

ingestion or skin or eye contact, statements reflecting requirements of applicable sections of the National Environmental Protection Act (NEPA), the Superfund Amendments and Reauthorization Act (SARA), the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations, and a contact address and telephone number for reporting adverse reactions experienced by users or to request a copy of the Material Safety Data Sheet (MSDS). These worker safety concerns are required by other regulations.

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Veterinary Medicine by appointment with the information contact person listed above. As provided in 21 CFR 571.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before May 9, 1996, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be

identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

1. The authority citation for 21 CFR part 573 continues to read as follows:

Authority: Secs. 201, 402, 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348).

2. Section 573.460 is amended by redesignating paragraphs (a) introductory text, (a)(1), (a)(2), (b), (c) introductory text, (c)(1), and (c)(2) as paragraphs (a)(1), (a)(1)(i), (a)(1)(ii), (a)(2), (a)(3), (a)(3)(i), and (a)(3)(ii) respectively; and by adding new paragraph (b) to read as follows:

§ 573.460 Formaldehyde.

* * * * *

(b)(1) The food additive is formaldehyde (37 percent aqueous solution). It is used at the rate of 5.4 pounds (2.5 kilograms) per ton of poultry feed. At this level, it is an antimicrobial agent used to maintain complete poultry feeds salmonella negative for up to 14 days.

(2) To assure safe use of the additive, in addition to the other information required by the Act, the label and labeling shall contain:

(i) The name of the additive.

(ii) A statement that formaldehyde solution which has been stored below 40 °F or allowed to freeze should not be applied to complete poultry feeds.

(iii) Adequate directions for use including a statement that formaldehyde should be thoroughly mixed into complete poultry feed and that the finished poultry feed shall be labeled as containing formaldehyde.

(3) To assure safe use of the additive, in addition to the other information required by the Act, the label and labeling shall contain: (i) Appropriate warnings and safety precautions concerning formaldehyde.

(ii) Statements identifying formaldehyde as a poison with potentials for adverse respiratory effects.

(iii) Information about emergency aid in case of accidental inhalation, ingestion or skin or eye contact.

(iv) Statements reflecting requirements of applicable sections of the National Environmental Protection Act (NEPA), the Superfund Amendments and Reauthorization Act (SARA), and the Occupational Safety and Health Administration's (OSHA) human safety guidance regulations.

(v) Contact address and phone number for reporting adverse reactions or to request a copy of the Materials Safety Data Sheet (MSDS).

Dated: March 11, 1996.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IN52-1-6978a; FRL-5452-4]

Approval and Promulgation of Implementation Plans; Indiana

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: On August 8, 1995, the State of Indiana submitted a State Implementation Plan (SIP) revision request to the United States Environmental Protection Agency (USEPA) for rule changes specific to Richmond Power and Light's (RPL's) Whitewater Generating Station located in Wayne County in Richmond, Indiana. The submittal provides for less stringent limits on particulate matter (PM) emissions than those currently in the SIP from both of the generating station's two primary boilers. The submittal also adds a combined PM limit for those times when both boilers are operating, establishes a site-specific opacity limit for the facility, and specifies a site-specific method for evaluating PM stack test results. The submittal includes air quality modeling which shows that the National Ambient Air Quality Standards (NAAQS) will still be protected under the new regulations.

DATES: The "direct final" rule is effective on June 10, 1996, unless USEPA receives adverse or critical comments by May 9, 1996. If the effective date is delayed, timely notice will be published in the Federal Register.

ADDRESSES: Copies of the revision request are available for inspection at

the following address: U.S. Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. (It is recommended that you telephone David Pohlman at (312) 886-3299 before visiting the Region 5 Office.)

Written comments should be sent to: J. Elmer Bortzer, Chief, Regulation Development Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: David Pohlman at (312) 886-3299.

SUPPLEMENTARY INFORMATION:

I. Background

Indiana's submittal of August 8, 1995, contains revisions to three rules. These rules are: Title 326 Indiana Administrative Code (326 IAC) 3-2.1-5, 326 IAC 5-1-2, and 326 IAC 6-1-14. The purpose of these changes is to revise emission limits and testing procedures for Richmond Power and Light's Whitewater Generating Station.

The proposed rules were published in the Indiana Register on July 1, 1994. Public hearings were held on the rules on January 5, 1994, and August 3, 1995, in Indianapolis, Indiana. The rules were adopted by the Indiana Air Pollution Control Board on August 3, 1994, became effective on July 15, 1995, and were published in the Indiana Register on August 1, 1995.

