

EPA-APPROVED NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES IN THE TEXAS SIP

Name of SIP provision	Applicable geographic or non-attainment area	State approval/ submittal date	EPA approval date	Comments
* Approval of the 1997 8-hour Ozone 15% Reasonable Further Progress Plan, and 2008 RFP Motor Vehicle Emission Budgets.	* Dallas/Fort Worth, TX	* 05/23/07	* 10/07/08 [Insert FR page number where document begins].	*
Revised 2002 Base Year Emissions Inventory	Dallas/Fort Worth, TX	05/23/07	10/07/08 [Insert FR page number where document begins].	

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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 59**

[EPA-HQ-OAR-2008-0411; FRL-8725-9]

RIN 2060-AP01

Consumer and Commercial Products, Group IV: Control Techniques Guidelines in Lieu of Regulations for Miscellaneous Metal Products Coatings, Plastic Parts Coatings, Auto and Light-Duty Truck Assembly Coatings, Fiberglass Boat Manufacturing Materials, and Miscellaneous Industrial Adhesives**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final rule; Notice of final determination and availability of final control techniques guidelines.

SUMMARY: Pursuant to Section 183(e)(3)(C) of the Clean Air Act, EPA has determined that control techniques guidelines will be substantially as effective as national regulations in reducing emissions of volatile organic compounds in ozone national ambient air quality standard nonattainment areas from the following five Group IV product categories: miscellaneous metal products coatings, plastic parts coatings, auto and light-duty truck assembly coatings, fiberglass boat manufacturing materials, and miscellaneous industrial adhesives. Based on this determination, EPA is issuing control techniques guidelines in lieu of national regulations for these product categories. These control techniques guidelines will provide guidance to the States concerning EPA's recommendations for reasonably available control technology-level controls for these product categories. EPA further takes final action to list the five Group IV consumer and commercial product categories

addressed in this notice pursuant to CAA Section 183(e).

DATES: This final action is effective on October 7, 2008.

ADDRESSES: EPA has established the following dockets for these actions: Consumer and Commercial Products, Group IV—Determination to Issue Control Techniques Guidelines in Lieu of Regulations, Docket No. EPA-HQ-OAR-2008-0411; Consumer and Commercial Products—Miscellaneous Metal and Plastic Parts Coatings, Docket No. EPA-HQ-OAR-2008-0412; Consumer and Commercial Products—Auto and Light-Duty Truck Assembly Coatings, Docket No. EPA-HQ-OAR-2008-0413; Consumer and Commercial Products—Fiberglass Boat Manufacturing Materials, Docket No. EPA-HQ-OAR-2008-0415; and Consumer and Commercial Products—Miscellaneous Industrial Adhesives, Docket No. EPA-HQ-OAR-2008-0460. 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., confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and is publicly available only in hard copy form. Publicly available docket materials are available either electronically through www.regulations.gov or in hard copy at the EPA Docket Center, Public Reading Room, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC 20460. 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 Docket is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: For information concerning the Clean Air Act (CAA) Section 183(e) consumer and commercial products program, contact

Mr. Bruce Moore, U.S. EPA, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Natural Resources and Commerce Group (E143-03), Research Triangle Park, North Carolina 27711, *telephone number:* (919) 541-5460, *fax number:* (919) 541-3470, *e-mail address:* moore.bruce@epa.gov. For further information on technical issues concerning the determination and control techniques guidelines (CTG) documents for miscellaneous metal and plastic parts coatings, or for fiberglass boat manufacturing materials, contact: Ms. Kaye Whitfield, U.S. EPA, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Natural Resources and Commerce Group (E143-03), Research Triangle Park, North Carolina 27711, *telephone number:* (919) 541-2509, *fax number:* (919) 541-3470, *e-mail address:* whitfield.kaye@epa.gov. For further information on technical issues concerning the determination and CTG for auto and light-duty truck assembly coatings or the revision of the Automobile Topcoat Protocol, contact: Mr. Dave Salman, U.S. EPA, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Coatings and Chemicals Group (E143-01), Research Triangle Park, North Carolina 27711, *telephone number:* (919) 541-0859, *fax number:* (919) 541-3470, *e-mail address:* salman.dave@epa.gov. For further information on technical issues concerning the determination and CTG for miscellaneous industrial adhesives, contact: Ms. Martha Smith, U.S. EPA, Office of Air Quality Planning and Standards, Sector Policies and Programs Division, Natural Resources and Commerce Group (E143-03), Research Triangle Park, North Carolina 27711, *telephone number:* (919) 541-2421, *fax number:* (919) 541-3470, *e-mail address:* smith.martha@epa.gov.

SUPPLEMENTARY INFORMATION:

Entities Potentially Affected by this Action. The entities potentially affected by this action include industrial facilities that use the respective consumer and commercial products covered in this action as follows:

Category	NAICS code ^a	Examples of affected entities
Miscellaneous metal and plastic parts coatings.	331, 332, 333, 334, 336, 482, 811	Facilities that manufacture and repair fabricated metal, machinery, computer and electronic equipment, transportation equipment, rail transportation equipment.
Auto and light-duty truck assembly coatings.	336111, 336112, 336211	Automobile and light-duty truck assembly plants, producers of automobile and light-duty truck bodies.
Fiberglass boat manufacturing materials.	336612	Boat building facilities.
Miscellaneous industrial adhesives ..	316, 321, 326, 331, 332, 333, 334, 336, 337, 339, 482, 811.	Facilities that manufacture and repair leather and allied products, wood products, plastic and rubber products, fabricated metal, machinery, computer and electronic equipment, transportation equipment, furniture and related products, rail transportation equipment, and facilities involved in miscellaneous manufacturing.
Federal Government	Not affected.
State/local/Tribal government	State, local and Tribal regulatory agencies.

^a North American Industry Classification System.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the appropriate EPA contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

World Wide Web (WWW). In addition to being available in the docket, an electronic copy of this final action will also be available on the Worldwide Web (WWW) through the Technology Transfer Network (TTN). Following signature, a copy of the final action will be posted on the TTN's policy and guidance page for newly proposed or promulgated rules at the following address: <http://www.epa.gov/ttn/oarpg/>. The TTN provides information and technology exchange in various areas of air pollution control.

Judicial Review. Under Section 307(b)(1) of the CAA, judicial review of EPA's listing and final determination is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit by December 8, 2008. Under Section 307(d)(7)(B) of the CAA, only an objection to the final determination that was raised with reasonable specificity during the period for public comment can be raised during judicial review.

Organization of this Document

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I. Background Information

A. The Ozone Problem

Ground-level ozone, a major component of smog, is formed in the atmosphere by reactions of volatile organic compounds (VOC)¹ and oxides of nitrogen in the presence of sunlight. The formation of ground-level ozone is a complex process that is affected by many variables.

