

(1) *For products containing any ingredient identified in § 343.10(a) through (f).* * * *

(5) *For products containing ibuprofen identified in § 343.10(g).* The labeling of the product contains any of the indications in § 343.50(b) except "sore throat."

(c) * * *

(1) * * *

(i) *For products containing any ingredient identified in § 343.10(a) through (f).* * * *

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(iv) * * *

(A) "Do not use this product if you have asthma unless directed by a doctor".

(B) The labeling contains the pregnancy/breast-feeding warnings set forth in § 201.63(a) and (e) of this chapter.

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(vi) *For products containing any ingredient identified in § 343.10(b) through (g).* The labeling of the product contains the allergy warnings set forth in § 201.324(a), (b), and (c) of this chapter.

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(ix) *For products containing ibuprofen identified in § 343.10(g).* (A) The alcohol warning set forth in § 201.322(a)(2) of this chapter appears after the subheading "Alcohol warning:."

(B) "Ask a doctor before use if you have: [bullet]¹ problems or serious side effects from taking pain relievers or fever reducers [bullet] stomach problems that last or come back, such as heartburn, upset stomach, or pain [bullet] ulcers [bullet] bleeding problems [bullet] high blood pressure, heart or kidney disease, are taking a diuretic, or are over 65 years of age".

(C) "Ask a doctor or pharmacist before use if you are: [bullet] under a doctor's care for any serious condition [bullet] taking any other product that contains ibuprofen, or any other pain reliever/fever reducer [bullet] taking a prescription drug for anticoagulation (blood thinning) [bullet] taking any other drug".

(D) "When using this product: [insert bullet if more than one warning occurs under this subheading] take with food or milk if stomach upset occurs".

(E) In addition to the warning required in § 201.324(c) of this chapter, the following statements appear after the subheading "Stop use and ask a doctor if: [bullet] pain gets worse or

lasts more than 10 days [bullet] fever gets worse or lasts more than 3 days [bullet] stomach pain gets worse or lasts [bullet] redness or swelling is present in the painful area [bullet] any new symptoms appear".

(F) The labeling contains the pregnancy/breast-feeding warnings set forth in § 201.63(a) and (e) of this chapter.

(2) * * *

(i) *For products containing any ingredient identified in § 343.10(a) through (f).* * * *

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(iv) * * *

(A) "Do not give this product to children who have asthma unless directed by a doctor".

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(vi) *For products containing any ingredient in § 343.10(b) through (g).* The labeling contains the allergy warnings set forth in § 201.324(a), (b), and (c) of this chapter.

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(d) * * *

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(7) *For products containing ibuprofen identified in § 343.10(g).* The labeling states "[bullet]¹ do not take more than directed [in bold type] [bullet] adults and children 12 years and over: [bullet] 200 milligrams² every 4 to 6 hours while symptoms persist [bullet] if pain or fever does not respond to 200 milligrams², 400 milligrams² may be used [bullet] do not exceed 1,200 milligrams² in 24 hours, unless directed by a doctor [bullet] the smallest effective dose should be used [bullet] children under 12 years: ask a doctor".

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Dated: January 10, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[AL-200234; FRL-7264-4]

Proposed Determination of Attainment of 1-hour Ozone Standard as of November 15, 1993, for the Birmingham, AL, Marginal Ozone Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to determine that the Birmingham marginal ozone nonattainment area (hereinafter referred to as the Birmingham area) attained the 1-hour ozone National Ambient Air Quality Standard (NAAQS) by November 15, 1993, the date required by the Clean Air Act (CAA). The Birmingham area is comprised of Jefferson and Shelby Counties. On July, 10, 2002, the United States District Court for the District of Columbia concluded that EPA failed to exercise its non-discretionary duty to make a final attainment determination for the Birmingham area by May 15, 1994. The Court required that EPA make a formal attainment determination within 120 days from date of opinion. *Sierra Club v. Whitman*, No. 00-2206 (D.D.C. July 10, 2002). Therefore, in response to the Court's order, EPA proposes to determine that the Birmingham area attained the 1-hour ozone standard by its statutory attainment date of November 15, 1993.

DATES: Written comments must be received on or before September 20, 2002.

ADDRESSES: All comments should be addressed to: Sean Lakeman; Regulatory Development Section; Air Planning Branch; Air, Pesticides and Toxics Management Division; U.S. Environmental Protection Agency Region 4; 61 Forsyth Street, SW, Atlanta, Georgia 30303-8960.

