to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because classification of this device into class II will relieve manufacturers of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.''

The current threshold after adjustment for inflation is $133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Does This Final Rule Have Federalism Implications?

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Federal law includes an express preemption provision that preempts certain State requirements ''different from or in addition to'' certain federal requirements applicable to devices (21 U.S.C. 360k; *Medtronic* v. *Lohr*, 518 U.S. 470 (1996); *Riegel* v. *Medtronic*, 128 S. Ct. 999 (2008)).

The special controls established by this final rule create ''requirements'' for specific medical devices under 21 U.S.C. 360k, even though product sponsors have some flexibility in how they meet those requirements (*Papike* v. *Tambrands, Inc.*, 107 F.3d 737, 740–42 (9th Cir. 1997)).

V. How Does This Rule Comply With the Paperwork Reduction Act of 1995?

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 is not required. Elsewhere in this issue of the **Federal Register**, FDA is issuing a notice announcing the guidance for the final rule. This guidance, ''Class II Special Controls Guidance Document: Wound Dressing With Poly (Diallyl Dimethyl Ammonium Chloride) (pDADMAC) Additive,'' references previously approved collections of information found in FDA regulations.

VI. What References Are on Display?

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Quick-Med Technologies, Inc., May 10, 2007.

List of Subjects in 21 CFR Part 878

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for 21 CFR part 878 continues to read as follows:

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

■ 2. Section 878.4015 is added to subpart E to read as follows:

§ 878.4015 Wound dressing with poly (diallyl dimethyl ammonium chloride) (pDADMAC) additive.

(a) *Identification.* A wound dressing with pDADMAC additive is intended for use as a primary dressing for exuding wounds, 1st and 2d degree burns, and surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing.

(b) *Classification.* Class II (special controls). The special control is: the FDA guidance document entitled ''Class II Special Controls Guidance Document: Wound Dressing With Poly (Diallyl Dimethyl Ammonium Chloride) (pDADMAC) Additive.'' See § 878.1(e) for availability of this guidance document.

Dated: October 2, 2009.

Jeffrey Shuren,

Acting Director, Center for Devices and Radiological Health.

[FR Doc. E9–24963 Filed 10–15–09; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2009–0455(a); FRL–8969–9]

Approval and Promulgation of Air Quality Implementation Plans; South Carolina; Clean Air Interstate Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve a revision to the South Carolina State Implementation Plan (SIP) submitted by the State of South Carolina through the South Carolina Department of Health and Environmental Control on December 4, 2008. This revision addresses the requirements of EPA's Clean Air Interstate Rule (CAIR) and the transition of the State's Nitrogen Oxides (NO_X) Budget Trading Program to the State's CAIR NO_X Ozone Season Program. Although the District of Columbia Circuit Court (D.C. Circuit Court) found CAIR to be flawed, the rule was remanded without vacatur and thus remains in place. Thus, EPA is continuing to approve CAIR provisions into SIPs as appropriate. CAIR, as promulgated, requires states to reduce emissions of sulfur dioxide (SO_2) and NO_X that significantly contribute to, or interfere with maintenance of, the national ambient air quality standards (NAAQS) for fine particulates and/or ozone in any downwind state. CAIR establishes budgets for SO_2 and NO_X for states that significantly contribute or interfere with maintenance and requires such states to submit SIP revisions that implement these budgets. States have the flexibility to choose which control measures to adopt to achieve the budgets, including participation in EPA-administered cap-and-trade programs

addressing SO_2, NO_X annual, and NO_X ozone season emissions. EPA is approving the full SIP revision, as interpreted and clarified herein, as fully implementing the CAIR requirements for South Carolina through participation in these cap-and-trade programs. Consequently, this action will also cause the CAIR Federal Implementation Plans (CAIR FIPs) concerning SO_2, NO_X annual, and NO_X ozone season emissions by South Carolina sources to be automatically withdrawn.

DATES: This direct final rule will be effective November 30, 2009, unless EPA receives adverse comments by November 16, 2009. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2009–0455, by one of the following methods:

1. *http://www.regulations.gov:* Follow the online instructions for submitting comments.
2. *E-mail: benjamin.lynorae@epa.gov.*
3. *Fax:* 404–562–9019.
4. *Mail:* EPA–R04–OAR–2009–0455, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960.
5. *Hand Delivery or Courier:* Lynorae Benjamin, Chief, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R04–OAR–2009–0455. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through *http://www.regulations.gov* or e-mail, information that you consider to be CBI or otherwise protected. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Steven Scofield, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9034. Mr. Scofield can also be reached via electronic mail at *scofield.steve@epa.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. What Action Is EPA Taking?

