

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 91N-0291]

General and Plastic Surgery Devices; Effective Date of Requirement for Premarket Approval of Silicone Inflatable Breast Prosthesis; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to April 8, 1993, the comment period on the proposed rule to amend its regulations to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the silicone inflatable breast prosthesis, a medical device. The proposed rule was published in the Federal Register of January 8, 1993 (58 FR 3436). FDA is taking this action in response to a request for an extension of the comment period.

DATES: Written comments by April 8, 1993.

ADDRESSES: Submit written comments to the Docket Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas J. Callahan, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 3390 Piccard Dr., Rockville, MD 20850, 301-427-1036.

SUPPLEMENTARY INFORMATION: In the Federal Register of January 8, 1993 (58 FR 3436), FDA issued a proposed rule to amend its regulations to require the filing of a PMA or a notice of completion of a PDP for the silicone inflatable breast prosthesis, a medical device. Interested persons were given until March 9, 1993, to respond to the proposed rule. FDA received one request for an extension of the comment period for 120 days. The request stated that additional time was needed to review all of the clinical issues, medical literature, clinical endpoint, and safety criteria in order to adequately address them.

FDA agrees with the request in part and is granting a 30-day extension. Accordingly, the comment period is extended to April 8, 1993.

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 4, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93-5437 Filed 3-9-93; 8:45 am]

BILLING CODE 4190-01-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[OR12-1-5464; AD-FRL-4603-1]

Approval and Promulgation of State Implementation Plans: Oregon

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: The EPA proposes approval of the state implementation plan (SIP) submitted by the State of Oregon for the purpose of bringing about the attainment of the national ambient air quality standards (NAAQS) for particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM-10). The implementation plan was submitted by the State to satisfy certain Federal Clean Air Act requirements for an approvable moderate PM-10 nonattainment area SIP for Grants Pass, Oregon. The rationale for the approval is set out both in this notice and in supporting technical information which is available at the address indicated below. The final action to approve this plan would have the effect of making requirements adopted by the State of Oregon, federally enforceable by EPA.

DATES: Comments on this proposed action must be received in writing by April 9, 1993.

ADDRESSES: Comments should be addressed to: Rindy Ramos, Environmental Protection Agency, Air and Radiation Branch, Docket No. OR12-1-5464, 1200 Sixth Avenue, AT-082 Seattle, Washington, 98101.

Copies of the State's submittal and other information are available for inspection during the following business hours at the following location:

Environmental Protection Agency, Air and Radiation Branch (OR12-1-5464), 1200 Sixth Avenue, AT-082, Seattle, Washington, 98101.

State of Oregon Department of Environmental Quality, 811 SW, Sixth Avenue, Portland, Oregon, 97204.

FOR FURTHER INFORMATION CONTACT:

Rindy Ramos, Environmental Protection Agency, 1200 Sixth Avenue, AT-082, Seattle, Washington, 98101. Telephone: (206) 553-6510.

SUPPLEMENTARY INFORMATION:

I. Background

The Grants Pass, Oregon, area was designated nonattainment for PM-10 and classified as moderate under sections 107(d)(4)(B) and 188(a) of the Clean Air Act, upon enactment of the Clean Air Act Amendments of 1990.¹ See 56 FR 56694 (November 6, 1991). The air quality planning requirements for moderate PM-10 nonattainment areas are set out in subparts 1 and 4 of part D, title I of the Act.² The EPA has issued a "General Preamble" describing EPA's preliminary views on how EPA intends to review SIP's and SIP revisions submitted under title I of the Act, including those State submittals containing moderate PM-10 nonattainment area SIP requirements. See generally 57 FR 13498 (April 16, 1992); see also 57 FR 18079 (April 28, 1992). Because EPA is describing its interpretations here only in broad terms, the reader should refer to the General Preamble for a more detailed discussion of the interpretations of title I advanced in today's proposal and the supporting rationale. In today's rulemaking action on the State of Oregon's moderate PM-10 SIP for the Grants Pass nonattainment area, EPA is proposing to apply its interpretations taking into consideration the specific factual issues presented. Additional information supporting EPA's action on this particular area is available for inspection at the address indicated above. EPA will consider any timely submitted comments before taking final action on today's proposal.

