

* * * * *

Paragraph 6013 Canadian Area Navigation Routes.

* * * * *

T-608 HOCKE, MI to REVER, MA [Amended]		
HOCKE, MI	WP	(Lat. 43°15'43.38" N, long. 082°42'38.27" W)
KATNO, Canada	WP	(Lat. 43°10'34.00" N, long. 082°19'32.00" W)
UKNIX, NY	WP	(Lat. 42°56'44.51" N, long. 078°55'05.60" W)
WOZEE, NY	WP	(Lat. 42°56'01.65" N, long. 078°44'19.64" W)
CLUNG, NY	WP	(Lat. 43°03'17.17" N, long. 078°00'13.38" W)
Rochester, NY (ROC)	VOR/DME	(Lat. 43°07'04.65" N, long. 077°40'22.06" W)
Syracuse, NY (SYR)	VORTAC	(Lat. 43°09'37.87" N, long. 076°12'16.41" W)
LAMMS, NY	WP	(Lat. 43°01'35.30" N, long. 075°09'51.50" W)
Albany, NY (ALB)	VORTAC	(Lat. 42°44'50.20" N, long. 073°48'11.47" W)
GRAVE, NY	WP	(Lat. 42°46'47.34" N, long. 073°22'20.91" W)
Gardner, MA (GDM)	VOR/DME	(Lat. 42°32'45.31" N, long. 072°03'29.48" W)
BRONC, MA	FIX	(Lat. 42°30'53.93" N, long. 071°43'21.61" W)
LOBBY, MA	FIX	(Lat. 42°30'15.53" N, long. 071°36'34.04" W)
SOSYO, MA	FIX	(Lat. 42°29'14.45" N, long. 071°25'55.75" W)
REVER, MA	FIX	(Lat. 42°26'27.48" N, long. 070°57'41.31" W)
Excluding the airspace within Canada.		

* * * * *

Issued in Washington, DC, on July 7, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and Regulations.

[FR Doc. 2022-14890 Filed 7-14-22; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 2

[Docket No. FDA-2020-N-1383]

Revocation of Methods of Analysis Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is proposing to revoke the Methods of analysis regulation describing an FDA policy to use certain methods of analysis for FDA enforcement programs when the method of analysis is not prescribed in a regulation. FDA is proposing this action because the existing regulation is unnecessary.

DATES: Either electronic or written comments on the proposed rule must be submitted by September 28, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 28, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-

2020-N-1383 for "Revocation of Methods of Analysis Regulation." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the

electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT:
Holli Kubicki, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Drive, Rockville, MD 20852, 240-402-4557.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Executive Summary
 - A. Purpose of the Proposed Rule
 - B. Summary of the Major Provisions of the Proposed Rule
 - C. Legal Authority
 - D. Costs and Benefits
- II. Background
 - A. Introduction
 - B. Need for Regulation
- III. Legal Authority
- IV. Description of the Proposed Rule
- V. Proposed Effective Date
- VI. Economic Analysis of Impacts
- VII. Analysis of Environmental Impact
- VIII. Paperwork Reduction Act of 1995
- IX. Federalism
- X. Consultation and Coordination With Indian Tribal Governments
- XI. Reference

I. Executive Summary

A. Purpose of the Proposed Rule

This proposed rule would revoke the Methods of analysis regulation, § 2.19 (21 CFR 2.19), describing an FDA policy to use certain methods of analysis for FDA enforcement programs when the method of analysis is not prescribed in a regulation. The regulation is unnecessary.

B. Summary of the Major Provisions of the Proposed Rule

The proposed rule revokes § 2.19, which states that it is FDA policy to use the methods of analysis of the Association of Analytical Chemists (AOAC) International as published in the 1980 edition of "Official Methods of Analysis of the Association of Analytical Chemists" for FDA enforcement programs when the method of analysis is not prescribed in a regulation.

C. Legal Authority

FDA is taking this action under the general administrative provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

D. Costs and Benefits

Because this proposed rule would not impose any additional regulatory burdens, this regulation is not anticipated to result in any compliance costs and the economic impact is expected to be minimal.