EPA is taking direct final action to approve the full SIP revision submitted by South Carolina on December 4, 2008, as interpreted and clarified herein, as meeting the applicable CAIR requirements by requiring certain electric generating units (EGUs) to participate in the EPA-administered CAIR cap-and-trade programs addressing SO_2, NO_X annual, and NO_X ozone season emissions. This action also approves the addition of non-EGUs (from the State's NO_X Budget Trading Program) to the CAIR NO_X Ozone Season Trading Program. Since EPA will no longer administer the NO_X Budget Trading Program and the requirements of that program are now addressed by the State's CAIR NO_X Ozone Season Program (Regulations 61–62.96, Subparts AAAA through IIII), South Carolina chose to terminate the State's NO_X Budget Program (Regulation 61–62.96, Subparts A through I), which was established to meet the requirements of the NO_X SIP Call. EPA is, therefore, approving provisions which terminate the State's NO_X Budget Trading Program (Regulation 61–62.96, Subparts A through I). As a consequence of the SIP approval, the CAIR FIPs concerning SO_2, NO_X annual, and NO_X ozone season emissions for South Carolina are automatically withdrawn. This notice deletes and reserves the provisions in Part 52 that establish the CAIR FIPs for South Carolina sources.

On October 9, 2007, EPA approved an ''abbreviated SIP'' for South Carolina, primarily consisting of rules governing allocation of NO_X allowances to EGUs for use in the trading programs established pursuant to CAIR and rules allowing sources to opt into the CAIR programs (72 FR 57209). The abbreviated SIP was implemented in

conjunction with a FIP for the State that specified requirements for emissions monitoring, permit provisions, and other elements of CAIR programs. EPA is now approving the addition of non-EGUs to the CAIR NO_X Ozone Season Trading Program and is issuing a ''full SIP'' approval under which various CAIR implementation provisions will be governed by State rules rather than FIP rules. EPA finds that South Carolina's rules meet the applicable CAIR requirements by requiring certain EGUs to participate in the EPA-administered CAIR cap-and-trade programs addressing SO_2, NO_X annual and NO_X ozone season emissions and by requiring the non-EGUs from the State's NO_X Budget Trading Program to participate in the CAIR program for NO_X ozone season emissions.

II. What Is the Regulatory History of the CAIR and the CAIR FIPs?

EPA published CAIR on May 12, 2005 (70 FR 25162). In this rule, EPA determined that 28 states and the District of Columbia contribute significantly to nonattainment and interfere with maintenance of the NAAQS for fine particles ($PM_{2.5}$) and/or 8-hour ozone in downwind states in the eastern part of the country. As a result, EPA required those upwind States to revise their SIPs to include control measures that reduce emissions of SO_2, which is a precursor to $PM_{2.5}$ formation, and/or NO_X, which is a precursor to both ozone and $PM_{2.5}$ formation. For jurisdictions that contribute significantly to downwind $PM_{2.5}$ nonattainment, CAIR sets annual State-wide emission reduction requirements (*i.e.,* budgets) for SO_2 and annual State-wide emission reduction requirements for NO_X. Similarly, for jurisdictions that contribute significantly to 8-hour ozone nonattainment, CAIR sets State-wide emission reduction requirements or budgets for NO_X for the ozone season (May 1st to September 30th). Under CAIR, states may implement these reduction requirements by participating in the EPA-administered cap-and-trade programs or by adopting any other control measures.

CAIR explains to subject States what must be included in SIPs to address the requirements of section 110(a)(2)(D) of the Clean Air Act (CAA) with regard to interstate transport with respect to the 8-hour ozone and $PM_{2.5}$ NAAQS. EPA made national findings, effective on May 25, 2005, that the states had failed to submit SIPs meeting the requirements of section 110(a)(2)(D). The SIPs were due in July 2000, 3 years after the promulgation of the 8-hour ozone and $PM_{2.5}$ NAAQS. These findings started a two-year clock for EPA to promulgate a FIP to address the requirements of section 110(a)(2)(D). Under CAA section 110(c)(1), EPA may issue a FIP anytime after such findings are made and must do so within two years unless a SIP revision correcting the deficiency is approved by EPA before the FIP is promulgated.

