

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule does not impose any new requirements, the Commissioner of Food and Drugs certifies that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate and, therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

List of Subjects in 21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 892 is amended as follows:

PART 892—RADIOLOGY DEVICES

1. The authority citation for 21 CFR part 892 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Sections 892.2010, 892.2020, 892.2030, 892.2040, and 892.2050 are added to subpart B to read as follows:

§ 892.2010 Medical image storage device.

(a) *Identification.* A medical image storage device is a device that provides electronic storage and retrieval functions for medical images without irreversible data compression. Examples include devices employing magnetic and optical discs, magnetic tape, and digital memory.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

§ 892.2020 Medical image communications device.

(a) *Identification.* A medical image communications device provides electronic transfer of medical image data between medical devices without irreversible data compression. It may include a physical communications medium, modems, interfaces, and a communications protocol.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

§ 892.2030 Medical image digitizer.

(a) *Identification.* A medical image digitizer is a device intended to convert

an analog medical image into a digital format. Examples include Isystems employing video frame grabbers, and scanners which use lasers or charge-coupled devices.

(b) *Classification.* Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std.).

§ 892.2040 Medical image hardcopy device.

(a) *Identification.* A medical image hardcopy device is a device that produces a visible printed record of a medical image and associated identification information. Examples include multifunction cameras and laser printers.

(b) *Classification.* Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).

§ 892.2050 Picture archiving and communications system.

Identification. A picture archiving and communications system is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. Its hardware components may include workstations, digitizers, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices, and hardcopy devices. The software components may provide functions for performing operations related to image manipulation, enhancement, compression or quantification.

(b) *Classification.* Class II (special controls; voluntary standards—Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).

Dated: April 13, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[GA-035-9807a; FRL-6004-8]

Approval and Promulgation of Implementation Plans; Georgia: Approval of Revisions for Transportation Control Measures

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving revisions to the Georgia State Implementation Plan (SIP) submitted by the Department of Natural Resources on August 29, 1997, requesting the incorporation of several transportation control measures (TCMs) and the deletion of two TCMs from the existing SIP. This action will only address the incorporation of four of the five TCMs requested for incorporation. The other TCM actions will be handled under separate rulemaking action. The four TCMs, subject to this action include: The addition of a high occupancy vehicle (HOV) lane, an employer-based program, a university ridershare program, development of transportation management associations. This action does not address the alternative fuel station vanpool project, the five express bus routes on Cobb Community Transportation (CCT) and two park and ride lots on CCT routes.

DATES: This final rule is effective June 15, 1998 unless adverse or critical comments are received by May 29, 1998. If adverse comments are received EPA will publish a timely withdrawal of this rule.

ADDRESSES: Written comments on this action should be addressed to Kelly A. Sheckler at the Environmental Protection Agency, Region 4 Air Planning Branch, 61 Forsyth Street, SW, Atlanta, Georgia 30303. Copies of documents relative to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day. Reference file GA35-9807. The Region 4 office may have additional background documents not available at the other locations. Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460 Environmental Protection Agency, Region 4 Air Planning Branch, 61

Forsyth Street, SW, Atlanta, Georgia 30303. Attn: Kelly Sheckler, 404/562-9042

Georgia Department of Natural Resources, Environmental Protection Division, Air Protection Division, 4244 International Parkway, Suite 136, Atlanta, Georgia 30354.

FOR FURTHER INFORMATION CONTACT: Kelly A. Sheckler at 404/562-9042.

SUPPLEMENTARY INFORMATION:

I. Background

Section 108(e) of the Clean Air Act, as amended 1990 (Act), provides for transportation air quality planning guidance for the development and implementation of transportation and other measures necessary to demonstrate and maintain attainment of national ambient air quality standards. Section 108(f)(1)(A) provides a list of transportation control measures (TCMs) with emission reduction potential. The USEPA has further provided guidance in the final report entitled *Transportation Control Measures: State Implementation Plan Guidance* dated September 1990; and also in *Transportation Control Measure Information Documents* dated March 1992.

Section 108(f)(1)(A) of the Act lists sixteen TCMs for consideration by States and planning agencies to use to reduce emissions and maintain the national ambient air quality standards. Programs to reduce motor vehicle emissions consistent with title II of the Act are listed in section 108(f)(1)(A)(xii).

II. Evaluation of the State Submittal

On August 29, 1997, Georgia submitted to the U.S. EPA a SIP revision request for Atlanta TCMs, specifically, the addition of an HOV lane, an employer-based program, a university ridershare program, development of transportation management associations and, an alternative fuel station. In addition, Georgia requested the removal of two existing TCMs because they will not be implemented. These include five express bus routes on Cobb Community Transit and two park and ride lots on Cobb Community Transit routes. A public hearing was held on August 27, 1997. The SIP submission was found complete by the USEPA in a letter dated October 27, 1997.

