Subpart C—Hearing Procedures

§ 515.30 Contents of notice of opportunity for a hearing.

(a) The notice to the applicant of opportunity for a hearing on a proposal by the Commissioner of Food and Drugs (the Commissioner) to refuse to approve a medicated feed mill license application or to revoke the approval of a medicated feed mill license will specify the grounds upon which the Commissioner proposes to issue this order. On request of the applicant, the Commissioner will explain the reasons for the action. The notice of opportunity for a hearing will be published in the **Federal Register** and will specify that the applicant has 30 days after issuance of the notice within which the Commissioner is required to file a written appearance electing whether:

(1) To avail himself of the opportunity for a hearing; or

(2) Not to avail himself of the opportunity for a hearing.

(b) If the applicant fails to file a written appearance in answer to the notice of opportunity for hearing, this failure will be construed as an election not to avail himself of the opportunity for the hearing, and the Commissioner without further notice may enter a final order.

(c) If the applicant elects to avail himself of the opportunity for a hearing, the applicant is required to file a written appearance requesting the hearing within 30 days after the publication of the notice, giving the reason why the application should not be refused or the medicated feed mill license should not be revoked, together with a well-organized and full-factual analysis of the information the applicant is prepared to prove in support of his opposition to the Commissioner's proposal. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing there is a genuine and substantial issue of fact that requires a hearing. When it clearly appears from the information in the application and from the reasons and factual analysis in the request for the hearing that no genuine and substantial issue of fact precludes the refusal to approve the application or the revocation of approval of the application, the Commissioner will enter an order on this information, stating his/her findings and conclusions. If a hearing is requested and is justified by the applicant's response to the notice of opportunity for a hearing, the issues will be defined, an Administrative Law Judge will be named, and the Judge shall issue a written notice of the time and place at which the hearing will commence. In the case of denial of approval, such time shall be not more than 90 days after the expiration of such 30 days unless the Administrative Law Judge and the applicant otherwise agree; and, in the case of withdrawal of approval, such time shall be as soon as practicable.

(d) The hearing will be open to the public; however, if the Commissioner finds that portions of the application which serve as a basis for the hearing contain information concerning a method or process entitled to protection as a trade secret, the part of the hearing involving such portions will not be public, unless the respondent so specifies in the appearance.

§ 515.31 Procedures for hearings.

Hearings relating to new animal drugs under section 512(m)(3) and (m)(4) of the Federal Food, Drug, and Cosmetic Act (the act) shall be governed by part 12 of this chapter.

Subpart D—Judicial Review

§ 515.40 Judicial review.

The transcript and record shall be certified by the Commissioner of Food and Drugs (the Commissioner). In any case in which the Commissioner enters an order without a hearing under § 314.200(g) of this chapter, the request(s) for hearing together with the data and information submitted and the Commissioner's findings and conclusions shall be included in the record certified by the Commissioner.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

22. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: U.S.C. 360b, 371.

§ 558.3 [Amended]

23. Section 558.3 *Definitions and general considerations applicable to this part* is amended in paragraphs (b)(3) and (b)(4) by removing the phrase ''an application approved under § 514.105(b) of this chapter'' and adding in its place ''a medicated feed mill license application approved under § 515.20 of this chapter''; and in paragraphs (b)(2) and (b)(5) by removing ''§ 514.105(a)'' and adding in its place ''§ 514.105''.

24. Section 558.4 is amended by revising the section heading and paragraphs (a), (b), and (c) to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

(a) A feed manufacturing facility must possess a medicated feed mill license in order to manufacture a Type B or Type C medicated feed from a Category II, Type A medicated article.

(b) The manufacture of the following types of feed are exempt from the required license, unless otherwise specified:

(1) Type B or Type C medicated feed using Category I, Type A medicated articles or Category I, Type B or Type C medicated feeds; and

(2) Type B or Type C medicated feed using Category II, Type B or Type C medicated feeds.

(c) The use of Type B and Type C medicated feeds shall also conform to the conditions of use provided for in subpart B of this part and in §§ 510.515 and 558.15 of this chapter.

* * * * *

Dated: August 12, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–29856 Filed 11–18–99; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CO–001–0035a; UT–001–0023a; WY–001–0004a; FRL–6471–4]

Approval and Promulgation of Air Quality Implementation Plans; States of Colorado, Utah and Wyoming; General Conformity

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving General Conformity SIP revisions submitted by the Governor of Wyoming on March 14, 1995; submitted by the Governor of Utah on February 12, 1996; and submitted by the Governor of Colorado on September 16, 1997. These SIP revisions were submitted to meet a requirement of section 176(c) of the Clean Air Act.

DATES: This direct final rule is effective on January 18, 2000, without further notice, unless EPA receives adverse comments by December 20, 1999. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Written comments may be mailed to: Richard R. Long, Director, Air and Radiation Program, Mailcode 8P–AR, United States Environmental Protection Agency, Region VIII, 999

18th Street, Suite 500, Denver, Colorado 80202–2466.

