

data in such a way that the data do not represent what actually occurred. Examples of falsification of data include, but are not limited to, the following:

(A) Creating data that were never obtained (e.g., making up data or results and recording or reporting them; reporting enrollment in a study of a subject who did not exist; forging the signature on an informed consent form);

(B) Altering data by replacing original data with something different that does not accurately reflect study conduct or results (e.g., changing a laboratory measurement to a less extreme deviation from normal);

(C) Recording or obtaining data from a specimen, sample, or test whose origin is not accurately described or in a way that does not accurately reflect the data (e.g., changing the date of a specimen, sample, or test; adding a substance not called for in the study to a specimen or sample; identifying a specimen, sample, or test as coming from a specific subject when it came from a source other than the subject);

(D) Omitting data that were obtained and would be appropriate for recording based on study design and conduct (e.g., not recording exclusionary medical history or prohibited concomitant medications or treatments; omitting data so that a statistical analysis yields a result that would not have been obtained had all data been analyzed).

(ii) The term *data* includes, but is not limited to, individual facts, tests, specimens, samples, results, statistics, items of information, or statements made by individuals.

(2) Sponsors should not report errors (e.g., typographical errors, transposed numbers or characters) to FDA under paragraph (d) of this section.

Dated: February 12, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-3123 Filed 2-18-10; 8:45 am]

BILLING CODE 4160-01-S

POSTAL REGULATORY COMMISSION

39 CFR Part 3050

[Docket No. RM2010-8; Order No. 406]

Periodic Reporting

AGENCY: Postal Regulatory Commission.

ACTION: Advance notice of proposed rulemaking; availability of rulemaking petition.

SUMMARY: The Commission is noticing a Postal Service petition proposing a change in transportation cost system

sampling. The proposal involves distributing rail costs using inter-BMC highway distribution factors. This notice briefly describes the Postal Service's rationale for proposing this change and addresses procedural steps associated with the petition.

DATES: Comments are due: February 24, 2010.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>. Commenters who cannot submit their views electronically should contact the person identified in **FOR FURTHER INFORMATION CONTACT** by telephone for advice on alternatives to electronic filing.

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, 202-789-6820 or stephen.sharfman@prc.gov.

SUPPLEMENTARY INFORMATION:

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I. Background

On February 9, 2010, the Postal Service filed a petition to initiate an informal rulemaking proceeding to consider a change in the analytical methods approved for use in periodic reporting.¹ The Postal Service labels its proposal "Proposal One" because it intends that it relate to the FY 2010 rather than the FY 2009 compliance reporting cycle. Proposal One seeks authorization from the Commission to immediately eliminate the rail portion of the Transportation Cost System (TRACS) sampling, and proposes instead to distribute rail costs using the Inter-BC highway distribution factors.

The Postal Service states that as part of a realignment of its transportation and distribution systems, it is shifting much of its transportation needs from rail to truck. Because rail costs are rapidly dwindling, it proposes to eliminate TRACS rail sampling, and to use the TRACS inter-BMC distribution in place of the Rail distribution key in Cost Segment 14. Table 1 of the supporting material accompanying the Petition (Proposal One) shows that Freight Rail and Rail Plant Load costs are expected to decline by 75 percent from FY 2009 to FY 2010, when they will amount to less than \$15 million. *Id.*, Proposal One, at 1. Table 2 shows that substituting the inter-BMC distribution key for the Rail

distribution key in FY 2009 would have had a small impact on the share of Segment 14 costs borne by each market dominant product. *Id.* at 2. The Postal Service comments that the impact will be *de minimis* in FY 2010 when Rail costs will make up a much smaller share of Segment 14 costs. The Postal Service states its desire to make the change before Quarter 3 of FY 2010 makes more efficient use of its data collection resources. *Id.*

II. Procedural Matters

The Commission sets February 24, 2010 as the due date for public comments. The Commission will determine the need for reply comments after reviewing the initial comments received.

Kenneth Moeller is designated as the Public Representative to represent the interests of the general public in this proceeding.

III. Ordering Paragraphs

It is ordered:

1. The Petition of the United States Postal Service Requesting Initiation of a Proceeding to Consider a Proposed Change in Analytic Principles (Proposal One), filed February 9, 2010, is granted.

2. The Commission establishes Docket No. RM2010-8 to consider the matters raised by the Postal Service's Petition.

3. Interested persons may submit comments on Proposal One no later than February 24, 2010.

4. Pursuant to 39 U.S.C. 505, Kenneth Moeller is appointed to serve as the Public Representative representing the interests of the general public.

5. The Secretary shall arrange for publication of this notice in the **Federal Register**.

By the Commission.

Shoshana M. Grove,
Secretary.

[FR Doc. 2010-3225 Filed 2-18-E8; 8:45 am]

BILLING CODE 7710-FW-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 80, 85, and 86

[EPA-HQ-OAR-2010-0052; FRL-9113-8]

RIN 2060-AI23; 2060-AQ12

Tier 2 Light-Duty Vehicle and Light-Duty Truck Emission Standards and Gasoline Sulfur Control Requirements (Section 610 Review)

AGENCY: Environmental Protection Agency (EPA).

¹Petition of the United States Postal Service Requesting Initiation of a Proceeding to Consider a Proposed Change in Analytic Principles (Proposal One), February 9, 2010 (Petition).

ACTION: Request for comments on Regulatory Flexibility Act Section 610 Review.