The TCMs for the Atlanta Metropolitan Area are described below. An emissions analysis was performed for all the TCMs being added to the SIP, which demonstrated that an emission benefit would result from the implementation of these TCMs. However, the State is not claiming

emission credit in the SIP for these measures. Therefore, the emissions analysis was review only to determine that no further air quality degradation would result from the implementation of these TCMs. EPA's reviewed determined that the data assumptions and calculations, while not exact, provided a reasonable assurance that an air quality benefit would occur.

HOV Lane

This project is referred to as AR 073B is the addition of HOV lanes on I-85 from Chamblee-Tucker Road to State Route 316. An emissions analysis performed by the Atlanta Regional Commission (ARC) indicated that this project will result in reductions of volatile organic compounds (VOCs) and oxides of nitrogen (NO_x) in the 13-county Atlanta ozone nonattainment area by reducing congestion, reducing single occupancy vehicles and improving traffic flows.

This project was formally endorsed by the Georgia Department of Transportation (DOT) letters dated April 14, 1997 and subsequently February 27, 1998. The primary funding source for this project is interstate maintenance funds from the Georgia Department of Transportation. Georgia DOT will be responsible for monitoring the I-85 HOV lanes. Georgia DOT currently monitors volumes and speeds in both SOV and HOV lanes with ATMS equipment in each HOV corridor. The I-85 corridor will also have similar ATMS equipment. With the ATMS system, traffic volumes are continuously monitored. Georgia DOT commits to produce weekly summary reports of vehicle volumes and speeds for the HOV lanes.

This project is included in the Atlanta Interim Transportation Plan (ITIP) contingent upon approval in the SIP. Based upon the schedule provided for in the ITIP, the HOV lane will be implemented in a timely manner and given funding priority. The project was proposed to begin construction in March 1998, based upon the assumption funding would be approved/awarded by January 1998. The schedule projected the lanes to be open to the traffic in September 1999 with the estimated emissions benefit being realized in December after stabilization. This schedule will be adjusted accordingly from the effective date of this document.

MARTA Transit Incentives Program

This project is referred to as AR-231. This program is sponsored by MARTA to work with employers to provide incentives such as free/ and /or reduced fare passes to encourage employees to

try transit or other alternative to driving alone. Through this partnership program, employers will be able to purchase MARTA TransCards at a discount of four to fifteen percent, based upon the volume purchased.

An emissions analysis performed by ARC indicates that this project will result in reductions of VOC and NO_x in the 13-county Atlanta ozone nonattainment area. In commitment letters dated May 6, 1997 and February 26, 1998, MARTA formally endorsed the project. The primary funding source is Congestion Mitigation and Air Quality (CMAQ) funds from the Department of Transportation (DOT).

This project is included in the Atlanta Interim Transportation Plan (ITIP) contingent upon approval in the SIP. Based upon the schedule provided for in the ITIP, the rider share incentive program with Marta will be implemented in a timely manner and given funding priority. The schedule for implementation of this project, provides for the distribution of transit incentives to new potential riders in the spring of 1998, assuming a spring approval of this TCM into the SIP. The estimated emission benefits occur in December 1999 when the incentive program has totally distributed incentives to new potential riders. This schedule of implementation will be adjusted accordingly from the effective date of this rulemaking.

Ridershare Program

This project is referred to as AR-220 and is a lump sum eligible to all colleges and universities with the 10 county ARC region. The intent is to provide start-up funds for a student and staff based ridershare program to encourage car and van pooling. An emissions analysis performed by the Atlanta Regional Commission (ARC) indicated that this project will result in reductions of volatile organic compounds (VOCs) and oxides of nitrogen (NO_x) in the 13-county Atlanta ozone nonattainment area.

This project was formally endorsed by the Atlanta Regional Commission (ARC) in letters dated May 6, 1997 and March 2, 1998. The primary funding source for this project is CMAQ funds from the DOT.

This project is included in the Atlanta Interim Transportation Plan (ITIP) contingent upon approval in the SIP. Based upon the schedule provided for in the ITIP, the university rider share program will be implemented in a timely manner and given funding priority. The schedule for implementation, based upon a spring 1998 authorization, provides for the

phase-in of Ridershare programs at participating schools in later 1998—early 1999. The Atlanta Regional Commission Task Force held meeting with participating schools in February 1998 to discuss implementation of the Ridershare programs. Complete implementation of the Ridershare programs will be in late 1997?? with estimated emission benefits occurring in December 2005. Again, the schedule will be adjusted accordingly to the effective date of this rulemaking action.

Transportation Management Associations

Referred to as project AR 221 is to set up a “pot” of funds set aside specially to assist in the development of transportation management associations and start-up ridershare services in the areas that are considered to be highly congested throughout the Region. ARC's Commute Connections staff will develop a selection process to identify those activity centers where the money would be best spent. An emissions analysis performed by the ARC indicated that this project will result in reductions of volatile organic compounds (VOCs) and oxides of nitrogen (NO_x) in the 13-county Atlanta ozone nonattainment area.