¹ The 1990 Amendments to the Clean Air Act made significant changes to the Act. See Pub. L. No. 101-549, 104 Stat. 2398. References herein are to the Clean Air Act, as amended ("the Act"). The Clean Air Act is codified, as amended, in the U.S. Code at 42 U.S.C. sections 7401, et seq.

² Subpart 1 contains provisions applicable to nonattainment areas generally and subpart 4 contains provisions specifically applicable to PM-10 nonattainment areas. At times, subpart 1 and subpart 4 overlap or conflict. EPA has attempted to clarify the relationship among these provisions in the "General Preamble" and, as appropriate, in today's notice and supporting information.

Those States containing initial moderate PM-10 nonattainment areas (those areas designated nonattainment under section 107(d)(4)(B)) were required to submit, among other things, the following provisions by November 15, 1991:

1. Provisions to assure that reasonably available control measures (RACM) (including such reductions in emissions from existing sources in the area as may be obtained through the adoption, at a minimum, of reasonably available control technology (RACT)) shall be implemented no later than December 10, 1993;

2. Either a demonstration (including air quality modeling) that the plan will provide for attainment as expeditiously as practicable but no later than December 31, 1994, or a demonstration that attainment by that date is impracticable;

3. Quantitative milestones which are to be achieved every 3 years and which demonstrate reasonable further progress (RFP) toward attainment by December 31, 1994; and

4. Provisions to assure that the control requirements applicable to major stationary sources of PM-10 also apply to major stationary sources of PM-10 precursors except where the Administrator determines that such sources do not contribute significantly to PM-10 levels which exceed the NAAQS in the area. See sections 172(c), 183, and 189 of the Act.

Additional provisions are due at a later date. States with initial moderate PM-10 nonattainment areas were required to submit a permit program for the construction and operation of new and modified major stationary sources of PM-10 by June 30, 1992 (see section 189(a)). Such States also must submit contingency measures by November 15, 1992, which become effective without further action by the State or EPA, upon a determination by EPA that the area has failed to achieve RFP or to attain the PM-10 NAAQS by the applicable statutory deadline (see section 172(c)(9) and 57 FR 13543-44).

II. Today's Action

Section 110(k) of the Act sets out provisions governing EPA's review and processing of SIP submittals (see 57 FR 13565-66). In today's action, EPA is proposing to approve the plan submitted to EPA on November 21, 1990, as revised by addenda submitted on November 15, 1991 (examined together herein as a comprehensive submittal for the area). EPA has determined that the submittal meets all of the applicable requirements of the Act.

A. Analysis of State Submission

1. Procedural Background

The Act requires States to observe certain procedural requirements in developing implementation plans and plan revisions for submission to EPA. Section 110(a)(2) of the Act provides that each implementation plan submitted by a State must be adopted after reasonable notice and public hearing.² Section 110(j) of the Act similarly provides that each revision to an implementation plan submitted by a State under the Act must be adopted by such State after reasonable notice and public hearing. EPA also must determine whether a submittal is complete and therefore warrants further EPA review and action (see section 110(k)(1) and 57 FR 13565). EPA's completeness criteria for SIP submittals are set out at 40 CFR part 51, appendix V (1991), as amended by 58 FR 42216 (August 26, 1991). EPA attempts to make completeness determinations within 60 days of receiving a submission. However, a submittal is deemed complete by operation of law if a completeness determination is not made by EPA six months after receipt of the submission.

The State of Oregon Department of Environmental Quality (ODEQ) adopted a Grants Pass PM-10 plan at a public hearing held on November 2, 1990, and submitted the plan to EPA for approval on November 21, 1990. ODEQ subsequently adopted an addendum to the plan on November 8, 1991, and submitted the addendum to EPA for approval on November 15, 1991. ODEQ held a public hearing on September 27, 1991, to entertain public comment on the plan.