Copies of documents relative to this action are available at the following address for inspection during normal business hours: Environmental Protection Agency, Region 4, Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303-8960.

The interested persons wanting to examine these documents should make an appointment at least 24 hours before the visiting day and reference file AL-200234.

FOR FURTHER INFORMATION CONTACT: Sean Lakeman, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, Region 4, U.S. Environmental Protection Agency, 61 Forsyth Street, SW, Atlanta, Georgia 30303-8960. The telephone number is (404) 562-9043. Mr. Lakeman can also be reached via electronic mail at lakeman.sean@epa.gov.

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¹ See § 201.66(b)(4) of this chapter for definition of bullet symbol.

¹ See § 201.66(b)(4) of this chapter for definition of bullet symbol.

² Convert number of milligrams to proper dosage.

IV. Proposed Action
V. Administrative Requirements.

I. What Action Is EPA Proposing To Take?

Pursuant to section 181(b)(2)(A) of the CAA, EPA is proposing to determine that the Birmingham area has attained the 1-hour NAAQS for ozone by November 15, 1993, the date required by section 181(a)(1) of the CAA. This determination is based upon three years of complete, quality-assured, ambient air monitoring data for the years 1991–1993 which indicate that Birmingham area attained the 1-hour ozone NAAQS.

II. What Is the Background for This Action?

The Clean Air Act (CAA) requires EPA to establish NAAQS for certain pollutants that cause or contribute to air pollution that is reasonably anticipated to endanger public health or welfare (CAA sections 108 and 109). In 1979, EPA promulgated the 1-hour 0.12 parts per million (ppm) ground-level ozone NAAQS (44 FR 8202 (February 8, 1979)). Ground-level ozone is not emitted directly by sources. Rather, emissions of nitrogen oxides (NO_x) and volatile organic compounds (VOC) react in the presence of sunlight to form ground-level ozone. NO_x and VOC are referred to as precursors of ozone.

An area exceeds the 1-hour ozone NAAQS each time an ambient air quality monitor records a 1-hour average ozone concentration above 0.124 ppm. An area is violating the NAAQS when the average of expected exceedances during a consecutive three-year period is greater than 1 at any one monitor (40 CFR part 50, appendix H). The CAA required EPA to designate as nonattainment any area that was violating the 1-hour ozone NAAQS, generally based on air quality monitoring data from the three-year period from 1987–1989, or any area

contributing to a violation (CAA section 107(d)(4); 56 FR 56694 (November 6, 1991)). The CAA further classified these areas, based on the area's design value (*i.e.*, the 4th highest ozone value during the relevant three year period at the violating monitor with the highest ozone levels), as marginal, moderate, serious, severe or extreme (CAA section 181(a)). Marginal areas were suffering the least significant air pollution problems.

The control requirements and dates by which attainment needs to be achieved vary with the area's classification. Marginal areas were subject to the fewest mandated control requirements and had the earliest attainment date. Marginal areas were required to attain the 1-hour NAAQS by November 15, 1993. Section 181(a) of the CAA.

The Birmingham area was originally designated as a 1-hour ozone nonattainment area by EPA on March 3, 1978 (43 FR 8962). The Birmingham nonattainment area at that time was geographically defined as Jefferson County, Alabama. On November 6, 1991, by operation of law under section 181(a) of the CAA, EPA classified the Birmingham nonattainment area as a marginal nonattainment area for ozone and added Shelby County to the nonattainment area (56 FR 56693). The nonattainment classification for the Birmingham marginal ozone area was based on ambient air sampling measurements for ozone made during 1987–1989. The area was required to attain the 1-hour ozone NAAQS by November 15, 1993, (*i.e.*, three years from the enactment of the CAA) which is the date set forth in section 181(a)(1).

For further background, see the Court's opinion in *Sierra Club v. Whitman*, No. 00–2206 (D.D.C. July 10, 2002).

Section 181(b)(2)(A) of the Clean Air Act states that:

Within 6 months following the applicable attainment date (including any extension thereof) for an ozone nonattainment area, the Administrator shall determine, based on the area's design value (as of the attainment date), whether the area attained the standard by that date. Except for any Severe or Extreme area, any area that the Administrator finds has not attained the standard by that date shall be reclassified by operation of law in accordance with table 1 of subsection (a) to the higher of—

(i) the next higher classification for the area, or

(ii) the classification applicable to the area's design value as determined at the time of the notice required under subparagraph (B).

No area shall be reclassified as extreme under clause (ii).

