

Web site addresses, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

1. National Heart, Lung, and Blood Institute, *Expert Panel Report: Update on Selected Topics 2002: Guidelines for the Diagnosis and Management of Asthma*, NIH publication No. 02-5074, June 2003.

2. Tasche, M. J. A. et al., "Inhaled Disodium Cromoglycate (DSCG) as Maintenance Therapy in Children with Asthma: A Systematic Review," *Thorax* 55:913–920, 2000; P. J. Helms, "Inhaled Disodium Cromoglycate as Maintenance Therapy for Childhood Asthma: Time to Consign to History?" (editorial), *Thorax* 55:886, 2000; Letter from A. Edwards et al., and reply by Tasche et al., *Thorax* 56:331–2, 2001; Letter from G. Laszlo, and separate replies by Helms and Tasche et al., *Thorax* 56:502–503, 2001; Letter from M. Silverman, and reply by Tasche, et al., *Thorax* 56:585, 2001; Letter from H. K. Reddel and C. R. Jenkins, *Thorax* 56:896, 2001; Letter from Edwards et al. *Thorax* 57:282, 2002; Letter from Tasche, et al., *Thorax* 57:751–752, 2002.

3. National Heart, Lung, and Blood Institute, *Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma*, NIH publication No. 97-4051, July 1997.

4. Hofstra, W. B. et al., "Dose-Responses Over Time to Inhaled Fluticasone Propionate Treatment of Exercise-and Methacholine-Induced Bronchoconstriction in Children with Asthma," *Pediatric Pulmonology*, 29:415–423, 2000.

5. Jonasson, G. et al., "Low-Dose Budesonide Improves Exercise-Induced Bronchospasm in Schoolchildren," *Pediatric Allergy and Immunology*, 11:120–123, 2000.

6. Blake, K.V., "Montelukast: Data from Clinical Trials in the Management of Asthma," *Annals of Pharmacotherapy*, 33 (12):1299–314, December 1999 (errata, 34:541, April 2000).

7. de Benedictis, F. M. et al., "Cromolyn Versus Nedocromil: Duration of Action in Exercise-Induced Asthma in Children" *Journal of Allergy and Clinical Immunology*, 96:510–4, 1995.

8. Chrischilles, E. et al., "Delivery of Ipratropium and Albuterol Combination Therapy for Chronic Obstructive Pulmonary Disease: Effectiveness of Two-in-one Inhaler Versus Separate Inhalers" *The American Journal of Managed Care*, 8:902–911, 2002.

9. Anthonisen, N. R. et al., "Hospitalizations and Mortality in the Lung Health Study" *American Journal of Respiratory and Critical Care Medicine*, 166:333–339, 2002.

10. United Nations Environmental Programme, *Production and Consumption of Ozone-Depleting Substances: 1986–2004*, 2005.

11. U.S. Environmental Protection Agency, "The Benefits and Costs of the Clean Air Act: 1990–2010" (<http://www.epa.gov/air/sect812/copy99.html>) (November 1999).

12. Mannino, D. M. et al., "Chronic Obstructive Pulmonary Disease Surveillance—United States, 1971–2000," *Morbidity and Mortality Weekly Report*, 51(SS06):1–16, August 2, 2002.

13. American Lung Association, "Trends in Asthma Morbidity and Mortality," Epidemiology & Statistics Unit, Research and Program Services, July 2006.

14. Mannino, D. M. et al., "Surveillance for Asthma—United States, 1980–1999," *Morbidity and Mortality Weekly Report*, 51(SS01):1–13, March 29, 2002.

15. Analysis completed by FDA based on information provided by IMS Health, IMS National Sales Perspective (TM), 2005, extracted March 2006. These data are available for purchase from IMS Health. Please send all inquiries to: IMS Health, Attn: Brian Palumbo, Account Manager, 660 West Germantown Pike, Plymouth Meeting, PA 19462.

16. Rozek, R. P., and E. R. Bishko, "Economics Issues Raised in the FDA's Proposed Rule on Removing the Essential-Use Designation for Albuterol MDIs," National Economic Research Associates, August 13, 2004 (FDA Docket No. 2003P-0029/C25).