The SIP revision was reviewed by EPA to determine completeness shortly after its submittal. In accordance with the completeness criteria set out at 40 CFR part 51, appendix V (1991), as amended by 56 FR 42216 (August 26, 1991). A letter dated February 24, 1991, was forwarded to the Director of the ODEQ indicating the completeness of the submittal and the next steps to be taken in the review process. In today's action EPA proposes to approve the State of Oregon Department of Environmental Quality's PM-10 SIP submittal for the Grants Pass PM-10 nonattainment area and invites public comment on the action.

² Section 172(c)(7) of the Act requires that plan provisions for nonattainment areas meet the applicable provisions of section 110(a)(2).

2. Accurate Emissions Inventory

Section 172(c)(3) of the Act requires that nonattainment plan provisions include a comprehensive, accurate, current inventory of actual emissions from all sources of relevant pollutants in the nonattainment area. Because the submission of the emissions inventory is a necessary adjunct to an area's attainment demonstration (or demonstration that the area cannot practicably attain), the emissions inventory must be received with the demonstration submission (see 57 FR 13539).

The emission inventory developed for the Grants Pass Urban Growth Boundary (UGB) identified that the sources of PM-10 concentrations during 24-hour worst case winter periods are the following: residential wood combustion (54%), industrial emissions (25%), fugitive dust (13%), and transportation (7%). The emission inventory was qualitatively confirmed through receptor modeling techniques apportioning source contributions on the basis of their chemical "fingerprints."

ODEQ made an assumption in determining residential wood combustion emissions in Grants Pass. ODEQ assumed that wood heating characteristics in the Medford-Ashland nonattainment area were representative of Grants Pass and therefore could be substituted for an actual residential wood combustion emissions inventory for the Grants Pass nonattainment area. Data from a 1987 wood user survey conducted in Medford-Ashland was used to estimate wood smoke emissions. This assumption was used because (1) a wood users survey for Grants Pass did not exist; (2) Grants Pass is located only twenty-nine miles to the west of Medford; and (3) Oregon Department of Environmental Quality (ODEQ) believed that the wood stove mix, percent of homes that burned wood, number of cords of wood burned per year, and percent of homes that used wood as their main source of heat would be very similar between the two areas.

To assess this assumption, ODEQ received funding from EPA to conduct a survey specific to Grants Pass during the 1991/1992 wood heating season. This study has been conducted. Preliminary results from the study indicate that the wood user characteristics, wood consumption, and stove mix are very similar between the two areas since the change in wood heating habits (due to public education and awareness) between 1987 and 1992 are taken into consideration.

EPA is proposing to approve the emissions inventory because it appears to be accurate and comprehensive, and provides a sufficient basis for determining the adequacy of the attainment demonstration for this area. For further details the reader is referred to the Technical Support Document (TSD) corresponding with this action, which is available at the address indicated above.

3. RACM (Including RACT)

As noted, the initial moderate PM-10 nonattainment areas must submit provisions to assure that RACM (including RACT) are implemented no later than December 10, 1993 (see sections 172(c)(1) and 189(a)(1)(C)). The General Preamble contains a detailed discussion of EPA's interpretation of the RACM (including RACT) requirement (see 57 FR 13539-45 and 13560-61). Attainment of the PM-10 standard in Grants Pass, Oregon is based on three control strategies: industrial controls, woodstove certification, and a voluntary wood-burning curtailment program. The available control measures to be implemented in the Grants Pass nonattainment area will include the following:

a. Industrial Controls

On September 7, 1989, the Oregon Environmental Quality Commission adopted changes to the Industrial Rules (OAR 340-30-0050 through 411), for, among other areas, Grants Pass. These rules became effective upon adoption and were submitted to EPA for approval on October 13, 1989. On November 13, 1989, EPA determined that the SIP revision was not approvable due to enforceability issues. In response to EPA's concerns, ODEQ corrected the deficiencies, added new provisions and the EQC adopted the revised rules on November 8, 1991. The corrected rules were submitted to EPA on November 15, 1991. Among other limits, these rules impose new emission limits for existing veneer dryers and existing large, wood-fired boilers (heat input capacity of greater than 35 million BTU/Hr). EPA proposed to approve these rules in a separate notice published on November 9, 1992 (57 FR 53394) and plans to take final action in the near future.