Exposure to ground-level ozone is associated with a wide variety of human health effects, as well as agricultural crop loss, and damage to forests and ecosystems. Controlled human exposure studies show that acute health effects are induced by short-term (1 to 2 hour) exposures (observed at concentrations

as low as 0.12 parts per million (ppm)), generally while individuals are engaged in moderate or heavy exertion, and by prolonged (6 to 8 hour) exposures to ozone (observed at concentrations as low as 0.08 ppm and possibly lower), typically while individuals are engaged in moderate exertion. Transient effects from acute exposures include pulmonary inflammation, respiratory symptoms, effects on exercise performance, and increased airway responsiveness. Epidemiological studies have shown associations between ambient ozone levels and increased susceptibility to respiratory infection, increased hospital admissions and emergency room visits. Groups at increased risk of experiencing elevated exposures include active children, outdoor workers, and others who regularly engage in outdoor activities. Those most susceptible to the effects of ozone include those with pre-existing respiratory disease, children, and older adults. The literature suggests the possibility that long-term exposures to ozone may cause chronic health effects (e.g., structural damage to lung tissue and accelerated decline in baseline lung function).

B. Statutory and Regulatory Background

Under CAA Section 183(e), EPA conducted a study of VOC emissions from the use of consumer and commercial products to assess their potential to contribute to levels of ozone that violate the National Ambient Air Quality Standards (NAAQS) for ozone, and to establish criteria for regulating VOC emissions from these products. Section 183(e) of the CAA directs EPA to list for regulation those categories of products that account for at least 80 percent of the VOC emissions, on a reactivity-adjusted basis, from consumer and commercial products in areas that

¹ See EPA's definition of VOC at 40 CFR 51.100(s).

violate the NAAQS for ozone (i.e., ozone nonattainment areas), and to divide the list of categories to be regulated into four groups. EPA published the initial list in the **Federal Register** on March 23, 1995 (60 FR 15264). In that notice, EPA stated that it may amend the list of products for regulation, and the groups of product categories, in order to achieve an effective regulatory program in accordance with the EPA's discretion under CAA Section 183(e).

EPA has revised the list several times. See 70 FR 69759 (November 17, 2005); 64 FR 13422 (March 18, 1999); and 71 FR 28320 (May 16, 2006). In the May 2006 revision, EPA added one product category, portable fuel containers, and removed one product category, petroleum dry cleaning solvents. As a result of these revisions, Group IV of the list comprises five product categories: miscellaneous metal products coatings, plastic parts coatings, auto and light-duty truck assembly coatings, fiberglass boat manufacturing materials, and miscellaneous industrial adhesives. Pursuant to the court's order in *Sierra Club v. EPA*, 1:01-cv-01597-PLF (D.C. Cir., March 31, 2006), EPA must take final action on the product categories in Group IV by September 30, 2008. On July 14, 2008, EPA published its proposed determination that a CTG is substantially as effective as a regulation for each of these five categories and announced availability of four draft CTGs (miscellaneous metal products coatings and plastic parts coatings are addressed in one CTG referred to as "miscellaneous metal and plastic parts coatings"). See 73 FR 40230.

Any regulations issued under CAA Section 183(e) must be based on "best available controls (BAC)." CAA Section 183(e)(1)(A) defines BAC as "the degree of emissions reduction that the Administrator determines, on the basis of technological and economic feasibility, health, environmental, and energy impacts, is achievable through the application of the most effective equipment, measures, processes, methods, systems or techniques, including chemical reformulation, product or feedstock substitution, repackaging, and directions for use, consumption, storage, or disposal." CAA Section 183(e) also provides EPA with authority to use any system or systems of regulation that EPA determines is the most appropriate for the product category. Under these provisions, EPA has previously issued "national" regulations for autobody refinishing coatings, consumer products, architectural coatings,

portable fuel containers, and aerosol coatings.²

CAA Section 183(e)(3)(C) further provides that EPA may issue a CTG in lieu of a national regulation for a product category where EPA determines that the CTG will be "substantially as effective as regulations" in reducing emissions of VOC in ozone nonattainment areas. The statute does not specify how EPA is to make this determination, but does provide a fundamental distinction between national regulations and CTGs.

Specifically, for national regulations, CAA Section 183(e) defines regulated entities as:

(i) . . . manufacturers, processors, wholesale distributors, or importers of consumer or commercial products for sale or distribution in interstate commerce in the United States; or (ii) manufacturers, processors, wholesale distributors, or importers that supply the entities listed under clause (i) with such products for sale or distribution in interstate commerce in the United States.

Thus, under CAA Section 183(e), a regulation for consumer or commercial products is limited to measures applicable to manufacturers, processors, distributors, or importers of consumer and commercial products supplied to the consumer or industry. CAA Section 183(e) does not authorize EPA to issue national regulations that would directly regulate end-users of these products. By contrast, CTGs are guidance documents that recommend reasonably available control technology (RACT) measures that States can adopt and apply to the end users of products. This dichotomy (i.e., that EPA cannot directly regulate end-users under CAA Section 183(e), but can address end-users through a CTG) created by Congress is relevant to EPA's evaluation of the relative merits of a national regulation versus a CTG.

C. Significance of Control Techniques Guidelines Documents (CTGs)

CAA Section 172(c)(1) provides that State implementation plans (SIPs) for nonattainment areas must include "reasonably available control measures (RACM)," including RACT, for sources of emissions. CAA Section 182(b)(2)(A) provides that for certain nonattainment areas, States must revise their SIPs to include RACT for each category of VOC sources covered by a CTG document issued between November 15, 1990, and the date of attainment.

EPA defines RACT as "the lowest emission limitation that a particular source is capable of meeting by the

application of control technology that is reasonably available considering technological and economic feasibility, 44 FR 53761 (September 17, 1979)." In subsequent notices, EPA has addressed how States can meet the RACT requirements of the CAA. Significantly, RACT for a particular industry is determined on a case-by-case basis, considering issues of technological and economic feasibility.

EPA provides States with guidance concerning what types of controls could constitute RACT for a given source category through issuance of a CTG. The recommendations in the CTG are based on available data and information and may not apply to a particular situation based upon the circumstances of a specific source. States can follow the CTG and adopt State regulations to implement the recommendations contained therein, or they can adopt alternative approaches. In either event, States must submit their RACT rules to EPA for review and approval as part of the SIP process. EPA will evaluate the rules and determine, through notice and comment rulemaking in the SIP approval process, whether the submitted rules meet the RACT requirements of the CAA and EPA's regulations. To the extent a State adopts any of the recommendations in a CTG into its State RACT rules, interested parties can raise questions and objections about the substance of the guidance and the appropriateness of the application of the guidance to a particular situation during the development of the State rules and EPA's SIP approval process.