On April 28, 2006, EPA promulgated FIPs for all states covered by CAIR in order to ensure the emissions reductions required by CAIR are achieved on schedule. The CAIR FIPs require EGUs to participate in the EPA-administered CAIR SO_2, NO_X annual, and NO_X ozone season trading programs, as appropriate. The CAIR FIP SO_2, NO_X annual, and NO_X ozone season trading programs impose essentially the same requirements as, and are integrated with, the respective CAIR SIP trading programs. The integration of the FIP and SIP trading programs means that these trading programs will work together to effectively create a single trading program for each regulated pollutant (SO_2, NO_X annual, and NO_X ozone season) in all states covered by the CAIR FIP or SIP trading program for that pollutant. Further, as provided in a rule published by EPA on November 2, 2007, a State's CAIR FIP is automatically withdrawn when EPA approves a SIP revision, in its entirety and without any conditions, as fully meeting the requirements of CAIR. Where only portions of the SIP revision are approved, the corresponding portions of the FIP are automatically withdrawn, and the remaining portions of the FIP stay in place. Finally, the CAIR FIPs also allow states to submit abbreviated SIP revisions that, if approved by EPA, will automatically replace or supplement certain CAIR FIP provisions (*e.g.,* the methodology for allocating NO_X allowances to sources in the State), while the CAIR FIP remains in place for all other provisions.

On April 28, 2006, EPA published two additional CAIR-related final rules that added the States of Delaware and New Jersey to the list of states subject to CAIR for $PM_{2.5}$ and announced EPA's final decisions on reconsideration of five issues, without making any substantive changes to the CAIR requirements. On October 19, 2007, EPA amended the CAIR model trading rules and the CAIR FIPs to clarify the definition of ''cogeneration unit'' and thus the applicability of the CAIR trading programs to cogeneration units.

EPA was sued by a number of parties on various aspects of CAIR, and on July 11, 2008, the U.S. Court of Appeals for the DC Circuit issued its decision to vacate and remand both CAIR and the associated CAIR FIPs in their entirety. *North Carolina* v. *EPA,* 531 F.3d 836 (DC Cir. Jul. 11, 2008). However, in response to EPA's petition for rehearing, the Court issued an order remanding CAIR to EPA without vacating either CAIR or the CAIR FIPs. *North Carolina* v. *EPA,* 550 F.3d 1176 (DC Cir. Dec. 23, 2008). The Court thereby left CAIR in place in order to ''temporarily preserve the environmental values covered by CAIR'' until EPA replaces it with a rule consistent with the Court's opinion. *Id.* at 1178. The Court directed EPA to ''remedy CAIR's flaws'' consistent with its July 11, 2008 opinion, but declined to impose a schedule on EPA for completing that action. *Id.* Therefore, CAIR and the CAIR FIP are currently in effect in South Carolina.

III. What Are the General Requirements of CAIR and the CAIR FIPs?

CAIR establishes State-wide emission budgets for SO_2 and NO_X and is to be implemented in two phases. The first phase of NO_X reductions starts in 2009 and continues through 2014, while the first phase of SO_2 reductions starts in 2010 and continues through 2014. The second phase of reductions for both NO_X and SO_2 starts in 2015 and continues thereafter. CAIR requires states to implement the budgets by either: (1) Requiring EGUs to participate in the EPA-administered cap-and-trade programs; or (2) adopting other control measures of the State's choosing and demonstrating that such control measures will result in compliance with the applicable State SO_2 and NO_X budgets.

The May 12, 2005, and April 28, 2006 CAIR rules provide model rules that states must adopt (with certain limited changes, if desired) if they want to participate in the EPA-administered trading programs. With two exceptions, only states that choose to meet the requirements of CAIR through methods that exclusively regulate EGUs are allowed to participate in the EPA-administered trading programs. One exception is for states that adopt the opt-in provisions of the model rules to allow non-EGUs individually to opt into the EPA-administered trading programs. The other exception is for states that include all non-EGUs from their NO_X SIP Call trading program in their CAIR NO_X ozone season trading program.