ODEQ projects a 55 percent reduction in PM-10 emissions between 1986 and 1992 due to implementation of its industrial control limitations. However,

*The EPA issued guidance on PM-10 emissions inventories prior to the enactment of the Clean Air Act Amendments in the form of the 1987 PM-10 SIP Developmental Guidelines. The guidance provided in this document appears to be consistent with the Act.

since the state's rules became effective, one of the two large wood-fired boilers in the area permanently shut down and did not bank its emissions (July 28, 1989). In addition, another source has switched from log fuel for its boiler and veneer drier to natural gas. The operating permit for this source will be modified to reflect the usage of natural gas. These additional reductions will further reduce PM-10 emissions in the nonattainment area to a projected 64 percent reduction in total point source emissions between 1986 and 1992.

EPA believes that the emission limits imposed on the board products industries, supported by their enforceability, will achieve the estimated emission reductions of 1,147 lbs/day. Therefore, EPA proposes to accept the 55 percent credit requested by the ODEQ.

b. Woodstove Certification

In 1983, the Oregon Legislature directed ODEQ to require that all new woodstoves sold in the state be certified through laboratory testing. As a result, stoves sold after July 1988, were required to emit particles at a rate of 50 percent less than conventional woodstoves. After July 1988, new woodstoves were required to emit 70 percent less.

The EQC adopted on March 2, 1990, and submitted to EPA on March 15, 1990, revisions to Oregon's Woodstove Certification Program making it consistent with EPA's New Source Performance Standard 40 CFR part 60, subpart AAA. Currently, all woodstoves sold in the State of Oregon must be both ODEQ and EPA certified. This SIP revision was approved by EPA as part of the Oregon SIP on June 9, 1992 (57 FR 24373).

ODEQ estimates that the woodstove certification program provides a 10.2 percent credit against baseline 1986 woodstove emissions by 1992. The 10.2 percent emission reduction credit requested equals 506 pounds per day by 1994. The projected emission reductions, in conjunction with a statewide ban (OAR 340-20-010(2)) on the sale of used uncertified stoves, and a ban on the installation of used uncertified stoves, supports EPA's

*This estimate uses a 1986 baseline inventory and assumes or relies on: (1) a 1% annual growth in firewood consumed by woodstoves, (2) a 2% annual decline in firewood consumed by fireplaces, (3) a useful stove life of 20 years, (4) a building permit survey conducted in Klamath Falls, Oregon indicating that 90% of permitted installations are certified stoves, (5) an annual growth in population of 1.7%, and (6) the fact that the typical certified woodstove emits 50% less than a conventional stove.

proposed acceptance of Oregon's woodstove certification credit claim.

c. Voluntary Woodburning Curtailment Program

The Grants Pass voluntary curtailment program includes a public education program that describes the need for the public's cooperation, the health, safety, energy, economic benefits to individuals and the community, and steps individuals can take to help reduce emissions.

Key elements of the voluntary program and public information program include: home weatherization, firewood seasoning, cleaner burning practices, proper stove installation and sizing, maintenance of woodburning systems, and curtailment of woodburning during poor ventilation episodes.

Woodburning forecasts are made after 9 a.m. but before 11 a.m. The forecasts are made before 11 a.m. so that a curtailment announcement can appear in the local daily newspaper. The advisory level is based upon expected meteorological conditions and the prior 24-hour ambient levels.

Woodburning curtailment advisories are issued at three levels: (1) a green advisory is made when the ambient concentration is expected to be 50 $\mu\text{g}/\text{m}^3$ or less, (2) a yellow advisory is made when the concentration is expected to be between 50 $\mu\text{g}/\text{m}^3$ and 120 $\mu\text{g}/\text{m}^3$, (3) a red advisory is made when the ambient concentration is expected to be greater than 120 $\mu\text{g}/\text{m}^3$.

Compliance with the advisories will be determined through surveys of woodburning activity. Data from the surveys are used to direct the public education program, evaluate progress toward achieving program goals, and in evaluating trends in PM-10 concentrations.