After the end of the 1993 ozone season, the Birmingham area had three years of quality assured air monitoring data (1991, 1992 and 1993) which demonstrated that the 1-hour ozone NAAQS was attained. Table 1 shows the number of exceedances at each of the monitoring sites in Jefferson and Shelby Counties. No individual monitor recorded more than two exceedances during the three year period. The national 1-hour primary and secondary ambient air quality standard for ozone is attained when the expected number of days per calendar year with maximum hourly average concentrations above 0.12 ppm is equal to or less than 1, averaged over a three year period (40 CFR part 50, appendix H). The design value for the Birmingham area is 0.124 ppm, based on the fourth highest 1-hour value recorded at the Bearden Farm monitor. The recorded values for that monitor were 0.144, 0.125, 0.124, and 0.124 ppm.

TABLE 1.—BIRMINGHAM AREA 1-HOUR OZONE NAAQS EXCEEDANCES FROM 1991 TO 1993

Year	Jefferson County					Shelby County
	Fairfield	Route 8 McAdory	Tamassee LA	Pinson High Sch	Tarrant Elem Sch	Bearden Farm
1991	0	0	0	0	0	0
1992	0	0	0	1	1	0
1993	0	0	1	0	0	2

Therefore, in accordance with section 181(b)(2) of the CAA, EPA proposes to determine that the Birmingham area attained the standard by the area's November 15, 1993, attainment date.

III. Why Is EPA Taking This Action?

In 2000, the Sierra Club brought suit in district court, seeking, among other claims, an order requiring EPA to issue a determination pursuant to section

181(b) as to whether the Birmingham area had attained the NAAQS.

On July, 10, 2002, the United States District Court for the District of Columbia concluded that EPA failed to perform its non-discretionary duty to

make a final attainment determination for the Birmingham area (CAA section 181(6)) by May 15, 1994. The Court required EPA to make a formal determination within 120 days from the date of its opinion. *Sierra Club v. Whitman*, No. 00-2206 (D.D.C. July 10, 2002). In compliance with the Court's order, EPA proposes to determine that the Birmingham area had attained the 1-hour ozone standard by November 15, 1993.

IV. Proposed Action

Pursuant to section 181(b)(2)(A) of the CAA, EPA is proposing to determine that the Birmingham area attained the 1-hour NAAQS for ozone by November 15, 1993. This determination is based upon the area's design value as of its attainment date, and upon three years of complete, quality-assured, ambient air monitoring data for the years 1991-1993 which indicate that Birmingham area attained the 1-hour ozone NAAQS.

V. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001). This proposed action merely proposes to approve state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule proposes to approve pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104-4).

This proposed rule also does not have tribal implications because it will not 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, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does not 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely proposes to approve a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This proposed rule also is not subject to Executive Order 13045 "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This proposed determination of attainment does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: August 9, 2002.

J. I. Palmer, Jr.,

Regional Administrator, Region 4.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 600

[I.D. 080702E]

Magnuson-Stevens Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits (EFPs)

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification of a proposal for EFPs to conduct experimental fishing; request for comments.

SUMMARY: NMFS announces that the Administrator, Northeast Region, NMFS (Regional Administrator), has determined that an application for EFPs contains all of the required information and warrants further consideration. The Regional Administrator is considering the impacts of the activities to be authorized under the EFPs with respect to the Northeast (NE) Multispecies Fishery Management Plan (FMP). However, further review and consultation may be necessary before a final determination is made to issue EFPs. Therefore, NMFS announces that the Regional Administrator proposes to issue EFPs in response to an application submitted by the Groundfish Group Associated Fisheries of Maine (Associated Fisheries of Maine), in collaboration with Manomet Center for Conservation Sciences (Manomet). These EFPs would allow up to 12 vessels to fish for yellowtail flounder in NE multispecies year-round Closed Area II (CA II) during the months of August through December, 2002, and July, 2003, with the potential of the August trips occurring in 2003 depending on when the EFPs are issued.

The purpose of the study is to collect observer-based data to determine whether seasonal access to portions of CA II for the purpose of harvesting Georges Bank (GB) yellowtail flounder is possible without significant bycatch and discard of other regulated NE multispecies, particularly Atlantic cod and haddock. This information could then be used by the New England Fishery Management Council (Council) and NMFS to determine the feasibility of establishing a seasonal access program that would allow the harvest of GB yellowtail flounder in portions of CA II.

DATES: Comments on this action must be received at the appropriate address or