We encourage States in developing their RACT rules to consider carefully the facts and circumstances of the particular sources in their States because, as noted above, RACT is determined on a case-by-case basis, considering issues of technological and economic feasibility. For example, a State may decide not to require 90 percent control efficiency at facilities that are already well controlled, if the additional emission reductions would not be cost-effective. States may also want to consider reactivity-based approaches, as appropriate, in developing their RACT regulations.³ Finally, if States consider requiring more stringent VOC content limits than those recommended in the CTGs, States may also wish to consider averaging, as appropriate. In general, the RACT requirement is applied on a short-term

² See 63 FR 48806, 48819, and 48848 (September 11, 1998); 72 FR 8428 (February 26, 2007); and 73 FR 15604 (March 24, 2008).

³ "Interim Guidance on Control of Volatile Organic Compounds in Ozone State Implementation Plans," 70 FR 54046 (September 13, 2005).

basis up to 24 hours.⁴ However, EPA guidance addresses averaging times longer than 24 hours under certain conditions.⁵ The EPA's "Economic Incentive Policy"⁶ provides guidance on use of long-term averages with regard to RACT and generally provides for averaging times of no greater than 30 days. Thus, if the appropriate conditions are present, States may wish to consider the use of averaging in conjunction with more stringent limits. Because of the nature of averaging, however, we would expect that any State RACT rules that allow for averaging also include appropriate recordkeeping and reporting requirements.

By this action, we are taking final action to list the five Group IV consumer and commercial product categories addressed in this notice pursuant to CAA Section 183(e). Further, we are issuing final CTGs that cover these five product categories in Group IV of the CAA Section 183(e) list. These CTGs are guidance to the States and provide recommendations only. A State can determine what constitutes RACT for these product categories, and EPA will review the State's rules reflecting RACT in the context of the SIP process and determine whether those rules meet the RACT requirements of the CAA and its implementing regulations.

Finally, CAA Section 182(b)(2) provides that a CTG issued after 1990 specify the date by which a State must submit a SIP revision in response to the CTG. In the CTGs at issue here, EPA provides that States should submit their SIP revisions within one year of the date that the CTGs are finalized.

II. Significant Changes to the Final CTGs

In response to comments, we have made certain changes to the final CTGs for the Group IV consumer and commercial product categories. Specifically, we have included definitions to clarify the scope of certain types of products to which our recommended VOC limits apply.

⁴ See, e.g., 52 FR 45108, col. 2, "Compliance Periods" (November 24, 1987). "VOC rules should describe explicitly the compliance timeframe associated with each emission limit (e.g., instantaneous or daily). However, where the rules are silent on compliance time, EPA will interpret it as instantaneous."

⁵ Memorandum from John O'Connor, Acting Director of the Office of Air Quality Planning and Standards, January 20, 1984, "Averaging Times for Compliance with VOC Emission Limits—SIP Revision Policy."

⁶ "Improving Air Quality with Economic Incentive Programs, January 2001," available at <http://www.epa.gov/region07/programs/artd/air/policy/search.htm>.

Further, for various reasons described below, we have either added recommended VOC limits specifically for certain specialty product categories that would have otherwise been covered by more generic VOC limits recommended in the CTG, or changed our draft recommended VOC limits for certain specialty products. We also recommended not applying the recommended limits to certain low-volume materials supplied in small containers and clarified that the recommended limits do not apply to aerosol spray cans. These changes, which are described in more detail below, do not affect our proposed determination in the July 14, 2008 notice that a CTG is substantially as effective as a national rule for addressing VOC emissions from the Group IV consumer and commercial products in ozone nonattainment areas. None of the comments raised issues with any of the rationales we provided in support of our proposed determination. Further, because the above-mentioned changes to our recommended limits make up only a very small percentage of the consumer and commercial products listed under CAA Section 183(e) Group IV, we do not believe that these changes alter the VOC emission reductions discussed in the July 14, 2008 notice in any material way. Thus, the rationales we expressed in the July notice in support of the determination are unaffected by these changes. For the reasons described in the July 2008 notice and this document, we have determined that CTGs are substantially as effective as national rules for these Group IV consumer and commercial products.

Provided below is a summary of the changes made in each of the final CTGs addressed in this notice.

A. Miscellaneous Metal and Plastic Parts Coatings

To further clarify the scope of each category for which we recommend specific VOC limits, the final CTG includes a definition for each of the coating categories with recommended VOC limits. These definitions are adopted from the South Coast Air Quality Management District (SCAQMD) and Michigan rules that are the basis for the recommended VOC limits.

In response to public comments, we have added to our recommendations in the final CTG specific VOC limits for eight categories of pleasure craft (i.e., recreational boats) surface coatings based on SCAQMD Rule 1106.1. We learned from the commenters that VOC limits for pleasure craft are covered

under SCAQMD Rule 1106.1 (February 12, 1999), and not under SCAQMD Rules 1107 and 1145, on which the recommended VOC limits in the draft CTG were based. The commenters also noted that pleasure craft surface coatings can not achieve the limits in SCAQMD Rules 1107 and 1145 and at the same time meet performance requirements for use in marine environments. In response to these comments, we reviewed the VOC limits for pleasure craft surface coatings in SCAQMD Rule 1106.1 and found that they reflect the RACT level of control for these coatings. These limits are the same as those in several other California Districts. All but three of these limits have been in place since 1994 and the remaining three (extreme high gloss coatings, finish primer/surfacer, and non-aluminum antifoulant coatings) have been in effect since 2001. There is no indication that the SCAQMD Rule 1106.1 VOC limits recommended by the commenters are unachievable or unreasonable for sources outside these California Districts. We are also not aware of any pleasure craft surface coating operation performing under VOC limits lower than those provided in SCAQMD Rule 1106.1. For the reasons stated above, we recommend in the final CTG the VOC limits in SCAQMD Rule 1106.1 for pleasure craft surface coatings to address these coatings' unique performance requirements.

In the draft CTG, we requested comment on whether certain materials (sealers, deadeners, transit coatings, and cavity waxes) used at automobile and light-duty truck assembly plants that were included in the miscellaneous metal and plastic parts coatings category and addressed in the draft CTG for miscellaneous metal and plastic parts coatings should instead be included in the auto and light-duty truck assembly coatings category and addressed in the CTG for that category. All commenters on the draft CTG responded that recommendations for these materials should be in the auto and light-duty truck assembly coatings category and addressed in the CTG for that category to simplify implementation and compliance and to clarify EPA's recommendations for these materials.

In response to these comments, we have clarified in the final auto and light-duty truck assembly coatings CTG that it covers the following materials: automobile and light-duty truck cavity wax, automobile and light-duty truck sealers, automobile and light-duty truck deadeners, automobile and light-duty truck gasket/gasket sealing material, automobile and light-duty truck

underbody coatings, and automobile and light-duty truck lubricating wax/compound. For further discussion on how we address these materials, please see section II.B of this notice and the final auto and light-duty truck assembly coatings CTG.

Similar materials are used in the production of vehicles other than automobiles or light-duty trucks, or are related to the production of a new automobile or new light-duty truck at a facility that is not an automobile or light-duty truck assembly coatings facility. These materials are included as "motor vehicle" materials in the miscellaneous metal and plastic parts coatings category and addressed in the final CTG for this category. The same limits that are recommended for "automobile and light-duty truck" materials in the auto and light-duty truck assembly coatings CTG are recommended for "motor vehicle" materials in this CTG. Please see section II.B of this notice for the rationale for these recommended limits.

