

regulation, require restrictions on the sale and distribution of a tobacco product (section 906(d)(1) of the FD&C Act (21 U.S.C. 387f(d)(1))). The restrictions on sale and distribution of a tobacco product may include restrictions on the access to, and the advertising and promotion of, the tobacco product, if the Secretary of HHS determines such regulation would be appropriate for the public health.

FDA intends to use the information submitted in response to this **Federal Register** document, FDA's preliminary independent scientific evaluation, and other appropriate information to inform its thinking about options for regulating menthol in cigarettes.

## II. Request for Comments and Information

FDA is seeking comments, including comments on its preliminary evaluation, and data, research (e.g., published or unpublished studies, case studies), and any other information related to the following questions. Please explain your responses and provide any evidence or other information supporting your responses to the following questions:

### A. Tobacco Product Standards

1. Should FDA consider establishing a tobacco product standard for menthol in menthol cigarettes? If so, what allowable level of menthol (e.g., maximum or minimum) would be appropriate for the protection of the public health?

2. Rather than a tobacco product standard for menthol in menthol cigarettes, should FDA consider a tobacco product standard for any additive, constituent, artificial or natural flavor, or other ingredient that produces a characterizing flavor of menthol in the tobacco product or its smoke?

3. If a tobacco product standard for menthol in menthol cigarettes were to be established, should FDA consider issuing regulations to address menthol in other tobacco products besides cigarettes? If so, what other tobacco products with menthol should be regulated: All tobacco products, just all combusted tobacco products, or some other category or group of tobacco products? If not, what distinctions should be made between products?

4. If a product standard prohibiting or limiting menthol were to be established, what length of time should manufacturers be provided to achieve compliance with the standard? If a product standard prohibiting or limiting menthol were to be established, would a stepped approach in which the level of menthol was gradually reduced be

appropriate for the protection of the public health?

5. If a product standard limiting menthol were to be established, are there alternatives that could be substituted by manufacturers to maintain the effect or appeal of menthol to menthol cigarette smokers and potential initiators? If so, what are these substitutes? Should they be regulated if menthol is regulated; and if so, how should they be regulated? If not, what distinctions should be made between menthol and potential substitutes?

### B. Sale and Distribution Restrictions

1. Should FDA consider establishing restrictions on the sale and/or distribution of menthol cigarettes? If so, what restrictions would be appropriate and what would be the impact on youth or adult smoking behavior, initiation, and cessation?

2. Should FDA consider establishing restrictions on the advertising and promotion of menthol cigarettes? If so, what restrictions would be appropriate and what would be the impact on youth or adult smoking behavior, initiation, and cessation?

### C. Other Actions and Considerations

1. Are there other tobacco product standards, regulatory, or other actions that FDA could implement that would more effectively reduce the harms caused by menthol cigarette smoking and better protect the public health than the tobacco product standards or regulatory actions discussed in the preceding questions?

2. To the extent that you have identified a tobacco product standard or other regulatory action in response to the prior questions, please provide additional information and comments on:

2.1 Is compliance with the tobacco product standard or other regulatory action you identified technically achievable?

2.2 How FDA would structure a corresponding rule to maximize compliance, facilitate enforcement, and otherwise maximize public health benefits?

3. If menthol cigarettes could no longer be legally sold, is there evidence that illicit trade in menthol cigarettes would become a significant problem? If so what would be the impact of any such illicit trade on public health? How would any such illicit trade compare to the existing illicit trade in cigarettes?

4. What additional information and research beyond that described in the evaluation is there on the potential impact of sale and distribution restrictions of menthol cigarettes on

specific subpopulations, such as those based on racial, ethnic, socioeconomic status, and sexuality/gender identity?

5. To what extent are you aware of current (within the past 5 years) advertising and/or promotion of menthol cigarettes that have targeted specific communities, subpopulations, and locations, beyond that described in the evaluation?

6. Might any current advertising or other marketing or public statements concerning menthol cigarettes, or menthol in other tobacco products, constitute reduced risk claims?

## III. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>.

1. CTP, Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes.
2. CTP, Reference Addendum to the "Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol versus Nonmenthol Cigarettes, 2013."

Dated: July 19, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013-17805 Filed 7-23-13; 8:45 am]

**BILLING CODE 4160-01-P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 50, 51, 70 and 71

[EPA-HQ-OAR-2010-0885, FRL-9836-5]

### Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of extension of comment period.

**SUMMARY:** The EPA is announcing an extension of the public comment period on the Proposed Rule Regarding “Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan Requirements” (June 6, 2013). The EPA is extending the comment period that originally was scheduled to end on August 5, 2013. The extended comment period will close on September 4, 2013. The EPA is extending the comment period because of a request we received in a timely manner.

**DATES:** *Comments.* Comments must be received on or before September 4, 2013.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2010–0885, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email:* [a-and-r-docket@epa.gov](mailto:a-and-r-docket@epa.gov).
- *Mail:* Air and Radiation Docket and Information Center, Attention Docket ID No. EPA–HQ–OAR–2010–0885, Environmental Protection Agency, 1301 Constitution Ave. NW., Washington, DC 20460. Mail Code: 2822T. Please include two copies if possible. In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th Street NW., Washington, DC 20503.
- *Hand Delivery:* Air and Radiation Docket and Information Center, Attention Docket ID No. EPA–HQ–OAR–2010–0885, Environmental Protection Agency in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, located at 1301 Constitution Ave. NW., Washington, DC. The EPA/DC Public Reading Room is open from 8:30 a.m. to 4:30 p.m. Eastern Standard Time (EST), Monday through Friday.