This project was formally endorsed by the ARC in letters dated May 6, 1997, and March 2, 1998. The primary funding source for this project is CMAQ funds from the DOT.

This project is included in the Atlanta Interim Transportation Plan (ITIP) contingent upon approval in the SIP. Based upon the schedule provided for in the ITIP, the Clifton Corridor TMA, Perimeter Center TMA and Buckhead TMA will be fully operational in spring 1998. The remaining two TMAs are estimated to become operational in January 2000–2003. It is anticipated that limited transportation improvements in the FY 1998–2000 ITIP and resulting traffic congestion will encourage the development of TMAs in the Atlanta region.

This SIP revision request thus meets the requirement for a TCM, as defined in section 108 of the Act.

III. USEPA Action

EPA is approving the aforementioned changes to the SIP. The Agency has reviewed this request for revision of the Federally-approved State implementation plan for conformance with the provisions of the 1990 amendments enacted on November 15, 1990. The Agency has determined that this action conforms with those requirements.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should relevant adverse comments be filed. This rule will be effective June 15, 1998 without further notice unless the Agency receives relevant adverse comments by May 29, 1998.

If the EPA receives such comments, then EPA will publish a document withdrawing the final rule and informing the public that the rule did not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on the proposed rule. Only parties interested in commenting on the proposed rule should do so at this time. If no such comments are received, the public is advised that this rule will be effective on June 15, 1998 and no further action will be taken on the proposed rule.

EPA has determined that today's rule falls under the “good cause” exemption in section 553(d)(3) of the Administrative Procedures Act (APA) which, upon finding “good cause,” allows an agency to make a rule effective prior to the 30-day delayed effective date otherwise provided for in the APA. Today's rule simply approves nonregulatory transportation control measures.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

IV. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from E.O. 12866 review.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant

impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D of the Clean Air Act do not create any new requirements but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP approval does not impose any new requirements, the Regional Administrator certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the CAA, preparation of a flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The Clean Air Act forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. U.S. EPA*, 427 U.S. 246, 255–66 (1976); 42 U.S.C. 7410(a)(2) and 7410(k)(3).

C. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (“Unfunded Mandates Act”), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated costs to State, local, or tribal governments in the aggregate; or to private sector, of \$100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that the approval action promulgated does not include a Federal mandate that may result in estimated costs of \$100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This Federal action approves pre-existing requirements under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

D. Submission to Congress and the General Accounting Office

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. However, section 808 provides that any rule for which the issuing agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule) that notice and public procedure thereon are impracticable, unnecessary or contrary to the public interest, shall take effect at such time as the agency promulgating the rule determines. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefore, and established an effective date of June 15, 1998. EPA will submit a report containing this rule 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 rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

E. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 29, 1998. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: April 6, 1998.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

Part 52 of chapter I, title 40, *Code of Federal Regulations*, is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

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

Subpart L—Georgia

2. Section 52.582 is amended by designating the existing text as paragraph (a) and adding paragraph (b) to read as follows:

§ 52.582 Control strategy: Ozone.

* * * * *

(b) On August 29, 1997, Harold F. Reheis, Director, Georgia Department of Natural Resources submitted to John Hankinson, Regional Administrator, United States Environmental Protection Agency Region IV, a State Implementation Plan revision including the following transportation control measures.

(1) *HOV Lane*—This project referred to as AR 073B is the addition of HOV lanes on I-85 from Chamblee-Tucker Road to State Route 316.

(2) *Ridershare Program*—This project is referred to as AR-220 and is a lump sum eligible to all colleges and universities with the 10 county ARC region.

(3) *Transportation Management Associations*—Referred to as project AR 221 is to set up a "pot" of funds set aside specially to assist in the development of transportation management associations and start-up ridershare services in the areas that are considered to be highly congested throughout the Region.

(4) *MARTA Transit Incentives Program*—This project is referred to as AR-231.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

OPP-300641; FRL-5784-7]

RIN 2070-AB78

Tebufenozide; Tolerance Extension for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule extends a time-limited tolerance for residues of the insecticide tebufenozide in or on apples at 1.0 part per million (ppm); apple pomace at 2.0 ppm; milk at 0.05 ppm; cattle, sheep and goat meat at 0.02 ppm, fat at 0.10, kidney at 0.02 ppm, liver at 1.0 ppm and meat byproducts at 0.10 ppm; and horse meat at 0.02 ppm for an additional 18 month period, to December 30, 1999. This action is in response to EPA's granting of an

emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on apples. Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA.

DATES: This regulation becomes effective April 29, 1998. Objections and requests for hearings must be received by EPA, on or before June 29, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300641], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300641], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP-300641]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington,