associated with this proposed rule

[4] There would be no impact from the update to the incorporation by reference for FDA's current methodology (i.e., the optimized Monier-Williams method) because only the reference would change, not the method.

ranges from $9,917 to $30,130, with a mean estimate of $18,893 (2017$).[5]

Materials Costs

As stated above, we estimate that FDA conducts about 774 analyses per year of sulfite concentrations in foods. In addition, we estimate that, relative to using the OMW Method, the cost of materials associated with using the LC-MS/MS method would be approximately $25 per analysis (2017$). Hence, our estimate of the total materials costs associated with this proposed rule comes to roughly $19,350 per year.

Total Costs

Using a standard 10 year time horizon, and illustrated below in Table 4, we estimate that the present value of the total costs of this proposed rule is $0.2 million, using a 3 percent discount rate, and ranges from $0.1 million to $0.2 million, with a mean estimate of $0.2 million, using a 7 percent discount rate (2017$). We estimate that annualized costs, which are also illustrated below in Table 4, are $0.02 million per year, using either a 3 percent or a 7 percent discount rate (2017$).

Table 4. Summary of the Costs of this Proposed Rule (millions of 2017$)

	Low	Mean	High
Present Value			
3%	$0.2	$0.2	$0.2
7%	$0.1	$0.2	$0.2
Annualized Amount			
3%	$0.02	$0.02	$0.02
7%	$0.02	$0.02	$0.02

Notes: Present value and annualized amounts estimated using a 10 year time horizon (t =1 through t = 10).

G. Net Benefits of the Proposed Rule

We estimate that the present value of the net benefits of this proposed rule, defined as the difference between the present value of the benefits of the rule and the present value of the costs of the rule and illustrated in Table 5, ranges from $0.3 million to $1.5 million, with a mean estimate of $0.8 million, using a 3 percent discount rate, and ranges from $0.3 million to $1.2 million, with a mean estimate of $0.7 million, using a 7 percent discount rate (2017$). Annualized net benefits, which are also present below in Table 5, are estimated to range from $0.04 million per year to $0.18 million per year, with a mean estimate of $0.09 million per year, using a 3 percent discount rate, and from $0.04 million per year to $0.17 million per year, with a

[5] We do not estimate validation costs associated with the LC-MS/MS method as incremental to the validation costs associated with the OMW Method because the latter are sunk costs (costs which have already been incurred and so therefore are considered incurred regardless of analysis scenario). Mathematically, let X = LC-MS/MS method validation costs and Y = OMW Method validation costs. Then, under the baseline, total validation costs are equal to Y. Under the proposed rule, total validation costs are equal to Y + X. As stated in Section II(D) of this regulatory impact analysis, we estimate proposed rule costs relative to the baseline. Hence, the validation costs associated with the proposed rule would be equal to Y + X – Y = X.

mean estimate of $0.10 million per year, using a 7 percent discount rate (2017$).

Table 5. Summary of the Net Benefits of this Proposed Rule (millions of 2017$)

	Low	Mean	High
Present Value			
3%	$0.3	$0.8	$1.5
7%	$0.3	$0.7	$1.2
Annualized Amount			
3%	$0.04	$0.09	$0.18
7%	$0.04	$0.10	$0.17

Notes: Present value and annualized amounts estimated using a 10 year time horizon (t =1 through t = 10).

H. Distributional Effects

We estimate that there would be no distributional effects associated with this proposed rule.

I. International Effects

We estimate that there would be no international effects associated with this proposed rule.

J. Uncertainty and Sensitivity Analysis

The greatest source of uncertainty in this analysis is our estimate of the time saved associated with using the LC-MS/MS method versus the current method (i.e., OMW Method) which, in turn, we use to estimate the benefits of this proposed rule. We explore this uncertainty by conducting a sensitivity analysis in the form of a breakeven analysis in which we estimate the amount of time saved that produces an estimate of benefits that equals our estimate of costs (zero net benefits). Our original estimate of the amount of time that the LC-MS/MS method would save relative to the OMW Method is 1,548 hours per year. Using a 3 percent discount rate, the breakeven amount of time saved ranges from 181 hours per year to 496 hours per year, with a mean estimate of 273 hours per year, and using a 7 percent discount rate, the breakeven amount of time saved would range from 186 hours per year to 500 hours per year, with a mean estimate of 278 hours per year. Our breakeven analysis is illustrated below in Table 6 and reveals that a time-savings estimate of just one-third of our original time savings estimate of 1,548 hours per year would still produce an estimate of the net benefits of this proposed rule that is positive.

Table 6. Breakeven Analysis of the Annual Time Savings of this Proposed Rule

	Low	Mean	High
Breakeven Time Saved Per Year			
3%	181 *(12%)*	273 *(18%)*	496 *(32%)*
7%	186 *(12%)*	278 *(18%)*	500 *(32%)*

Notes: Breakeven time savings as a percentage of original time savings estimate of 1,548 hours per year given in parentheses.

K. Analysis of Regulatory Alternatives to the Proposed Rule

The only feasible regulatory alternative to the proposed rule is the baseline.

III. Initial Small Entity Analysis

This proposed rule would amend the regulations that specify the method of analysis that the FDA uses to determine the concentration of sulfites in foods and would not require other entities to use these methods. Hence, the scope of this proposed rule would be limited to the FDA and we therefore propose to certify that this proposed rule would not have a significant economic impact on a substantial number of small entities.