IV. What Are the Types of CAIR SIP Submittals?

States have the flexibility to choose the type of control measures they will use to meet the requirements of CAIR. EPA notes that all states chose to meet the CAIR requirements by selecting an

option that requires EGUs to participate in the EPA-administered CAIR cap-and-trade programs. EPA provided states two approaches for submitting and obtaining approval for CAIR SIP revisions implementing that option. States may submit full SIP revisions that adopt the model CAIR cap-and-trade rules. If approved, these SIP revisions will fully replace the CAIR FIPs. Alternatively, states may submit abbreviated SIP revisions. These SIP revisions will not replace the CAIR FIPs; however, the CAIR FIPs provide that, when approved, the provisions in these abbreviated SIP revisions will be used instead of or in conjunction with, as appropriate, the corresponding provisions of the CAIR FIPs (*e.g.,* the NO_X allowance allocation methodology).

A State submitting a full SIP revision may either adopt regulations that are substantively identical to the model rules or incorporate by reference the model rules. CAIR provides that states may only make limited changes to the model rules if the states want to participate in the EPA-administered trading programs. A full SIP revision may change the model rules only by altering their applicability and allowance allocation provisions to:

1. Include all NO_X SIP Call trading sources that are not EGUs under CAIR in the CAIR NO_X ozone season trading program;

2. Provide for State allocation of NO_X annual or ozone season allowances using a methodology chosen by the State;

3. Provide for State allocation of NO_X annual allowances from the compliance supplement pool (CSP) using the State's choice of allowed, alternative methodologies; or

4. Allow units that are not otherwise CAIR units to opt individually into the CAIR SO_2, NO_X annual, or NO_X ozone season trading programs under the opt-in provisions in the model rules.

An approved CAIR full SIP revision addressing EGUs' SO_2, NO_X annual, or NO_X ozone season emissions will replace the CAIR FIP for that State for the respective EGU emissions. As discussed above, EPA approval in full, without any conditions, of a CAIR full SIP revision causes the CAIR FIPs to be automatically withdrawn.

V. Analysis of South Carolina's CAIR SIP Submittal

A. Elements of South Carolina's SIP Submittal

The rulemaking EPA completed on October 9, 2007 (72 FR 57209), granting South Carolina abbreviated SIP approval, addressed annual and ozone season NO_X allocations and opt-in provisions. EPA is today acting on South Carolina's full set of rules, submitted on December 4, 2008, and constituting a full SIP that will supersede the FIPs that are currently in effect in South Carolina. Although some rules approved on October 9, 2007, have not changed, and thus arguably need not be approved again, EPA is acting again on these rules in conjunction with the remainder of South Carolina's rule for the purposes of clarity and administrative convenience.

B. State Budgets for Allowance Allocations

The CAIR NO_X annual and ozone season budgets were developed from historical heat input data for EGUs. Using these data, EPA calculated annual and ozone season regional heat input values, which were multiplied by 0.15 pounds per million British thermal unit (lb/mmBtu) for phase 1, and 0.125 lb/mmBtu, for phase 2, to obtain regional NO_X budgets for 2009–2014 and for 2015 and thereafter, respectively. EPA derived the State NO_X annual and ozone season budgets from the regional budgets using State heat input data adjusted by fuel factors.

The CAIR State SO_2 budgets were derived by discounting the tonnage of emissions authorized by annual allowance allocations under the Acid Rain Program under title IV of the CAA. Under CAIR, each allowance allocated in the Acid Rain Program for the years in phase 1 of CAIR (2010 through 2014) authorizes 0.50 ton of SO_2 emissions in the CAIR trading program, and each Acid Rain Program allowance allocated for the years in phase 2 of CAIR (2015 and thereafter) authorizes 0.35 ton of SO_2 emissions in the CAIR trading program.

In today's action, EPA is approving South Carolina's SIP revision that adopts the budgets established for the State in CAIR. These budgets are 32,662 tons for NO_X annual emissions from 2009 through 2014, and 27,219 tons from 2015 and thereafter; 15,249 tons for NO_X ozone season emissions from 2009 through 2014, and 12,707 tons from 2015 and thereafter; and 57,271 tons for SO_2 annual emissions from 2010 through 2014, and 40,089 tons from 2015 and thereafter. Additionally, because South Carolina has chosen to include all non-EGUs in the State's NO_X Budget Trading Program, the CAIR NO_X ozone season budget will be increased annually by 3,479 tons to account for such NO_X SIP Call trading sources. This results in a total budget of 18,728 tons for NOx ozone season emissions from 2009 through 2014 and 16,186 tons from 2015 and thereafter. South Carolina's SIP revision sets these budgets as the total amounts of allowances available for allocation for each year under the EPA-administered cap-and-trade programs.