II. Analysis of State Submittal

326 IAC 3-2.1-5 contains specific testing procedures for particulate matter, sulfur dioxide, nitrogen oxides, and volatile organic compounds. This rule was previously submitted to the USEPA on January 11, 1991. On February 8, 1994 (59 FR 5742), the USEPA proposed to disapprove this rule because it contained unacceptable "Commissioner's discretion" language. This language allowed the Commissioner of the Indiana Department of Environmental Management (IDEM) to authorize alternate emission test methods, changes in test procedures, and alternate operating load levels. At this time, IDEM has begun rulemaking to address the "Commissioner's discretion" issue. In addition, in the cover letter to its August 8, 1995 submission, IDEM stated that, until that rulemaking can be completed and approved by USEPA, no alternate emission test method, changes in test procedures, or alternate operating load levels during testing will be granted to RPL. Based on this representation, the submitted revisions

to 326 IAC 3-2.1-5 are approvable as they apply to RPL.

The revisions to 326 IAC 3-2.1-5 also add the option for RPL to use a time-weighted averaging period when evaluating stack tests that require sootblowing. The time-weighted averaging provision contains an equation to be used when averaging stack test results to determine compliance. The equation is from a March 6, 1979 USEPA memorandum titled "NSPS Determination—Subpart D." This same guidance was restated in a May 7, 1982, Memorandum from the Assistant Administrator for Air, Noise and Radiation to the Directors of the Regional Air Divisions. The time-weighted averaging provision is, therefore, consistent with USEPA policy and is approvable.

326 IAC 5-1-2 has been amended to establish a site-specific opacity limit of 30 percent for Richmond Power and Light. The opacity limit is reduced to 25 percent in May, 1999. Since this revision represents a tightening of the SIP opacity limit from its previous level of 40 percent, this provision is approvable by the USEPA.

326 IAC 6-1-14 has been amended to provide PM limits of 0.19 pounds per million British Thermal Units (lb/MMBTU) and 0.22 lb/MMBTU for coal boilers numbers 1 and 2, respectively, at RPL's Whitewater Generating Station. This is an increase from the former limits of 0.040 and 0.070 for boilers 1 and 2, respectively. The rule also provides for a combined limit of 0.22 lb/MMBTU when boilers 1 and 2 are operating together. Further changes to this rule were made to update the source names in the table of Wayne County emission limits. The State conducted, and submitted, a dispersion modeling analysis to demonstrate that the relaxation of these limits would not cause a violation of the NAAQS for PM. The analysis showed that highest, sixth-highest 24-hour concentrations of PM would be 87.4 micrograms per cubic meter, and that the maximum annual concentration would be 42.5 micrograms per cubic meter. The NAAQS for PM are 150 and 50 micrograms per cubic meter for 24-hour and annual averages, respectively. Thus, the requested SIP revision will protect the PM NAAQS in Wayne County, Indiana.

III. Final Rulemaking Action

Indiana's submittal includes revisions to 326 IAC 3-2.1-5, 5-1-2, and 6-1-14. The USEPA has undertaken an analysis of this SIP revision request based on a review of the materials presented by IDEM and has determined that it is

approvable because it is consistent with applicable Clean Air Act provisions, including protection of the NAAQS for PM in the Wayne County area.

The USEPA is publishing this action without prior proposal because USEPA views this action as a noncontroversial revision and anticipates no adverse comments. However, USEPA is publishing a separate document in this Federal Register publication, which constitutes a "proposed approval" of the requested SIP revision and clarifies that the rulemaking will not be deemed final if timely adverse or critical comments are filed. The "direct final" approval shall be effective on June 10, 1996, unless USEPA receives adverse or critical comments by May 9, 1996. If USEPA receives comments adverse to or critical of the approval discussed above, USEPA will withdraw this approval before its effective date by publishing a subsequent Federal Register document which withdraws this final action. All public comments received will then be addressed in subsequent rulemaking. Please be aware that USEPA will institute another comment period on this action only if warranted by significant revisions to the rulemaking based on any comments received in response to today's action. Any parties interested in commenting on this action should do so at this time. If no such comments are received, USEPA hereby advises the public that this action will be effective on June 10, 1996.

This action has been classified as a Table 3 action for signature by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989 (54 FR 2214-2225), as revised by a July 9, 1995, memorandum from Mary D. Nichols, Assistant Administrator for Air and Radiation. The Office of Management and Budget has exempted this regulatory action from Executive Order 12866 review.