17. Goldman, D. P. et al., "Pharmacy Benefits and the Use of Drugs by the Chronically Ill," *JAMA: The Journal of the American Medical Association*, 291:2344–2350, May 19, 2004.

18. DeNavas-Walt, C., B.D. Proctor, and C. H. Lee, U.S. Census Bureau, *Current Population Reports, P60–229, Income, Poverty, and Health Insurance Coverage in the United States: 2004*, p. 18, 2005.

19. Hurd, S., "The Impact of COPD on Lung Health Worldwide: Epidemiology and Incidence," *Chest*, 117:2 (supplement):1S–4S, February 2000.

## List of Subjects in 21 CFR Part 2

Administrative practice and procedure, Cosmetics, Drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Clean Air Act and under authority delegated to the Commissioner of Food and Drugs, after consultation with the Administrator of the Environmental Protection Agency, it is proposed that 21 CFR part 2 be amended as follows:

## PART 2—GENERAL ADMINISTRATIVE RULINGS AND DECISIONS

1. The authority citation for 21 CFR part 2 continues to read as follows:

**Authority:** 15 U.S.C. 402, 409; 21 U.S.C. 321, 331, 335, 342, 343, 346a, 348, 351, 352, 355, 360b, 361, 362, 371, 372, 374; 42 U.S.C. 7671 *et seq.*

### § 2.125 [Amended]

2. Section 2.125 is amended by removing and reserving paragraphs (e)(1)(iii), (e)(1)(v), (e)(2)(iii), (e)(2)(iv), (e)(4)(iv), (e)(4)(vii), and (e)(4)(viii).

Dated: June 4, 2007.

**Jeffrey Shuren,**  
Assistant Commissioner for Policy.  
[FR Doc. 07-2883 Filed 6-6-07; 1:35 pm]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

#### 30 CFR Part 943

[Docket No. TX-057-FOR]

### Texas Regulatory Program and Abandoned Mine Land Reclamation Plan

**AGENCY:** Office of Surface Mining Reclamation and Enforcement, Interior.

**ACTION:** Proposed rule; reopening and extension of public comment period on proposed amendment.

**SUMMARY:** We, the Office of Surface Mining Reclamation and Enforcement (OSM), are announcing receipt of revisions to a previously proposed amendment to the Texas regulatory program (Texas program) and the Texas abandoned mine land plan (Texas plan) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The revisions concern "determination of amount of penalty" in the Texas regulations and "administrative penalties for violation of permit conditions" in the Texas statute. Texas intends to improve operational efficiency.

This document gives the times and locations that the Texas program and Texas plan and proposed amendments to that program and plan are available for your inspection and the comment period during which you may submit written comments on the revisions to the amendment.

**DATES:** We will accept written comments until 4 p.m., c.t., June 26, 2007.

**ADDRESSES:** You may submit comments, identified by Docket No. TX-057-FOR, by any of the following methods:

- *E-mail:* [athomas@osmre.gov](mailto:athomas@osmre.gov). Include "Docket No. TX-057-FOR" in the subject line of the message.
- *Mail/Hand Delivery:* A. Dwight Thomas, Acting Director, Tulsa Field Office, Office of Surface Mining Reclamation and Enforcement, 1645 South 101st East Avenue, Suite 145, Tulsa, Oklahoma 74128.
- *Fax:* (918) 581–6419.
- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

**Instructions:** All submissions received must include the agency name and docket number for this rulemaking. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Comment Procedures" heading

of the **SUPPLEMENTARY INFORMATION** section of this document.

**Docket:** For access to the docket to review copies of the Texas program and Texas plan, this amendment, a listing of any scheduled public hearings, and all written comments received in response to this document, you must go to the address listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSM's Tulsa Field Office: A. Dwight Thomas, Acting Director, Tulsa Field Office, Office of Surface Mining Reclamation and Enforcement, 1645 South 101st East Avenue, Suite 145, Tulsa, Oklahoma 74128, Telephone: (918) 581-6430, *E-mail: athomas@osmre.gov*.