The recommended VOC emission limits in the final miscellaneous metal and plastic parts coatings CTG for the motor vehicle materials described above are as follows (grams VOC per liter of coating, less water and exempt compounds,⁷ g/l):

- Motor vehicle cavity wax—650 g/l.
- Motor vehicle sealer—650 g/l.
- Motor vehicle deadener—650 g/l.
- Motor vehicle gasket/gasket sealing material—200 g/l.
- Motor vehicle underbody coating—650 g/l.
- Motor vehicle lubricating wax/compound—700 g/l.
- Motor vehicle trunk interior coating—650 g/l.
- Motor vehicle bedliner—200 g/l.

In the final CTG, we revised the recommended VOC content limit for high performance architectural coatings. The limit for this category in the draft CTG was 3.5 lb VOC/gallon, less water and exempt compounds. We received a comment that there are no liquid high performance architectural coatings available today that can meet this limit. The commenter suggested a limit of 6.2 lb VOC/gallon. According to the commenter, reformulated liquid coatings can meet this limit, and further reformulation may not be technically feasible while still meeting the requisite performance characteristics for high performance architectural coatings. The

commenter also referenced the organic HAP content limit for these coatings in the Miscellaneous Metal Parts and Products NESHAP, 40 CFR part 63, subpart M. The commenter noted that the NESHAP limit is consistent with a VOC content of 6.2 lb VOC/gallon. The commenter also noted that converting from a liquid coating to a powder coating or installing and operating add-on controls would be necessary in order to meet the VOC limit recommended for this coating category in the draft CTG, and that each of these approaches would be cost prohibitive. The commenter therefore argued that the VOC limit for high performance architectural coatings recommended in the draft CTG is not reflective of RACT for these coatings.

We agree with the commenter that liquid high performance architectural coatings currently available and in use today contain significantly more than 3.5 lb VOC/gallon. We believe that the cost of converting to powder coatings or installing and operating add-on controls to meet a limit of 3.5 lb VOC/gallon generally would be unreasonable compared to the emission reduction that would be achieved. We further agree with the commenter that a limit of 6.2 lb VOC/gallon can be achieved by the liquid high performance architectural coatings currently available and in use today and that further reformulation may not be technically feasible. In light of all of the above, we believe that the 6.2 lb VOC/gallon limit represents RACT for high performance architectural coatings. Accordingly, in the final CTG, we revised our recommended VOC limit for high performance architectural coatings to be 6.2 lb/gal.

In the draft CTG, we recommended that VOC limits for red and black coatings used for automotive/transportation plastic parts could be 15 percent higher than for other colors. Higher limits were allowed for red and black coatings because the organic pigments used for these colors absorb oil and require more VOC to maintain proper coating viscosity. Commenters requested that the same allowance should also be made for yellow coatings since these coatings now use organic pigments instead of inorganic pigments, and these organic pigments also absorb oil and require more VOC to maintain proper coating viscosity. The inorganic pigments formerly used in yellow coatings often contain hexavalent chromium. Other environmental and worker health programs restrict the use of hexavalent chromium in pigments because it is a known human carcinogen, and it is being replaced with

organic yellow pigments. So as not to create a barrier to the use of organic yellow pigments in place of hexavalent chromium, we are recommending in the final CTG higher VOC limits for yellow coatings used for automotive/transportation plastic parts.

In response to comments on how to determine the VOC content of materials, we recommend in the final CTG that the VOC content of coatings used at miscellaneous metal and plastic part coating facilities be determined using EPA Method 24. In addition, we recommend that manufacturer's formulation data be accepted as an alternative to EPA Method 24. If there is a disagreement between manufacturer's formulation data and the results of a subsequent test, we recommend that States use the test method results unless the facility can make a demonstration to the States' satisfaction that the manufacturer's formulation data are correct.

B. Auto and Light-Duty Truck Assembly Coatings

In the July 2008 notice we requested comment on whether certain materials (sealers, deadeners, transit coatings, cavity waxes, glass bonding primers, and glass bonding adhesives) used at automobile and light-duty truck assembly plants that were included in either the miscellaneous metal and plastic parts coatings categories or the miscellaneous industrial adhesives and addressed in the respective draft CTG should instead be included in the auto and light-duty truck assembly coatings category and addressed in the CTG for this category. All commenters on the draft CTG responded that recommendations for these materials should be in the auto and light-duty truck assembly coatings category and addressed in the CTG for this category to simplify implementation and compliance and to clarify EPA's recommendations for these materials.

In response to these comments, we have clarified in the final auto and light-duty truck assembly coatings CTG that it covers the following materials:

Automobile and light-duty truck glass bonding primer, automobile and light-duty truck adhesive, automobile and light-duty truck cavity wax, automobile and light-duty truck sealer, automobile and light-duty truck deadener, automobile and light-duty truck gasket/gasket sealing material, automobile and light-duty truck underbody coating, automobile and light-duty truck trunk interior coating, automobile and light-duty truck bedliner, automobile and light-duty truck weatherstrip adhesive, and automobile and light-duty truck

⁷ Exempt compounds are those classified by EPA as having negligible photochemical reactivity as listed in 40 CFR 51.100(s). Exempt compounds are not considered to be VOC.

lubricating wax/compound. To clarify the scope of these materials, the final CTG includes definitions for these materials. It also includes the following recommended VOC emission limits for the application of these materials:

- Automobile and light-duty truck glass bonding primer—900 g/l.
- Automobile and light-duty truck adhesive—250 g/l.
- Automobile and light-duty truck cavity wax—650 g/l.
- Automobile and light-duty truck sealer—650 g/l.
- Automobile and light-duty truck deadener—650 g/l.
- Automobile and light-duty truck gasket/gasket sealing material—200 g/l.
- Automobile and light-duty truck underbody coating—650 g/l.
- Automobile and light-duty truck trunk interior coating—650 g/l.
- Automobile and light-duty truck bedliner—200 g/l.
- Automobile and light-duty truck weatherstrip adhesive—750 g/l.
- Automobile and light-duty truck lubricating wax/compound—700 g/l.

We have provided below a brief summary of our rationale for each of these limits. As discussed in sections II.A and II.D of this notice, similar materials are used in the production of vehicles other than automobiles or light-duty trucks, or are related to the production of a new automobile or new light-duty truck at a facility that is not an automobile or light-duty truck assembly coatings facility. These materials are included as “motor vehicle” materials in the miscellaneous metal products, plastic parts coatings, or miscellaneous industrial adhesives categories and addressed in the CTGs for those categories. The same limits that are recommended for “automobile and light-duty truck” materials in the auto and light-duty truck assembly coatings CTG are recommended for “motor vehicle” materials in those CTGs, and the following rationale applies both to “automobile and light-duty truck” materials and “motor vehicle” materials.