Nothing in this action should be construed as permitting, allowing or establishing a precedent for any future request for revision to any SIP. USEPA shall consider each request for revision to the SIP in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Section 202 of the Unfunded Mandates Reform Act of 1995 ("Unfunded Mandates Act") (signed into law on March 22, 1995) requires that the USEPA prepare a budgetary impact statement before promulgating a rule that includes a Federal mandate that may result in expenditure by State, local, and tribal governments, in aggregate, or by the private sector, of

\$100 million or more in any one year. Section 203 requires the USEPA to establish a plan for obtaining input from and informing, educating, and advising any small governments that may be significantly or uniquely affected by the rule.

Under section 205 of the Unfunded Mandates Act, the USEPA must identify and consider a reasonable number of regulatory alternatives before promulgating a rule for which a budgetary impact statement must be prepared. The USEPA must select from those alternatives the least costly, most cost-effective, or least burdensome alternative that achieves the objectives of the rule, unless the USEPA explains why this alternative is not selected or the selection of this alternative is inconsistent with law.

Because this final rule is estimated to result in the expenditure by State, local, and tribal governments or the private sector of less than \$100 million in any one year, the USEPA has not prepared a budgetary impact statement or specifically addressed the selection of the least costly, most cost-effective, or least burdensome alternative. Because small governments will not be significantly or uniquely affected by this rule, the USEPA is not required to develop a plan with regard to small governments. This rule only approves the incorporation of existing state rules into the SIP. It imposes no additional requirements.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 et seq., USEPA 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, USEPA 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, I certify 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 Act, preparation of a regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of the State action. The Clean Air Act forbids USEPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. USEPA*,

427 U.S. 246, 256-66 (S.Ct. 1976); 42 U.S.C. 7410(a)(2).

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 10, 1996. 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, Incorporation by reference.

Dated: March 22, 1996.

Valdas V. Adamkus,
Regional Administrator.

For the reasons stated in the preamble, part 52, chapter I, title 40 of the 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. 7401-7671q.

Subpart P—Indiana

2. Section 52.770 is amended by adding paragraph (c)(107) to read as follows:

§ 52.770 Identification of plan.

* * * * *

(c) * * *

(107) On August 8, 1995, Indiana submitted a site specific SIP revision request for Richmond Power and Light in Wayne County Indiana. The submitted revisions provide for revised particulate matter and opacity limitations on the number 1 and number 2 coal fired boilers at Richmond Power and Light's Whitewater Generating Station. The revisions also allow for time weighted averaging of stack test results at Richmond Power and Light to account for soot blowing. Indiana is making revisions to 326 IAC 3-2-1, which currently allows Indiana to authorize alternative emission test methods for Richmond Power and Light. Until the rule is revised to remove this authority, and approved by the United States Environmental Protection Agency, no alternate emission test method, changes in test procedures or alternate operating load levels during

testing is to be granted to Richmond Power and Light.

(i) Incorporation by reference. Indiana Administrative Code Title 326: Air Pollution Control Board, Article 3: Monitoring Requirements, Rule 2.1: Source Sampling Procedures, Section 5: Specific Testing Procedures; Particulate Matter; Sulfur Dioxide; Nitrogen Oxides; Volatile Organic Compounds; Article 5: Opacity Regulations, Rule 1: Opacity Limitations, Section 2: Visible Emission Limitations; and Article 6: Particulate Rules, Rule 1: Nonattainment Area Limitations, Section 14: Wayne County. Added at 18 In. Reg. 2725. Effective July 15, 1995.

(ii) Additional Information. (A) August 8, 1995 letter from the Indiana Department of Environmental Management to USEPA Region 5 regarding submittal of a state implementation plan revision for Richmond Power and Light.

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40 CFR Part 52

[W161-01-7144a; FRL-5426-2]

Approval and Promulgation of State Implementation Plan; Wisconsin; Lithographic Printing SIP Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The EPA approves a revision to the Wisconsin State Implementation Plan (SIP) for ozone that was submitted on May 12, 1995, and supplemented on June 14, 1995, and November 14, 1995. This revision consists of a volatile organic compound (VOC) regulation which establishes reasonably available control technology (RACT) for lithographic printing facilities. This regulation was submitted to address, in part, the requirement of section 182(b)(2)(C) of the Clean Air Act (CAA or Act) that states revise their SIPs to establish RACT regulations for major sources of VOCs for which the USEPA has not issued a control technology guidelines (CTG) document. In addition, emission reductions resulting from this rule are being used by the State to fulfill, in part, the requirement of section 182(b)(1) of the Act that States submit a plan that provides for a 15 percent reduction in VOC emissions by 1996.

In the proposed rules section of this Federal Register, the EPA is proposing approval of, and soliciting comments on, this requested SIP revision. If