In addition, you may review a copy of the amendment during regular business hours at the following location: Surface Mining and Reclamation Division, Railroad Commission of Texas, 1701 North Congress Avenue, Austin, Texas 78711-2967, Telephone: (512) 463-6900.

**FOR FURTHER INFORMATION CONTACT:** A. Dwight Thomas, Acting Director, Tulsa Field Office. Telephone: (918) 581-6430. *E-mail: athomas@osmre.gov*.

**SUPPLEMENTARY INFORMATION:**

- I. Background on the Texas Program and Texas Plan
- II. Description of the Proposed Amendment
- III. Public Comment Procedures
- IV. Procedural Determinations

**I. Background on the Texas Program and Texas Plan**

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, "a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act \* \* \*, and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act." See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Texas program effective February 16, 1980. You can find background information on the Texas program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Texas program in the February 27, 1980, **Federal Register** (45 FR 12998). You can also find later actions concerning the Texas program and program amendments at 30 CFR 943.10, 943.15 and 943.16.

The Abandoned Mine Land Reclamation Program was established by Title IV of the Act (30 U.S.C. 1201 *et seq.*) in response to concerns over extensive environmental damage caused by past coal mining activities. The program is funded by a reclamation fee collected on each ton of coal that is produced. The money collected is used to finance the reclamation of abandoned coal mines and for other authorized activities. Section 405 of the Act allows States and Indian Tribes to assume exclusive responsibility for reclamation activity within the State or on Indian lands if they develop and submit to the Secretary of the Interior (Secretary) for approval, a program (often referred to as a plan) for the reclamation of abandoned coal mines. On the basis of these criteria, the Secretary approved the Texas plan on June 23, 1980. You can find background information on the Texas plan, including the Secretary's findings, the disposition of comments, and the approval of the plan in the June 23, 1980, **Federal Register** (45 FR 41937). You can find later actions concerning the Texas plan and amendments to the plan at 30 CFR 943.25.

**II. Description of the Proposed Amendment**

By letter dated February 14, 2007 (Administrative Record No. TX-662), and at its own initiative, Texas sent us an amendment to its program and plan under SMCRA (30 U.S.C. 1201 *et seq.*). We announced receipt of the proposed amendment in the April 30, 2007, **Federal Register** (72 FR 21185) and invited public comment on its adequacy. The public comment period ended May 30, 2007.

During our review of the amendment, the Railroad Commission of Texas notified us that the Texas legislation that would raise the State's administrative penalty for violations had been capped at \$10,000 instead of the \$13,000 as proposed in the amendment to the Texas program submitted to us on February 14, 2007 (Administrative Record No. TX-662). On May 7, 2007, Texas sent us a revision to its amendment that pertains to its regulatory program (Administrative Record No. TX-662.03).

Texas submitted additional revisions for the following provisions of the amendment:

**A. Revisions to Texas' Regulations, Title 16 Texas Administrative Code (TAC)**

**Section 12.688 Determination of Amount of Penalty**

Texas' penalty schedule currently begins with a minimum penalty of \$20 and increases to a maximum penalty of \$5,000. Texas proposes to change the penalty schedule so that it begins with a minimum penalty of \$550 and increases to a maximum penalty of \$10,000. Texas proposes to increase the penalties to reflect the decreased value in the dollar since the penalty schedule was promulgated in 1979.

**B. Revisions to Texas' Statute, Chapter 134 Texas Natural Resources Code**

**Section 134.174 Administrative Penalty for Violation of Permit Condition of this Chapter**

Texas proposes to revise subsection (b) to read as follows:

(b) The penalty may not exceed \$10,000 for each violation. Each day a violation continues may be considered a separate violation for purposes of penalty assessments.

**III. Public Comment Procedures**

We are reopening the comment period on the proposed Texas program and Texas plan amendment to provide the public an opportunity to reconsider the adequacy of the proposed amendment in light of the additional materials submitted. Under the provisions of 30 CFR 732.17(h) and 30 CFR 884.15(a), we are seeking comments on whether the proposed amendment satisfies the applicable program and plan approval criteria of 30 CFR 732.15 and 30 CFR 884.14, respectively. If we approve the amendment, it will become part of the Texas program and Texas plan, as appropriate.