*Instructions:* Direct your comments to Docket ID No. EPA–HQ–OAR–2010–0885. The EPA’s policy is that all comments received will be included in the public docket without change and may be made available on-line at [www.regulations.gov](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 [www.regulations.gov](http://www.regulations.gov) or email. The [www.regulations.gov](http://www.regulations.gov) Web site is an “anonymous access” system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through [www.regulations.gov](http://www.regulations.gov), your email 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, the EPA recommends that you include your name and other contact information in the body of your comment and with any CD you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters and any form of encryption and be free of any defects or viruses. For additional information about the EPA’s public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>. For additional instructions on submitting comments, go to the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* All documents in the docket are listed in [www.regulations.gov](http://www.regulations.gov). Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in [www.regulations.gov](http://www.regulations.gov) or in hard copy at the Air and Radiation Docket and Information Center in the EPA Headquarters Library, Room Number 3334 in the EPA West Building, located at 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.

**FOR FURTHER INFORMATION CONTACT:** For further general information on this rulemaking, contact Dr. Karl Pepple, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, by phone at (206) 553–1778, or by email at [pepple.karl@epa.gov](mailto:pepple.karl@epa.gov); or Mr. Butch Stackhouse, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, by

phone at (919) 541–5208, or by email at [stackhouse.butch@epa.gov](mailto:stackhouse.butch@epa.gov). For information on the public hearings, contact Ms. Pamela S. Long by phone at (919) 541–0641 or by email at [long.pam@epa.gov](mailto:long.pam@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this action apply to me?*

Entities potentially affected directly by this proposal include state, local and tribal governments. Entities potentially affected indirectly by this proposal include owners and operators of sources of emissions (volatile organic compounds (VOCs) and nitrogen oxides (NO<sub>x</sub>)) that contribute to ground-level ozone formation.

#### *B. What should I consider as I prepare my comments for the EPA?*

*1. Submitting CBI.* Do not submit CBI information to the EPA through [www.regulations.gov](http://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD ROM that you mail to the EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed to be CBI must be submitted for inclusion in the public docket. Information marked CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

*2. Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.

- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

*C. Where can I get a copy of this document and other related information?*

In addition to being available in the docket, an electronic copy of this notice will be posted at <http://www.epa.gov/air/ozonepollution/actions.html#impl>.

Dated: July 17, 2013.

**Mary E. Henigin,**

*Acting Director, Office of Air Quality Planning and Standards.*

[FR Doc. 2013-17830 Filed 7-23-13; 8:45 am]

BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 52 and 81

[EPA-R03-OAR-2012-0368; FRL-9836-1]

#### Approval and Promulgation of Air Quality Implementation Plans; West Virginia; Redesignation of the West Virginia Portion of the Wheeling, WV-OH 1997 Annual Fine Particulate Matter Nonattainment Area to Attainment and Approval of the Associated Maintenance Plan

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule; supplemental.

**SUMMARY:** EPA is issuing a supplement to its proposed approval of the State of West Virginia's request to redesignate the West Virginia portion of the Wheeling, WV-OH fine particulate matter (PM<sub>2.5</sub>) nonattainment area (Wheeling Area or Area) to attainment for the 1997 annual PM<sub>2.5</sub> national ambient air quality standard (NAAQS). This supplemental proposal revises and expands the basis for proposing approval of the State's request in light of developments since EPA issued its initial proposal on December 11, 2012. This supplemental proposal addresses the effects of the decision of the United States Court of Appeals for the District of Columbia (D.C. Circuit Court) on January 4, 2013 to remand to EPA two final rules implementing the PM<sub>2.5</sub> NAAQS. EPA is seeking comment only on the issues raised in this supplemental proposal and is not reopening for comment other issues raised in its prior proposal.

**DATES:** Written comments must be received on or before August 23, 2013.

**ADDRESSES:** Submit your comments, identified by Docket ID Number EPA-R03-OAR-2012-0368 by one of the following methods:

A. *www.regulations.gov*. Follow the on-line instructions for submitting comments.

B. *Email:* [fernandez.cristina@epa.gov](mailto:fernandez.cristina@epa.gov).  
C. *Mail:* EPA-R03-OAR-2012-0368, Cristina Fernandez, Associate Director, Office of Air Program Planning, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. 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-R03-OAR-2012-0368. 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 email. 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 email comment directly to EPA without going through *www.regulations.gov*, your email 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 electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material,

is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the West Virginia Department of Environmental Protection, Division of Air Quality, 601 57th Street SE., Charleston, West Virginia 25304.

**FOR FURTHER INFORMATION CONTACT:** Rose Quinto, (215) 814-2182, or by email at [quinto.rose@epa.gov](mailto:quinto.rose@epa.gov).

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### I. Background

On March 8, 2012, the State of West Virginia through the West Virginia Department of Environmental Protection (WVDEP) formally submitted a request to redesignate the West Virginia portion of the Wheeling Area from nonattainment to attainment of the 1997 annual PM<sub>2.5</sub> NAAQS. Concurrently, West Virginia submitted a maintenance plan for the Area as a SIP revision to ensure continued attainment throughout the Area over the next 10 years.

On December 11, 2012 (77 FR 73575), EPA published a notice of proposed rulemaking (NPR) determining that the Wheeling Area has attained the 1997 annual PM<sub>2.5</sub> NAAQS and that the Area has met the requirements for redesignation under section 107(d)(3)(E) of the Clean Air Act (CAA). In the December 11, 2012 NPR, EPA proposed several actions related to the redesignation of the Area to attainment for the 1997 annual PM<sub>2.5</sub> NAAQS. First, EPA proposed to approve West Virginia's request to change the legal definition of the West Virginia portion of the Wheeling Area from nonattainment to attainment for the