Copies of the documents relevant to this action are available for public inspection during normal business hours at the following offices:

United States Environmental Protection Agency, Region VIII, Air and Radiation Program, 999 18th Street, Suite 500, Denver, Colorado 80202–2466; and,

United States Environmental Protection Agency, Air and Radiation Docket and Information Center, 401 M Street, SW, Washington, DC 20460.

Copies of the State documents relevant to this action are available for public inspection at:

Colorado Air Pollution Control Division, Colorado Department of Public Health and Environment, 4300 Cherry Creek Drive South, Denver, Colorado, 80246–1530.

Utah Division of Air Quality, Department of Environmental Quality, 150 North 1950 West, Salt Lake City, Utah, 84114–4820.

Air Quality Division, Department of Environmental Quality, 122 West 25th Street, Cheyenne, Wyoming, 82002.

FOR FURTHER INFORMATION CONTACT: Jeff Houk, Air and Radiation Program, Mailcode 8P–AR, United States Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, Colorado 80202–2466; Telephone number: (303) 312–6446.

SUPPLEMENTARY INFORMATION: Throughout this document, wherever ''we,'' ''our,'' or ''us'' is used, we mean EPA.

I. Summary of EPA's Actions

Today we are approving the General Conformity SIP revisions submitted by the Governor of Wyoming on March 14, 1995; submitted by the Governor of Utah on February 12, 1996; and submitted by the Governor of Colorado on September 16, 1997. Our approval means that the SIP criteria and procedures will govern future general conformity determinations instead of the Federal rules at 40 CFR part 93, subpart B.

II. Evaluation of the States' Submittals

Section 110(k) of the Act addresses our actions on submissions of SIP revisions. The Act also requires States to observe certain procedures in developing SIP revisions. Section 110(a)(2) of the Act requires that each SIP revision be adopted after reasonable notice and public hearing. We have evaluated the States' submissions and determined that the necessary procedures were followed. We found that Wyoming's SIP revision was administratively and technically complete in a letter to the Governor dated May 26, 1995. Utah's SIP revision became complete by operation of law on April 12, 1996. Colorado's SIP revision became complete by operation of law on November 15, 1997.

The States' General Conformity SIP revisions must contain criteria and procedures that are at least as stringent as those in the Federal rule. States may incorporate the Federal rule into State rules.

Wyoming's New Air Quality Standards Regulation Section 32

We are approving Wyoming's General Conformity SIP revision because section 32 includes every requirement of the federal rule except for 40 CFR 93.151 (''State Implementation Plan (SIP) revision''), which discusses how the Federal and State conformity rules interact. State rules govern conformity determinations once we approve them. 40 CFR 93.151 has the same effect whether or not it is incorporated into the State SIP because it specifies that any part of the Federal rule not included in EPA-approved State rules remains in effect at the federal level.

Wyoming also added a definition to its rule that wasn't included in the Federal rule, for ''CAA'' (Clean Air Act), and slightly modified the definitions for ''Milestone,'' and ''Nonattainment Area (NAA).'' We agree with these minor changes to the Federal rule language.

Utah's General Conformity SIP Revision

We are approving Utah's General Conformity SIP, which simply adopts the Federal rule into State rules. It was adopted in three separate actions: (1) A new section XXII to the SIP, General Conformity; (2) a new State rule, R307–2–30, incorporating this section of the SIP into State rules, and (3) a new rule R307–19, formally incorporating the Federal rule into State rules.

The effective date for the Federal rule cited in the State rule and the SIP (November 30, 1992) is incorrect. The Federal rule took effect on January 31, 1994. This error does not affect the applicability or the approvability of Utah's SIP.

Colorado's revisions to its Regulation No. 10, ''Criteria for Analysis of Conformity''

We are approving these revisions, which incorporate 40 CFR part 51, subpart W, and 40 CFR 6.303 into the State rule. Colorado should have incorporated the Federal conformity rule (40 CFR part 93, subpart B) rather than the General Conformity SIP requirements of 40 CFR part 51, subpart W. However, these two regulations are identical except for the conformity SIP requirement itself (40 CFR 51.851(a)), which no longer applies because the State has submitted its SIP.

Colorado also incorporated changes that we made to 40 CFR part 6 at the time we finalized our conformity rule. 40 CFR part 6 contains regulations to ensure that our actions meet the requirements of the National Environmental Policy Act of 1969 and the Council on Environmental Quality's implementing regulations of November 29, 1978 (43 FR 55978). We revised 40 CFR 6.303 to reference the general conformity requirements and to state that our actions must meet these requirements. We don't require states to incorporate these requirements into general conformity SIPs, but they can.

III. Background on our General Conformity Requirements

The SIPs we are approving today were submitted to meet a requirement of Clean Air Act section 176(c), which spells out the Act's conformity requirements and directs each State to submit conformity SIPs. Under section 176(c), ''no Federal department, agency, or instrumentality shall engage in, support in any way or provide financial assistance for, license or permit or approve any activity which does not conform to a SIP that has been approved or promulgated pursuant to the Act.'' This section defines conformity as compliance with the SIP's purpose of attaining the National Ambient Air Quality Standards, and states that federal activities will not cause or contribute to a new violation of any standard in any area, increase the frequency or severity of an existing violation of any standard in any area, or delay timely attainment of a standard or any required interim emission reductions or other milestones in any area.