EPA notes that, in *North Carolina,* 531 F.3d at 916–21, the Court determined, among other things, that the State SO_2 and NO_X budgets established in CAIR were arbitrary and capricious.[1] However, as discussed above, the Court also decided to remand CAIR but to leave the rule in place in order to ''temporarily preserve the environmental values covered by CAIR'' pending EPA's development and promulgation of a replacement rule that remedies CAIR's flaws. *North Carolina,* 550 F.3d at 1178. EPA had indicated to the Court that development and promulgation of a replacement rule would take about two years. *Reply in Support of Petition for Rehearing or Rehearing en Banc* at 5 (filed Nov. 17, 2008, in *North Carolina* v. *EPA,* Case No. 05–1224, D.C. Cir.). The process at EPA of developing a proposal that will undergo notice and comment and result in a final replacement rule is ongoing. In the meantime, consistent with the Court's orders, EPA is implementing CAIR by approving State SIP revisions that are consistent with CAIR (such as the provisions setting State SO_2 and NO_X budgets for the CAIR trading programs) in order to temporarily preserve the environmental benefits achievable under the CAIR trading programs.

C. CAIR Cap-and-Trade Programs

The CAIR NO_X annual and ozone-season model trading rules both largely mirror the structure of the NO_X SIP Call model trading rule in 40 CFR Part 96, subparts A through I. While the provisions of the NO_X annual and ozone-season model rules are similar, there are some differences. For example, the NO_X annual model rule (but not the NO_X ozone season model rule) provides for a CSP, which is discussed below and under which allowances may be awarded for early reductions of NO_X annual emissions. As a further example, the NO_X ozone season model rule

[1] The Court also determined that the CAIR trading programs were unlawful (*Id.* at 906–8) and that the treatment of CAA title IV allowances in CAIR was unlawful (*Id.* at 921–23). For the same reasons that EPA is approving the provisions of South Carolina's SIP revision that use the SO_2 and NO_X budgets set in CAIR, EPA is also approving, as discussed below, South Carolina's SIP revision to the extent the SIP revision adopts the CAIR trading programs, including the provisions addressing applicability, allowance allocations, and use of title IV allowances.

reflects the fact that the CAIR NO_X ozone season trading program replaces the NO_X SIP Call trading program after the 2008 ozone season and is coordinated with the NO_X SIP Call program. The NO_X ozone season model rule provides incentives for early emissions reductions by allowing banked, pre-2009 NO_X SIP Call allowances to be used for compliance in the CAIR NO_X ozone-season trading program. In addition, states have the option of continuing to meet their NO_X SIP Call requirement by participating in the CAIR NO_X ozone season trading program and including all their NO_X SIP Call trading sources in that program.

The provisions of the CAIR SO_2 model rule are also similar to the provisions of the NO_X annual and ozone season model rules. However, the SO_2 model rule is coordinated with the ongoing Acid Rain SO_2 cap-and-trade program under CAA title IV. The SO_2 model rule uses the title IV allowances for compliance, with each allowance allocated for 2010–2014 authorizing only 0.50 ton of emissions and each allowance allocated for 2015 and thereafter authorizing only 0.35 ton of emissions. Banked title IV allowances allocated for years before 2010 can be used at any time in the CAIR SO_2 cap-and-trade program, with each such allowance authorizing 1 ton of emissions. Title IV allowances are to be freely transferable among sources covered by the Acid Rain Program and sources covered by the CAIR SO_2 cap-and-trade program.

EPA also used the CAIR model trading rules as the basis for the trading programs in the CAIR FIPs. The CAIR FIP trading rules are virtually identical to the CAIR model trading rules, with changes made to account for federal rather than state implementation. The CAIR model SO_2, NO_X annual, and NO_X ozone season trading rules and the respective CAIR FIP trading rules are designed to work together as integrated SO_2, NO_X annual, and NO_X ozone season trading programs.