ODEQ requests a 25 percent emission reduction credit for its voluntary woodburning curtailment program. The 25 percent credit is greater than the 10 percent generally suggested by EPA. The recommended 10 percent credit is viewed by EPA as a "starting point in assessing the effectiveness of residential wood combustion control programs". However, final judgment of the amount of credit to be granted, is determined by EPA's regional offices, based on the program elements outlined in EPA's *Guidance Document for Residential Wood Combustion Emission Control Measures*. EPA has reviewed the ODEQ curtailment program elements, considering public education and participation, and ODEQ's experience in developing and managing curtailment programs. EPA proposes to accept the

25 percent credit claimed for this control measure. Further description of this program and justification for EPA's proposed action is set out in the TSD.

d. Other Sources

Where sources of PM-10 contribute insignificantly to the PM-10 problem in the area, EPA's policy is that it would be unreasonable (and would not constitute RACM) to require the sources to implement potentially available control measures. (57 FR 13540)

ODEQ has determined that fugitive dust is not a significant source of PM-10 emissions in the area. Nevertheless, various control measures addressing sources of fugitive dust are currently required by ODEQ. While the implementation of all available fugitive dust measures would not expedite attainment in the area, those measures currently required by ODEQ should help to ensure on-going maintenance of the PM-10 NAAQS in the area. These rules are enforced under OAR 340-21-060 and are currently a part of Oregon's state adopted, federally approved SIP.

EPA views these rules as strengthening the PM-10 SIP. A similar situation exists for sources of prescribed burning. Therefore, EPA is proposing to approve a year-round ban on open burning within the city limits of Grants Pass as strengthening the SIP. A ban on open burning within the Rogue Basin Open Burning Special Control Area when the ventilation index is less than 300, was approved by EPA on June 6, 1992 (57 FR 24373) as a SIP strengthening measure.

A more detailed discussion of the control measures (including available control technology) contained in the SIP, and an explanation as to why certain available control measures were not implemented, can be found in ODEQ's submittals and in the TSD. EPA has reviewed ODEQ's submittals and associated documentation and concluded that they adequately justify the control measures to be implemented. The implementation of Grants Pass Oregon's PM-10 nonattainment plan control strategy will result in the attainment of the PM-10 NAAQS as expeditiously as practicable by December 31, 1994. By this notice, EPA is proposing to approve ODEQ's control strategy as satisfying the RACM (including RACT) requirement.

4. Demonstration

As noted, the initial moderate PM-10 nonattainment areas must submit a demonstration (including air quality modeling) showing that the plan will provide for attainment as expeditiously as practicable but no later than September

December 31, 1994 (see section 189(a)(1)(B) of the Act). The General Preamble sets out EPA's guidance on the use of modeling for moderate area attainment demonstrations (57 FR 13539). Alternatively, the state must show that attainment by December 31, 1994, is impracticable.

ODEQ conducted an attainment demonstration based upon a roll-forward and roll-back modeling analysis in the Grants Pass nonattainment area. In addition, a roll-back approach was applied to the results of a receptor modeling analysis (Chemical Mass Balance version 7.0). Both approaches were in very close agreement as to the amount of reductions needed to attain the standard (e.g. 17 percent vs 20 percent).

This demonstration indicates that the NAAQS for PM-10 will be attained by December 31, 1994, in Grants Pass, with an ambient concentration of 150 micrograms/cubic meter ($\mu\text{g}/\text{m}^3$), and will be maintained in future years. The 24-hour PM-10 NAAQS is 150 $\mu\text{g}/\text{m}^3$ and the standard is attained when the expected number of days per calendar year with a 24-hour average concentration above 150 $\mu\text{g}/\text{m}^3$ is equal to or less than one (see 40 CFR section 50.6). The annual PM-10 NAAQS is 50 $\mu\text{g}/\text{m}^3$ and the standard is attained when the expected annual arithmetic mean concentration is less than or equal to 50 $\mu\text{g}/\text{m}^3$ (id.).

The demonstration predicted that the 24-hour design concentration in the attainment year of 1994 will be 150 $\mu\text{g}/\text{m}^3$, thus demonstrating attainment of the 24-hour PM-10 NAAQS. The demonstration also showed that the PM-10 NAAQS will be maintained in future years by predicting a 24-hour "worst day" design concentration of 105 $\mu\text{g}/\text{m}^3$ for the year 2000. The control strategy used to achieve these design concentrations is summarized in the section titled "RACM (including RACT)". More detailed description of the attainment demonstration is contained in the TSD accompanying this notice.