Section 176(c)(4)(A) requires us to issue criteria and procedures for determining conformity of all Federal actions to applicable SIPs. 40 CFR part 93, subpart A spells out criteria and procedures for determining conformity of Federal actions related to transportation projects funded or approved under Title 23 U.S.C. or the Federal Transit Act. 40 CFR part 93, Subpart B (''Determining Conformity of General Federal Actions to State or Federal Implementation Plans'') spells out criteria and procedures for determining conformity of all other Federal actions. These are the requirements that we are acting on with

respect to the State SIPs in this approval.

IV. Final Action

In this action, EPA is approving the General Conformity SIP revisions submitted by the Governor of Wyoming on March 14, 1995; submitted by the Governor of Utah on February 12, 1996; and submitted by the Governor of Colorado on August 19, 1998.

EPA is publishing this action 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, we are publishing a separate document that will serve as the proposal to approve the SIP revision should adverse comments be filed. This rule will be effective January 18, 2000, without further notice unless the Agency receives adverse comments by December 20, 1999.

If EPA receives such comments, then we will publish a timely withdrawal of the direct final rule informing the public that the rule will 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 this rule. Any parties interested in commenting on this rule should do so at this time. If no such comments are received, the public is advised that this rule will be effective on January 18, 2000, and no further action will be taken on the proposed rule.

Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, entitled ''Regulatory Planning and Review.''

B. Executive Orders 12875

Under E.O. 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected state, local, and tribal governments, the nature of their concerns, copies of written communications from the governments, and a statement supporting the need to issue the regulation.

In addition, E.O. 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.'' Today's rule does not create a mandate on state, local or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

On August 4, 1999, President Clinton issued a new executive order on federalism, Executive Order 13132, (64 FR 43255 (August 10, 1999),) which will take effect on November 2, 1999. In the interim, the current Executive Order 12612, (52 FR 41685 (October 30, 1987),) on federalism still applies. This rule will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 12612. The rule affects only three states, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

D. Executive Order 13084

Under E.O. 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation.

In addition, E.O. 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.'' Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

This final rule will not have a significant impact on a substantial number of small entities because 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 create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of 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).

F. 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 annual 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 annual 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.

G. Submission to Congress and the Comptroller General

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 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This rule is not a ''major'' rule as defined by 5 U.S.C. 804(2).

H. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are inapplicable to this action. Today's action does not require the public to perform activities conducive to the use of VCS.

I. 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 January 18, 2000. 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, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: October 13, 1999

Jack W. McGraw,

Acting Regional Administrator, Region VIII.

Chapter I, title 40, parts 52 and 81 of the Code of Federal Regulations are 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 G—Colorado

2. Section 52.320 is amended by adding paragraph (c)(85) to read as follows:

§ 52.320 Identification of plan.

* * * * *

(c) * * *

(85) On September 16, 1997, the Governor of Colorado submitted revisions to Regulation No. 10 ''Criteria for Analysis of Conformity'' that incorporate the General Conformity requirements of 40 CFR part 51, Subpart W into State regulation.

(i) Incorporation by reference.

(A) Regulation No. 10 ''Criteria for Analysis of Conformity'', 5 CCR 1001–12, as adopted on October 17, 1996, effective December 30, 1996.

Subpart TT—Utah

3. Section 52.2320 is amended by adding paragraph (c)(42) to read as follows:

§ 52.2320 Identification of plan.

* * * * *

(c) * * *

(42) On February 12, 1996, the Governor of Utah submitted revisions submitted revisions to the SIP that incorporate the General Conformity requirements of 40 CFR part 93, subpart B into the SIP and State regulation.

(i) Incorporation by reference.

(A) UACR R307–2–30, Section XXII, General Conformity, as adopted on October 4, 1995, effective October 12, 1995.

(B) UACR R307–19, General Conformity, as adopted on October 4, 1995, effective October 12, 1995.

Subpart ZZ—Wyoming

4. Section 52.2620 is amended by adding paragraph (c)(28) to read as follows:

§ 52.2620 Identification of plan.

* * * * *

(c) * * *

(28) On March 14, 1995, the Governor of Wyoming submitted revisions to the SIP that incorporate the General Conformity requirements of 40 CFR part 93, Subpart B into State regulation.

(i) Incorporation by reference.

(A) Section 32 of the Wyoming Air Quality Standards, ''Conformity of General Federal Actions to State Implementation Plans,'' effective February 13, 1995.

[FR Doc. 99–30232 Filed 11–18–99; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 63, 261, and 266

[FRL–6477–9]

RIN 2050–AE01

NESHAPS: Final Standards for Hazardous Air Pollutants for Hazardous Waste Combustors

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; technical correction.

SUMMARY: On June 19, 1998, EPA published the Revised Standards for Hazardous Waste Combustors Final Rule and on September 30, 1999 published the Hazardous Waste Combustors NESHAP Final Rule. In today's action we are clarifying our intention associated with the Notification of Intent to Comply and Progress Report requirements of the 1998 rule. Additionally, we are correcting a typographical error in the