In the SIP revision, South Carolina chooses to implement its CAIR budgets by requiring EGUs to participate in EPA-administered cap-and-trade programs for SO_2, NO_X annual, and NO_X ozone season emissions. South Carolina adopted a full SIP revision that adopts, with certain allowed changes discussed below, the CAIR model cap-and-trade rules for SO_2, NO_X annual, and NO_X ozone season emissions. Finally, South Carolina's rules provide that non-EGUs that were required to participate in the NOx Budget Trading Program must participate in the CAIR NO_X Ozone Season Trading Program.

D. Applicability Provisions

In general, the CAIR model trading rules apply to any stationary, fossil-fuel-fired boiler or stationary, fossil-fuel-fired combustion turbine serving at any time, since the later of November 15, 1990, or the start-up of the unit's combustion chamber, a generator with nameplate capacity of more than 25 megawatt electrical (MWe) producing electricity for sale.

States have the option of bringing in, for the CAIR NO_X ozone season program only, those units in the State's NO_X SIP Call trading program that are not EGUs as defined under CAIR. Under this option, the CAIR NO_X ozone season program must cover all large industrial boilers and combustion turbines, as well as any small EGUs (*i.e.* units serving a generator with a nameplate capacity of 25 MWe or less) that the State currently requires to be in the NO_X SIP Call trading program.

South Carolina chose to expand the applicability provisions of the CAIR NO_X ozone season trading program to include all non-EGUs in the State's NO_X SIP Call trading program. Additionally, South Carolina has initiated rulemaking to revise the applicability section in its CAIR NO_X ozone season rule in order to clarify that, as intended by the State, all non-EGUs subject to its NO_X Budget Trading Program are brought into its CAIR NOx ozone season trading program and are to be treated as CAIR NO_X ozone season units and that certain definitions (such as the definition of ''fossil-fuel-fired'') from Regulation 61–62.96, Subparts A through I apply to the applicability provisions that bring these units into the CAIR program. EPA determined after review of South Carolina's CAIR rules, including the amended rules submitted on December 4, 2008, that these provisions need clarification. However, while the clarifications are needed, EPA interprets South Carolina's current rules to provide that all non-EGUs covered by the State's NOx Budget Trading Program are subject to the requirements for CAIR NO_X ozone season units and that the NO_X Budget Trading Program definitions are used in applying the applicability provisions that bring in those non-EGUs.

South Carolina has also initiated rulemaking to further revise the definitions of ''commence commercial operation'' and ''commence operation'' in its CAIR NO_X ozone season rule in order to clarify that, for non-EGUs brought into the CAIR trading program, those definitions shall be consistent with the corresponding definitions in the NOx SIP Call model trading rule (40 CFR 96.2). EPA determined after review of South Carolina's CAIR rules that these provisions needed clarification.

EPA received a letter from South Carolina dated October 8, 2009, concurring with EPA's interpretation of the current applicability provisions concerning non-EGUs and provides a commitment to make these revisions in its CAIR rules. In the October 8, 2009, letter, South Carolina commits to make the revisions discussed above to its CAIR NO_X Ozone Season trading rule, Regulation 61–62.96. However, while the clarifications are needed, EPA interprets South Carolina's current rules to apply to non-EGUs the definitions in 40 CFR 96 of these terms.

Finally, as discussed above, EPA amended the definition of ''cogeneration unit'' in CAIR on October 19, 2007. South Carolina's SIP revision incorporates by reference the definitions in the CAIR model trading rules as of October 19, 2007, consistent with the change.

E. NO_X Allowance Allocations

Under the NO_X allowance allocation methodology in the CAIR model trading rules and in the CAIR FIP, NO_X annual and ozone season allowances are allocated to units that have operated for five years, based on heat input data from a three-year period that are adjusted for fuel type by using fuel factors of 1.0 for coal, 0.6 for oil, and 0.4 for other fuels. The CAIR model trading rules and the CAIR FIP also provide a new unit set-aside from which units without five years of operation are allocated allowances based on the units' prior year emissions.