The draft miscellaneous industrial adhesives CTG recommended a material specific limit of 700 grams of VOC per liter for glass bonding primer (referred to as “automotive glass adhesive primer” in that document). Commenters indicated that currently used materials contain up to 900 grams of VOC per liter. Eliminating the use of the materials in the 700 to 900 grams of VOC per liter range may not be technically feasible. The cost of the testing required to confirm material performance and compliance with Federal crash safety standards and

windshield integrity requirements would be unreasonable compared to the small emission reduction that would be achieved. As a result, we conclude that the 900 grams of VOC per liter limit recommended in the final CTG is representative of RACT for automobile and light-duty truck glass bonding primer.

The draft CTGs for miscellaneous metal and plastic parts coatings and for miscellaneous industrial adhesives did not have product specific recommendations for automobile and light-duty truck adhesive, automobile and light-duty truck cavity wax, automobile and light-duty truck sealer, automobile and light-duty truck deadener, automobile and light-duty truck gasket/gasket sealing material, automobile and light-duty truck underbody coating, automobile and light-duty truck trunk interior coating, automobile and light-duty truck weatherstrip adhesive, or automobile and light-duty truck lubricating wax/compound. Rather, these materials fell under general product categories in these draft CTGs. For each of these types of materials, commenters provided information on the VOC content of the materials currently in use and asserted that the cost of the testing required to confirm the performance of lower VOC content materials would be unreasonable compared to the small emission reduction that would be achieved. We agree with the commenter’s assertion and conclude that the limits recommended for these materials in the final CTG are representative of RACT.

Bedliner is an air dried multi-component coating typically applied by vehicle dealers or aftermarket applicators. In the draft CTG for miscellaneous metal and plastic parts coatings, bedliner would have fallen under the general multi-component coating category which had a recommended limit of 340 grams of VOC per liter. One commenter indicated that bedliner is applied at some of its automobile and light-duty truck assembly plants. We are not aware of any other automobile and light-duty truck assembly plants that apply bedliner. The bedliner applied at the commenter’s plants contains less than 200 grams of VOC per liter. This is similar to the VOC content of aftermarket bedliner in the miscellaneous metal products, or plastic parts coatings categories and addressed in the CTG for miscellaneous metal and plastic parts coatings. As a result, we conclude that the 200 grams of VOC per liter limit recommended in the final CTG for auto and light-duty truck

assembly coatings is representative of RACT for automobile and light-duty truck bedliner.

We also revised the final auto and light-duty truck assembly coatings CTG to recommend not applying the recommended limits to materials that are supplied to the automobile and light-duty truck assembly plants in containers with a net volume of 16 ounces or less, or a net weight of one pound or less. We made this change in response to comments that these low volume materials have small VOC emissions and the cost of controlling them outweighs the emission reductions that could be achieved. We agree with this assessment.

In response to comments on how to determine the VOC content of materials, we recommend in the final CTG that the VOC content of coatings, other than reactive adhesives, used at automobile and light-duty truck assembly plants be determined using EPA Method 24. We recommend that the procedure for reactive adhesives in Appendix A of the NESHAP for surface coating of plastic parts (40 CFR Part 63, subpart PPPP) be used to determine the VOC content of reactive adhesives. In addition, we recommend that manufacturer’s formulation data be accepted as an alternative to these methods. If there is a disagreement between manufacturer’s formulation data and the results of a subsequent test, we recommend that States use the test method results unless the facility can make a demonstration to the States’ satisfaction that the manufacturer’s formulation data are correct.

Finally, in conjunction with the draft CTG we prepared a draft revision of the Automobile Topcoat Protocol. Commenters supported the revision of the protocol. We are issuing the final revised protocol concurrent with the final CTG.

C. Fiberglass Boat Manufacturing Materials

In response to public comments, several changes were made to the final CTG to clarify the recommended control measures. We clarified that certain non-atomizing resin application technologies, such as fluid impingement technology, meet the recommended resin application equipment specifications under certain recommended compliance options. We also revised the description of “hand application” to include non-spray and non-atomizing application methods similar to hand- or mechanically-powered caulking guns (e.g., similar to those used to apply bonding putty), brush, and direct hand application.

These are low-emission application methods used by many boat builders.

In the final CTG, we clarified that polyester bonding putties are included in the fiberglass boat manufacturing materials category and addressed in the final CTG for this category. We explained that these putties, which are made from a mixture of resin and filler, are not considered adhesives since they are part of the composite structure. However, no VOC content limits are recommended for polyester bonding putties in the final fiberglass boat manufacturing CTG, but we do recommend covers for mixing containers used to prepare these putties. Because these putties are encapsulated between the parts or surfaces they are bonding, minimal area is exposed to the air and most of the styrene is incorporated into the cured resin matrix. Therefore, VOC emissions from these putties are inherently low. For this reason, polyester bonding putties are not subject to HAP limits, which are based on styrene and methyl methacrylate (MMA) emissions in the Boat Manufacturing NESHAP, 40 CFR part 63, subpart VVVV. Similarly, no VOC content limits are recommended for these materials in the final CTG, but covers are recommended for the putty mixing containers.

The final CTG also does not include recommended VOC limits for resin and gel coat used for mold and part touch up and repair. No VOC limits are recommended because these materials are used in small volumes (e.g., just an ounce or two at a time); therefore, VOC emissions from these materials are quite low. Further, these materials need to have higher VOC contents so that the repairs will bond to the existing mold or part. For these reasons, resin and gel coat used for mold and part touch up and repair are not subject to HAP content limits in the boat manufacturing NESHAP; however, under the NESHAP, they are subject to a usage limit and must not account for more than 1 percent of the total resin and gel coat used at a facility. Similarly, no VOC limits are recommended for these materials in the final CTG, but we are also recommending that resin and gel coat used for mold and part touch up and repair not exceed 1 percent by weight of all resin and gel coat used at a facility on a 12-month rolling-average basis.

In response to public comments, we are revising the VOC content limits for resins and gel coats such that they now consist of a monomer VOC content limit and a limit on the non-monomer VOC content. We received comments that compliance with our recommended

VOC limits, which were equal to the HAP content limits in the NESHAP, may not be feasible because the VOC content in resins and gel coats may be greater than the HAP content. As previously explained in the draft CTG, the NESHAP HAP content limits were based on styrene and MMA contents in resins and gel coats. Because nearly all VOC in resins and gel coats used in fiberglass boat manufacturing are styrene and MMA, we recommended the NESHAP HAP content limits as the VOC limits in the draft CTG. However, commenters noted that the VOC content of resins and gel coats may exceed the HAP content since these materials may include a small percent of non-HAP VOC, about 0.5 to 5 percent of the total weight of the resin or gel coat. Therefore, it may not be feasible for some materials to achieve the recommended VOC limits in the draft CTG, which only accounted for styrene and MMA.