**Written Comments**

Send your written or electronic comments to OSM at the address given above. Your written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of your recommendations. We will not consider or respond to your comments when developing the final rule if they are received after the close of the comment period (see **DATES**). We will make every attempt to log all comments into the administrative record, but comments delivered to an address other than the Tulsa Field Office may not be logged in.

**Electronic Comments**

Please submit Internet comments as an ASCII or Word file avoiding the use of special characters and any form of

encryption. Please also include "Attn: Docket No. TX-057-FOR" and your name and return address in your Internet message. If you do not receive a confirmation that we have received your Internet message, contact the Tulsa Field Office at (918) 581-6430.

#### *Public Availability of Comments*

Before including your address, phone number, e-mail address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

#### **IV. Procedural Determinations**

##### *Executive Order 12630—Takings*

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulation.

##### *Executive Order 12866—Regulatory Planning and Review*

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866.

##### *Executive Order 12988—Civil Justice Reform*

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

##### *Executive Order 13132—Federalism*

This rule does not have Federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and

reclamation operations. One of the purposes of SMCRA is to "establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations." Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be "in accordance with" the requirements of SMCRA, and section 503(a)(7) requires that State programs contain rules and regulations "consistent with" regulations issued by the Secretary pursuant to SMCRA.

##### *Executive Order 13175—Consultation and Coordination With Indian Tribal Governments*

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on Federally-recognized Indian tribes and have determined that the rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. This determination is based on the fact that the Texas program does not regulate coal exploration and surface coal mining and reclamation operations on Indian lands. Therefore, the Texas program has no effect on Federally-recognized Indian tribes.

##### *Executive Order 13211—Regulations That Significantly Affect The Supply, Distribution, or Use of Energy*

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

##### *National Environmental Policy Act*

This rule does not require an environmental impact statement because section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

#### *Paperwork Reduction Act*

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

#### *Regulatory Flexibility Act*

The Department of the Interior certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

#### *Small Business Regulatory Enforcement Fairness Act*

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) Does not have an annual effect on the economy of \$100 million; (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

#### *Unfunded Mandates*

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of \$100 million or more in any given year. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation did not impose an unfunded mandate.

**List of Subjects in 30 CFR Part 943**

Intergovernmental relations, Surface mining, Underground mining.

Dated: May 25, 2007.

**Ervin J. Barchenger,**

*Acting Regional Director, Mid-Continent Region.*

[FR Doc. E7-11193 Filed 6-8-07; 8:45 am]

**BILLING CODE 4310-05-P**

**DEPARTMENT OF COMMERCE****National Oceanic and Atmospheric Administration****50 CFR Part 300**

[Docket No. 070514119-7120-01; I.D. 042307D]

**RIN 0648-AV51**

**Certification of Nations Whose Fishing Vessels Are Engaged in Illegal, Unreported, or Unregulated Fishing or Bycatch of Protected Living Marine Resources**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Advance notice of proposed rulemaking; request for comments.

**SUMMARY:** NMFS issues this advance notice of proposed rulemaking to announce that it is developing certification procedures to address illegal, unreported, or unregulated (IUU) fishing activities and bycatch of protected living marine resources pursuant to the High Seas Driftnet Fishing Moratorium Protection Act (Moratorium Protection Act). NMFS is seeking advance public comment on the development of these procedures and on the sources and types of information to be considered in the process. NMFS plans to arrange for one or more opportunities to obtain public input on the certification procedures. Dates and locations of any such opportunities will be published in the **Federal Register** at a later date.

**DATES:** Written comments must be received by July 26, 2007.

**ADDRESSES:** Written comments on this action and requests for background information should be addressed to Christopher Rogers, Trade and Marine Stewardship Division, Office of International Affairs, NMFS. Comments and requests may be submitted by any of the following methods:

- Email: [0648-AV51@noaa.gov](mailto:0648-AV51@noaa.gov). Including “0648-AV51” in the subject line of the e-mail comment. Comments

sent via e-mail, including all attachments, must not exceed a 10 megabyte file size.