States may establish in their SIP submissions a different NO_X allowance allocation methodology that will be used to allocate allowances to sources in the states if certain requirements are met concerning the timing of submission of units' allocations to the Administrator for recordation and the total amount of allowances allocated for each control period. In adopting alternative NO_X allowance allocation methodologies, states have flexibility with regard to:

1. The cost to recipients of the allowances, which may be distributed for free or auctioned;

2. The frequency of allocations;

3. The basis for allocating allowances, which may be distributed, for example, based on historical heat input or electric and thermal output; and

4. The use of allowance set-asides and, if used, their size.

South Carolina chose to distribute NO_X annual and NO_X ozone season allowances with its own methodology. South Carolina chose to distribute NO_X

allowances by largely adopting, with certain revisions, the CAIR NO_X annual and CAIR NO_X ozone season trading program model rule provisions. The State's NO_X ozone season allocation provisions have been further modified to add requirements associated with South Carolina's option to bring its non-EGUs into the CAIR NO_X ozone season trading program. Specifically, the State chose to distribute CAIR NO_X ozone season allowances to non-EGU's in accordance with South Carolina's Regulation 61–62.96.342(e). Additionally, South Carolina chose to allocate in four-year blocks of time rather than adding one additional year of allowances each year. EPA finds these modifications consistent with the flexibility given to states in CAIR.

In South Carolina's Regulation 61–62.96, Subparts FF and FFFF, the State largely incorporates by reference the model rule language for allowance recordation and adopts a minor modification to Sections 96.153(c) and 96.353(c). The timing for recordation of allowances by EPA in the recordation schedules, as referenced and modified, do not exactly match the timing for the State's submission to EPA of allowance allocations as set forth in Sections 96.141(b) and 96.341(b) for existing units. EPA interprets, and South Carolina confirms in a letter dated October 8, 2009, that the allowance recordation should occur in 4 year blocks every four years to match up with the allocation submissions to EPA. In other words, EPA will record allowance allocations for existing sources by December 1 of the year in which the allocations are determined by the State and submitted to EPA. South Carolina commits in its October 8, 2009, letter to revise its CAIR rules to make the allowance and recordation dates match.

F. Allocation of NO_X Allowances From Compliance Supplement Pool

The CAIR establishes a CSP to provide an incentive for early reductions in NO_X annual emissions. The CSP consists of 200,000 CAIR NO_X annual allowances of vintage 2009 for the entire CAIR region, and a State's share of the CSP is based upon the projected magnitude of the emission reductions required by CAIR in that State. States may distribute CSP allowances, one allowance for each ton of early reduction, to sources that make NO_X reductions during 2007 or 2008 beyond what is required by any applicable State or Federal emission limitation. States also may distribute CSP allowances based upon a demonstration of need for an extension of the 2009 deadline for implementing emission controls.

The CAIR annual NO_X model trading rule establishes specific methodologies for allocations of CSP allowances. States may choose an allowed, alternative CSP allocation methodology to be used to allocate CSP allowances to sources in the states.

Consistent with the flexibility given to states in the model trading rule, South Carolina has chosen to modify the provisions of the CAIR NO_X annual model trading rule concerning the allocation of allowances from the CSP. South Carolina has chosen to distribute CSP allowances by essentially adopting the CAIR NO_X annual CSP provisions in the model rule at 40 CFR 96.143.

G. Individual Opt-in Units

The opt-in provisions of the CAIR SIP model trading rules allow certain non-EGUs (*i.e.,* boilers, combustion turbines, and other stationary fossil-fuel-fired devices) that do not meet the applicability criteria for a CAIR trading program to participate voluntarily in (*i.e.,* opt into) the CAIR trading program. A non-EGU may opt into one or more of the CAIR trading programs. In order to qualify to opt into a CAIR trading program, a unit must vent all emissions through a stack and be able to meet monitoring, recordkeeping, and recording requirements of 40 CFR part 75. The owners and operators seeking to opt a unit into a CAIR trading program must apply for a CAIR opt-in permit. If the unit is issued a CAIR opt-in permit, the unit becomes a CAIR unit, is allocated allowances, and must meet the same allowance-holding and emissions monitoring and reporting requirements as other units subject to the CAIR trading program. The opt-in provisions provide for two methodologies for allocating allowances for opt-in units, one methodology that applies to opt-in units in general and a second methodology that allocates allowances only to opt-in units that the owners and operators intend to repower before January 1, 2015.

States have several options concerning the opt-in provisions. States may adopt the CAIR opt-in provisions entirely or may adopt them but exclude one of the methodologies for allocating allowances. States may also decline to adopt the opt-in provisions at all.

Consistent with the flexibility given to states in the FIPs, South Carolina has chosen to allow non-EGUs meeting the requirements in the CAIR model trading rule's opt-in provisions to participate in the CAIR NO_X annual, NO_X ozone season, and SO_2 trading programs. The South Carolina rule allows for both of the opt-in allocation methods as specified in the CAIR model rules.