The control requirements which are applicable to major stationary sources of PM-10, also apply to major stationary

sources of PM-10 precursors unless EPA determines such sources do not contribute significantly to PM-10 levels in excess of the NAAQS in that area (see section 189(e) of the Act). The General Preamble contains guidance addressing how EPA intends to implement section 189(e) (see 57 FR 13539-40 and 13541-42).

The filter analyses (chemical mass balance) indicated that on average, only 3 percent of the mass was comprised of secondary particulate. EPA believes that this is an insignificant portion and is therefore proposing to grant the exclusion from control requirements authorized under section 189(e) for major stationary sources of PM-10 precursors.

G. Enforceability Issues

All measures and other elements in the SIP must be enforceable by ODEQ and EPA (see sections 172(c)(6) and 110(a)(2)(A), and 57 FR 13556). EPA criteria addressing the enforceability of SIP's and SIP revisions were stated in a September 23, 1987 memorandum (with attachments) from J. Craig Potter, Assistant Administrator for Air and Radiation, et al. (see 52 FR 43541). Nonattainment area plan provisions must also contain a program that will provide for enforcement of the control measures and other elements in the SIP (see section 110(a)(2)(C)).

The particular control measures that are contained in the SIP are addressed above under the section headed "RACM (including RACT)". These control measures apply to the types of activities identified in that discussion including, for example, wood drying, existing large wood-fired boilers with a heat input capacity of greater than 5 million BTU/hr, and woodstoves and other woodburning activities. The SIP also provides that the control measures for the affected activities apply throughout the entire nonattainment area.

Consistent with the attainment demonstration described above, the SIP requires that all affected activities must be in full compliance with the applicable SIP provisions by December 10, 1993. In addition to the applicable control measures, this includes the applicable recordkeeping requirements which are addressed in supporting technical information.

ODEQ's submittals and TSD contain further information on enforceability requirements including enforceable emission limitations, a description of the rules contained in the SIP and the source types subject to them, test methods and compliance schedules, averaging times for compliance, test methods, correctly labeled emissions

* EPA believes that an attainment demonstration for the annual PM-10 NAAQS is unnecessary for Ambient Air for the four years between December 1995 and November 1999. The annual average of 42 $\mu\text{g}/\text{m}^3$ which is below the 50 $\mu\text{g}/\text{m}^3$ annual standard. Note also that because the implementation of RACT (including RACT) will reduce the worst case 24-hour design value below the 24-hour NAAQS, this should also result in further margin for meeting the annual NAAQS.

incorporated methods/rules; and reporting and recordkeeping requirements.

ODEQ also has a program that will ensure that the control measures contained in the Grants Pass PM-10 SIP are adequately enforced. The TSD contains a discussion of the personnel and funding intended to support effective implementation of the control measures.

7. Contingency Measures

As provided in section 172(c)(9) of the Act, all moderate nonattainment area SIPs that demonstrate attainment must include contingency measures (see generally 57 FR 13543-13544). These measures must be submitted by November 15, 1993, for the initial moderate nonattainment areas.

Contingency measures should consist of other available measures that are not part of the area's control strategy. These measures must take effect without further action by the State or EPA, upon a determination by EPA that the area has failed to achieve reasonable further progress (RFP) to attain the PM-10 NAAQS by the applicable statutory deadline. The Grants Pass nonattainment area SIP contains the following contingency measures:

a. A mandatory woodsmoke curtailment program that is to take effect if the EPA determines that the area fails to achieve RFP to attain the NAAQS by December 31, 1994. ODEQ has the authority to implement and enforce a mandatory curtailment program upon notification by EPA that the area has failed to attain the NAAQS, should the City of Grants Pass or the County of Josephine fail to implement one. EPA approved these rules (OAR 340-34-150 through 175) as part of the Oregon SIP on June 9, 1992 (57 FR 24373).