II. Background

A. Introduction

FDA's regulation concerning its policy on methods of analysis in enforcement programs dates back nearly 50 years (37 FR 16174, Aug. 11, 1972). Early versions of the regulation stated that unless a regulation prescribed a specific method of analysis, it would be FDA's policy to use the methods of analysis in the "latest edition of [the AOAC's] publication . . . and supplements thereto. . . ." (see, e.g., 21 CFR 3.89 (1976 ed.)). However, in 1982, 1 CFR 51.1 was amended to limit incorporation by reference of a publication to the edition of the publication that is approved, and to exclude future amendments or revisions of the publication.

FDA has revised the methods of analysis regulation several times, including in 1982 to meet the drafting requirements for incorporation by reference set forth in 1 CFR part 51, and after to make several technical amendments to update names and addresses. However, since the 1982 revision, the regulation has referred to the methods of analysis in the 13th Edition, 1980 of AOAC's publication. FDA is now proposing to revoke the methods of analysis regulation as specified in this proposed rule.

B. Need for Regulation

The Agency believes that the regulation is unnecessary as a general matter. Absent specifying a method of analysis 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 Office of Regulatory Affairs Laboratory Procedures Manual, FDA compliance programs, and other resources.

III. Legal Authority

FDA is issuing this proposed rule under the following provisions of the FD&C Act: 21 U.S.C. 321, 331, 335, 342, 343, 346a, 348, 351, 352, 355, 360b, 361, 362, 371, 372, 374.

IV. Description of the Proposed Rule

The proposed rule revokes § 2.19, which states that it is FDA policy to use the methods of analysis of the AOAC International as published in the 1980

edition of "Official Methods of Analysis of the Association of Analytical Chemists" for FDA enforcement programs when the method of analysis is not prescribed in a regulation. Repeal of this regulation would eliminate an unnecessary policy.

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. Unless a method of analysis is specified in regulations, 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 Laboratory Procedures Manual and other resources.

FDA is proposing to remove § 2.19 from the regulations.

V. Proposed Effective Date

FDA is proposing that any final rule based on this proposed rule become effective 30 days after the date of its publication in the **Federal Register**.

VI. Economic Analysis of Impacts

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.

We believe industry will largely maintain their current practices following the removal of § 2.19 Methods of analysis regulation. FDA will also

maintain its current practices, similarly generating no quantifiable cost savings. Therefore, we expect this proposed rule to be cost neutral. Table 1 summarizes the estimated benefits and costs of the proposed rule, if finalized.

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 (years)	Period covered (%)	
Benefits:							
Annualized	\$0	\$0	\$0	2019	7	10	
Monetized \$millions/year	0	0	0	2019	3	10	
Annualized	
Quantified	
Qualitative	There would no longer be any inefficiencies due to keeping unnecessary regulations on the books.			
Costs:							
Annualized	\$0	\$0	\$0	2019	7	10	
Monetized \$millions/year	0	0	0	2019	3	10	
Annualized	7	
Quantified	3	
Qualitative	
Transfers:							
Federal Annualized	7	
Monetized \$millions/year	3	
From/To	From:			To:			
Other Annualized	7	
Monetized \$millions/year	3	
From/To	From:			To:			
Effects:							
State, Local or Tribal Government: None.							
Small Business: None.							
Wages: None.							
Growth: None.							

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule and at <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.31(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under

the Paperwork Reduction Act of 1995 is not required.

IX. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that this proposed rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

X. Consultation and Coordination With Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set

forth in Executive Order 13175. We have tentatively determined that this proposed rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XI. Reference

The following reference is on display at the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m. Monday through Friday; it is also available electronically at <https://www.regulations.gov>. FDA has verified the website address, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA/Economics Staff, "Revocation of Methods of Analysis Regulation, Preliminary Regulatory Impact Analysis, Preliminary Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis," 2020. (Available at: <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.)

List of Subjects in 21 CFR Part 2

Administrative practice and procedure, Cosmetics, Drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, FDA proposes that 21 CFR part 2 be amended as follows:

PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

- 1. The authority citation for part 2 continues to read as follows:

Authority: 15 U.S.C. 402, 409; 21 U.S.C. 321, 331, 335, 342, 343, 346a, 348, 351, 352, 355, 360b, 361, 362, 371, 372, 374; 42 U.S.C. 7671 *et seq.*

§ 2.19 [Removed]

- 2. Remove § 2.19.