VI. Final Action

EPA is approving, as interpreted and clarified herein, South Carolina's full CAIR SIP revision submitted on December 4, 2008. Under the approved SIP revision, South Carolina is providing for continued participation in the EPA-administered CAIR cap-and-trade programs for SO_2, NO_X annual, and NO_X ozone season emissions. The SIP revision, as interpreted and clarified herein, meets the applicable requirements of CAIR, which are set forth in 40 CFR 51.123(o) and (aa), with regard to NO_X annual and NO_X ozone season emissions, and 40 CFR 51.124(o), with regard to SO_2 emissions. EPA is also approving provisions that terminate the State's NO_X Budget Trading Program (Regulation 61–62.96, Subparts A through I) because those requirements are now addressed by the CAIR NO_X ozone season trading program, as clarified herein. In accordance with 40 CFR 52.35 and 52.36, as an automatic consequence of the approval of South Carolina's full SIP revision, EPA is also withdrawing the CAIR FIPs for SO_2, NO_X annual, and NO_X ozone season emissions for South Carolina sources.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial submittal 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 South Carolina's SIP revision if adverse written comments on this direct final rule are filed. This direct final rule will be effective on November 30, 2009 without further notice unless we receive relevant adverse written comments by November 16, 2009. If EPA receives such comments, EPA will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the proposed action. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. If we do not receive any comments, this action will be effective November 30, 2009. EPA also notes that, if an adverse comment is timely received, that may be insufficient time for EPA to respond and issue a subsequent final rule before the 2009 compliance deadline (November 30, 2009) for the CAIR NO_X ozone season trading program. In that event, EPA may determine that the

applicability provisions of that trading program cannot be expanded for 2009 to include non-EGUs and that non-EGUs cannot be allocated CAIR NO_X ozone season allowances for 2009.

VII. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this final action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

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 action 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.** 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).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 30, 2009. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action 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. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of today's **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. 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, Electric utilities, Intergovernmental relations, Incorporation by Reference, Carbon monoxide, Nitrogen oxides, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide.

Dated: October 9, 2009.

A. Stanley Meiburg,

Acting Regional Administrator, Region 4.

■ 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 PP—South Carolina

■ 2. Section 52.2120(c) is amended by revising the entry for ''Regulation No. 62.96: to read as follows:

§ 52.2120 Identification of plan.

* * * * *

(c) * * *

AIR POLLUTION CONTROL REGULATIONS FOR SOUTH CAROLINA

State citation	Title/subject	State effective date	EPA approval date	Federal register notice
* *	* * *		*	*
Regulation No. 62.96	Nitrogen Oxides (NO_X) and Sulfur Dioxide (SO_2) Budget Trading Program General Provisions.	10/24/2009 ...	*10/16/2009* ...	[Insert citation of publication]
* *	* * *		*	*

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[FR Doc. E9–25055 Filed 10–15–09; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0076; FRL–8794–4]

Azoxystrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation amends the established tolerances for residues of azoxystrobin in or on barley bran; barley grain; and barley straw. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 16, 2009. Objections and requests for hearings must be received on or before December 15, 2009, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0076. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., 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 will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7390; e-mail address: *nollen.laura@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0076 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before December 15, 2009.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2009–0076, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

In the **Federal Register** of April 8, 2009 (74 FR 15971) (FRL–8407–4), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 8E7474) by Interregional Research Project Number 4 (IR-4), IR-4 Project Headquarters, 500 College Rd. East, Suite 201 W., Princeton, NJ 08540. The petition requested that 40 CFR 180.507 be amended by increasing established tolerances for residues of the fungicide azoxystrobin, [methyl(*E*)-2-(2-(6-(2-cyanophenoxy) pyrimidin-4-yloxy)phenyl)-3-methoxyacrylate] and the Z-isomer of azoxystrobin, [methyl(*Z*)-2-(2-(6-(2-cyanophenoxy)pyrimidin-4-yloxy)phenyl)-3 methoxyacrylate], in or on barley, grain from 0.1 parts per million (ppm) to 3.0 ppm and barley, straw from 4.0 ppm to 7.0 ppm. That notice referenced a summary of the petition prepared on behalf of IR-4 by Syngenta Crop Protection, Inc., the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting these petitions, EPA has determined that the currently established tolerance in or on barley bran should also be increased and has