To resolve this issue, the final CTG recommends a control option to address all VOC in these materials based on monomer VOC and non-monomer VOC. Monomer VOCs react in a chemical cross linking reaction to convert these materials from liquids to solids. The only monomer VOCs in these materials that we have identified are styrene and MMA. According to the commenters, other VOC that are not monomers may be present in these materials at 0.5 to 5 percent by weight of the resin and gel coat. In light of the above information, we recommend in the final CTG that States adopt the HAP content limits in the NESHAP as monomer VOC content limits. In addition, we recommend that the States limit the non-monomer VOC content of resins and gel coats to 5 percent by weight of the resin or gel coat. If the non-monomer VOC content exceeds 5 percent, we recommend that the amount over 5 percent be counted toward the monomer VOC content of the material. For example, if a resin contained 34 percent monomer VOC, but 6 percent non-monomer VOC, then the resin would be treated in each recommended compliance option as if it had a monomer VOC content of 35 percent because of the 1 percent non-monomer VOC that was over the 5 percent recommended limit for non-monomer VOC.

In response to comments on how to determine the VOC content of materials, we recommend in the final CTG that the monomer VOC content of resin and gel coat materials be determined using SCAQMD Method 312-91, Determination of Percent Monomer in Polyester Resins. In addition, we recommend that manufacturer's

formulation data be accepted as an alternative to this method. If there is a disagreement between manufacturer's formulation data and the results of a subsequent test, we recommend that States use the test method results unless the facility can make a demonstration to the States' satisfaction that the manufacturer's formulation data are correct.

D. Miscellaneous Industrial Adhesives

We revised the final CTG to recommend not applying the recommended limits to materials that are supplied to the facilities operating miscellaneous industrial adhesive application processes in containers with a net volume of 16 ounces or less, or a net weight of one pound or less. We made this change in response to comments that these low volume materials have small VOC emissions and the cost of controlling them outweighs the emission reductions that could be achieved. We agree with this assessment. This is also consistent with the small container exemption in the Ozone Transport Commission (OTC) model rule.

In response to comments on how to determine the VOC content of materials, we recommend in the final CTG that the VOC content of adhesives, other than reactive adhesives, used at facilities operating miscellaneous industrial adhesive application processes be determined using EPA Method 24. We recommend that the procedure for reactive adhesives in Appendix A of the NESHAP for surface coating of plastic parts (40 CFR part 63, subpart PPPP) be used to determine the VOC content of reactive adhesives. In addition, we recommend that manufacturer's formulation data be accepted as an alternative to these methods. If there is a disagreement between manufacturer's formulation data and the results of a subsequent test, we recommend that States use the test method results unless the facility can make a demonstration to the States' satisfaction that the manufacturer's formulation data are correct.

We also clarified in the final CTG that polyester bonding putties used to assemble fiberglass parts at fiberglass boat manufacturing facilities and at other reinforced plastic composite manufacturing facilities are not included in the miscellaneous industrial adhesives category and are not addressed in the CTG for this category. These bonding putties are part of the composite structure and are not adhesives. For further discussions on these putties, please see section II.C of

this notice and the final fiberglass boat manufacturing materials CTG.

In the final miscellaneous industrial adhesives CTG, we also revised the definition of porous material to exclude wood. In the draft CTG, we recommended separate emission limits for wood application processes and for porous material (except wood) application processes. However, we inadvertently included wood in the definition of porous material in the draft CTG. This was an oversight, and wood has been excluded from the definition of porous material in the final CTG.

We also replaced the term “tire retreading” in the CTG with “tire repair”. This change was made in response to a comment that the OTC model rule, on which the CTG definition was based, uses the term “tire repair” for the same definition. We made this change to be consistent with the OTC model rule and to more accurately describe the specific process being defined.

In the draft CTG we requested comment on whether certain materials (glass bonding primers and glass bonding adhesives) used at automobile and light-duty truck assembly plants that were included in the miscellaneous industrial adhesives category and addressed in the draft CTG for miscellaneous industrial adhesives should instead be included in the auto and light-duty truck assembly coatings category and addressed in the CTG for that category. All commenters on the draft CTG responded that recommendations for these materials should be in the auto and light-duty truck assembly coatings category and addressed in the CTG for that category to simplify implementation and compliance and to clarify EPA’s recommendations for these materials.

In response to these comments, we have clarified in the final auto and light-duty truck assembly coatings CTG that it covers the following materials: automobile and light-duty truck glass bonding primer, automobile and light-duty truck adhesive, and automobile and light-duty truck weatherstrip adhesive. For further discussion on how we address these materials, please see section II.B of this notice and the final auto and light-duty truck assembly coatings CTG.

Similar materials are used in the production of vehicles other than automobiles or light-duty trucks, or are related to the production of a new automobile or new light-duty truck at a facility that is not an automobile or light-duty truck assembly coatings facility. These materials are included as “motor vehicle” materials in the

miscellaneous industrial adhesives category and addressed in the final CTG for this category. The same limits that are recommended for “automobile and light-duty truck” materials in the auto and light-duty truck assembly coatings CTG are recommended for “motor vehicle” materials in this CTG. Please see section II.B of this notice for the rationale for these recommended limits.

The recommended VOC emission limits in the final miscellaneous industrial adhesives CTG for the motor vehicle materials described above are as follows:

- Motor vehicle glass bonding primer—900 g/l.
- Motor vehicle adhesive—250 g/l.
- Motor vehicle weatherstrip adhesive—750 g/l.

Please note that, in the final CTG, the term “motor vehicle glass bonding primer” replaces the term “automotive glass adhesive primer” provided in the draft CTG. The terms have the same definition, but “glass bonding primer” is the term more commonly used in the automotive and motor vehicle industry.

III. Responses to Significant Comments on EPA’s Determination

All commenters that addressed EPA’s proposed CAA Section 183(e)(3)(C) determination that CTGs will be substantially as effective as national regulations in reducing emissions of VOC in ozone nonattainment areas from the miscellaneous metal products coatings, plastic parts coatings, auto and light-duty truck assembly coatings, and fiberglass boat manufacturing materials product categories agreed with the proposed determination.

In support of EPA’s proposed determination and issuance of draft CTGs for these product categories, commenters remarked that the CTG approach would afford industry flexibility to achieve VOC emission reductions while not compromising their ability to meet customer needs. We received comments noting that the CTG approach allows States greater flexibility to tailor regulatory requirements to their specific circumstances. The commenter stated that site-specific factors necessitate the need for flexible controls. According to the commenters, because there can be great variation in the operations of facilities and the environmental conditions in which they operate, State regulators should be granted some latitude to fashion control strategies to address the variables that are inherent to the formation of ground-level ozone in their States. The commenters concluded that the CTG approach affords this flexibility by allowing the use of a

variety of mechanisms to achieve emission reductions.