b. Removal of unclassified woodstoves upon home sale for any area that fails to meet the PM-10 attainment date of December 31, 1994. These stoves would have to be removed and destroyed prior to sale of the home. EPA approved these rules (OAR 340-34-200 through 215) as part of the Oregon SIP on June 9, 1992 (57 FR 24373).

c. Reduction in industrial emissions (including source-specific emission limits) should the area fail to attain by December 31, 1994. EPA approved these rules (OAR 340-34-200 through 245) as part of the SIP on August 19, 1992 (57 FR 37460).

d. The banning of all open burning in the Rogue Basin Open Burning Control Area during November, December, January, and February of each year, should the area fail to attain by December 31, 1994. EPA approved these

rule (OAR 340-23-090) as part of the SIP on June 9, 1992 (57 FR 24373).

The expected emission reductions to be achieved by implementation of the contingency measures is estimated at more than 82 tons per year. This represents at least a 30 percent reduction when compared with the 275 tons per year emission reduction in the attainment plan.

The SIP provides that each of these measures can take effect without further action by the state or EPA, should EPA determine that the Grants Pass nonattainment area has failed to achieve RFP or to attain the PM-10 standard by the statutory attainment date of December 31, 1994.

EPA is proposing to approve the Grants Pass nonattainment area contingency measures.

III. Implications of Today's Action

EPA is proposing to approve the plan revision submitted to EPA for the Grants Pass, Oregon nonattainment area on November 21, 1990, as revised by addenda submitted on November 15, 1991. Among other things, ODEQ has demonstrated that the Grants Pass moderate PM-10 nonattainment area will attain the PM-10 NAAQS by December 31, 1994. Note that EPA's proposed action includes proposed approval of the contingency measures for the Grants Pass nonattainment area.

IV. Request for Public Comments

EPA is requesting comments on all aspects of today's proposal, as indicated at the outset of this notice. EPA will consider any comments received by April 9, 1993.

V. Administrative Matters

The Office of Management and Budget has exempted this rule from the requirements of Section 8 of Executive Order 12291.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 et seq., EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant economic 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 CAA do not create any new requirements, but simply approve requirements that the State is already implementing. Because the federal SIP approval does not impose any new requirements, EPA

certify that it does not have a significant impact on small entities affected. Moreover, due to the nature of the federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. U.S. E.P.A.*, 427 U.S. 248, 256-68 (S.Ct. 1976); 42 U.S.C. 7410(e)(2).

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

List of Subjects in 40 CFR Part 52

Air pollution control, hydrocarbons, intergovernmental relations, nitrogen dioxide, particulate matter, reporting and recordkeeping requirements, sulfur dioxide, and volatile organic compounds.

Authority: 42 U.S.C. 7401-7410.

Dated: February 9, 1993.

Dana A. Rasmussen,

Regional Administrator.

(FR Doc. 93-3485 Filed 3-9-93; 8:25 am)

BILLING CODE 6050-01-2

40 CFR Part 180

PP 2E4056/P554; FRN 4153-51

FRN No. 2070-AB78

Pesticide Tolerance for Paraquat

(EPA) Environmental Protection Agency (EPA)

AGENCY: Environmental Protection Agency (EPA)

ACTION: Proposed rule.

SUMMARY: This document proposes that a tolerance be established for residues of the pesticide paraquat in or on the raw agricultural commodity cacao beans. The proposed regulation to establish a maximum permissible level for residues of the herbicide in or on the commodity was requested in a petition submitted by the Interregional Research Project No. 4 (IR-4).

DATES: Comments, identified by the document control number (PP 2E4056/P554), must be received on or before April 9, 1993.

ADDRESSES: By mail, submit written comments for Public Response and Program Resource Branch, Field Operations Division (H7505-B), Office of

Registration, U.S. Environmental Protection Agency, Washington, DC 20460.

For more information, contact the Registration Branch, U.S. Environmental Protection Agency, Washington, DC 20460.

For a complete list of the Agency's regulations, see the Federal Register, Vol. 58, No. 1, January 3, 1993, page 1.

For a complete list of the Agency's regulations, see the Federal Register, Vol. 58, No. 1, January 3, 1993, page 1.

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