Dated: July 11, 2022.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2022–15109 Filed 7–14–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 490

[Docket No. FHWA–2021–0004]

RIN 2125–AF99

National Performance Management Measures; Assessing Performance of the National Highway System, Greenhouse Gas Emissions Measure

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: Extreme weather due to climate change threatens the safety and mobility of Americans and challenges the stability of supply chains. To help address the climate crisis, FHWA proposes to amend its regulations governing national performance management measures to require State departments of transportation (State DOTs) and metropolitan planning organizations (MPOs) to establish declining carbon dioxide (CO₂) targets

and to establish a method for the measurement and reporting of greenhouse gas (GHG) emissions associated with transportation under the Highways title of the United States Code (U.S.C.). The proposed rule would not mandate the level of the targets. Rather, State DOTs and MPOs would have flexibility to set targets that are appropriate for their communities and that work for their respective climate change and other policy priorities, as long as the targets would reduce emissions over time. Specifically, the proposed rule would require State DOTs and MPOs that have National Highway System (NHS) mileage within their State geographic boundaries and metropolitan planning area boundaries, respectively, to establish declining CO₂ emissions targets to reduce CO₂ emissions generated by on-road mobile sources relative to a reference year defined as calendar year 2021, that align with the Administration's net-zero targets as outlined in the national policy established under Executive orders entitled "Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis" and "Tackling the Climate Crisis at Home and Abroad" and at the Leaders Summit on Climate. The proposed rule would require MPOs serving urbanized areas with multiple MPOs to establish additional joint targets. The proposed rule also would require State DOTs and MPOs to biennially report on their progress in meeting the targets and require FHWA to assess significant progress toward achieving the targets. **DATES:** Comments must be received on or before October 13, 2022.

ADDRESSES: To ensure that you do not duplicate your docket submissions, please submit comments by only one of the following means:

- **Federal eRulemaking Portal:** Go to <https://www.regulations.gov> and follow the online instructions for submitting comments.
- **Mail:** Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590.
- **Hand Delivery:** U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329.

All submissions should include the agency name and the docket number that appears in the heading of this document or the Regulation Identifier Number (RIN) for the rulemaking. All

comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Mr. John Davies, Office of Planning, Environment, and Realty, (202) 366–6039, or via email at JohnG.Davies@dot.gov, or Mr. Lev Gabrilovich, Office of the Chief Counsel (HCC–30), (202) 366–3813, or via email at Lev.Gabrilovich@dot.gov. Office hours are from 8:00 a.m. to 4:30 p.m., E.T., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document and all comments received may be viewed online through the Federal eRulemaking portal at www.regulations.gov using the docket number listed above. Electronic retrieval help and guidelines are also available at www.regulations.gov. An electronic copy of this document may also be downloaded from the Office of the Federal Register's website at www.FederalRegister.gov and the Government Publishing Office's website at www.GovInfo.gov.

All comments received before the close of business on the comment closing date indicated above will be considered and will be available for examination in the docket at the above address. Comments received after the comment closing date will be filed in the docket and will be considered to the extent practicable. In addition to late comments, FHWA will also continue to file relevant information in the docket as it becomes available after the comment period closing date and interested persons should continue to examine the docket for new material. A final rule may be published at any time after close of the comment period and after DOT has had the opportunity to review the comments submitted.

Table of Contents for Supplementary Information

- I. Executive Summary
- II. Background and Regulatory History
- III. Statement of the Problem, Legal Authority, and Rationale
 - A. Confronting the Climate Crisis
 - B. Legal Authority for the Proposed GHG Measure
 - C. Additional Rationale for the Proposed GHG Measure
 1. Costs and Benefits
 2. Duplication of Efforts
 - D. Expected Schedule for Implementation
- IV. Section-by-Section Discussion of the Proposed Changes
 - A. Subpart A—General Information
 - B. Subpart E—National Performance Management Measures to Assess