With respect to the miscellaneous industrial adhesives category, we similarly received comments agreeing with EPA’s determination that a CTG is substantially as effective as a rule. However, we also received comments supporting the issuance of a national rule rather than a CTG for this product category. These commenters raised no concerns or issues with EPA’s rationales for its proposed determination that a CTG is substantially as effective as a rule in reducing VOC emissions from miscellaneous industrial adhesives in ozone nonattainment areas. Rather, the commenters explained that regulation of manufacturers of industrial adhesives would cover a wider variety of materials, and thus achieve greater VOC emissions reductions, than measures limiting emissions from the products at the point of use. The commenters further argued that manufacturers have greater control over the VOC content and associated emissions of industrial adhesives than do users, given that individual industrial adhesives are formulated to perform specific functions and, unlike other coating materials, are not ordinarily thinned or otherwise altered prior to use by the user. The commenters stated that, among the categories of adhesive materials covered in the proposed CTG, a number of them are more likely to be used “in the field” or at construction sites rather than in manufacturing facilities. One commenter added that any uncertainty regarding the industry sectors that are covered by the miscellaneous industrial adhesives source category would be resolved by regulating industrial adhesives at the point of manufacture rather than the point of use. The commenter expressed concern that a CTG for adhesives would require enforcement at innumerable manufacturing facilities nationwide, resulting in significant costs. The commenter added that in contrast, a national rule applicable to manufacturers of industrial adhesives would greatly reduce the number of regulated entities and simplify enforcement, and reduce costs.

EPA appreciates the commenters’ concerns and suggestions. However, for the following reasons, EPA rejects the commenters’ suggestion that EPA should issue a national rule for the Section 183(e) miscellaneous industrial adhesives category. As an initial matter, the scope of adhesives that the commenters suggest that EPA cover under a national rule is broader than the Section 183(e) miscellaneous industrial adhesives category. In EPA’s Report to

Congress, *Study of Volatile Organic Compound Emissions from Consumer and Commercial Products—Comprehensive Emissions Inventory* (EPA-453/R-94-066-B, March 1995), supporting the Section 183(e) consumer and commercial product category list that EPA compiled in 1995 and the schedule for taking action on the listed product categories,⁸ the “miscellaneous industrial adhesives” product category was clearly described as comprising adhesives used in industrial manufacturing operations. Accordingly, this product category does not include field-applied adhesives (e.g., plastic solvent welding cements used by plumbers to join plumbing pipes on construction jobs in the field).

In the July 2008 notice, EPA proposed to finalize the miscellaneous industrial adhesives product category, as that category was listed in 1995. EPA did not propose to broaden that product category, as EPA had determined that the category properly reflected the scope of sources needed, in conjunction with the other product categories, to meet the requirements of Section 183(e)(3)(A). Petitioners have not alleged or demonstrated that EPA’s proposed listing is contrary to the requirements of Section 183(e)(3)(A). EPA therefore takes final action to list the miscellaneous industrial adhesives product category, which again includes those adhesives used in industrial manufacturing operations.

Further, as discussed in the July 14, 2008 notice, the effect of a national rule that sets VOC limits only for miscellaneous industrial adhesives (i.e., adhesives used in industrial manufacturing operations) could be easily subverted because such a rule could not require that a manufacturing facility use only those low-VOC content adhesives materials that are specifically marketed for miscellaneous industrial adhesive application operations. By contrast, the miscellaneous industrial adhesives CTG applies specifically to the products in the Section 183(e) miscellaneous industrial adhesives category, i.e., adhesives used at industrial manufacturing operations.

Moreover, as discussed above and in the July 14, 2008 notice, EPA has identified in the CTG flexible and effective options for controlling VOC emissions from the miscellaneous industrial adhesives category, and these recommended control options are consistent with existing State and local VOC control strategies. The

recommended control options, which are directed at the use of these adhesives, can only be implemented through the CTG approach because the regulated entities subject to a national rule would be adhesives manufacturers and suppliers, not the users. The commenters have raised no concerns or issues with EPA’s rationales, including those reiterated above, supporting its proposed Section 183(e)(3)(C) determination that a CTG is substantially as effective as a regulation in reducing VOC emissions from miscellaneous industrial adhesives in ozone nonattainment areas. For the foregoing reasons, EPA is finalizing its 183(e)(3)(C) determination for miscellaneous industrial adhesives in this notice.

IV. Statutory and Executive Order (EO) Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under EO 12866 (58 FR 51735, October 4, 1993), this action is a “significant regulatory action,” since it is deemed to raise novel legal or policy issues. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under EO 12866, and any changes made in response to OMB recommendations have been documented in the docket for this action.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b). This action does not contain any information collection requirements.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration’s (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or

special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This final rule will not impose any requirements on small entities. EPA is taking final action to list the five Group IV consumer and commercial product categories addressed in this notice for purposes of CAA Section 183(e). The listing action alone does not impose any regulatory requirements. EPA has also determined that, for each of the five product categories at issue, a CTG will be substantially as effective as a national regulation in achieving VOC emission reductions in ozone nonattainment areas. This final determination means that EPA has concluded that it is not appropriate to issue Federal regulations under CAA Section 183(e) to regulate VOC emissions from these five product categories. Instead, EPA has concluded that it is appropriate to issue guidance in the form of CTGs that provide recommendations to States concerning potential methods to achieve needed VOC emission reductions from these product categories. In addition to the final determination, EPA is also announcing availability of the final CTGs for these five product categories. These CTGs are guidance documents. EPA does not directly regulate any small entities through the issuance of a CTG. Instead, EPA issues CTGs to provide States with guidance on developing appropriate State regulations to obtain VOC emission reductions from the affected sources within certain nonattainment areas. EPA’s issuance of a CTG does trigger an obligation on the part of certain States to issue State regulations, but States are not obligated to issue regulations identical to the EPA’s CTG. States may follow the recommendations in the CTG or deviate from them, and the ultimate determination of whether a State regulation meets the RACT requirements of the CAA would be determined through notice and comment rulemaking in the EPA’s action on each State’s SIP. Thus, States retain discretion in determining to what degree to follow the CTGs.

D. Unfunded Mandates Reform Act

This rule contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–

⁸ See “Consumer and Commercial Products: Schedule for Regulation” (60 FR 15264, March 23, 1995)

1538 for State, local, or tribal governments or the private sector because it imposes no enforceable duty on any State, local, or Tribal governments or the private sector. Therefore, this action is not subject to the requirements of sections 202 or 205 of the UMRA. In addition, we have determined that this rule is not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. As stated in section IV.C. this action serves to list five product categories, finalize a determination that a CTG will be substantially as effective as a national regulation in achieving VOC emission reductions in ozone nonattainment areas for the five categories, and announce the availability of the final CTGs (i.e., guidance documents) for these five product categories. These actions do not impose any regulatory requirements; therefore, EPA is not directly regulating any small entities. Please refer to section IV.C. for additional details.

E. Executive Order 13132: Federalism

EO 13132, entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. "Policies that have federalism implications" is defined in the EO to include regulations 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."