- Federal e-Rulemaking portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Christopher Rogers, Trade and Marine Stewardship Division, Office of International Affairs, NMFS, 1315 East-West Highway, Silver Spring, MD 20910.

**FOR FURTHER INFORMATION CONTACT:**

Christopher Rogers (ph. 301-713-9090, fax 301-713-9106, e-mail [christopher.rogers@noaa.gov](mailto:christopher.rogers@noaa.gov)).

**SUPPLEMENTARY INFORMATION:****Background**

The Magnuson-Stevens Fishery Conservation and Management Reauthorization Act of 2006 (Public Law 109-479), which was signed into law in January 2007, amends the Moratorium Protection Act (Public Law 104-43) to require actions be taken by the United States to strengthen international fishery management organizations and address IUU fishing and bycatch of protected living marine resources. Specifically, the Moratorium Protection Act requires the Secretary of Commerce to identify in a biennial report to Congress those foreign nations whose vessels are engaged in IUU fishing or fishing that results in bycatch of protected living marine resources. The Moratorium Protection Act also requires the establishment of procedures to certify whether nations identified in the biennial report are taking appropriate corrective actions to address IUU fishing or bycatch of protected living marine resources by fishing vessels of that nation. Based upon the outcome of the certification procedures developed in this rulemaking, nations could be subject to import prohibitions and other measures under the authority provided in the High Seas Driftnet Fisheries Enforcement Act at 16 U.S.C. 1826a (Enforcement Act) if they are not positively certified by the Secretary of Commerce. The Secretary of Commerce has delegated authority under this Act and the Moratorium Protection Act to NMFS. In addition to the Moratorium Protection and Enforcement Acts, NMFS notes that there are identification and/or certification procedures in other statutes, including the Pelly Amendment to the Fishermen’s Protective Act at 22 U.S.C. 1978. This advance notice of proposed rulemaking solicits public input on the new Moratorium Protection Act provisions and applicable Enforcement Act provisions, as well as general

identification and certification considerations.

**Definitions under the Moratorium Protection Act**

For purposes of the Moratorium Protection Act, “IUU fishing” is defined as fishing activities that violate conservation and management measures required under an international fishery management agreement to which the United States is a party, including catch limits or quotas, capacity restrictions, and bycatch reduction requirements; overfishing of fish stocks shared by the United States, for which there are no applicable international conservation or management measures or in areas with no applicable international fishery management organization or agreement, that has adverse impacts on such stocks; and fishing activity that has an adverse impact on seamounts, hydrothermal vents, and cold water corals located beyond national jurisdiction, for which there are no applicable conservation or management measures or in areas with no applicable international fishery management organization or agreement. See 16 U.S.C. 1826j. This definition of IUU fishing was published in the **Federal Register** on April 12, 2007 (72 FR 18404) and is codified at 50 CFR part 300.

“Protected living marine resources” is defined in the Moratorium Protection Act as non-target fish, sea turtles, or marine mammals that are protected under United States law or international agreement, including the Marine Mammal Protection Act, the Endangered Species Act, the Shark Finning Prohibition Act, and the Convention on International Trade in Endangered Species of Wild Flora and Fauna; but they do not include species, except sharks, that are managed under the Magnuson-Stevens Fishery Conservation and Management Act, the Atlantic Tunas Convention Act, or any international fishery management organization. See 16 U.S.C. 1826k.

**Biennial Report to Congress on International Compliance**

The Moratorium Protection Act (see 16 U.S.C. 1826h) requires that the Secretary, in consultation with the Secretary of State, provide Congress (by no later than January 12, 2009, and every two years thereafter), a report that includes:

1. the state of knowledge on the status of international living marine resources shared by the United States or subject to treaties or agreements to which the United States is a party, including a list of all such fish stocks classified as overfished, overexploited, depleted,