SUMMARY: On February 10, 2000 (65 FR 6698), EPA published emission standards for light-duty vehicles and light-duty trucks requiring vehicle manufacturers to reduce tailpipe emissions. Specifically, EPA sought to reduce emissions of nitrogen oxides and non-methane hydrocarbons, pollutants which contribute to ozone pollution. The rulemaking also required oil refiners to limit the sulfur content of the gasoline they produce. Sulfur in gasoline has a detrimental impact on catalyst performance and the sulfur requirements have enabled the introduction of advanced technology emission control systems on motor vehicles.

Pursuant to Section 610 of the Regulatory Flexibility Act, EPA is now initiating a review of this rule to determine if the provisions related to small entities should be continued without change, or should be rescinded or amended to minimize adverse economic impacts on small entities.

DATES: Comments must be received on or before March 22, 2010.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OAR-2010-0052, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail:* a-and-r-Docket@epa.gov.
- *Fax:* 202-566-9744.
- *Mail:* Docket No. EPA-HQ-OAR-2010-0052, Environmental Protection Agency, Mail code 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.
- *Hand Delivery:* Docket No. EPA-HQ-OAR-2010-0052, Environmental Protection Agency, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC 20004. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-HQ-OAR-2010-0052. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise

protected through www.regulations.gov or e-mail. The www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the Air and Radiation Docket and Information Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744 and the telephone number for the Air and Radiation Docket and Information Center is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: Tad Wysor, Office of Transportation and Air Quality, Assessment and Standards Division, Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; *telephone number:* (734) 214-4332; *fax number* (734) 214-4816; *e-mail address:* wysor.tad@epa.gov, or Assessment and Standards Division Hotline; *telephone number* (734) 214-4636; *e-mail address* asinfo@epa.gov.

SUPPLEMENTARY INFORMATION: The Agency published the Tier 2 Motor Vehicle Emissions Standards and Gasoline Sulfur Control Requirements rule (Tier 2 Program) on February 10, 2000 (65 FR 6698). The program

significantly reduced emissions related to ozone and particulate matter from new passenger cars and light trucks, including pickup trucks, vans, minivans, and sport-utility vehicles. The program also required refiners to significantly reduce the level of sulfur in their gasoline.

The Tier 2 program required vehicle manufacturers to reduce new vehicle emissions, primarily nitrogen oxide, volatile organic compounds, and particulate matter. Included as 'manufacturers' were several companies that convert gasoline vehicles to operate on alternative fuel, and several that import vehicles into the U.S. and upgrade their emission control systems to EPA specifications. Most of these companies are small entities, and a SBREFA panel recommended that EPA provide special flexibility to these types of vehicle manufacturers. In the final rule, EPA adopted these recommendations, including providing more time before the companies' vehicles were required to meet the emission standards otherwise applicable to larger manufacturers.

The Tier 2 program also required oil refiners to produce gasoline with much-reduced content of sulfur, primarily to protect the improved catalyst systems anticipated on new Tier 2 vehicles. An informal coalition of small refining companies formed to participate in the rulemaking and the SBREFA panel. In this case as well, EPA adopted recommendations of the small refiners, providing more lead time for meeting the gasoline sulfur requirements.

This notice announces that EPA will review the provisions of this regulation related to small entities pursuant to section 610 of the Regulatory Flexibility Act (RFA) (5 U.S.C. 610). EPA solicits comments on the following factors: (1) The continued need for the rule; (2) the Nature of complaints or comments received concerning the rule; (3) the complexity of the rule; (4) the extent to which the rule overlaps, duplicates, or conflicts with other Federal, State, or local government rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

Comments must be received by March 22, 2010. In submitting comments, please reference Docket ID number EPA-HQ-OAR-2010-0052, and follow the instructions provided in the **ADDRESSES** section of this notice. The results of EPA's review will be summarized in a report and placed in the rulemaking docket referenced above. This docket can be accessed at <http://www.regulations.gov>.

Dated: February 12, 2010.

Alexander Cristofaro,

Director, Office of Regulatory Policy and Management.

[FR Doc. 2010-3249 Filed 2-18-10; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 790

[EPA-HQ-OPPT-2009-0894; FRL-8802-6]

RIN 2070-AJ59

Amendments to Enforceable Consent Agreement Procedural Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to revise the procedures for developing Enforceable Consent Agreements (ECAs) to generate test data under the Toxic Substances Control Act (TSCA). The main features of the ECA process that EPA is proposing to change include when and how to initiate negotiations and inserting a firm deadline at which negotiations will terminate. EPA is also proposing to amend several sections in 40 CFR part 790 to place the ECA provisions in one section and the Interagency Testing Committee (ITC) provisions in a separate section, to make it clearer that there is one ECA negotiation procedure applicable to all circumstances when an ECA would be appropriate and to make conforming changes in other sections that reference the ECA procedures.

DATES: Comments must be received on or before March 22, 2010.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2009-0894, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number EPA-HQ-OPPT-2009-0894. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's

normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2009-0894. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or e-mail. The [regulations.gov](http://www.regulations.gov) website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign

the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: *For general information contact:* Colby Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Jessica Barkas, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 250-8880; e-mail address: barkas.jessica@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

You may be potentially affected by this action if you manufacture (defined by statute to include import) or process chemical substances. Potentially affected entities may include, but are not limited to:

- Manufacturers (defined by statute to include importers) of chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.
- Processors of chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider As I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that