This final rule does not have federalism implications. It will 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 EO 13132. The CAA establishes the relationship between the Federal Government and the States, and this action does not impact that relationship. Thus, EO 13132 does not apply to this rule. However, in the spirit of EO 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA solicited comments (see 73 FR 40230, July 14, 2008) from State and local officials. EPA received no adverse comments from State or local governments on these issues.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in EO 13175 (65 FR 67249, November 9, 2000). It does not have a substantial direct effect on one or more Indian Tribes, in that the listing action and the final determination impose no regulatory burdens on tribes. Furthermore, the listing action and the final determination do not affect the relationship or distribution of power and responsibilities between the Federal government and Indian Tribes. The CAA and the Tribal Authority Rule (TAR) establish the relationship of the Federal government and Tribes in implementing the CAA. Thus, EO 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

EPA interprets EO 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that are based on health and safety risks, such that the analysis required under section 5-501 of the EO has the potential to influence the regulations. This rule is not subject to EO 13045 because it is based solely on technology performance.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a "significant energy action" as defined in EO 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. These actions impose no regulatory requirements and are therefore not likely to have any adverse energy effects.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law No. 104-113, Section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in their regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices, etc.) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide

Congress, through OMB, with explanations when the Agency does not use available and applicable voluntary consensus standards.

This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

EO 12898 (59 FR 7629, Feb. 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any populations, including any minority or low-income populations. The purpose of CAA Section 183(e) is to obtain VOC emission reductions to assist in the attainment of the ozone NAAQS. The health and environmental risks associated with ozone were considered in the establishment of the ozone NAAQS. The level is designed to be protective of the public with an adequate margin of safety. EPA's listing of the products and its determination that CTGs are substantially as effective as regulations are actions intended to help States achieve the NAAQS in the most appropriate fashion.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this notice and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United

States prior to publication of the notice in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective October 7, 2008.

List of Subjects in 40 CFR Part 59

Air pollution control, Consumer and commercial products, Confidential business information, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: September 30, 2008.

Stephen L. Johnson,

Administrator.

■ For the reasons stated in the preamble, title 40, chapter I of the Code of Federal Regulations is amended as follows:

PART 59—[AMENDED]

■ 1. The authority citation for part 59 continues to read as follows:

Authority: 42 U.S.C. 7414 and 7511b(e).

Subpart A—General

■ 2. Section 59.1 is revised to read as follows:

§ 59.1 Final determinations under Section 183(e)(3)(C) of the CAA.

This section identifies the consumer and commercial product categories for which EPA has determined that CTGs will be substantially as effective as regulations in reducing VOC emissions in ozone nonattainment areas:

- (a) Wood furniture coatings;
- (b) Aerospace coatings;
- (c) Shipbuilding and repair coatings;
- (d) Lithographic printing materials;
- (e) Letterpress printing materials;
- (f) Flexible packaging printing materials;
- (g) Flat wood paneling coatings;
- (h) Industrial cleaning solvents;
- (i) Paper, film, and foil coatings;
- (j) Metal furniture coatings;
- (k) Large appliance coatings;
- (l) Miscellaneous metal products coatings;
- (m) Plastic parts coatings;
- (n) Auto and light-duty truck assembly coatings;
- (o) Fiberglass boat manufacturing materials; and
- (p) Miscellaneous industrial adhesives.

[FR Doc. E8-23750 Filed 10-6-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 447

[CMS-2238-F]

RIN 0938-AP26

Medicaid Program; Multiple Source Drug Definition

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises the definition of "multiple source drug" to better conform the regulatory definition to the provisions of section 1927(k)(7) of the Social Security Act. It also responds to public comments received on the March 14, 2008 interim final rule with comment period.

DATES: *Effective Date:* This final rule is effective November 6, 2008.

FOR FURTHER INFORMATION CONTACT: Gail Sexton, (410) 786-4583.

SUPPLEMENTARY INFORMATION:

I. Background

In the July 17, 2007 **Federal Register** we published a final rule with comment period (72 FR 39142) implementing the provisions of the Deficit Reduction Act of 2005 (DRA) pertaining to prescription drugs under the Medicaid Program. In that rule, we codified terms pertaining to the calculation and reporting of average manufacturer price (AMP) and best price and amended existing regulations regarding the calculation of the Federal upper limits (FULs) for certain covered outpatient drugs. The rule was effective October 1, 2007. On March 14, 2008, we issued an interim final rule with comment period (73 FR 13785) that revised the definition of multiple source drug to conform to the statutory provisions. As stated in that rule, the interim final rule with comment period was not issued in response to public comments received on the Medicaid prescription drug rule. We are still considering those comments. On November 15, 2007, the National Association of Chain Drug Stores and the National Community Pharmacists Association filed a motion for a preliminary injunction in the United States District Court for the District of Columbia. They contended, in part, that the definition of "multiple source drug" adopted in the Medicaid prescription drug rule is contrary to the statutory language in that it defined a multiple source drug, in part, as a drug

which is sold or marketed in the United States, as opposed to the State. Plaintiffs argued that all drugs are not generally available in every State. *National Association of Chain Drug Stores et al. v. Health and Human Services*, Civil Action No. 1:07-cv-02017 (RCL). Although we continue to believe that, when an FDA-approved, therapeutically, pharmaceutically, and bioequivalent drug is sold or marketed in the United States, at least one therapeutically, pharmaceutically, and bioequivalent drug is sold or marketed in every State, we issued an interim final rule with comment period to revise the definition of "multiple source drug." We stated that we expected the effect of the revision, if any, to be minimal.

We are publishing this final rule to address comments received on the interim final rule with comment period published on March 14, 2008 (73 FR 13785). Specifically, we are addressing comments pertaining to the definition of "multiple source drug" in the March 14, 2008 interim final rule with comment period. For a full discussion of the multiple source drug definition provisions see the March 14, 2008 interim final rule with comment period (73 FR 13785).

As noted in the interim final rule with comment period, this rule to the extent that it may affect Medicaid reimbursement rates for retail pharmacies, is subject to the injunction issued by the United States District Court for the District of Columbia in *National Association of Chain Drug Stores et al. v. Health and Human Services*, Civil Action No. 1:07-cv-02017 (RCL).

II. Provisions of the Interim Final Rule

In § 447.502, we defined key terms used for payment and rebates for Medicaid covered outpatient drugs. We defined multiple source drug, with respect to a rebate period, as a covered outpatient drug for which there is at least one other drug product which is: (1) Rated as therapeutically equivalent (for the list of drug products rated as therapeutically equivalent, see the FDA's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations" which is available at <http://www.fda.gov/cder/orange/default.htm> or can be viewed at the FDA's Freedom of Information Public Reading Room at 5600 Fishers Lane, rm. 12A-30, Rockville, MD 20857); (2) pharmaceutically equivalent and bioequivalent, as determined by the FDA; and (3) sold or marketed in the United States during the rebate period.